REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 1 OF 2022
ON
CONTROL OF CLAIM ON PROCESSED FOOD LABELS
AND ADVERTISEMENTS

BY THE BLESSINGS OF ALMIGHTY GOD

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

Considering : a. that the provisions concerning control of claim on processed food labels and advertisements as regulated in Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 13 of 2016 on Control of Claim on Processed Food Labels and Advertisements need to be adjusted with the development in legal and scientific needs of knowledge and technology in the field of processed food, so it is necessary to be replaced;

b. that based on the provisions of Article 3 section (1) point d of Presidential Regulation Number 80 of 2017 on Indonesian Food and Drug Authority, the Indonesian Food and Drug Authority has a controlling function prior to the circulation and during circulation;

c. that based on the considerations as referred to in point a and point b, it is necessary to establish Regulation of the Indonesian Food and Drug Authority on Control of Claim on Processed Food Labels and Advertisements;

Observing : 1. Law Number 18 of 2012 on Food (State Gazette of the Republic of Indonesia of 2012 Number 227, Supplement to the State Gazette of the Republic of Indonesia Number 5360);

2. Government Regulation Number 69 of 1999 on Food Labels and Advertisements (State Gazette of the Republic of Indonesia of 1999 Number 131, Supplement to the State Gazette of the Republic of Indonesia Number 3867);

3. Presidential Regulation Number 80 of 2017 on Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia of 2017 Number 180);

4. Regulation of the Indonesian Food and Drug Authority Number 31 of 2018 on Processed Food Labels (State Bulletin of the Republic of Indonesia of 2018 Number 1452) as amended by Regulation of the Indonesian Food and Drug Authority Number 20 of 2021 on Amendment to

Regulation of the Indonesian Food and Drug Authority Number 31 of 2018 on Processed Food Labels (State Bulletin of the Republic of Indonesia of 2021 Number 884);

5. Regulation of the Indonesian Food and Drug Authority Number 21 of 2020 on Organization and Work Procedures of Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2020 Number 1002);
6. Regulation of the Indonesian Food and Drug Authority Number 22 of 2020 on Organization and Work Procedures of Technical Implementation Units within Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2020 Number 1003) as amended by Regulation of the Indonesian Food and Drug Authority Number 23 of 2021 on Amendment to Regulation of the Indonesian Food and Drug Authority Number 22 of 2020 on Organization and Work Procedures of Technical Implementation Units within Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2021 Number 1151);
7. Regulation of the Indonesian Food and Drug Authority Number 23 of 2020 on Organization and Work Procedures of Technical Implementation Units within National Food and Drug Testing Development Center of Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2020 Number 1004);

HAS DECIDED:

To issue : REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON CONTROL OF CLAIM ON PROCESSED FOOD LABELS AND ADVERTISEMENTS.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Authority Regulation:

1. Processed Food means food or beverage that is processed in a certain way or method with or without food additives.
2. Claim means any form of description that states, suggests or indirectly states that certain characteristics of a food are related to origin, nutritional content, nature, production, processing, composition or other quality factors.
3. Processed Food Label, hereinafter referred to as Label, means any information regarding Processed Food in the form of images, writing, a combination of both, or other forms included in Processed Food, inserted into, affixed to, or constituting part of food packaging.
4. Processed Food Advertisement, hereinafter referred to as Advertisement, means any information or statement regarding food in the form of images, texts, sound, audio-visual, or other forms which are delivered through various means for the marketing and/or trade of Processed Food.

5. Nutrient means any substances or chemical compounds found in food consisting of carbohydrates, protein, fat, vitamin, mineral, dietary fiber, water, and other components that are useful for human growth, development and health.
6. Non-nutrient means any chemical compounds or bioactive/functional components found in food which do not function as Nutrients but may affect health.
7. Nutrition/Non-Nutrition Claim means any statement which states, indicates, or implies that a food has particular nutritional/non-nutritional properties including the energy value and the content of protein, fat and carbohydrates, and vitamins and minerals.
8. Health Claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health.
9. Nutrient Content Claim means a nutrition claim that describes the level of a Nutrient contained in food.
10. Non-nutrient Content Claim means a claim that describes the level of a Non-nutrient contained in food.
11. Nutrient/Non-nutrient Comparative Claim means a claim that compares the energy value and/or the Nutrient or Non-nutrient levels of two or more foods.
12. Nutrient/Non-nutrient Function Claim means a claim that describes the physiological role of the Nutrient/Non-nutrient for growth, development and normal functions of the body.
13. Reduction of Disease Risk Claim means a claim 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.
14. Food Category means a grouping of food based on the type of food concerned.
15. Nutrient Reference Values, hereinafter abbreviated as NRVs means a reference to the inclusion of nutritional content information on the Labels.
16. Infant means a person under the age of 12 (twelve) months.
17. Complementary Foods (*Makanan Pendamping Air Susu Ibu*), hereinafter abbreviated as MP-ASI, means nutritious food that is given in addition to breast milk for infants aged 6 (six) months and up to children aged 24 (twenty-four) months or out of the age range based on medical indication in order to achieve nutritional adequacy.
18. Food for Special Medical Purposes), hereinafter abbreviated as FSMP, means Processed Food that is specially processed or formulated for dietary management for people with specific diseases/disorders.
19. Business Actor means an individual or business enterprise, operating either as a legal entity or otherwise, that has been established and is domiciled or performs activities in the jurisdiction of the Republic of Indonesia, either individually or collectively, under an agreement to perform business activities in various business sectors.

20. Chairperson of the Authority means the Chairperson of the Indonesian Food and Drug Authority.

Article 2

(1) Claims on the Labels include:
    a. Nutrition/Non-nutrition Claims;
    b. Health Claims;
    c. isotonic Claims;
    d. vegan Claims; and
    e. microorganism-related Claims.
(2) Nutrition/Non-Nutrition Claims as referred to in section (1) point a include:
    a. Nutrient/Non-nutrient Content Claims;
    b. Nutrient/Non-nutrient Comparative Claims;
    c. no added sugars Claims;
    d. no added salt Claims;
    e. lactose Claims; and
    f. gluten Claims.
(3) Health Claims as referred to in section (1) point b include:
    a. Nutrient/Non-nutrient Function Claims;
    b. Reduction of Disease Risk Claims; and
    c. glycemic Claims.

Article 3

Claims as referred to in Article 2 are stated with the following considerations:
a. type, amount, and function of Nutrients or Non-nutrients;
b. a reasonable amount of food consumed daily;
c. balanced nutrition consumption patterns;
d. public health condition;
e. food suitability as Nutrient or Non-nutrient carriers; and
f. food suitability to include Claims.

Article 4

Information in the form of Claims as referred to in Article 2 conveyed in the Advertisement must be in accordance with the Label approved at the time of obtaining the marketing authorization in accordance with the provisions of the legislation.

CHAPTER II
REQUIREMENTS

Part One
General

Article 5

(1) Processed Food can only include Claims after fulfilling the basic characteristics of the Food Category in accordance with the provisions of legislation.
(2) Processed Food can only include Claims on the Label if it complies with the requirements of intake per serving no more than:
    a. 18 g (eighteen grams) of total fat;
    b. 6 g (six grams) of saturated fat;

c. 60 mg (sixty milligrams) of cholesterol; and
d. 300 mg (three hundred milligrams) of sodium.

(3) Requirements of intake per serving as referred to in section (2) are not valid for Claim requirements related to fat, saturated fat, cholesterol, salt (sodium), and/or dietary fiber as set forth in Annex I and Annex VII as an integral part of this Authority Regulation.

(4) Claim Requirements as referred to in section (3) are related to:
a. fat, only the total fat requirement is excluded;
b. saturated fat, only the saturated fat requirement is excluded;
c. cholesterol, only the cholesterol requirement is excluded;
d. salt (sodium), only the sodium requirement is excluded; and
e. dietary fiber, only the total fat, saturated fat, and cholesterol requirements are excluded.

(5) Exempted from the provisions as referred to in section (2) are the following Claims:
a. vegan Claims; and
b. Claims used for intermediate Processed Food that requires further processing with the addition of other food ingredients.

Article 6

(1) Claims used for intermediate Processed Food as referred to in Article 5 section (5) point b can only include:
a. Nutrient Content Claims as referred to in Article 2 section (2) point a for intermediate Processed Food that requires certain additional Nutrients; and/or
b. gluten Claims as referred to in Article 2 section (2) point f.

(2) The intermediate Processed Food as referred to in section (1) can be in the form of flour, cooking oil, and food premixes that still require processing with the addition of raw materials other than water prior to consumption.

(3) Nutrient Content Claims for intermediate Processed Food as referred to in section (1) point a are only valid for certain Nutrients required to be added in order to overcome nutrition problems in accordance with the provisions of legislation.

(4) Processed Food that is not categorized into intermediate Processed Food includes:
a. Processed Food that is commonly consumed directly;
b. Processed Food that can be added/consumed with another food without further processing, e.g. margarine, butter, sugar, salt, creamer, and coconut milk; or
c. Processed Food that is simply processed with the addition of water, e.g. agar powder, cocoa powder, and instant noodle.

Article 7

MP-ASI can only include Nutrient/Non-nutrient Content Claims, Nutrient/Non-nutrient Comparative Claims, no added sugars Claims, gluten Claims, and/or Nutrient/Non-nutrient Function Claims.

Article 8

FSMP can only include Claims in accordance with Regulation of the Indonesian Food and Drug Authority that regulates FSMP.

Part Two
Nutrient/Non-nutrient Claims

Article 9

The Nutrients or Non-nutrients that can be used in Nutrient/Non-Nutrient Claims as referred to in Article 2 section (1) point a include:

a. the Nutrients that have been stated in NRVs;
b. other Nutrients that have been stated in accordance with the provisions of legislation; and
c. the Non-nutrients that have been stated in accordance with the provisions of legislation;

Paragraph 1
Nutrient/Non-nutrient Content Claims

Article 10

(1) The Nutrient Content Claims which are permitted consist of:
    a. Claims that state low Nutrient or Nutrient free; and
    b. Claims that state source of or high/rich in Nutrients.
(2) The Nutrient Content Claims as referred to in section (1) must fulfill the requirements as set forth in Annex I as an integral part of this Authority Regulation.
(3) Claims that state low Nutrient or Nutrient free as referred to in section (1) point a can be used for Processed Food that has performed a particular process or used particular ingredients so that the Nutrient content becomes low or free in accordance with the requirements as set forth in Annex I as an integral part of this Authority Regulation.

Article 11

The inclusion of other Nutrient Content Claims as referred to in Article 9 point b and Non-nutrient Content Claims as referred to in Article 9 point c must fulfill the following requirements:

a. include the name of Nutrients and/or Non-nutrients; and
b. include the amount of Nutrients and/or Non-nutrients per serving.

Paragraph 2
Nutrient/Non-nutrient Comparative Claims

Article 12
Processed Food that includes Nutrient/Non-nutrient Comparative Claims as referred to in Article 2 section (2) point b must fulfill the requirements as set forth in Annex II as an integral part of this Authority Regulation.

Paragraph 3
No Added Sugars Claims

Article 13
Processed Food that includes No Added Sugars Claims as referred to in Article 2 section (2) point c must fulfill the requirements as set forth in Annex III as an integral part of this Authority Regulation.

