

REGULATION OF HEAD OF DRUG AND FOOD CONTROL AGENCY OF THE
REPUBLIC OF INDONESIA
NO. HK.03.1.5.12.11.09956 YEAR 2011
CONCERNING
PROCESSED FOOD REGISTRATION PROCEDURE
WITH THE GRACE OF THE ALMIGHTY GOD
HEAD OF DRUG AND FOOD CONTROL AGENCY OF THE REPUBLIC OF
INDONESIA

Considering:

that, to implement the provisions of Article 42 paragraphs (5) and (6) of Government Regulation No. 28/2004 on Food Safety, Quality, and Nutrition, it is necessary to stipulate Regulation of Head of Drug and Food Control Agency on Processed Food Registration Procedure;

In view of:

1. Law No. 7/1996 on Food (Statute Book of 1996 No. 99, Supplement No. 3656);
2. Law No. 8/1999 on Consumer Protection (Statute Book of 1999 No. 42, Supplement No. 3821);
3. Law No. 36/2009 on Health (Statute Book of 2009 No. 144, Supplement No. 5063);

4. Government Regulation No. 69/1999 on Food Label and Advertisement (Statute Book of 1999 No. 131, Supplement No. 3867);
5. Government Regulation No. 28/2004 on Food Safety, Quality, and Nutrition (Statute Book of 2004 No. 107, Supplement No. 4424);
6. Presidential Decree No. 103/2001 on Position, Task, Function, Authority, Organization Structure, and Work Procedure of Non-Departmental Government Institution as already amended several times and lastly by Presidential Regulation No. 64/2005;
7. Presidential Decree No. 110/2001 on Organization Unit and Task of Echelon I of Non-Departmental Government Institution as already amended several times and lastly by Presidential Regulation No. 52/2005;
8. Decree of Head of Drug and Food Control Agency No. 02001/SK/KBPOM Year 2001 on Organization and Work Procedure of Drug and Food Control Agency as already amended by Decree of Head of Drug and Food Control Agency No. HK.00.05.21.4231 Year 2004;
9. Regulation of Head of Drug and Food Control Agency No. HK.03.1.5.12.11.09955 Year 2011 on Processed Food Registration.

DECIDED:

To stipulate: REGULATION OF HEAD OF DRUG AND FOOD CONTROL AGENCY
CONCERNING PROCESSED FOOD REGISTRATION PROCEDURE.

CHAPTER I

GENERAL PROVISIONS

Article 1

Hereinafter referred to as:

1. Food is anything derived from biological and water sources, processed or unprocessed, intended as food or beverage for human consumption including Food Additive, food raw material, and other material used in the process of preparation, processing, and/or production of food or beverages.
2. Processed Food is food or beverage as a result of processing by specific means or method with or without additive, including Certain Processed Food, Food Additive, Genetically Engineered Food, and Irradiated Food.
3. Food Additive (BTP) is a material added into Food to affect Food characteristic or form.

4. Registration is procedure of assessment of safety, quality, and nutrition of Processed Food to obtain Registration Approval Letter.
5. Registration Approval Letter is approval on result of Processed Food Assessment issued by Agency Head in the framework of Processed Food Distribution.
6. Label is every information concerning Food in the form of picture, word, a combination of both, or other form that accompanies the Food, inserted into, attached to, or is a part of Food package.
7. Company is processed food producer, importer, or distributor who already obtains business license in accordance with the prevailing legislation.
8. Registerer is a company or a party authorized by the company to perform Processed Food Registration in the framework of obtaining Registration Approval Letter.
9. Evaluation and Registration Cost is cost imposed in the framework of Processed Food Assessment in accordance with the provisions of the legislation.

10. Director is the Director of Food Safety Assessment.

11. Agency Head is Head of Drug and Food Control Agency of the Republic of Indonesia.

12. Day is working day.

CHAPTER II

PROCESSED FOOD REGISTRATION PROCEDURE

Part One

General Registration

Article 2

(1) Registration application shall be submitted in writing by filling out Registration Form accompanied with completeness of Registration document.

(2) Format of Registration form, as referred to in paragraph (2), is as specified in Attachment I which forms an inseparable integral part of this Regulation.

Article 3

(1) Processed Food Registration form shall be filled out by using Indonesian language.

(2)Registration document may use Indonesian or English language.

(3)Registration form and document shall be filled out completely and correctly in accordance with guidelines on form and registration document completion.

(4)Guidelines on form and registration document completion, as referred to in paragraph (3), is specified in Attachment 2 which forms an inseparable part of this Regulation.

Article 4

The Registerer shall submit application, as referred to in Article 2, in two (2) copies (original and duplicate) to Agency Head c.q. Director to undergo document inspection and designation of Evaluation and Registration Cost.

Article 5

Result of document inspection, as referred to in Article 4, could be in the form of:

- a. received to be further evaluated;
- b. returned to be completed; or
- c. rejected.

Article 6

(1) In case that result of document inspection declares received to be further evaluated, the Registerer will be given Bank Payment Introduction Letter.

(2) Bank Payment Introduction Letter, as referred to in paragraph (1), shall contain Evaluation and Registration Cost that must be paid as non-tax state revenue in accordance with the provisions of the legislation.

Article 7

(1) Registration application that has been completed with proof of payment of Evaluation and Registration Cost from the bank shall be submitted to Agency Head c.q. Director for further evaluation.

(2) Application, as referred to in paragraph (1), shall be submitted not later than one (1) month since Bank Payment Introduction Letter is given to the Registerer, as referred to in Article 6 paragraph (1).

Article 8

Result of further evaluation, as referred to in Article 7, could be in the form of:

a. issuance of Registration Approval Letter; or

b. issuance of Registration Rejection letter.

Article 9

(1) Registration Approval Letter or Registration Rejection Letter, as referred to in Article 8, for:

a. certain processed food shall be issued within not later than one hundred fifty (150) days;

b. functional food/food with claims, food with herbal shall be issued within not later than one hundred twenty (120) days;

c. irradiated food, genetically engineered food, flavor (food additive), organic food, milk and products thereof, meat and products thereof, fish and products thereof, and alcoholic beverages shall be issued within not later than one hundred (100) days;

d. food additive in addition to flavor and other food shall be issued within not later than sixty (60) days.

(2) Other food, as referred to in paragraph (1) letter d, includes food types other than those mentioned in paragraph (1) letters a, c, and c, and food additives in addition to flavor.

(3)The length of time, as referred to in paragraph (1) shall be counted since receipt of Registration form, as referred to in Article 7.

(4)In case that result of further evaluation requires additional data and or further analysis, calculation of the time, as referred to in paragraph (1), shall be temporarily stopped and shall be counted after date of letter of request for additional data.

(5)Calculation of time which is temporarily stopped, as referred to in paragraph (43), will be continued since date of receipt of letter of fulfillment of additional data.

Article 10

(1)In case that result of further evaluation requires additional data and or further assessment, as referred to in Article 9 paragraph (4), letter of request for additional data shall be issued in accordance with the format as specified Attachment 3 which forms an inseparable part of this Regulation.

(2)Within not later than fifty (50) days since date of letter of request for additional data, as referred to in paragraph (1), the register shall submit additional data.

(3) In case that the fifty (50) day period, as referred to in paragraph (2), is deemed insufficient, the registerer may submit request for extension of time to complete additional data to the Director for one (1) time at the maximum within a period of twenty-five (25) days.

(4) Registerer who does not submit additional data within fifty (50) days as referred to in paragraph (2) and/or twenty-five (25) days as referred to in paragraph (3), will be given Registration Rejection letter and the application document will be destroyed.

(5) If data completeness submitted by registerer does not meet the requirements stipulated in accordance with letter of request for additional data, as referred to in paragraph (1), the registerer will be given a subsequent letter of request for additional data in accordance with the format as specified in Attachment 4 which forms an inseparable part of this Regulation, and the registerer shall submit additional data within not later than fifteen (15) days since date of letter of request for additional data.

Article 11

In case that decision result is in the form of Registration Approval Letter, a Registration Approval Letter will be issued

according to the format as specified in Attachment 5 which forms an inseparable part of this Regulation.

Article 12

In case that decision is in the form of Registration Rejection, a rejection letter will be issued along with reasons of rejection according to the format as specified in Attachment 6 which forms an inseparable part of this Regulation.

Part Two

Amendment of Processed Food Data

Article 13

(1) To obtain data amendment approval, the Company shall submit a written application to Agency Head c.q. Director for document inspection and designation of Evaluation and Registration Cost.

(2) Application for data amendment, as referred to in paragraph (1), shall be submitted using the format as specified in Attachment 7 which forms an inseparable part of this Regulation.

Article 14

Result of inspection of application document, as referred to in Article 13 paragraph (1), could be in the form of:

- a. received to be further evaluated;
- b. returned to be completed; or
- c. rejected.

Article 15

(1) If result of document inspection declares received to be further evaluated, the Registerer shall be given Bank Payment Introduction Letter.

(2) Bank Payment Introduction Letter, as referred to in paragraph (1), shall state Evaluation and Registration Cost that must be paid as non-tax state revenue in accordance with the provisions of the legislation.

Article 16

Document of application for amendment of Processed Food data that has been completed with bank payment proof shall be submitted to Agency Head c.q. Director for further evaluation

Article 17

Result of further evaluation, as referred to in Article 16, could be in the form of:

- a. issuance of data amendment approval letter; or
- b. issuance of data amendment rejection letter.

Article 18

(1) For change of name of company, change of name of importer/distributor, change of trade name, and change for promotional purposes within a certain time, data amendment approval letter or data amendment rejection letter, as referred to in Article 17, shall be issued within not later than ten (10) days.

(2) For amendment in the form of inclusion and or change of nutritional value information and or claim addition, and change of composition, data amendment approval letter or data amendment rejection, letter, as referred to in Article 17, for:

- a. Certain Processed Food shall be issued within not later than sixty (60) days;
- b. Functional Food/Food with Claim, Food with herbal shall be issued within not later than forty-five (45) days;

c. Irradiated Food, Genetically Engineered Food, Food Additive, Organic Food, and Other Food shall be issued within not later than thirty (30) days.

(3) Other Food, as referred to in paragraph (2) letter c, consists of food types other than those referred to in paragraph (2) letters a and b, Irradiated Food, Genetically Engineered Food, Food Additive, and Organic Food.

(4) The period of time, as referred to in paragraphs (1) and (2), shall begin since receipt of data amendment application, as referred to in Article 16.

(5) In case that result of further evaluation requires additional data and or further assessment, calculation of time, as referred to in paragraphs (1) and (2), shall be temporarily stopped after date of letter of request for additional data.

(6) Time calculation which is temporarily stopped, as referred to in paragraph (5), will be continued since date of receipt of letter of fulfillment of additional data.

Article 19

(1) In case that result of evaluation is in the form of data amendment approval, as referred to in Article 17 letter a, data amendment approval letter shall be issued according to

the format as specified in Attachment 8 which forms an inseparable part of this Regulation.

- (2) Data amendment approval, as referred to in paragraph (1), shall be accompanied with approved Label design.
- (3) Excepted from the provisions of paragraph (2), for change of name of company or change of name of importer/distributor, data amendment approval is not accompanied with Label design.
- (4) Processed Food with old data could may be distributed within not later than six (6) months since date of data amendment approval, except for amendment of Processed Food data in the framework of promotion license.

Article 20

- (1) In case that result of further evaluation requires additional data and/or further assessment, as referred to in Article 18 paragraph (5), a letter of request for additional data shall be issued according to the format as specified in Attachment 9 which forms an inseparable part of this Regulation.
- (2) Within not later than fifty (50) days since date of letter of request for additional data, as referred to in paragraph (1), the registerer shall submit additional data.

(3) In case that the fifty (50) day-period, as referred to in paragraph (2), is deemed insufficient, the registerer may file a request for extension of time to complete additional data to the Director for one (1) time at the maximum for a period of twenty-five (25) days.