Paragraph 4
'No Added Salt' Claims

Article 14
Processed Food that includes No Added Salt Claims as referred to in Article 2 section (2) point d must fulfill the requirements as set forth in Annex IV as an integral part of this Authority Regulation.

Paragraph 5
Lactose Claims

Article 15
Processed Food that includes Lactose Claims as referred to in Article 2 section (2) point e must fulfill the requirements as set forth in Annex V as an integral part of this Authority Regulation.

Paragraph 6
Gluten Claims

Article 16
Processed Food that includes Gluten Claims as referred to in Article 2 section (2) point f must fulfill the requirements as set forth in Annex VI as an integral part of this Authority Regulation.

Part Three
Health Claims

Paragraph 1
Nutrient/Non-nutrient Function Claims

Article 17
(1) Processed Food that includes Nutrient/Non-nutrient Function Claims as referred to in Article 2 section (3) point a must at least fulfill the Claim requirements stating source of.

(2) Exempted from the provisions as referred to in section (1) are for Nutrients/Non-nutrients that do not possess Claim requirements stating source of.
(3) Permitted Nutrient/Non-nutrient Function Claims as referred to in section (1) and section (2) are set forth in Annex VII as an integral part of this Authority Regulation.

Paragraph 2
Reduction of Disease Risk Claims

Article 18
Reduction of Disease Risk Claims as referred to in Article 2 section (3) point b can only be applied after obtaining a written approval from the Chairperson of the Authority.

Paragraph 3
Glycemic Claims

Article 19
Processed Food that includes glycemic Claims as referred to in Article 2 section (3) point c must fulfill the requirements as set forth in Annex VIII as an integral part of this Authority Regulation.

Part Four
Isotonic Claims

Article 20
Processed Food that includes isotonic Claims as referred to in Article 2 section (1) point c must fulfill the requirements as set forth in Annex IX as an integral part of this Authority Regulation.

Part Five
Vegan Claims

Article 21
Processed Food that includes vegan Claims as referred to in Article 2 section (1) point d must fulfill the requirements as set forth in Annex X as an integral part of this Authority Regulation.

Part Six
Microorganism-Related Claims

Article 22
(1) Processed Food using living microorganisms must fulfill the requirements of safety, quality, and benefit.
(2) Types of microorganisms that can be used on Processed Food are stipulated by the Chairperson of the Authority.
(3) Microorganism-related Claims as referred to in Article 2 section (1) point e can only be applied after obtaining a written approval from the Chairperson of the Authority.

CHAPTER III
CLAIM ASSESSMENT

Article 23

Claims and Claim requirements other than those stated in this Authority Regulation can only be applicable after obtaining a written approval from the Chairperson of the Authority, *c.q.* Director of Processed Food Standardization.

Article 24

(1) In order to obtain a written approval as referred to in Article 18, Article 22 section (3), and Article 23, Business Actors must submit an application for assessment to the Chairperson of the Authority *c.q.* Director of Processed Food Standardization.
(2) The application for assessment as referred to in section (1) is submitted online through the official website of public service of the Indonesian Food and Drug Authority.
(3) The application as referred to in section (1) must be supported by complete data according to the objective as set forth in Annex XI as an integral part of this Authority Regulation.

Article 25

(1) The assessment of application as referred to in Article 24 section (1) is carried out in accordance with the procedures of Claim assessment as set forth in Annex XII as an integral part of this Authority Regulation.
(2) The assessment of application as referred to in Article 24 section (1) for Microorganism-related Claims is carried out with reference to the Claim assessment procedure as referred to in section (1) and microorganism assessment procedure in Processed Food as set forth in Annex XIII as an integral part of this Authority Regulation.
(3) The Chairperson of the Authority conducts an assessment for the application as referred to in section (1) and section (2) in accordance with the provisions of legislation.
(4) Based on the results of the assessment as referred to in section (3), the Chairperson of the Authority issues a decision in the form of:
    a. an approval; or
    b. a rejection

Article 26

Claims submitted as referred to in Article 24 must:
a. support national health and/or nutrition policies;
b. be not related to treatment and prevention of a disease;
c. not encourage false consumption patterns; and
d. be truthful and not misleading.

CHAPTER IV
LABORATORY TESTING

Article 27

(1) The Claims as referred to in Article 2 must be proven by the analysis results of accredited laboratories or government laboratories.
(2) In the event of imported Processed Food, the analysis results as referred to in section (1) can be issued by:
    a. a laboratory from the country of origin that has been accredited by the competent authority in the country of origin; or
    b. a laboratory from the country of origin that has mutual recognition agreements with both authorized institutions and/or an accredited laboratory in Indonesia in accordance with the provisions of legislation.

CHAPTER V
PROHIBITION

Article 28

On Processed Food Labels and Advertisements, Business Actors are prohibited from:
a. including Claims for Processed Food intended for infants, unless specifically regulated in accordance with the provisions of legislation;
b. including Reduction of Disease Risk Claims for Processed Food intended for children aged 1 (one) to 3 (three) years, unless specifically regulated in accordance with the provisions of legislation;
c. including Claims stating Nutrients/Non-nutrients free in Processed Food that naturally does not contain Nutrients/Non-nutrients, unless specifically regulated in accordance with the provisions of legislation;
d. including statements that the consumption of such Processed Food can fulfill the needs of all Nutrients;
e. including Claims that manipulate consumer's concerns;
f. including Claims that cause consumers consume a type of Processed Food incorrectly ; and/or
g. including Claims that illustrate such Processed Food can prevent, treat, or cure diseases.

CHAPTER VI
TRANSITIONAL PROVISION

Article 29

(1) Processed Food that has obtained a marketing authorization prior to the enforcement of this Authority Regulation is necessary to comply with the provisions of this Authority Regulation not later than 30 (thirty) months from the promulgation of this Authority Regulation.
(2) Processed Food which is in the process of applying for a marketing authorization will still be processed in

accordance with the provisions of the Authority Regulation serving as the basis for the application and is required to comply with the provisions of this Authority Regulation not later than 30 (thirty) months from the promulgation of this Authority Regulation.

CHAPTER VII
CLOSING PROVISIONS

Article 30

At the time this Authority Regulation comes into force, Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 13 of 2016 on Control of Claim on Processed Food Labels and Advertisements (State Bulletin of the Republic of Indonesia of 2016 Number 887), is repealed and declared ineffective.

Article 31

This Authority Regulation comes into force on the date of its promulgation.

In order that every person may know thereof, it is ordered to promulgate this Authority Regulation by its placement in the State Bulletin of the Republic of Indonesia.

Issued in Jakarta
on 3 January 2022

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

Promulgated in Jakarta
on 4 January 2022

DIRECTOR GENERAL OF LEGISLATION
OF THE MINISTRY OF LAW AND HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA,

signed

BENNY RIYANTO

STATE BULLETIN OF THE REPUBLIC OF INDONESIA OF 2022 NUMBER 2

Jakarta, 20 November 2023
Has been translated as an Official Translation
on behalf of Minister of Law and Human Rights
of the Republic of Indonesia

DIRECTOR GENERAL OF LEGISLATION,

ASEP N. MULYANA

ANNEX I
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 1 OF 2022 ON
CONTROL OF CLAIM ON PROCESSED FOOD LABELS AND ADVERTISEMENTS

NUTRIENT CONTENT CLAIMS

A. Claims that State Low Nutrient or Nutrient Free

Components	Claims	Requirements Not More Than
Energy	Low	40 kcal (170 kJ) per 100 g (in solid form); 20 kcal (80 kJ) per 100 ml (in liquid form); or 5 kcal per serving (only for table top sweetener).
	Free[1]	4 kcal per 100 g (in solid form); 4 kcal per 100 ml (in liquid form) or 1 kcal per serving (only for table top sweetener).
Fat	Low	3 g per 100 g (in solid form); or 1.5 g per 100 ml (in liquid form).
	Free[1]	0.5 g per 100 g (in solid form); or 0.5 g per 100 ml (in liquid form).
Saturated Fat	Low	1.5 g per 100 g (in solid form); or 0.75 g per 100 ml (in liquid form). Other requirements: Meet the requirements of low trans fat.
	Free[1]	0.1 g per 100 g (in solid form); or 0.1 g per 100 ml (in liquid form). Other requirements: Meet the requirements of low trans fat.
Trans Fat	Low	1.5 g per 100 g (in solid form); or 0.75 g per 100 ml (in liquid form).
	Free[1]	0.1 g per 100 g (in solid form); or 0.1 g per 100 ml (liquid form).
Cholesterol	Low	20 mg per 100 g (in solid form); or

[1] In addition to the word “free”, the claim can use equivalent words, namely “no”, or “does not contain”. Specifically for energy, the word " free" can be expressed by "0 calore".

		10 mg per 100 ml (in liquid form). Other requirements: Meet the requirements of low trans fat.

	Free[1]	5 mg per 100 g (in solid form); or 5 mg per 100 ml (in liquid form). Other requirements: Meet the requirements of low trans fat.
Sugar[2],[3]	Low	5 g per 100 g (in solid form); or 2.5 g per 100 ml (in liquid form).
	Free[1]	0.5 g per 100 g (in solid form); or 0.5 mg per 100 ml (in liquid form).
Salt (Sodium)	Low	120 mg per 100 g
	Very Low	40 mg per 100 g
	Free[1]	5 mg per 100 g

[1] In addition to the word “free”, the claim can use equivalent words, namely “no”, “does not contain“.

[2] All monosaccharides and disaccharides.

[3] Applied to products that commonly have a sweet taste, including candies, powdered drinks, jellies, jams, ready-to-drink beverages (flavored milk, milk drinks, milk-contained drinks, fermented milk drinks, chocolate drinks, soybean beverages , fruit juices, vegetable juices, carbonated flavored drinks, non-carbonated flavored drinks, and mung bean beverages , cakes (cookies), decorations (e.g. for bakeries), toppings (non-fruit), sweet sauces and sweet soy sauce.

B. Claims that State Source of or High/Rich in Nutrients

Components	**Claims**	**Requirements** **Not Less Than**
Protein	Source[1]	20% NRVs per 100 g (in solid form); or 10% NRVs per 100 ml (in liquid form).
	High/ Rich	35% NRVs per 100 g (in solid form); or 17.5% NRVs per 100 ml (in liquid form).
Vitamin and Mineral	Source[1]	15% NRVs per 100 g (in solid form); or 7.5% NRVs per 100 ml (in liquid form).
	High/ Rich	2 times the amount for 'source'.
Dietary Fiber[2]	Source[1]	3 g per 100 g (in solid form); or 1.5 g per 100 kcal (in liquid form).
	High/ Rich	6 g per 100 g (in solid form); or 3 g per 100 kcal (in liquid form).

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

[1] In addition to the word "source of" the claim can use equivalent words, namely "contain", "with". Specifically, for protein, the word "source of protein" can be stated with "source of peptide".

[2] Dietary fiber is a carbohydrate polymer with three or more monomer units, which cannot be hydrolyzed by digestive enzymes in the human small intestine and consists of:

- edible carbohydrate polymers, which are naturally found in food; or
- carbohydrate polymers, which are obtained through physical, enzymatic or chemical processes of food ingredients which have been scientifically proven to have beneficial physiological effects as dietary fiber; or
- synthetic carbohydrate polymers that have been scientifically proven to have beneficial physiological effects as dietary fiber.