(4) Registerer who does not submit additional data within fifty (50) days, as referred to in paragraph (2), and/or twenty-five (25) days, as referred to in paragraph (3), will be given data amendment rejection letter, and the application document will be destroyed.

(5) If data completeness submitted by registerer does not meet the requirement stipulated in accordance with letter of request for additional data, as referred to in paragraph (1), the registerer will be given subsequent letter of request for additional data in accordance with the format as specified in Attachment 10 which forms an inseparable part of this Regulation, and the Registerer shall submit additional data within not later than fifteen (15) days after date of letter of request for additional data.

Article 21

(1) In case that the decision is in the form of rejection of data amendment, as referred to in Article 17 letter b, rejection letter shall be issued along with reasons of rejection.

(2) The rejection letter, as referred to in paragraph (1), shall be in accordance with the format as specified in Attachment 11 which forms an inseparable part of this Regulation.

CHAPTER III

COST

Article 22

(1) Application for processed food registration, amendment of processed food data, and re-registration shall be subjected to cost as non-tax state revenue in accordance with the provisions of the legislation.

(2) In case that the application, as referred to in paragraph (1), is rejected, cost that has been paid is non-refundable.

CHAPTER IV

HEARING

Article 23

(1) In case of objection to result of safety assessment of processed food, the company may file a request for hearing in writing to the Agency Head.

(2) Request for hearing, as referred to in paragraph (1), shall be submitted within not later than twenty-five (25) days since date of letter on additional data.

CHAPTER V

REVIEW

Article 24

(1) In case there is objection to registration rejection, the company may file a request for review to the Agency Head in writing.

(2) The request for review, as referred to in paragraph (1), may only be submitted for one (1) time within a period of not later than fifty (50) days since date of rejection letter.

(3) Request for review shall be completed with supporting data required.

(4) Decision on request for review, as referred to in paragraph (3), shall be given within not later than one hundred fifty (150) days since date of request for review.

CHAPTER VI

RE-REGISTRATION

Article 25

- (1) Re-registration of Processed Food can be performed at least six (6) months before expiry of Registration Approval Letter.
- (2) Re-registration, as referred to in paragraph (1), shall be performed in accordance with procedure of general registration.
- (3) In the framework of re-registration, as referred to in paragraph (1), the company may perform amendment of processed food data.
- (4) Issuance of Registration Approval Letter or Registration Rejection Letter in the framework of re-registration which experiences amendment shall be in accordance with the length of time as specified in Article 9 paragraph (1).
- (5) Registration Approval Letter or Registration Rejection Letter in the framework of re-registration which does not experience amendment, for:
 - a. Certain Processed Food shall be issued within not later than seventy-five (75) days;
 - b. Functional Food/Food with Claims, Food with herbal, shall be issued within not later than fifty (50) days;

c. Irradiated food, genetically engineered food, flavor (food additive), and organic food shall be issued within not later than forty-five (45) days;

d. Food additive other than flavor and other food shall be issued within not later than thirty (30) days.

(6) Other food, as referred to in paragraph (5) letter d, consists of food types other than those referred to in paragraph (5) letters a, b, and c and food additives other than flavor.

(7) Calculation of length of time of assessment in the framework of re-registration shall be in accordance with the provisions of Article 9 paragraphs (3), (4), and (5).

CHAPTER VI

RE-ASSESSMENT

Article 26

(1) On Processed Food which has obtained Registration Approval Letter, Re-Assessment may be performed by the Agency Head.

(2) Re-assessment, as referred to in paragraph (1), shall be performed if there is new data and/or information concerning safety, quality, nutrition, and label of Processed Food.

(3)Result of re-assessment shall be submitted in writing to the Company as holder of Registration Approval Letter.

(4)The Company as holder of Registration Approval Letter shall perform action in accordance with result of re-assessment as referred to in paragraph (3).

CHAPTER VIII

TRANSITORY PROVISIONS

Article 27

Application for Processed Food Registration that has been submitted before this Regulation comes into effect, shall be processed based on Decree of Head of Drug and Food Control Agency No. HK.00.05.1.2569 Year 2004 on Criteria and Procedure of Food product Assessment.

CHAPTER IX

CLOSING PROVISIONS

Article 28

On the date this Regulation comes into effect, Decree of Head of Drug and Food Control Agency No. HK.00.05.1.2569 Year 2004 on Criteria and Procedure of Food Product Assessment is revoked and declared inapplicable.

Article 29

This Regulation comes into effect since the date of enactment.

In order that everyone shall take cognizance, it is ordered to enact this Regulation by placing it in the State Gazette of the Republic of Indonesia.

Stipulated in Jakarta

December 5, 2012

HEAD OF DRUG AND FOOD CONTROL AGENCY
OF THE REPUBLIC OF INDONESIA

Sgd

KUSTANTINAH

Enacted in Jakarta

December 12, 2011

MINISTER OF JUSTICE AND HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA

Sgd

AMIR SYAMSUDDIN

STATE GAZETTE OF THE REPUBLIC OF INDONESIA OF 2011 NO. 811

Attachment 1

Regulation of Head of Drug and Food Control Agency

No. HK.03.1.5.12.11.09956 Year 2011

Concerning

Processed Food Registration Procedure

FORMAT OF PROCESSED FOOD REGISTRATION FORM

PROCESSED FOOD REGISTRATION DOCUMENT

NAME OF FOOD TYPE:

TRADE NAME:

PACKAGE TYPE:

NET WEIGHT/CONTENT:

NAME OF COMPANY:

NAME OF REGISTERER:

PROCESSED FOOD REGISTRATION FORM

Food Registration Number*	File Number*
B POM RI MD/ML ...	Date of Receipt*
Date of approval*	

REGISTRATION STATUS:	NEW/REPEAT	FAST/NORMAL
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1.	Name of Food Type:
2.	Trade Name:
3.	Package Type: Net weight/content:

4.	Name and address of company:
	<p>For self-produced food</p> <p>Name of factory:</p> <p>Address of factory:</p> <p>Phone/Fax Number/email:</p>
	<p>For food produced based on contract</p> <p>Name of factory:</p> <p>Address of factory:</p> <p>Phone/Fax Number/email:</p> <p>Name of Contract Giver:</p> <p>Address of Contract Giver:</p> <p>Phone/fax Number/email:</p>
	<p>For repackaged food</p> <p>Name of repackaging factory:</p> <p>Address of repackaging factory:</p> <p>Phone/Fax Number/email:</p> <p>Name of factory of origin:</p> <p>Address of factory of origin:</p>
	<p>For food produced by license</p> <p>Name of factory:</p> <p>Address of factory:</p> <p>Phone/Fax number/email:</p> <p>Name of Company as License Giver:</p>

	Address of Company as License Giver: Phone/Fax number/email:
	For imported food: Name of overseas factory: Address of overseas factory: Name of importer/distributor: Address of importer/distributor: Phone/Fax number/email:
5.	Name of contact person: Phone/Fax number/email:
6.	Correspondence address:

....., 20...