ANNEX II
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 1 OF 2022 ON
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NUTRIENT/NON-NUTRIENT COMPARATIVE CLAIMS

Claim Type	**Requirements**	**Other Requirements**
Reduced/fewer/less/light or other terms that have the same meaning	1. The relative difference of micronutrient content excluding sodium with the food being compared is at least 10% of NRVs. 2. The relative difference of energy, sugar, fat, saturated fat, cholesterol, and sodium content with the food being compared is at least 25%. 3. The absolute difference is at least fulfilling the claim requirements stating low as specified in nutrient content claims.	1. The product is a new formulation. 2. The Processed Food being compared is similar Processed Food that has been circulated. 3. The Processed Food is manufactured by the same manufacturer or the same marketing authorization holder if the manufacture is contracted. 4. Similar Processed Food includes food with different taste variants. 5. The product
Improved/more than/more/extra/ enriched/plus/added/fortified	1. The relative difference of micronutrient content excluding sodium with the food being compared is at least 10% of NRVs. 2. The relative difference	

	of protein, dietary fiber, linoleic acid, and alpha linoleic acid with the food being compared is at least 25%. 3. The absolute difference is at least fulfilling the claim requirements stating source as specified in nutrient content claims.	being compared must be clearly stated on the Processed Food label and advertisement.
Reduced/fewer/less /light/ or other terms that have the same meaning Improved / more than / more / extra / enriched / plus / added / fortified	1. The relative difference of nutrient content that has not been stated in NRVs, with the food being compared is at least 20%. 2. The relative difference of non-nutrient content with the food being compared is at least 15%.	

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

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ANNEX III
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 1 OF 2022 ON
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NO ADDED SUGARS CLAIMS

A. Requirements

1. The “no added sugars” claims can only be included on products which are commonly sweet, including candies, powdered drinks, jellies, jams, ready-to-drink beverages (flavored milk, milk drinks, milk-contained drinks, fermented milk drinks, chocolate drinks, soybean beverages, fruit juice, vegetable juice, flavored carbonated drinks, flavored non-carbonated drinks, and mung bean beverages), growing-up formula, MP-ASI, snacks intended for children, cakes (cookies), decorations (e.g. for bakery), toppings (non-fruit), sweet sauce and sweet soy sauce.
2. Processed Food as referred to in point 1 is not added with any type of sugar that still has calories, including sucrose, glucose, honey, high fructose corn syrup.
3. Processed Food as referred to in point 1 does not contain ingredients containing sugars as its composition, including jams, jellies, sweetened chocolate, and candied fruit.
4. Processed Food as referred to in point 1 does not contain ingredients with sugar as a substitute for the added sugar. Ingredients such as non-reconstituted concentrated fruit juice and dried fruit paste cannot be used. Ingredients such as unconcentrated fruit pulp or fruit puree can be used.
5. The sugar content of Processed Food as referred to in point 1 does not increase above the amount contributed by the ingredients, among others, by the use of enzymes to hydrolyze starch in order to release sugars.

B. Inclusion

1. Claim is expressed with the statement “No Added Sugars”.
2. The no added sugars Claims can be stated as “no added ….. (sucrose/ lactose/fructose/or other types of sugar)”.

3. The no added sugars Claims can be stated with the word “Unsweetened”, if sweetener as food additives is not added.
4. Processed Food which naturally contains sugar must be supported by the inclusion of statement “naturally contain sugar” and the word “sugar” in that statement can be replaced by another type of sugar, e.g. lactose/fructose/or other types of sugar.

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

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PENNY K. LUKITO

ANNEX IV
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
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NO ADDED SALT CLAIMS

1. The no added salt Claims can only be included on Processed Food with the following conditions:
   a. No addition of sodium salt, among others, in the form of sodium chloride, sodium tripolyphosphate, sodium L-ascorbate, sodium selenate, sodium benzoate, monosodium L-glutamate or any other types of sodium salt.
   b. Not made of ingredients containing sodium salt, including pickles, soybean sauce, salted fish, fish sauce, sweet soy sauce, and salty soy sauce.
   c. Not made of ingredients containing sodium salt, which is used to replace added salts, e.g. seaweed.
   d. The total sodium content in Processed Food must comply with “Low Sodium” claim requirements.
2. The no added salt Claims can be stated with the word “unsalted”.

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

ANNEX V
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
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LACTOSE CLAIMS

1. Lactose Claims can only be included on the products commonly containing lactose, e.g. powdered milk, yoghurt; and its substitutes such as soybean beverages, almond beverages.
2. Lactose Claims as referred to in point 1 must meet the following requirements:

No.	Claims	Requirements
1.	Low Lactose	≤ 2 g / 100 g
2.	Lactose Free	≤ 10 mg / 100 kcal

3. In addition to the word "free", the claim may contain equivalent words such as "no", "does not contain".

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

ANNEX VI
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
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GLUTEN CLAIMS

1. Gluten Claims can only be included on Processed Foods that are produced using the following raw materials:
   a. Raw materials from cereals such as wheat (all Triticum species, such as durum wheat, spelt and khorasan wheat), rye, barley or oats or their cross varieties which have been processed to reduce the gluten content; and/or
   b. Raw materials do not contain gluten which are intended to replace the use of raw materials mentioned in point a. Those raw materials are rice, corn, sago, sorghum, cassava, sweet potatoes, potatoes, taro, and *gadung*.
2. Processed Food as referred to in point 1 must meet the following requirements:

No.	**Claims**	**Requirements**
1.	Low Gluten	21 – 100 mg/kg
2.	Gluten Free	≤ 20 mg / kg

3. In addition to the word “free”, the claim may contain equivalent words, such as “no”, “does not contain”.

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

ANNEX VII
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 1 OF 2022 ON
CONTROL OF CLAIM ON PROCESSED FOOD LABELS AND ADVERTISEMENTS

NUTRIENT / NON-NUTRIENT FUNCTION CLAIMS

No.	Nutrients	Statements
1	Protein[1]	1. Protein helps build and repair body tissues. 2. Protein is an essential component in the growth and development of children.
2.	Unsaturated Fat	Replacing saturated fats with unsaturated fats in the diet plays a role in maintaining normal blood cholesterol levels. Requirements: 1. Processed Food must contain a combination of monounsaturated fat and polyunsaturated fat at least 2/3 of the total fat; and 2. Processed Food must meet the requirements of a low cholesterol claim.
3.	Saturated Fat	Reducing consumption of saturated fat contributes to the maintenance of normal blood cholesterol levels. Requirement: Processed Food must meet the requirements of low saturated fat and low cholesterol claims.
4.	Dietary fiber[2]	1. Soluble dietary fiber (psyllium, beta glucan from oats and/or barley, inulin from chicory, pectin from fruits) can help

[1] Must at least meet Claim requirement stating the source of.
[2] Must at least meet Claim requirement stating the source of.

		maintain/ preserve the function of the digestive tract. Other requirements: a. Processed Food must state the constituent components of dietary fiber; and b. Processed Food contains at least 3 g of soluble dietary fiber per serving.
		2. Soluble dietary fiber (resistant maltodextrin / resistant dextrin) can help maintain/ preserve the function of the digestive tract. Other requirements: a. Processed Food must state the constituent components of dietary fiber; and b. Processed Food contains at least 5 g of soluble dietary fiber per serving.
		3. Soluble dietary fiber (psyllium, beta glucan from oats and/or barley, inulin from chicory, pectin from fruits) can help lower blood cholesterol levels when accompanied by a diet low in saturated fat and low in cholesterol. Other requirements: a. Processed Food must state the constituent components of dietary fiber; b. Processed Food contains soluble dietary fiber of at least 3 g per serving; c. The maximum total fat 3 g per serving, or if the serving size is less than 50 g then the total fat content is maximum 3 g per

		50 g; d. The saturated fat is maximum 1 g per serving and calories from saturated fat are maximum 15%, if the amount per serving is less than 100 grams, then the saturated fat content is maximum 1 gram per 100 grams and calories from saturated fat are maximum 10%; and e. The cholesterol is maximum 20 mg per serving, or if a serving size is less than 50 g then the cholesterol content is maximum 20 mg per 50 g. Warning: Claims must be accompanied by a statement: a. The food consumption must be accompanied by consumption of foods that are low in fat, low in saturated fat and/or low in cholesterol; and b. The consumption of this product must be accompanied by a healthy lifestyle.
		4. Soluble dietary fiber (psyllium, beta glucan from oats and/or barley, inulin from chicory, pectin from fruits) and resistant maltodextrin/ resistant dextrin, can contribute to lower blood sugar rise after meal, if accompanied by a balanced nutritional diet. Other requirements: a. Processed Food must state the constituent components of dietary fiber; b. Processed Food contains soluble dietary fiber of at least 3 g per serving; and c. If the source of soluble dietary fiber used

		is resistant maltodextrin/ resistant dextrin, then the amount of soluble dietary fiber is at least 5 g per serving.
		5. Insoluble dietary fiber can help facilitate bowel movements (laxative), if accompanied by drinking enough water. Other requirements: a. Processed Food must state the constituent components of dietary fiber; and b. Processed Food contains at least 3 g of insoluble dietary fiber per serving.
		6. Contains slowly digestible starch (SDS) …% of total starch. Other requirements: a. At least 55% of energy comes from available carbohydrates [21]; b. At least 55% of available carbohydrates[2] are total starch; and c. At least 40% of total starch is slowly digestible starch (SDS).
5.	Isomaltulose	Isomaltulose is a sugar substitute that does not cause a rapid rise in blood glucose after the consumption of this product. Requirement: Processed Food must meet the claim requirement of low sugar.
6.	Sucromalt	Sucromalt is a sugar substitute that does not cause a rapid rise in blood glucose after the consumption of this product.

1

[2] The available carbohydrate is the total carbohydrates reduced by dietary fiber

		Requirements: 1. Processed Food must meet the claim requirement of low sugar; 2. The composition of sucromalt consists of fructose (35-45% of dry weight), leucrose (7-15% of dry weight), mono- and disaccharides (maximum 3% of dry weight) and oligosaccharides (40-60% of dry weight).
7.	Xylitol	Helps maintain naturally white teeth. Requirements: 1. Processed Food contains at least 15% of xylitol; 2. Processed Food must also contain at least 0.5% of calcium carbonate; and 3. The inclusion of such claims must be supported by the inclusion of recommendation to consumers to continue brushing their teeth regularly.
8.	Vitamin A[1]	1. Vitamin A can help maintain the integrity of the surface layer (eyes, digestive tract, respiratory tract, and skin). 2. Vitamin A helps maintain healthy skin. 3. Vitamin A helps in the maintenance of normal skin. 4. Vitamin A helps maintain normal vision. 5. Adequate Vitamin A consumption can contribute to the normal function of the immune system, if supported by a balanced diet.
9.	Vitamin B1 (Thiamin)[2]	1. Vitamin B1 acts as a coenzyme in metabolism of carbohydrates into energy. 2. Vitamin B1 helps convert carbohydrates

[1] Must at least meet Claim requirement stating the source.
[2] Must at least meet Claim requirement stating the source.

		into energy. 3. Vitamin B1 helps maintain the normal function of the nervous system.
10.	Vitamin B2 (Riboflavin)[1]	1. Vitamin B2 acts as a coenzyme in metabolism of carbohydrates into energy. 2. Vitamin B2 helps convert carbohydrates into energy.
11.	Vitamin B3 (Niacin)[1]	1. Vitamin B3 acts as a coenzyme in metabolism of carbohydrates into energy. 2. Vitamin B3 helps convert carbohydrates into energy.
12	Folic Acid[1]	1. Folic acid has a role in cell growth and division. 2. Folic acid contributes to the formation of red blood cells. 3. Folic acid contributes to maintain the growth and development of the fetus (only for products intended to pregnant women). 4. Folic acid, consumed before and during early pregnancy, helps the fetal development. 5. Supplemental folic acid intake improves maternal folate status. Low maternal folate status is a risk factor for neural tube defects in the growing fetus. 6. Folic acid is one of the essential nutrients for normal/overall development of the fetus.
13.	Vitamin B6 (Piridoksin)[1]	1. Vitamin B6 acts as a coenzyme in metabolism of carbohydrates into energy. 2. Vitamin B6 helps convert carbohydrates into energy. 3. Vitamin B6 helps maintain the normal function of the nervous system.

[1] Must at least meet Claim requirement stating the source of.

14.	Vitamin B12 (Kobalamin)[1]	1. Vitamin B12 helps the formation of red blood cells. 2. Vitamin B12 helps maintain the normal function of the nervous system.
15.	Vitamin C[1]	1. Vitamin C helps build and maintain collagen tissues.
		2. Vitamin C improves the absorption of iron; or Vitamin C helps the absorption of iron. Another requirement: Processed food must meet the claim requirements 'high in vitamin C' and meet the claim requirements of 'source of iron.
		3. Adequate Vitamin C consumption can contribute to the normal function of the immune system, if supported by a balanced diet. Other requirements: a. For products that must be reconstituted with warm or hot water, the Vitamin C content is calculated on the ready-to-products (after being reconstituted with warm or hot water) to meet the requirements for source claims; and b. include direction of appropriate product preparation.
16.	Vitamin D[1]	1. Vitamin D helps the maintenance of bones and teeth. 2. Vitamin D helps the maintenance of bones. 3. Vitamin D helps the maintenance of teeth. 4. Vitamin D helps the normal growth of bones in children.

[1] Must at least meet Claim requirement stating the source.

		Other requirements: Processed Food must meet the claim requirements as a source of calcium. 5. Vitamin D can help the absorption of calcium. Other requirements: 1. Processed Food must meet the claim requirements as a source of calcium; and 2. The ratio of calcium : phosphorous = 1 – 2 : 1.
17.	Vitamin E[1]	Adequate Vitamin E consumption can contribute to the normal function of the immune system, if supported by a balanced diet.
18.	Calsium[1]	1. Calcium helps build and maintain bone and tooth density. 2. Calcium helps build strong bones and teeth. 3. Calcium helps build strong bones. 4. Calcium helps build strong teeth. 5. Calcium helps maintain bone and tooth density. 6. Calcium helps maintain bone density. 7. Calcium helps maintain tooth density. 8. Calcium helps build and maintain bone density. 9. Calcium helps build and maintain tooth density. Other requirements: 1. Processed Food containing more than 400 mg of calcium per serving must be supported by the statement:

		"Consumption of more than 2000 mg per day will not add benefits in maintaining bone density"; and 2. The ratio of calcium : phosphorus = 1 – 2 : 1.
19.	Iron[1]	1. Iron is a component of hemoglobin in red blood cells which carries oxygen to all parts of the body. 2. Iron contributes to the normal formation of red blood cells and hemoglobin.
20.	Iodine[1]	Iodine supports the formation of thyroid hormone.
21.	Magnesium[1]	1. Magnesium supports maintaining the bone density; Other requirements: a. Processed Food must meet the claim requirements as a source of calcium; and b. The phosphorus content in such Processed Food must not exceed the calcium content. 2. Magnesium contributes to normal muscle function. 3. Magnesium contributes to the maintenance of normal bones. 4. Magnesium supports maintaining the structure of bones and/or teeth.
22.	Selenium[2]	1. Adequate Selenium consumption can contribute to the normal functioning of the immune system, if supported by a balanced diet. 2. For people with Iodine deficiency, Selenium contributes to normal thyroid

[1] Must at least meet Claim requirement stating the source of.
[2] Must at least meet Claim requirement stating the source.

		function.
23.	Zinc[1]	Adequate Zinc consumption can contribute to the normal function of the immune system, if supported by a balanced diet.
24.	Copper[1]	Adequate Copper consumption can contribute to the normal function of the immune system, if supported by a balanced diet.
25.	Phytosterols/Phytostanols, both in the form of esters and free	"phytosterols / phytostanols/ phytosterol ester / phytostanol ester helps lower cholesterol in patients with hyperlipidemia / hypercholesterolemia, when accompanied by a diet low in saturated fat and cholesterol". Requirements: 1. Processed Food contains 1.5 – 3 g of phytosterols/phytostanols per day; and 2. Such claims may only be included on margarine, spreadable margarine, dairy products, breakfast cereals, mayonnaise, salad dressings and milk-flavored drinks.

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

ANNEX VIII
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 1 OF 2022 ON
CONTROL OF CLAIM ON PROCESSED FOOD LABELS AND ADVERTISEMENTS

GLYCEMIC CLAIMS

A. General Provisions

1. The glycemic load is a value that takes into account the amount of carbohydrate in a portion of food together with how quickly it raises blood glucose levels. Glycemic load values help to compare the increase of blood glucose levels by consuming food with different types and servings size.
2. The glycemic index is a value reflecting the increase rate of blood glucose levels after consuming food containing carbohydrate. The higher the glycemic index is, the higher the blood glucose levels increase after food is consumed. The increase of blood glucose levels is not only determined by the glycemic index but also by the amount of carbohydrates consumed (glycemic load).

B. Requirements

1. Processed food that includes a glycemic claim must contain at least 25 grams of available carbohydrates per serving, excluding dietary fiber.
2. The value of the glycemic index must be proven by clinical trials using ready-to-consume food.
3. Clinical trials are conducted under the following conditions:
   a. for food intended for diabetics, clinical trials are carried out on persons with type 2 diabetes mellitus who are controlled by diet, or by diet and use of oral hypoglycemic drugs; and
   b. for food intended for general consumers, clinical trials are carried out on healthy persons (normal blood glucose levels).
4. Clinical trials for determining the glycemic index are carried out using the method of measuring the glycemic index of food as stated in point D.

C. Inclusion

1. Claims related to glycemic that can be included in Processed Food are in the form of:

a. value and category of glycemic load; or
b. value and category of glycemic load; accompanied by a glycemic index value and category.

2. The value and category of glycemic load and glycemic index consist of:

Criteria	Value	
	Glycemic Load	Glycemic Index
High	≥ 20	≥ 71
Medium	11 - 19	56 - 70
Low	≤ 10	≤ 55

3. Food labels containing glycemic-related claims must include a warning: “Persons with diabetes should consult a doctor or nutritionist”, placed close to glycemic-related claims.

D. Food Glycemic Index Measurement Method

1. The scope of research
   a. For food intended for persons with diabetes.
      The aim of this research is to determine the glycemic index of food in persons with controlled diabetes mellitus type 2.
   b. For food intended for healthy persons (normal blood glucose levels).
      The aim of this research is to determine the glycemic index of food in healthy persons (normal blood glucose levels).
2. Method of selecting subjects
   The subjects used are adjusted to the designation of the product. If the product is intended for general consumers, use healthy persons (normal blood glucose levels). If the product is intended for persons with diabetes, the subjects must meet the following criteria:
   a. persons with diabetes who are well controlled, not pregnant, not breastfeeding and do not have other complications such as kidney disorders, liver function, do not suffer from anemia.
   b. Selection of subjects based on laboratory tests:
      1) Blood glucose to determine whether diabetes mellitus is under control, namely fasting blood glucose and 2 hours postprandial.
      2) SGPT
      3) Blood creatinine
      4) Hb
      5) Albumins, globulins

All laboratory test results from points 1 to 5 are within the normal range.

3. The minimum number of subjects is 10 persons.
4. Data collection

   The collected data is blood glucose level data from all subjects after being given 50 g of pure glucose. On different days, the subjects is given test food for the glycemic index. The test food is containing 50 g of available carbohydrates.

   In the event that food contains carbohydrates available in small quantities, to prevent unreasonable amounts of consumption, the test food may contain available carbohydrates of 25 g (for example: fruits, or other foods). The administration of pure glucose for this case is also adjusted to 25 g.

   Procedure for determining the glycemic index of food

   a. Initially, the subject needs to do fasting for at least 10 hours (e.g. from 10.00 p.m. to 08.00 a.m.), but the subject is still allowed to consume water. The blood glucose level of the subject is recorded and checked through capillary blood vessels (finger prick) as the 0th minute, followed by administration of pure glucose 50 g in a glass of water (200 ml). For subjects with type 2 diabetes mellitus, administration of oral hypoglycemic drugs is carried out before or after meals according to the recommended consumption method.
   b. The blood glucose of the subjects is re-taken and re-examined at 15th, 30th, 45th, 60th, 90th and 120th minutes after being given pure glucose.
   c. For subsequent treatment with predetermined time intervals, pure glucose is replaced with test food for its glycemic index.
   d. If there is more than one test food for the glycemic index, then the gap between tests for each food is 4-7 days.
   e. The results of all blood glucose measurements are included in the table.
   f. Blood glucose levels (at each time blood glucose is taken) are spread on two axes, namely the time axis (abscissa) and the blood glucose level axis (ordinate).
   g. The glycemic index is determined by comparing the area under the curve (Area Under Curve/AUC) between the test food for the glycemic index and pure glucose.

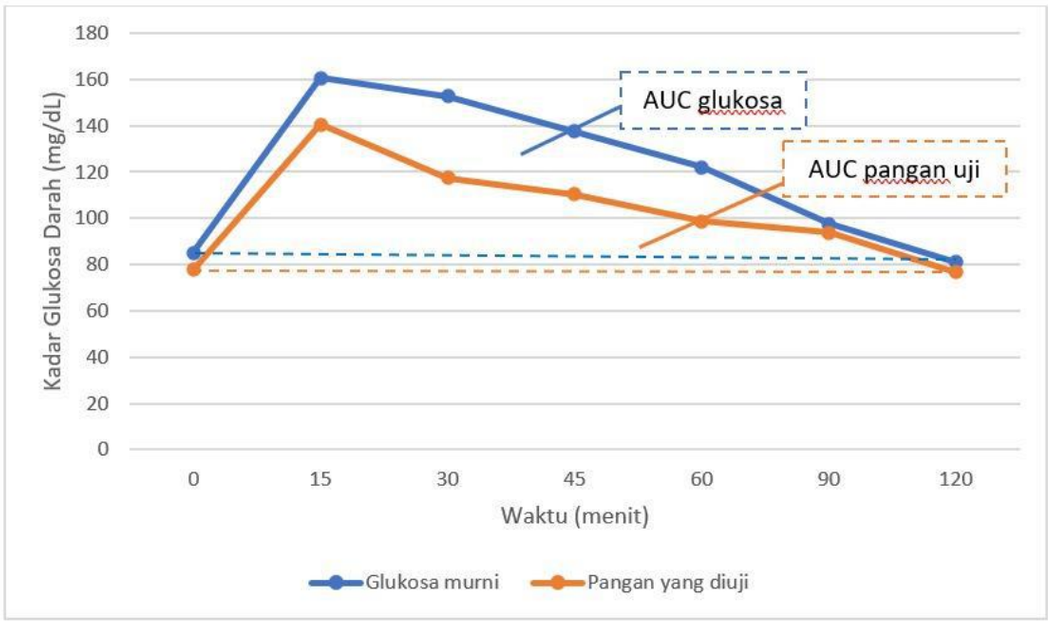


Image of Food Glycemic Index Measurement Curve

Notes:

Kadar Glukosa Darah = Blood Glucose Level

AUC glukosa = glucose AUC

AUC pangan uji = test food AUC

Waktu (menit) = Time (minute)

Glukosa murni = Pure glucose

Pangan yang diuji = Test food

Formula/Calculation of glycemic index:

$$\text{Glycemic Index} = \frac{\text{AUC of Test Food}}{\text{AUC of Pure Glucose}} x\ 100$$

Formula/Calculation of glycemic load:

$$\text{Glycemic Load} = \frac{\text{Glycemic Index x Total Carbohydrates in 1 serving size}}{100}$$

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

ANNEX IX
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 1 OF 2022 ON
CONTROL OF CLAIM ON PROCESSED FOOD LABELS AND ADVERTISEMENTS

ISOTONIC CLAIMS[1]

No	Parameters	Requirements
1	Osmolality	250 – 340 miliOsmol/Kg
2	Carbohydrate	
	2.1 Type of carbohydrate which can be added	Glucose, maltodextrin, sucrose, and fructose
	2.2 Carbohydrate content	2 – 8%
	2.3 Fructose (if added)	Not more than 5%
3	Sodium	200 – 690 mg/L
4	Potassium	125 – 200 mg/L
5	Designation	"For those who carry out activities until sweating and requiring fast electrolyte replacement."