Person Responsible

signature and company's seal

Complete name and Title

.....

Number of Registration Approval Letter*
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* to be filled by officer

HEAD OF DRUG AND FOOD CONTROL AGENCY

OF THE REPUBLIC OF INDONESIA

Sgd

KUSTANTINAH

Attachment 2

Regulation of Head of Drug and Food Control Agency

No. HK.03.1.5.12.11.09956 Year 2011

Concerning

Processed Food Registration Procedure

GUIDELINES ON FORM AND REGISTRATION DOCUMENT COMPLETION

I. GENERAL INFORMATION

1. Form shall be filled out using Indonesian language.
2. Registration form shall be filled completely and correctly and shall be typed neatly.
3. All information provided shall be correct and in accordance with facts.
4. If company has had registration approval letters for similar product, please attach photocopy of one of the registration approval letters.

5. If the space in this form is insufficient, please use a separate sheet.

6. Registration Number, File Number, Date of Receipt, Date of Approval, and Number of Registration Approval Letter is not to be filled by applicant.

II. COMPLETION GUIDELINES

1. Name of Food Type

- a. Type name shall be in accordance with SNI that has been applied mandatorily.
- b. Type name which is not incorporated in letter a, shall meet requirement of food category.
- c. In case that type name is not yet stipulated in SNI and/or Food Category, the type name concerned may only be used after obtaining prior approval from the Directorate of Food Product Standardization.
- d. Type name shall be completed with variant (flavor) and intended use is there is any.

2. Trade Name

- a. Trade name on label shall not, amongst others:

- 1) be in contradictory to the prevailing legislation, religious morality, decency, or public order;
- 2) have distinguishing features;
- 3) have become public property;
- 4) constitute information or related to the food registered;
- 5) trade name shall not use type name or common name which is possibly related to the food concerned;
- 6) use adjective which may, directly or indirectly, affect interpretation of food, such as natural, pure, sacred, and other words having similar meaning.

b. Trade name used shall not be a trade name that has obtained brand certificate for similar processed food under the name of another person or business entity.

c. Trade name that has obtained brand certificate may be used by stating ® or ™ mark on label as long as it is not related to safety and nutritional aspect.

3. Package Type and Net Weight/Content

a. Package Type

- 1) Package type stated is all package, whether the one which has direct contact or indirect contact with product, in retail package.
- 2) If the package used is more than one (1), the type name shall be stated consecutively starting from the package which has direct contact with food.
- 3) Completed with container form, such as glass bottle, plastic bottle, plastic gallon, paper bag, etc.

For example:

- Glass bottle with can cap and rubber lid.
- Aluminum foil, cardboard.
- Paper, aluminum foil, box.

Examples of package type:

- 1) Glass
- 2) Plastic (OPP, PET, PE, PP, Styrofoam, metalized, nylon, etc)
- 3) Paper (paper, cardboard, box)
- 4) Cardboard for thermal process (tetra brix aseptic)
- 5) Can
- 6) Aluminum foil
- 7) Composite

8) Other package types (for example: rubber, ceramic, cloth).

b. Net weight/content

- 1) Solid food shall be stated by net weight;
- 2) Semi solid or viscous food shall be stated by net weight or content;
- 3) Liquid food shall be stated by net weight;
- 4) Net weight or net content on label shall be stated in metric unit. The following is example of statement of net weight or net content:

- 1) Solid: milligram (mg), gram (g), kilogram (kg)
- 2) Liquid: milliliter (ml or mL), liter (l or L)
- 3) Semi solid: milligram (mg), gram (g), kilogram (kg), milliliter (ml or mL), or liter (l or L).

- 5) Inclusion of information about piece or unit is as follows:

"Net weight: 1 gram (content 5 pieces @ 200 mg)"

"Net weight: 1 gram (5 pieces @ 200 mg).

4. Name and Address of Company

a. Name and address stated shall be in accordance with name and address contained in the license attached.

b. Name and address of producer including factory of origin, repackager, contract acceptor, and contract giver shall be in accordance with the name and address stated in industrial business license or Industry Registration Certificate from the Ministry of Industry/Industry Agency or Investment Coordinating Board (BKPM)/Regional Investment Coordinating Board (BKPMMD).

c. Name and address of company as license giver and license acceptor shall be in accordance with the name and address stated in license agreement letter.

d. Name and address of overseas company shall be in accordance with the name and address stated in Health Certificate or Certificate of Free Sale.

e. Name and address of importer/distributor shall be in accordance with the name and address contained in SIUP.

f. Address shall be complete, consisting of name of street, city, province, postal code, phone number, and fax number if there is any, e-mail and website address.

5. CONTACT PERSON

a. Contact person is a person appointed by Registerer to represent his or her interest in registration process.

b. Contact person shall state name, phone number, fax number if there is any, and e-mail address.

6. CORRESPONDENCE ADDRESS

a. If correspondence address is different from Company's address, as referred to in point 4, address used for correspondence shall be stated clearly and completely.

b. Correctness of address shall be the full responsibility of the company.

7. PERSON RESPONSIBLE (the one who signs Registration Form)

a. Person responsible for the company is company's owner, company's director, or head of unit appointed by company's director responsible for production or quality of processed food registered. For example, Director or Manager of Production, Quality Assurance or Research & Development (R&D) for local products. And, the person responsible for importer or distributor may be the Marketing Director or Manager.

b. Name and title of person responsible of the company shall be stated and completed with date, signature, and company's seal.