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

[1] For products that require reconstitution, the calculation is performed on the product after it has been reconstituted.

ANNEX X
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 1 OF 2022 ON
CONTROL OF CLAIM ON PROCESSED FOOD LABELS AND ADVERTISEMENTS

VEGAN CLAIMS

1. Vegans are persons who do not consume food from animals and its products and products derived from meat, fish, eggs, milk or honey.
2. Inclusion of vegan Claims can be made as long as the Processed Food does not contain animal-based food ingredients and its products including honey.
3. The evidence that Processed Food does not contain animal-based food ingredients and its products as referred to in number 2 must be proven by analysis of deoxyribonucleic acid (DNA).
4. Inclusion of vegan Claims can be accompanied by a vegan logo.

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

ANNEX XI
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 1 OF 2022 ON
CONTROL OF CLAIM ON PROCESSED FOOD LABELS AND ADVERTISEMENTS

ASSESSMENT APPLICATION DATA

A. NEW CLAIMS OTHER THAN MICROORGANISM RELATED CLAIMS

1. APPLICANT ADMINISTRATION DATA

Applicant Name : .....
Position : .....
Business Entity Name : .....
Name of Person in Charge : .....
Business Entity Address : .....
Business Entity Phone Number : .....
PiC's Phone Number : .....
Business Entity Fax : .....
Business Entity Email : .....
PiC's Email : .....
Integrity Pact : .....

2. NUTRIENT / NON-NUTRIENT DATA

Nutrient/Non-Nutrient added : .....
Nutrient/Non-Nutrient trade name : .....
Total intake of nutrient/
non-nutrient per day (if any) : .....
Nutrient/Non-Nutrient specification : .....
History of use as food : .....
Production process of nutrient/
non-nutrient : .....
Regulation status of nutrient/
non-nutrient : .....

3. CLAIM SUBMISSION DATA

Proposed Claim : .....
Amount of nutrient/

non-nutrient added : .....

Marketing of Processed food with proposed claim in other countries : .....

Regulation status of claim : .....

4. PROCESSED FOOD DATA

Food type : .....

Trade name : .....

Net content : .....

Packaging type : .....

Production process : .....

Processed food analysis methods and results* : .....

Processed food composition : .....

5. SCIENTIFIC REFERENCE OR EVIDENCE*

Document title : .....

Publication date : .....

Authors : .....

Publication media : .....

Summary : .....

B. STARTER CULTURE WITH UNDEFINED MICROORGANISMS IN FERMENTED FOODS

1. STARTER CULTURE DATA

Type* (may choose more than one) : ☐ Bacteria
☐ Yeast
☐ Mold

Starter Culture

No	Genus	Species
etc.		

Starter culture trade name : .....

Total number of microorganisms in starter culture (CFU/g or CFU/ml) : .....

Production process of starter culture* : (document attached)

2. PROCESSED FOOD DATA

Food category* : .....

Food type* : .....

Amount of starter culture added during fermentation (%) : .....

Production process* : (document attached)

Fermentation condition and duration* : .....

Method to stop fermentation* : .....

Processed food composition*

No.	Name of Ingredients	Percentage (%)	Function
etc.			

Marketing of similar processed food in other countries

No.	Trade Name	Country	Document

			(attached)
etc.			

3. SAFETY DATA

History of use of fermented food*

No.	Document Title	Summary	Document (attached)
etc.			

Other safety data

No.	Document Title	Summary	Document (attached)
etc.			

C. STARTER CULTURE WITH DEFINED MICROORGANISMS IN FERMENTED FOODS

1. STARTER CULTURE DATA

Starter culture identity :

No.	Type* (bacteria/yeast/mold)	Genus*	Species*	Strain
etc.				

Starter culture trade name : .....

Total number of microorganisms in

starter culture (CFU/g or CFU/ml)* : .....

Production process of starter culture* : (document attached)

2. PROCESSED FOOD DATA

Food category* : .....

Food type* : .....

Amount of starter culture added

during fermentation (%) : .....

Production process* : (document attached)

Fermentation condition and duration* : .....

Method to stop fermentation* : .....

Processed Food Composition*

No.	Name of Ingredients	Percentage (%)	Function
etc.			

Marketing of similar processed food in other countries

No.	Trade Name	Country	Document (attached)
etc.			

3. SAFETY DATA

History of use of fermented food*

No.	Document Title	Summary	Document (attached)
etc.			

Regulation status*

No.	Document Title	Summary	Document (attached)

etc.			

Other safety data*

No.	Document Title	Summary	Document (attached)
etc.			

D. MICROORGANISMS AS FOOD INGREDIENTS (WITHOUT PROBIOTIC CLAIMS)

1. MICROORGANISM DATA

Microorganism identity

No	Type* (bacteria/ yeast)	Genus*	Species*	Strain	Form# (vegetative cells/spores)	Amount in dosage (CFU/g or CFU/ml)
etc.						

#only for bacteria

Microorganism identification method* : (document attached)

Culture collection evidence, if the strain is identified* : (document attached)

Trade name : .....

Production process of microorganism* : (document attached)

2. PROCESSED FOOD DATA

Food category* : .....

Food type* : .....

Trade name : .....

Net content : .....

Packaging type : .....

Production process* : (document attached)

Amount of microorganism added* : .....

(CFU/100g or CFU/100ml product) Note: If multi microorganisms, mention each microorganism added

Target number of living microorganisms at the time of consumption* (up to the expiry date and according to the instructions for use) : Cfu/g; cfu/ml Note: If multi microorganisms, mention target number of living microorganism during consumption

Shelf life* : .....

Serving size* : .....

Instructions for use* : .....

Label design : (document attached)

Processed Food Composition*

No.	Name of Ingredients	Percentage (%)	Function
etc.			

Marketing of similar processed food in other countries

No.	Trade Name	Country	Document (attached)
etc.			

3. MICROORGANISM FUNCTION CHARACTERISTICS DATA

In-Vitro Test Data and/or Experimental Animals

Resistant to gastric acidity*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Bile acids resistance*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Adherence to mucus and/or epithelial cells and colonize*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Antimicrobial activity against potential pathogenic bacteria*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Ability to reduce pathogenic bacteria adhesion (direct antagonist) to the surface of the intestinal mucosa*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Does not carry transferable antibiotic resistance genes*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

4. SAFETY DATA

Phase 1* clinical trial results

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

If multiple microorganisms are used, the safety data are carried out for each microorganism, and compatibility data are added.

Multi-strain and/or multispecies compatibility (synergistic and antagonistic)*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

E. PROBIOTICS IN PROCESSED FOOD

1. PROBIOTIC DATA

Probiotic identity

No.	Type*	Genus*	Species*	Strain*	Form#	Amount

	(bacteria/ yeast)				(vegetative cells/spores)	in dosage (CFU/g or CFU/ml)
etc.						

#only for bacteria

Strain identification method* : (document attached)

Culture collection* : (document attached)

Trade name : .....

Production process of probiotic : (document attached)

2. PROCESSED FOOD DATA

Food category* : .....

Food type* : .....

Trade name : .....

Net content : .....

Packaging type : .....

Production process* : (document attached)

Amount of microorganism added* : .....

(CFU/100g or CFU/100ml product) Note: If multi microorganisms, mention each microorganism added

Target number of probiotic : Cfu/g; cfu/ml

at the time of consumption* Note: If multi microorganisms,

(up to the expiry date and according mention target number of living

to the instructions for use) microorganism during consumption

Shelf life * : .....

Serving size* : .....

Instructions for use* : .....

Label design : (document attached)

Processed Food Composition*

No.	Name of Ingredients	Percentage (%)	Function
etc.			

Marketing of similar processed food in other countries

No.	Trade Name	Country	Document (attached)
etc.			

3. PROBIOTIC FUNCTION CHARACTERISTICS DATA

In-Vitro Test Data

Resistant to gastric acidity*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Resistant to bile acids*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Adherence to mucus and/or epithelial cells and colonize*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Antimicrobial activity against potential pathogenic bacteria*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Ability to reduce pathogenic bacteria adhesion (direct antagonist) to the surface of the intestinal mucosa*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Does not carry transferable antibiotic resistance genes*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Experimental Animal Data

Resistant to gastric acidity*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Bile acids resistance*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Adherence to mucus and/or epithelial cells and colonize*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Antimicrobial activity against potential pathogenic bacteria*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Ability to reduce pathogenic bacteria adhesion (direct antagonist) to the surface of the intestinal mucosa*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Does not carry transferable antibiotic resistance genes*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

4. SAFETY DATA

Phase 1* clinical trial results

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

If multi-strain microorganisms are used, the safety data are carried out for each microorganism, and compatibility data are added.

Multi-strain and/or multispecies compatibility (synergistic and antagonistic)*

Document title* : .....

Publication date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

5. EFFICACY DATA

Clinical trial document*

Document title* : .....

Publication date/accepted date* : .....

Authors* : .....

Publication media* : .....

Summary* : the observation results are mainly carried out on:

- feces quality
- qualitative and quantitative microorganisms living in the feces
- short chain fatty acid content in feces

Document link : .....

Complete document : (document attached)

F. HEALTH FUNCTION CLAIMS AND/OR REDUCTION OF DISEASE RISK CLAIMS ASSOCIATED WITH PROBIOTICS

Note: This form is used if microorganisms have been permitted as probiotics in processed food

1. PROBIOTIC DATA

Probiotic identity

No	Type* (bacteria/ yeast)	Genus*	Species*	Strain*	Form# (vegetative cells/spores)	Amount in dosage (CFU/g or CFU/ml)
etc.						

#only for bacteria

Strain identification method* : (document attached)

Culture collection* : (document attached)

Trade name : .....

Production process of probiotics : (document attached)

2. PROCESSED FOOD DATA

Food category* : .....

Food type* : .....

Trade name : .....

Net content : .....

Packaging type : .....

Production process* : (document attached)

Amount of probiotics added* : .....

(CFU/100g or CFU/100ml product) Note: If multi microorganisms, mention each microorganism added

Target number of probiotic : Cfu/g; cfu/ml

at the time of consumption* Note: If multi microorganisms,

(up to the expiry date and according mention target number of living

to the instructions for use) microorganism during consumption

Shelf life* : .....

Serving size* : .....

Instructions for use* : .....

Label design : (document attached)

Processed Food Composition*

No.	Name of Ingredients	Percentage (%)	Function
etc.			

Marketing of processed food with probiotics supported by health claims according to those submitted in other countries

No.	Trade Name	Country	Document (attached)
etc.			

1. CLAIM SUPPORTING DATA

Proposed claims*:

.....

.....

Clinical trial document*

Document title* : .....

Publication date/accepted date* : .....

Authors* : .....

Publication media* : .....

Summary* : .....

Document link : .....

Complete document : (document attached)

Regulation status of probiotic processed food with proposed claims

No.	Document Title	Summary	Document (attached)
etc.			

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

ANNEX XII
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 1 OF 2022 ON
CONTROL OF CLAIM ON PROCESSED FOOD LABELS AND ADVERTISEMENTS

CLAIM ASSESSMENT PROCEDURE

A. Introduction

The message conveyed through the advertisements and listed on the Processed Food label is a message that will advance Processed Food; however, the information from other sources may provide the opposite message. The advantages of Processed Food products can be assessed from the physical, chemical or organoleptic and Nutrient or Non-nutrient content that provide health benefits. The government has carried out certain measures so that any statements made by the manufacturer are true, not misleading, and in accordance with prevailing regulations, with the aim to protect the public and encourage fair and responsible food trade.

Information on Processed Food label that is specifically related to nutrition and health can be in the form of:

1. Nutrition label (Nutrition Information); and
2. Claim.

In accordance with the improvement of public awareness on the role of food and consumption patterns in maintaining health, it is expected that any information related to nutrition and health which is listed on the Processed Food label will aim to achieve the expected public health.

Claim as one of the components that may be included on labels and advertisements, must previously go through the assessment by the relevant and independent experts, and also based on scientific evidence that can be accountable so that it will meet the following criteria:

1. support national health and/or nutrition policies ;
2. be not related to treatment and prevention of a disease ;
3. not encourage false consumption patterns ;
4. based on total diet especially for health claims (reduction of disease risk claim); and
5. be truthful and not misleading.

B. Scope

This guideline is used to assess the claim on Processed Food which is not defined in the legislation.

C. Objective

To protect the public from the use of false and misleading claims included on the Processed Food labels and advertisements.

D. Assessment Principles

1. A research needed for the process of proposing a new claim.
   a. A research must be conducted on Processed Food products in the forms which are ready to consume and proven to be safe.
   b. The Nutrients/Non-Nutrients used are based on the following data:
      1) history of use as food;
      2) physical and chemical properties;
      3) the potential allergenicity;
      4) metabolism;
      5) sub-chronic toxicity studies in animals;
      6) studies of human tolerance;
      7) if a component is in the form of extracts of plant or animal, it must be supported by information of extraction method and extract composition; and
      8) safety assessment report by international institutions or other state government institutions, if any.
   c. Reduction of Disease Risk Claims must be based on a human research that meets applicable scientific principles, namely randomized controlled trials (RCT) experimental researches or observational researches if experimental research is not possible to be conducted. The research use a number of samples that represent population in various regions and are reproduceable, both self-conducted research and meta-analysis. If RCT research is conducted, it must apply Good Clinical Trial Method according to the legislation. In vitro and animal research can be submitted in addition to data on humans.

      Conditions that must be considered in the experimental research on human:

1) research objectives must be in accordance with the proposed claims;
2) test subject group and the control group must be relevant to the proposed claims and in accordance with the target population. Under certain conditions, it is necessary to do the research in Indonesia;
3) statistical strength to test hypotheses and clinical significance must be considered;
4) the number of test subject, the duration of interventions and observations must be sufficient to show the expected effect;
5) consistency of consuming test food containing the Food Component must be monitored;
6) Nutrient intake as well as components which are tested must be known and monitored with appropriate methods as a part of the experimental research;
7) the food consumption pattern used in the research did not exceed the normal consumption pattern according to the principle of balanced nutrition with the consideration that the treatment group and control group are equal;
8) the test product must be equivalent to the marketed product;
9) the food nature, direction of food preparation and food consumption manner associated with the Food Component benefits must be considered; and
10) the research should have been approved by an authorized ethical committee.

d. Nutrient Function Claims can only be used on foods that meet the criteria of “source of”. Nutrient Function Claims other than those listed in Annex III of this Regulation must meet the following requirements:
   1) functions of Nutrients have been recognized nationally and/or internationally; and
   2) there is a Nutrient usage relevancy in Indonesian society based on the problems and needs in Indonesia and proven by a valid scientific method.

2. Biomarker and End point
   a. Claimed benefits should be measured directly as the end point.

b. Biomarkers are substances used as parameters to see biological or physiological effects. Biomarkers are needed when functional benefits cannot or are difficult to measure directly as intermediate end points.
c. Biomarkers selected must be an indicator of biological, physiological, clinical, or epidemiological that have been recognized internationally, and can be affected by the consumption of food, Food Component or Food ingredients being researched. WHO Technical Report Series 916 can be used as a guide.
d. Variations in individual responses / between population groups must be considered in researches using biomarkers.
e. Biomarker measurement method must be commonly used by the international scientific community.

3. Systematic Evaluation of the Existing Data
   a. Research that has been published in peer-reviewed journals is preferred.
   b. Research is carried out by researchers or independent institutions (among others: universities, research institutes) or institutions that have no conflict of interest.
   c. The results must demonstrate that the use of the product has shown statistically and clinically significant effects based on the claim and the amount of the recommended intake.

4. Monitoring and Evaluation

   Monitoring and Evaluation is conducted periodically and/or whenever there is a new finding.

CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

ANNEX XIII
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 1 OF 2022 ON
CONTROL OF CLAIM ON PROCESSED FOOD LABELS AND ADVERTISEMENTS

ASSESSMENT PROCEDURES OF MICROORGANISMS IN PROCESSED FOOD

I. INTRODUCTION

I.A. Background

The manufacture and consumption of fermented food have been existing for a long time and are based on hereditary traditions. The fermentation process in food ingredients can produce food with different characteristics from the original food. Fermentation is a biochemical change process in food that involves the activity of microorganisms through enzymatic processes produced by these microorganisms. Fermentation products are mainly produced by the activities of lactic acid bacteria, acetic acid bacteria, fungi/mold, and yeast. The purpose of traditional food fermentation is originally to preserve seasonal and perishable food. In line with the advancement of science and technology and changes in people's lifestyles, the current development of fermented food products is not only for its unique texture, aroma and taste, but also for health benefits.

In addition, the advancement of science and technology also encourages innovation in the use of microorganisms in food. The use of microorganisms in food is not limited to the fermentation process but is added to food for the purpose of health benefits known as probiotics. Probiotics are also experiencing quite rapid development, both with claims for other health benefits, additions in combination form (multi-strains and/or multispecies), combinations of probiotics with prebiotics, and others.

In order to ensure the products and truthful information for the public in accordance with existing scientific evidence, as well as to safeguard fair and accountable food trade, so the government, in this case the Indonesian Food and Drug Authority, according to its duties and functions, is given a mandate to formulate regulations for this type of processed food. It is expected that this regulation will not only guarantee that processed food in circulation is safe and useful, but also provide guidance for business actors to be able to produce processed food that is

safe and useful. With regard to the use of these microorganisms, the Indonesian Food and Drug Authority has prepared guidelines for the assessment of microorganisms in processed food.

I.B. Objective

This guideline is used as a guide in conducting safety assessments and the utilization of live microorganisms in processed food, either to assist the fermentation process or to be added to food, with or without the inclusion of probiotic claims and/or health claims.

I.C. Scope

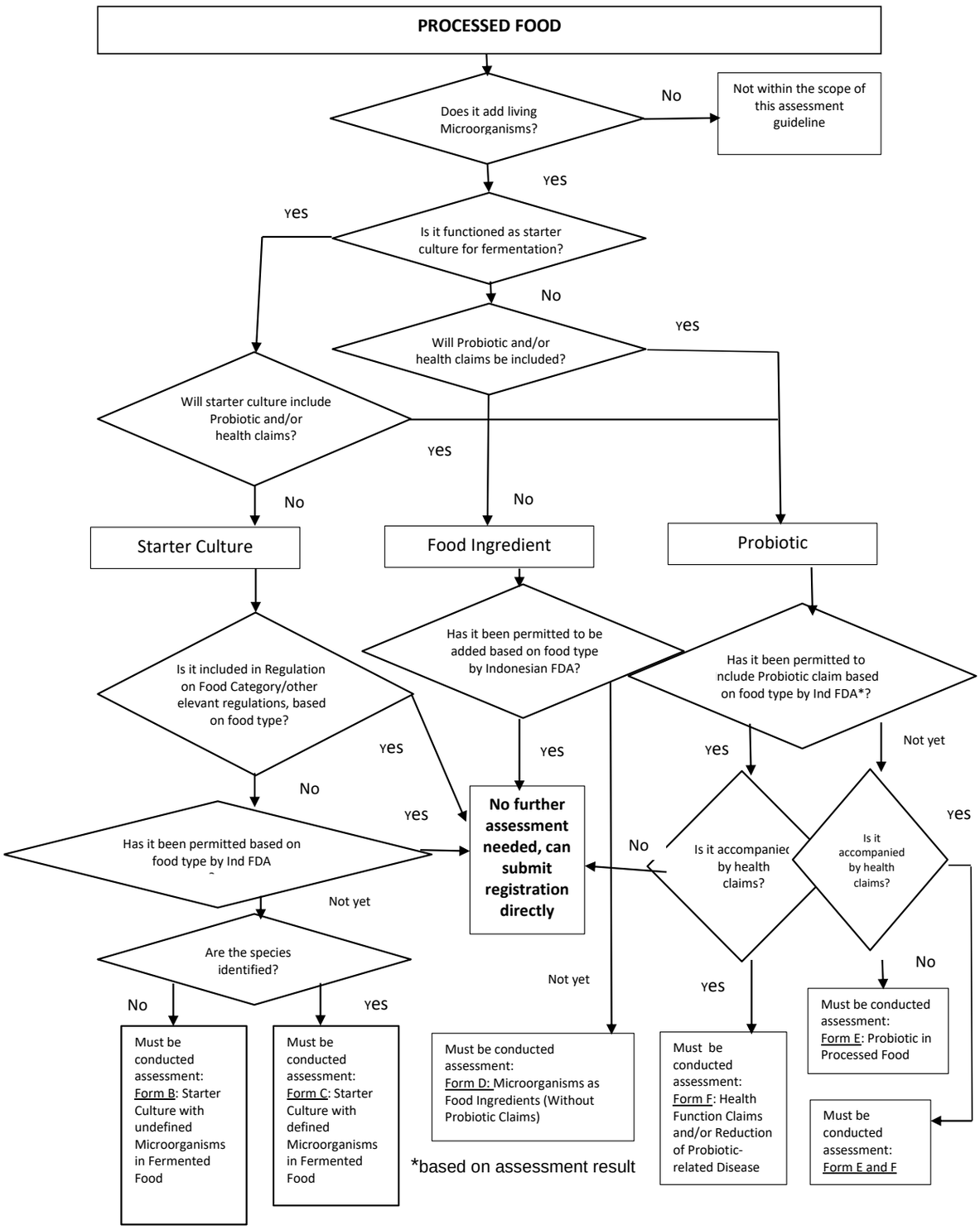
This guideline applies only for the utilization of microorganisms in processed food, namely:

1. The use of microorganisms as starter cultures for food fermentation processes, including:
   1.1. Starter cultures with undefined microorganisms; and
   1.2. Starter cultures with defined microorganisms.
   1.3. Starter cultures as probiotics.