III. INFORMATION ON COMPLETENESS OF PROCESSED FOOD REGISTRATION DOCUMENT

A. ADMINISTRATIVE COMPLETENESS

1. Power of Attorney

a. shall be typed and shall use company's letterhead containing company's identity (company's name and address) with Rp.6,000 duty stamp.

b. stating:

* name and address of principal and agent in accordance with identity;

* title of principal and agent;

* signature of principal and agent

c. Agent is person responsible for the company who signs Registration Form

d. Intended for registration purpose

e. Maximum validity period of the power of attorney is three (3) months since date of signing

f. Completed with photocopy of identity of registerer (KTP/Driver's License (SIM)).

2. Industrial Business License

a. Industrial Business License shall be issued by the authorized institution (Ministry of Industry/Industry Agency);

b. Name and address of producer stated shall be complete;

c. Industrial Business License shall be in accordance with type of food registered;

d. If name of food registered is not contained in Industrial Business License attached, the company shall submit request for license for industrial expansion in accordance with the food registered;

e. Industrial Business License shall still be valid (in accordance with validity period stated in the license).

3. Agreement/Contract Letter between Contract Giver and Contract Acceptor

a. shall contain rights and obligations of both parties, including the provisions that the contract giver is responsible for the processed food produced.

b. name and address of producer contained in cooperation letter shall be in accordance with Industrial Business License.

c. is still valid at the time of food registration.

4. Agreement Letter between factory of origin and repackaging factory

a. shall contain rights and obligations of both parties

b. name and address of producer stated in Agreement Letter shall be in accordance with Industrial Business License

c. is still valid at the time of food registration.

5. Agreement letter between License Giver and Producer

a. shall contain rights and obligations of both parties

b. name and address of producer stated in agreement letter shall be in accordance with Industrial Business License

c. is still valid at the time of food registration.

6. Trading Business License (SIUP)

a. SIUP shall be issued by the authorized institution (Trade Ministry/Agency)

b. SIUP shall state food and beverage commodities

c. name and address of producer stated shall be complete

d. is still valid at the time of registration.

7. Result of audit of production/distribution facility

a. Company shall file request for audit of production/distribution facility to Head of local Center before submitting processed food registration application.

b. Audit of production/distribution facility shall be performed by officer of the local Center.

c. Company submitting request for re-registration shall attach result of audit of production/distribution facility of the last five (5) years.

8. Appointment letter from overseas company to importer or distributor

a. shall be issued by overseas producer or distributor appointed by overseas company

b. Appointment letter shall state grant of authority as importer or distributor in Indonesia.

c. Name and address of importer or distributor shall be in accordance with the one stated in SIUP.

d. Name and address of overseas company stated in appointment letter shall be in accordance with Health Certificate or Certificate of Free Sale.

e. The validity period shall be in accordance with the one contained in appointment letter. If it is not contained in appointment letter, the validity period shall be one (1) year since date of issuance at the maximum.

f. shall attach photocopy by showing the original copy.

g. If importer or distributor is not directly appointed by producer in country of origin, it shall be completed with certificate stating relationship between those parties.

9. Health Certificate of Certificate of Free Sale

a. shall be issued by authorized institution in country of origin

b. shall state type name of the food registered.

c. shall state name and address of producer in country of origin.

d. Validity period shall be in accordance with the one stated in appointment letter. If it is not stated in appointment letter, the validity period shall be at the maximum one (1) year since date of issuance.

e. shall attach photocopy by showing the original copy.

10. Certificate stating inter-company relationship

a. is only required if processed food is produced for other party or distributed by other party.

b. shall state appointment for producing or distributing the food registered.

c. name and address of both parties shall be stated clearly.

B. TECHNICAL COMPLETENESS

1. Composition or list of ingredients used

a. All ingredients used shall be stated consecutively starting from the largest quantity.

b. Inclusion of name of ingredients shall be complete and shall not be abbreviated by using official name or common name.

c. If using food additive, it shall be accompanied with quantity of ingredients used and function (food additive category).

d. For food additive coloring, index number (Cl...) shall be stated.

e. For ingredients derived from animals, name of ingredient followed by origin of ingredient (vegetable or animal) shall be mentioned. If it is derived from animal, it shall be accompanied with type of the animal from which the ingredient is derived, for example, beef, pork fat.

f. Ingredients consisting of some formulation materials shall mention all the formation materials including food additive. For example, food containing soybean sauce shall be accompanied with information about formulation materials of soybean sauce.

g. If using concentrate or fruit extract, specification of ingredients stated by brix ratio shall be attached.

2. Information on certain raw materials used

a. Information on GMO status of raw material, amongst others, corn, soybean, tomatoes, and potatoes.

b. Information on origin of raw material, amongst others, milk, flour, egg, and ammonium bicarbonate.

c. Information on origin of certain ingredients that may be derived from vegetable and/or animal.

d. Information on chloramphenicol content in honey raw material.

3. Production process of GMP/HACCP certificate

a. Production process shall be in accordance with the food registered.

b. Production process shall be described in the form of narration or flowchart of production process completely, including temperature, pressure, and time of heating process.

c. shall explain about method of cleaning of package for food with refill package, for example bottled drinking water in gallon.

d. production process can be replaced with GMP or HACCP certificate or ISO 22000 Application Certificate.

4. Result of analysis of finished product (Certificate of Analysis)

a. Testing shall be performed in accredited laboratory or government's laboratory.

b. Result of analysis shall be issued by accredited laboratory or government's laboratory.

c. Result of analysis attached shall be the original copy and its validity period shall be in accordance with the one contained in result of analysis or not later than one (1) year since date of issuance.

d. Result of analysis shall state clearly:

1) name of food registered,

2) name and address of producer contained in result of analysis shall be in accordance with name and address of producer stated in the form.

3) Test parameter, test result, and unit shall be in accordance with requirement.