   However, this does not include spontaneous fermentation processes and the use of fermented food as a starter (back sloping).
2. Addition of microorganisms to processed food:
   2.1. As a food ingredient (without the “probiotic” claim)
   2.2. As a probiotic
      2.2.1. with “Probiotics” claims.
      2.2.2. with health claims.

The assessment of microorganisms in processed food is conducted based on the decision tree as follows:

Notes:


PROCESSED FOOD
Does it add living Microorganisms?
No
Not within the scope of this assessment guideline
yes
Is it functioned as starter culture for fermentation?
yes
No
Will Probiotic and/or health claims be included?
yes
Will starter culture include Probiotic and/or health claims?
yes
No
No
Starter Culture
Food Ingredient
Probiotic
Is it included in Regulation on Food Category/other elevant regulations, based on food type?
Has it been permitted to be added based on food type by Indonesian FDA?
Has it been permitted to nclude Probiotic claim based on food type by Ind FDA*?
yes
yes
yes
Not yet
No
yes
No further assessment needed, can submit registration directly
Has it been permitted based on food type by Ind FDA
Is it accompanied by health claims?
Is it accompanied by health claims?
yes
No
Not yet
Are the species identified?
Not yet
yes
No
No
yes
Must be conducted assessment: Form B: Starter Culture with undefined Microorganisms in Fermented Food
Must be conducted assessment: Form C: Starter Culture with defined Microorganisms in Fermented Food
Must be conducted assessment: Form D: Microorganisms as Food Ingredients (Without Probiotic Claims)
Must be conducted assessment: Form F: Health Function Claims and/or Reduction of Probiotic-related Disease
Must be conducted assessment: Form E: Probiotic in Processed Food
Must be conducted assessment: Form E and F
*based on assessment result

II. GENERAL PROVISION

II.A Definition

1) Strains mean species that genetically different, expressing several different characters.
2) Food starter cultures mean microorganisms that are safe for use in food (food grade), and active cultures that are deliberately inoculated and grown in food ingredients to initiate and carry out necessary food changes and provide the expected sensory characteristics.
3) Food fermentation means a process of changing biochemically in food ingredients that involves the activity of microorganisms.
4) Probiotics mean live microorganisms if consumed in adequate amount can provide health benefits to consumers.
   (Live microorganisms which when administered in adequate amounts confer a health benefit on the host – WHO/FAO 2001)"
5) Probiotic food means processed food containing live microorganisms if consumed in adequate amounts can provide health benefit for consumers.
6) Clinical Trial means a research activity involving human subjects supported by intervention of test products, to find or confirm other clinical, pharmacological and/or pharmacodynamic effects, and/or identify any adverse reactions, and/or study absorption, distribution, metabolism and excretion with the aim of ensuring the safety and/or effectiveness of the product being examined.
7) The Phase 1 Clinical Trial means the first biomedical test conducted on a small group of healthy humans to evaluate the range of safe doses and identify side effects.

II.B The following conditions are required in the utilization of microorganisms in processed food

1) Microorganisms added to processed food with or without inclusion of probiotic claims must comply with the provisions, namely not being pathogenic, not producing toxins, not causing hemolysis, and not carrying transferable antibiotic resistance genes.
2) Microorganisms added to processed food as Probiotics:
   a) Live microorganisms, and proven safe and beneficial for health;

b) the accurate amount of each important Probiotic bacterium is determined to provide a health effect. The number of live microorganisms for probiotics is specific to the strain, depending on the benefits based on valid and consistent clinical trial results;

c) in order to be included in Processed Food, Probiotic microorganisms not only need to survive in the digestive tract but also to proliferate (grow and multiply) in the digestive tract;

d) the ability of probiotic microorganisms to survive and proliferate in the digestive tract is highly dependent on the strain, microbiota profile in the digestive tract, and environmental conditions of the digestive tract which are heavily influenced by the local environment and living habits.

e) the use of Probiotics as Food ingredients must be based on scientific evidence including identification of strains, number of live microorganisms, history of use and health benefits as well as possible side effects;

f) scientific evidence in the form of clinical trial results must be conducted in accordance with the principles of Good Clinical Practice (GCP) and guidelines for processed food clinical trials.

g) In order to clarify the identity of Probiotics in Processed Foods, it is mandatory to include the genus, species and strain of Probiotics on the label, because the effects of Probiotics are specific to each strain and the effects of these strains cannot be extrapolated to other types of strains.

III. ASSESSMENT

III.A. ASSESSMENT OF MICROORGANISMS USED AS STARTER CULTURES IN THE FOOD FERMENTATION PROCESS

The food fermentation process is divided into two, namely:

a) Spontaneous fermentation is food fermentation in which microorganisms are not added in the form of starters during the production; however, natural microorganisms that play active roles in the fermentation process, reproduce spontaneously because their environment is made suitable for their growth. E.g. the growth of lactic acid bacteria in the production of salted vegetables.

b) Non-spontaneous fermentation is fermentation that occurs in food in

which microorganisms are added in the form of starter culture during the production. These microorganisms will grow and reproduce actively, changing fermented food into the desired food product, which has a longer shelf life, is preferable and is easier to digest, as well as can improve the texture, taste, and nutrition, e.g., in the production of tempeh.

In the fermentation process, the microorganisms must hold 3 (three) important characteristics, namely:

a) Microorganisms must be able to grow and reproduce rapidly in a suitable substrate and environment to reproduce
b) Microorganisms must have the ability to regulate physiological resistance and have certain enzymes according to the substrate contained in the food ingredients so that the expected chemical changes may occur
c) The environmental conditions needed for growth must be suitable so that the fermentation process will run in an optimal manner.

The assessment in this section is used to evaluate the safety of using live microorganisms as starter cultures in food fermentation processes, but does not include spontaneous fermentation processes and use fermented food as a starter (back sloping).

The assessment includes starter cultures with undefined microorganisms and starter cultures with defined microorganisms.

A.1 **Assessment of Starter Cultures with <u>Undefined</u> Microorganisms**

Starter cultures with undefined microorganisms are commonly found in traditional fermented foods (examples of starter cultures: yeast tape, yeast/ tempeh yeast, sour bread yeast, kefir seeds, etc.). The composition of the types of microorganisms in this starter culture cannot be completely confirmed in relation to both its specific quality or quantity, resulting in the unclarity of their characteristics.

1) Taxonomic identification

Information on the taxonomic group (genus or species) of starter culture (if any). Evidence is based on the results of scientific publications.

2) Starter culture production process

Information on starter culture production process

3) Fermented food information

a) Food category and fermented food type
b) List of ingredients or composition of fermented food
c) Marketing of fermented food using the same starter culture in other countries (if any).

4) Fermented food production process

a) Information regarding fermented food production including the stages of adding starter culture and the amount of addition, if any.
b) Conditions, duration of fermentation and how to stop fermentation.

5) Safety Data

Safety data can be in the form of information regarding the consumption of fermented food with certain starter cultures for several generations in the population to obtain an illustration that there is no hazard arising from the consumption of these foods.

The history of such use can be proven by scientific publications and/or letters of information from the local government or authorized institutions from the country of origin.

6) Labeling

For fermented food with undefined starter culture is required to include information of the starter culture in the list of ingredients or composition. Information in the form of the name of the starter culture, such as: *tape* yeast, tempeh yeast, etc. needs to be included.

A.2 **Assessment of Starter cultures with <u>defined</u> microorganisms**

Starter cultures with defined microorganisms are one or more microorganisms whose characteristics are completely confirmed.

1) Identification of microorganisms

Information in the form of genus, species and/or starter culture strains.

2) Starter culture production process

Information on starter culture production process

3) Fermented food information

a) Food category and fermented food type
b) List of ingredients or composition of fermented food
c) Marketing of fermented food using the same starter culture in

other countries (if any)

4) Process of fermented food production

a) Information regarding fermented food production including the stages of adding starter culture and the amount of addition, if any

b) Conditions, duration of fermentation and how to stop fermentation

5) Safety Data

Safety data can be in the form of:

a) Information regarding consumption of fermented food with certain starter cultures for several generations in the population, to obtain an illustration that there is no hazard arising from the consumption of these foods.

The history of such use can be proven by scientific publications or letters of information from local governments or authorized institutions from the country of origin; and

b) supporting data such as safety acknowledgments from authorized institutions in other countries, such as: Generally Recognized As Safe (GRAS), Qualified Presumption of Safety (QPS), etc.

6) Labeling

Fermented food with an defined starter culture is required to include an information of the starter culture in the list of ingredients or compositions.

Information in the form of starter culture is supported by the genus, species and/or strain of such starter culture. E.g.: "*Lactobacillus bulgaricus* and *Streptococcus thermophilus* starter cultures".

A.3 **Assessment of Probiotic Starter Cultures**

Assessment of starter cultures as probiotics see section B2.

III.B. ASSESSMENT ON MICROORGANISMS ADDED TO PROCESSED FOOD

This stage is used to assess the safety and/or benefits of adding live microorganisms to processed food with or without the inclusion of probiotic claims and or other health claims; however, the purpose of adding these microorganisms is not as a starter culture for food fermentation processes. The processed food added with live microorganisms can be in the form of fermented food or non-fermented food.

B.1 Assessment of Microorganisms as Food Ingredients (Without "Probiotic" Claim)

1. Identification of microorganisms

a) Genus and species of microorganisms

The genus and species of live microorganisms must be defined.

For microorganisms added more than one genus/species, each genus/species must be defined.

b) Nomenclature of microorganisms

The nomenclature of microorganisms must match their scientific names. Misleading microorganism names must not be used.

The latest nomenclature of microorganisms can refer to the recent publication in the "International Journal of Systematic and Evolutionary Microbiology".

c) Types and Forms of microorganisms

- Bacteria

  Forms of bacteria include vegetative cells (non-spores) and spores
- Yeast
- Mold

d) Identification method

The identification method of microorganisms uses phenotypic and genotypic methods

- Genotypic methods based on DNA sequences encoding 16S rRNA for prokaryotes or

- Genotypic methods based on DNA sequences encoding 18S rRNA or other equivalent methods for eukaryotes.

Those methods can be carried out by using the following techniques:

1. WGS (whole genome sequencing); or
2. PCR and sequencing

e) Deposit of strains

If a microorganism is identified to a strain, then evidence of keeping the strain of the microorganism in national and/or international culture collections must be shown.