4) Package type shall be in accordance with type of food package stated in the form.

e. Result of analysis consists of

- 1) microbial contaminant;
- 2) chemical contaminant;
- 3) food additive quantitatively, for food using coloring, artificial sweetener, preservative, and/or antioxidant;
- 4) drained volume, for solid food having liquid medium;
- 5) quality parameter in accordance with characteristics of food category;
- 6) all parameters in SNI for product required to have SNI;
- 7) nutritional substance in accordance with Nutritional Value Information for food which includes nutritional value information on label;
- 8) nutritional/non-nutritional substance according to claim, for food containing claim on label;
- 9) alcohol for food containing or using alcohol;

10) caffeine for food using/adding caffeine;

11) chloramphenicol for honey;

12) formaline, melamine, methyl yellow, rhodamine B (for certain products);

f. For food required to have SNI, its analysis result shall be in accordance with the entire test parameter contained in SNI.

g. Maximum limit of microbial and chemical contaminants shall be in accordance with Regulation of Head of Drug and Food Control Agency No. HK.00.06.1.52.4011 on Stipulation of Maximum Limit of Microbial and Chemical Contaminants in Food.

h. Provisions concerning food additive shall refer to:

* Regulation of Minister of Health No. 722/1988 on Food Additive;

* Regulation of Minister of Health of the Republic of Indonesia No. 1168/Menkes/Per/X/1999 on Amendment to Regulation of Minister of Health No. 722/Menkes/Per/IX/1988 on Food Additive;

* Decree of Head of Drug and Food Control Agency No. HK.00.05.5.1.4547 Year 2004 on Requirement on Use of Food Additive Artificial Sweetener in Food Product;

or other prevailing regulations.

i. Requirement of quality parameter shall refer to Decree of Head of Drug and Food Control Agency No. HK.00.05.52.4040 Year 2006 on Food Category.

j. Test parameter for nutritional substance shall be adjusted to nutritional value information and claim stated on label and shall refer to other prevailing regulations.

5. Information on storage period

a. Information on storage period of the food registered.

b. Storage period shall be in accordance with characteristic of the food registered.

c. Company may complete with result of stability test performed on the food registered.

6. Information on production code

Example of inclusion of production code and information on the meaning of production code of the food registered.

7. Label Design

a. Label design shall be in accordance with the label to be circulated.

b. Inclusion of information on food label shall refer to the legislation concerning food label and processed food labeling requirement.

C. OTHER SUPPORTING DOCUMENTS

1. Brand Certificate

a. shall be attached if label contains ® or ™ mark,

b. shall be issued by the authorized institution (Directorate of Mark, Ministry of Justice and Human Rights of the Republic of Indonesia),

c. is still valid at the time of food registration,

d. trade name submitted shall be in accordance with brand sample stated in Brand Certificate.

e. Type of food submitted shall be in accordance with description of goods/services stated in Brand Certificate.

f. Name and address of registerer shall be in accordance with name and address of brand owner stated in Brand Certificate.

g. If name and address of brand owner is not in accordance with the registerer, agreement or similar letter on

use of brand to the party performing registration shall be attached.

2. Certificate on Use of SNI Mark

a. shall be attached only for products required to have SNI, amongst others, wheat flour, iodized salt for consumption, bottled drinking water, refined sugar, and cocoa powder.

b. Certificate on Use of SNI shall refer to the latest SNI issued by Certification Institution accredited by National Accreditation Committee (KAN).

c. Trade name submitted shall be in accordance with brand stated in Certificate on Use of SNI.

d. Name and address of registerer shall be in accordance with name and address of company as stated in Certificate on Use of SNI.

e. is still valid at the time of food registration.

f. Photocopy of certificate shall be attached by showing the original copy.

3. Organic Certificate

a. If food label contains statement as organic food or uses ingredient derived from organic food, organic Certificate from certification institution that has been verified by Organic Food Competent Authority (OKPO) of Ministry of Agriculture shall be attached.

b. For imported product, organic certificate, as referred to in letter a, shall be legalized by Competent Authority in Indonesia (Recommendation on Integrity Assurance of Imported Organic Product).

4. Information on GMO (Genetically Modified Organism) Free Status

If using soybean, potatoes, corn, and tomato raw material which is not Genetically Modified Organism (GMO), the following documents shall be attached:

a. statement from company (producer/importer) certifying that the food does not contain GMO; and/or

b. statement of GMO-free status from supplier or factory of origin (overseas).

Statement on GMO-free status could be in the form of result of analysis from accredited laboratory.

5. Information on Food Irradiation

For processed food undergoing irradiation treatment or using ingredients which undergo irradiation treatment, certificate from irradiation facility stating the following matters shall be attached:

- a. type and quantity of irradiated food
- b. batch number of irradiated food
- c. objective of irradiation
- d. type of package used
- e. date of performance of irradiation
- f. source of radiation and radiation dosage used
- g. maximum dosage absorbed
- h. deviation occurring during irradiation
- i. name and address of irradiation facility
- j. number of license on use from Nuclear Energy Regulatory Agency (BAPETEN)
- k. international code number of irradiation facility, for imported food.

6. Establishment Number (NKV) of Slaughterhouse

a. For processed food derived from animals produced in Indonesia.

b. Issued by Ministry of Agriculture.

7. Approval Letter on Inclusion of the Word "Halal" on Food label

a. For food stating the word "Halal" on label.

b. Issued by the Directorate for Food Inspection and Certification.

c. is still valid at the time of registration.

8. Other supporting data

For food whose label contains claim or certain information requiring supporting data, scientific reference that supports the claim or information shall be attached.

HEAD OF DRUG AND FOOD CONTROL AGENCY

OF THE REPUBLIC OF INDONESIA

Sgd

KUSTANTINAH

Attachment 3

Regulation of Head of Drug and Food Control Agency

No. HK.03.1.5.12.11.09956 Year 2011

Concerning

Processed Food Registration Procedure

Format of Letter of Request for Additional Data I

DRUG AND FOOD CONTROL AGENCY

Jl. Percetakan Negara 23, Building B, 3rd Floor, Jakarta 10560

Phone: (021) 42800221 Fax: (021) 4245267

No: Jakarta, ...

Attachment:

Matter: Data Completeness Request I

To:

Person Responsible

...

Based on result of assessment of safety, quality, and nutrition
and label of processed food:

No	Trade Name	Type Name	Package	File No.

it is hereby informed that there is data shortage as follows:

- 1.
 - 2.
 - 3.
- etc.

Completeness of the data shall be submitted within not later than fifty (50) days after date of this letter of request for data completion. If data is not submitted within the abovementioned period, your application will be rejected.

Please be informed accordingly.

On behalf of Director of Food Safety Assessment

Head of ... Assessment Sub-Directorate

seal

Name

Employee Identification Number

HEAD OF DRUG AND FOOD CONTROL AGENCY

OF THE REPUBLIC OF INDONESIA

Sgd

KUSTANTINAH

Attachment 4

Regulation of Head of Drug and Food Control Agency

No. HK.03.1.5.12.11.09956 Year 2011

Concerning

Processed Food Registration Procedure

Format of Letter of Request for Additional Data II, etc.

DRUG AND FOOD CONTROL AGENCY

Jl. Percetakan Negara 23, Building B, 3rd Floor, Jakarta 10560

Phone: (021) 42800221 Fax: (021) 4245267

No: Jakarta, ...

Attachment:

Matter: Data Completeness Request II, etc.

To:

Person Responsible

...

With regard to data completeness submitted on date ..., it is hereby informed that application for processed food registration:

No	Trade Name	Type Name	Package	File No.

is not approved as it does not meet data completeness with reference to our letter No... dated..., as follows:

- 1.
 - 2.
 - 3.
- etc.

The data shortage shall be submitted within not later than fifteen (15) days after date of this letter of request for data completeness. If the data is not submitted within the above period, your application will be rejected.

Please be informed accordingly.

On behalf of Director of Food Safety Assessment

Head of ... Assessment Sub-Directorate

seal

Name

Employee Identification Number

HEAD OF DRUG AND FOOD CONTROL AGENCY

OF THE REPUBLIC OF INDONESIA

Sgd

KUSTANTINAH

Attachment 5

Regulation of Head of Drug and Food Control Agency

No. HK.03.1.5.12.11.09956 Year 2011

Concerning

Processed Food Registration Procedure

PROCESSED FOOD REGISTRATION APPROVAL LETTER

DRUG AND FOOD CONTROL AGENCY

PROCESSED FOOD REGISTRATION APPROVAL

NO: ...

Pursuant to Regulation of Drug and Food Control Agency No. HK.03.1.5.12.11.09955 Year 2011 on Processed Food Registration and Regulation of Drug and Food Control Agency No. HK.03.1.5.12.11.09956 Year 2011 on Processed Food Registration Procedure, processed food registration approval is hereby granted:

1. Name of Food Type:

2. Trade Name:

3. Package Type and Net Content/Weight:

4. a. Name of Producer:

b. Address of Producer:

5. a. Name of Producer

b. Address of Producer

for

a. Name of Producer/Company:

b. Address of Producer/Company:

6. a. Name of Repackaging Producer:

b. Address of Repackaging Producer:

a. Name of Producer of Origin

b. Address of Producer of Origin

7. a. Name of Producer:

b. Address of Producer:

a. Name of Company as License Giver:

b. Address of Company as License Giver:

8. a. Name of Producer

b. Address of Producer

a. Name of Importer/Distributor

b. Address of Importer/Distributor:

Food Registration Number:

BPOM RO MD/ML...

with requirements:

1. Processed food distributed shall meet the provisions of the legislation.
2. Processed food distributed shall use label in accordance with approved label design as attached herein which is an inseparable part of this Registration Approval Letter.
3. Processed Food circulating shall be in accordance with the data approved during registration.
4. The Drug and Food Control Agency is not responsible for intellectual property rights related to issuance of Registration Approval Letter for the Processed Food.

Issued: in Jakarta

Date:

Valid until:

This Registration Approval Letter is revocable in accordance with the provisions of the legislation.

Head of Drug and Food Control Agency

or his authorized officer

seal

Name

HEAD OF DRUG AND FOOD CONTROL AGENCY

OF THE REPUBLIC OF INDONESIA

Sgd

KUSTANTINAH

Attachment 6

Regulation of Head of Drug and Food Control Agency

No. HK.03.1.5.12.11.09956 Year 2011

Concerning

Processed Food Registration Procedure

Format of Processed Food Registration Rejection Letter

DRUG AND FOOD CONTROL AGENCY

Jl. Percetakan Negara 23, Building B, 3rd Floor, Jakarta 10560

Phone: (021) 42800221 Fax: (021) 4245267

No: Jakarta, ...

Attachment:

Matter: Processed Food Registration Rejection Letter

To:

Person Responsible

...

Based on result of assessment of safety, quality, nutrition and label of processed food:

Name of food type:

Trade name:

Package type, net weight/content:

File No:

Name and address of producer:

(for imported product)

hereby informs that processed food registration is REJECTED

because it does not meet the following requirements:

Please be informed accordingly.

on behalf of Head of Drug and Food Control Agency
Deputy for Food Safety and Hazardous Substance Control

seal

Employee Identification Number

Cc:

1. Director for Food Inspection and Certification
2. Head of Drug and Food Control Center ...

HEAD OF DRUG AND FOOD CONTROL AGENCY

OF THE REPUBLIC OF INDONESIA

Sgd

KUSTANTINAH

Attachment 7

Regulation of Head of Drug and Food Control Agency

No. HK.03.1.5.12.11.09956 Year 2011

Concerning

Processed Food Registration Procedure

FORMAT OF LETTER OF APPLICATION FOR AMENDMENT OF PROCESSED FOOD

DATA

Name of Company:

Address:

No:

Attachment:

Matter: Application for Data Amendment

To:

Head of Drug and Food Control Agency

c.q. Director of Food Safety Assessment

in JAKARTA

Pursuant to Article 17 of Regulation of Head of Drug and Food Control Agency No. HK.03.1.5.12.1.09955 Year 2011 on Processed Food Registration, we hereby file application for processed food data amendment as follows:

Name of food type:

Trade name:

Package type:

Food Registration Number:

Valid until:

Old Data*)	New Data*)	Remark

If this application is approved, processed food with the old data will no longer be in circulation within not later than ... months since date of amendment approval.

....., 20..

Person Responsible for Company

seal

.....

Note:

*) fill in all amended data completely and clearly.

HEAD OF DRUG AND FOOD CONTROL AGENCY

OF THE REPUBLIC OF INDONESIA

Sgd

KUSTANTINAH

Attachment 8

Regulation of Head of Drug and Food Control Agency

No. HK.03.1.5.12.11.09956 Year 2011

Concerning

Processed Food Registration Procedure

FORMAT OF LETTER OF REQUEST FOR ADDITIONAL DATA I

FOR AMENDMENT OF PROCESSED FOOD DATA

DRUG AND FOOD CONTROL AGENCY

Jl. Percetakan Negara 23, Building B, 3rd Floor, Jakarta 10560

Phone: (021) 42800221 Fax: (021) 4245267

No: Jakarta, ...

Attachment:

Matter: Data Completeness Request I

To:

Person Responsible

...

With reference to your letter No... dated ... matter: ... that we received on date ..., it is hereby informed that application for amendment of processed food data:

No	Type Name	Trade Name	Package and net	Food
----	-----------	------------	-----------------	------

			weight/content	Registration Number

With the following data amendment:

Old Data	New Data

is not approved as there is data shortage as follows:

.....

The data shortage shall be submitted within not later than fifty (50) days after date of this letter of request for data completeness. If the data is not submitted within the abovementioned period, your application will be rejected.

Please be informed accordingly.

on behalf of Director of Food Safety Assessment

Head of ... Assessment Sub-Directorate

seal

Name

Employee Identification Number

HEAD OF DRUG AND FOOD CONTROL AGENCY

OF THE REPUBLIC OF INDONESIA

Sgd

KUSTANTINAH

Attachment 9

Regulation of Head of Drug and Food Control Agency

No. HK.03.1.5.12.11.09956 Year 2011

Concerning

Processed Food Registration Procedure

FORMAT OF LETTER OF REQUEST FOR ADDITIONAL DATA II, ETC.

FOR AMENDMENT OF PROCESSED FOOD DATA

DRUG AND FOOD CONTROL AGENCY

Jl. Percetakan Negara 23, Building B, 3rd Floor, Jakarta 10560

Phone: (021) 42800221 Fax: (021) 4245267

No:

Jakarta, ...

Attachment:

Matter: Data Completeness Request II, etc.

To:

Person Responsible

...

With reference to data completeness submitted on date ..., it is hereby informed that application for amendment processed food data:

No	Type Name	Trade Name	Package and net weight/content	Food Registration Number

With the following data amendment:

Old Data	New Data

The data does not meet request for data completeness as referred to in our letter No... dated... matter: ... as follows:

- 1.
 - 2.
- etc.

The data shortage shall be submitted within not later than fifteen (15) days after date of this letter of request for data completeness. If the data is not submitted within the abovementioned period, your application will be rejected.

Please be informed accordingly.

on behalf of Director of Food Safety Assessment

Head of ... Assessment Sub-Directorate

seal

Name

Employee Identification Number

HEAD OF DRUG AND FOOD CONTROL AGENCY

OF THE REPUBLIC OF INDONESIA

Sgd

KUSTANTINAH

Attachment 10

Regulation of Head of Drug and Food Control Agency

No. HK.03.1.5.12.11.09956 Year 2011

Concerning

Processed Food Registration Procedure

FORMAT OF APPROVAL LETTER ON PROCESSED FOOD DATA AMENDMENT

DRUG AND FOOD CONTROL AGENCY

Jl. Percetakan Negara 23, Building B, 3rd Floor, Jakarta 10560

Phone: (021) 42800221 Fax: (021) 4245267

No: Jakarta, ...

Attachment:

Matter: Data Amendment Approval

To:

Person Responsible

...

With reference to your letter No... dated ... matter: ... that we received on date ..., it is hereby informed that application for processed food data amendment as follows:

No	Type Name	Trade Name	Package and net weight/content	Food Registration Number

Old Data	New Data

is approved with the following conditions:

1. Using label design as specified in Attachment which forms an inseparable part of this approval letter.
2. Processed Food with old data may still be distributed within not later than six (6) months after date of this data amendment approval letter.
3. This approval is applicable as long as registration approval letter on the processed food is still valid.

This is for your information and implementation.

on behalf of Head of Drug and Food Control Agency

Head of Director of Food Safety Assessment

seal

Name

Employee Identification Number

Cc:

1. Director for Food Inspection and Certification
2. Head of Drug and Food Control Center ...

HEAD OF DRUG AND FOOD CONTROL AGENCY

OF THE REPUBLIC OF INDONESIA

Sgd

KUSTANTINAH

Attachment 11

Regulation of Head of Drug and Food Control Agency

No. HK.03.1.5.12.11.09956 Year 2011

Concerning

Processed Food Registration Procedure

FORMAT OF LETTER OF REJECTION OF PROCESSED FOOD DATA AMENDMENT

DRUG AND FOOD CONTROL AGENCY

Jl. Percetakan Negara 23, Building B, 3rd Floor, Jakarta 10560

Phone: (021) 42800221 Fax: (021) 4245267

No:

Jakarta, ...

Attachment:

Matter: Rejection of Data Amendment

To:

Person Responsible

...

With reference to your letter No... dated ... matter: ... that we received on date ..., it is hereby informed that application for processed food data amendment as follows:

No	Type Name	Trade Name	Package and net weight/content	Food Registration Number

With data amendment as follows:

Old Data	New Data

is not approved because ...

Please be informed accordingly.

on behalf of Director of Food Safety Assessment

Head of Director of Food Safety Assessment

seal

Name

Employee Identification Number

Cc:

1. Director for Food Inspection and Certification

2. Head of Drug and Food Control Center ...

HEAD OF DRUG AND FOOD CONTROL AGENCY

OF THE REPUBLIC OF INDONESIA

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KUSTANTINAH