Examples of national cultural collections include:

- InaCC (Indonesia Culture Collection)-LIPI
- FNCC (Food and Nutrition culture collection)-UGM
- IPBCC (Institut Pertanian Bogor Culture Collection)-IPB

2. Microorganism production process

Information on the microorganism production process

3. Processed food information

a) Food category and food type

b) List of ingredients or composition of processed food

c) Information on food production including the stages of adding microorganisms and the amount added.

If multi-microorganisms are added, the amount of each micro-organism (CFU/100g or CFU/100ml of product) is mentioned.

d) The amount of live microorganisms in processed food when consumed (according to the instructions for use) until the end of the shelf life must comply with the safety evidence submitted. Analysis of the amount of microorganisms must use a valid method.

If multi microorganisms are used, then the provision above apply to each live microorganism.

e) Marketing of processed food added with the same microorganism in other countries (if any).

4. Characterization of the function of microorganisms

a) In vitro test; and/or

In vitro test is to screen for potential microorganisms.

In vitro tests that need to be carried out specifically to determine the characteristics of microorganisms as follows:

- Resistant to gastric acidity;
- Resistant to bile acids;
- Able to attach to mucus and/or epithelial cells and human intestinal cell line and colonize;
- Has antimicrobial activity against potential pathogenic bacteria;
- Able to reduce the adherence of pathogenic bacteria (direct antagonist) on the surface of the intestinal mucus; and
- Do not carry transferable antibiotic resistance genes.

b) In vivo test/experimental animals

All the aforementioned tests can be validated using in vivo tests. It uses experimental animals (e.g., rats) which is proven by the persistence of microorganisms in the digestive tract of experimental animals.

5. Safety Assessment

Safety assessments are carried out to determine whether the microorganisms that will be consumed by humans are proven safe and will not cause side effects such as:

- systemic infection;
- deleterious of metabolic activity;
- excessive immune stimulation in vulnerable individuals; and/or
- gene transfer.

Safety support data includes phase 1 clinical trials.

The evidence of clinical trials can use:

a) safety acknowledgment from authorized institutions in other countries, such as: Generally Recognized As Safe (GRAS), Qualified Presumption of Safety (QPS), etc.; and/or
b) results of phase 1 clinical trials, preferably results published in peer-reviewed journals.

If multiple microorganisms are used, the safety data is carried out for each microorganism. In addition, it is necessary to add compatibility data (synergistic and antagonistic) in the form of clinical trial results.

6. Labeling

Labels of processed food containing microorganisms, in addition to comply with Regulations of Indonesian FDA concerning Processed Food Labels, must also include the following information:

a) a description of the genus, species and/or strain in the list of

ingredients or composition;

b) the minimum amount of live microorganisms can be stated in Colony forming units (CFU) per serving on a part of the label that is easy to see;

e.g.:

"contains ... (name of microorganism) $1x10^8$ CFU per serving" or

”contains … (name of microorganism) 100 million CFUs per serving”. This minimum amount is the result of an analysis of the number of microorganisms which is proven in each type of ready-to-consume processed food until the end of its shelf life. The evidence must use a valid method.

c) proper storage instructions to maintain the viability of the microorganism.

B.2 **Assessment of Probiotics With or Without Accompanied by Health Claims**

1. Identification of microorganisms

a) Genus, species, and strains of microorganisms

The genus, species, and strain of live microorganisms must be defined. For microorganisms added more than one strain (multi-strain), then each strain must be defined.

b) Nomenclature of microorganisms

The nomenclature of microorganisms must match their scientific names. Misleading microorganism names must not be used.

The latest nomenclature of microorganisms can refer to the recent publication in the "International Journal of Systematic and Evolutionary Microbiology".

c) Types and Forms of microorganisms

- Bacteria

  Forms of bacteria include vegetative cells (non-spores) and spores
- Yeast
- Mold

d) Identification method

The identification method of microorganisms uses phenotypic and genotypic methods

- Genotypic methods based on DNA sequences encoding 16S

rRNA for prokaryotes; or

- Genotypic methods based on DNA sequences encoding 18S rRNA or other equivalent methods for eukaryotic

Those methods can be carried out by using the following techniques:

3. WGS (whole genome sequencing); or
4. PCR (polymerase chain reaction) and sequencing

e) Deposit of Strain

Deposit of microorganism strains is evidenced in national and/or international culture collections. Example: national culture collections, among others:

- InaCC (Indonesia Culture Collection)-LIPI
- FNCC (Food and Nutrition culture collection) -UGM
- IPBCC (Institut Pertanian Bogor Culture Collection)

2. Microorganism production process

Information on microorganism production process

3. Processed food information

a) Food category and food type
b) List of ingredients or composition of processed food
c) Information on food production includes the stages of addition microorganisms and the amount added. If multi-microorganisms are used, the amount of each micro-organism added (CFU/100g or CFU/100ml of product) is mentioned.
d) The amount of live microorganisms in processed food when consumed (according to the instructions for use) until the end of the shelf life must comply with the evidence of benefits during clinical trials. Analysis of the amount of microorganisms must use a valid method.

   If multi microorganisms are used, then the provision applies to each live microorganism.
e) Marketing of processed food added with the same microorganism in other countries (if any).

4. Characterization of probiotic function

a) In vitro test; and

In vitro test is to screen for potential microorganisms.

In vitro tests that need to be carried out specifically to determine the characteristics of microorganisms as follows:

- Resistant to gastric acidity;
- Resistant to bile acids;
- Able to adhere to mucus and/or epithelial cells and human intestinal cell line and colonize;
- Has antimicrobial activity against potential pathogenic bacteria;
- Able to reduce the adherence of pathogenic bacteria (direct antagonist) on the surface of the intestinal mucus; and
- Do not carry transferable antibiotic resistance genes.

b) In vivo test/experimental animals

All the aforementioned tests can be validated using in vivo tests. It uses experimental animals (e.g., rats) which is proven by the persistence of microorganisms in the digestive tract of experimental animals.

5. Safety Assessment

Safety assessment are carried out to determine whether the microorganisms that will be consumed by humans are proven safe and will not cause side effects such as:

- systemic infection;
- deleterious of metabolic activity;
- excessive immune stimulation in vulnerable individuals ; and/or
- gene transfer.

Safety support data includes phase 1 clinical trials.

The evidence of clinical trials can use:

a) safety acknowledgment from authorized institutions in other countries, such as: Generally Recognized As Safe (GRAS), Qualified Presumption of Safety (QPS), etc.; and/or
b) results of phase 1 clinical trials, preferably results published in peer-reviewed journals.

If multiple microorganisms are used, the safety data is carried out for each microorganism. In addition, it is necessary to add compatibility data (synergistic and antagonistic) in the form of clinical trial results.

6. Efficacy Assessment

The efficacy assessment is carried out based on the evaluation of clinical trial results adjusted for the type of claim.

Types of claims related to microorganisms added to processed food are:

i. The “Probiotic” Claim; and/or

ii. Health claims regarding probiotics;

a) <u>Evaluation of clinical trial results for “Probiotic” function claims</u>

Clinical trials for "Probiotic" claims are carried out with the following requirements:

1. Preferably using a double-blind randomized, placebo-controlled trial (DBPC), which aims to determine the efficacy of probiotic products compared to controls and to determine the possible adverse (negative) effects.
2. Placebo is Processed Food that does not contain Probiotics.
3. The number of samples is calculated based on the minimum number of samples statistically according to the primary outcome.
4. Observation of clinical trials for the "Probiotic" claim is mainly carried out on:
   - feces quality (by measurement, among other things, the pH and feces scale using the Bristol method or other validated and scientifically recognized methods);
   - qualitative (molecular) and quantitative (cultural and/or molecular) microorganisms living in feces; and
   - content of short chain fatty acids (butyric acid, acetic acid, propionic acid) in feces.

If using supporting data in the form of clinical trial results with test products that have different matrices (other forms), the data can be used as long as their viability can be proven until the end of the shelf life according to the method of use, with the consideration of the product composition, e.g. the presence of anti-microbials or preservatives.

The confirmation of clinical trial results to support "probiotic" claims is prioritized in Indonesia with healthy subjects, not as medicines for medicinal purposes.

If the clinical trial has not been conducted in Indonesia, the confirmation of efficacy can use the results of clinical trials conducted in countries with consumption patterns, sanitation hygiene practices and public health problems that are equivalent with those in Indonesia, such as: Malaysia,

Thailand, and Vietnam.

If the results of clinical trials are used in countries other than the aforementioned results, the supporting data in the form of consumption patterns, sanitation hygiene practices, and public health problems which are equivalent to those in Indonesia are necessary.

If all the requirements have been completed, in addition to the "Probiotic" claim, the following claim can also be included: "helps maintain the health of the digestive tract".

b) <u>Evaluation of clinical trial results for health claims (function claims and reduction of disease risk claims)</u>

Health claims related to probiotics including function claims and reduction of disease risk claims must be based on the results of human studies that comply with applicable scientific principles, namely, several double-blind randomized, placebo-controlled trials (DBPC), or other designs with clear main outcome to determine that the strain has an efficacy with a minimal sample size that is suitable for responding to the main outcome.

The confirmation of clinical trial results to support proposed claims is prioritized in Indonesia. If clinical trials for proposed claims have not been carried out in Indonesia, confirmation of efficacy can use the results of clinical trials conducted in countries with consumption patterns, hygiene practices, sanitation, and public health problems that are equivalent to those in Indonesia, such as: Malaysia, Thailand, and Vietnam.

If the results of clinical trials are used in countries other than the results, the supporting data in the form of consumption patterns, sanitation hygiene practices, and public health problems which are equivalent to those in Indonesia are necessary.

The research is preferably conducted by more than one institution and applies Good Clinical Practice in accordance with the provisions of legislations.

Conditions that must be considered in experimental research on humans must refer to Guidelines for Clinical Trials on

Processed Food, which include, among others:

i. research objectives must be in accordance with the proposed claims;
ii. test subject group and the control group must be relevant to the proposed claims and in accordance with the target population;
iii. research results must show that the use of the product shows a statistically and clinically significant effect according to the claim and the recommended intake amount;
iv. the number of subjects studied, the duration of the intervention and the parameters observed (end points/biomarkers) must be sufficient to show the expected effect;
v. consistency to consuming foods containing the test probiotics must be monitored;
vi. the intake of the tested probiotics must be identified and monitored by suitable methods as a part of the experimental research;
vii. The food consumption patterns used in the research did not exceed the typical consumption patterns and were confirmed to be equal between the treatment and control groups.

7. Labeling

Labels of processed food containing probiotics, in addition to compliance with Regulations of the Indonesian FDA, must also include the following information:

a) a description of the genus, species and strains in the list of ingredients or composition;
b) the minimum amount of live microorganisms can be stated in Colony forming units (CFU) per serving on a part of the label that is easy to see;

example:

"contains Probiotics ... (name of microorganism (up to strain)) $1x10^8$ CFU per serving" or

”contains Probiotics … (name of microorganism (up to strain)) 100 million CFUs per serving”.

This minimum amount is the result of an analysis of the amount of microorganisms which is proven in each type of ready-to-consume processed food until the end of its shelf life. The evidence must use a valid method.

c) proper storage instructions to maintain the viability of the microorganism.

d) Claims can be listed after a case-by-case assessment.

e) Claims that can be included are as follows:
   - the "Probiotics" claim which can be supported by the claim "helps maintain the health of the digestive tract".
   - health claims (functional claims and reduction of disease risk claims) can be listed according to the results of efficacy test.

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO