

AMENDMENT TO REGULATION OF THE HEAD OF THE DRUG AND FOOD CONTROL AGENCY NO. HK.03.1.5.12.11.09955 OF 2011 ON THE REGISTRATION OF PROCESSED FOODS (Regulation of the Head of the Drug and Food Control Agency No. 42/2013 dated June 28, 2013)

BY THE GRACE OF GOD ALMIGHTY
THE HEAD OF THE DRUG AND FOOD CONTROL
AGENCY OF THE REPUBLIC OF INDONESIA,

Considering :

Regulation of the Head of the Drug and Food Control Agency No. HK.03.1.5.12.11.09955 of 2011 on the Registration of Processed Foods needs to be adjusted to amendment to legislation in the food sector, and scientific and technological developments so that it is necessary to stipulate Regulation of the Head of the Drug and Food Control Agency on Amendment to Regulation of the Head of Drug and Food Control Agency No. HK.03.1.5.12.11.09955 of 2011 on the Registration of Processed Foods;

In view of :

1. Law No. 8/1999 on Consumers Protection (Statute Book of 1999 No. 42, Supplement to Statute Book No. 3281);
2. Law No. 36/2009 on Health (Statute Book of 2009 No. 114, Supplement to Statute Book No. 5063);
3. Law No. 18/2012 on Food (Statute Book of 2012 No. 227, Supplement to Statute Book No. 5360);
4. Government Regulation No. 69/1999 on Food Labels and Advertisements (Statute Book of 1999 No. 131, Supplement to Statute Book No. 3867);
5. Government Regulation No. 28/2004 on Food Security, Quality and Nutrition (Statute Book of 2004 No. 107, Supplement to Statute Book No. 4244);
6. Presidential Decree No. 103/2001 on the Position, Tasks, Functions, Authority, Organizational Structure and Work Mechanism of Non-Ministerial Government Institutions as already several times amended the latest by Presidential Regulation No. 3/2013;
7. Presidential Decree No. 110/2001 on Organizational Units and Tasks of Echelon I Officials of Non-Ministerial Government Institutions as already several times amended the latest by Presidential Regulation No. 4/2013;
8. Decision of the Head of the Drug and Food Control Agency No. 02001/SK/KBPOM of 2001 on the Organization and Work Mechanism of the

Drug and Food Control Agency as already amended by Decision of the Head of the Drug and Food Control Agency No. HK.00.05.21.4231 of 2004;

DECIDES :

To stipulate :

REGULATION OF THE HEAD OF THE DRUG AND FOOD CONTROL AGENCY ON AMENDMENT TO REGULATION OF THE HEAD OF THE DRUG AND FOOD CONTROL AGENCY NO. HK.03.1.5.12.11.09955 OF 2011 ON THE REGISTRATION OF PROCESSED FOODS.

Article I

Several provisions in Regulation of the Head of the Drug and Food Control Agency No. HK.03.1.5.12.11.09955 of 2011 on the Registration of Processed Foods are amended as follows:

1. Article 1 is amended so that it reads as follows:

Article 1

Referred to in this Regulation as :

1. Food is anything which originates from biological sources of agricultural, plantation, forestry, fishery, husbandry, waters and water products, whether or not they are processed, which are designed as food or beverage for human consumption including food additive, food raw material, and other materials which are used in the process of preparing, processing and/or making food or beverage.

2. Processed food is food or beverage which results from a process through a certain way or method with or without food additive, including certain processed food, food additive, genetically engineered food product and irradiation food.
3. Food additive, hereinafter abbreviated into BTP, is a material which is added to food to influence the characteristics and shape of the food.
4. Registration is a procedure of assessing the security, quality and nutrition of processed food to obtain a registration approval.
5. New registration is the registration of processed food which has not received a registration approval.
6. Variation registration is the registration of a change in data of processed food which has received a processed food registration approval without changing food registration number and/or evaluation and registration fees.
7. Repeat registration is the registration of extended validity period of processed food registration approval.
8. Certificate of registration approval is approval of the result of processed food assessment which is issued by the Agency Head within the framework of circulating food.
9. Label is any piece of information on food which comes in the form of picture, text, combination of both, or other form which is

attached to food, put inside, stuck on or part of food pack.

10. Company is a producer, importer and/or distributor of processed food who has secured a business permit according to the legislation.
11. Producer is an individual and/or corporate body that makes, processes, alters, preserves, or repacks processed food for circulation.
12. Importer is an individual and/or corporate body that imports processed food to the Indonesian territory.
13. Distributor is an individual and/or corporate body that circulates processed food in the Indonesian territory.
14. Register is a company or party which is given authority by company to register processed food to receive a registration approval.
15. Licensed processed food is a processed food which is produced based on a license.
16. Repacked processed food is a processed food which is repacked into processed food in a smaller or larger pack.
17. Processed food produced based on a contract is a food which is produced by a contract recipient at the request of contract provider.
18. License provider is a producer or research body which has formula and technology at home or abroad and gives a license to the company which applies for registration.
19. Contract recipient is a processed food indus-

try which receives a job order for the production of processed food based on a contract and holds an industrial business permit according to the type of processed food which is produced.

20. Contract provider is an individual and/or corporate body that holds a business permit in the field of food production and uses production facilities of other party based on a contract.
 21. Food registration number is a number which is given to processed food to circulate food contained in the registration approval.
 22. Evaluation and registration fees are fees which are imposed within the framework of evaluating processed food according to the legislation.
 23. Head of Center is the Head of the Center/ Agency of Drug and Food Control in the capacity as head of technical unit at the Drug and Food Control Agency.
 24. Director is the Director of Food Security Evaluation.
 25. Agency Head is the Head of the Drug and Food Control Agency of the Republic of Indonesia.
2. In-between Articles 6 and 7, one new article, namely Article 6A is inserted as follows:

Article 6A

The registration of processed foods consists of :

- a. new registration;
- b. variation registration; and
- c. repeat registration.

3. The title of Part Two, Chapter III, Requirements for the Registration of Processed Foods is changed so that it reads as follows:

Part Two

Variation Registration of Processed Foods

4. Article 17 is amended so that it reads as follows:

Article 17

- (1) Companies can change data of processed foods that have received registration approval through the variation registration of processed foods.
- (2) The change in data as referred to in paragraph (1) shall be approved by the Agency Head.
- (3) The change in data of processed foods as referred to in paragraph (1) can be made, provided it does not lead to a change in food registration number and/or a change in evaluation and registration fees.
- (4) If a change in data of processed foods leads to a change in food registration number and/or a change in evaluation fees, the register shall apply for new registration.

5. Article 18 is amended so that it reads as follows:

Article 18

- (1) The change as referred to in Article 17 para-

graph (1) consists of :

- a. a change in major data; and
- b. a change in minor data.

- (2) The change in major data as referred to in paragraph (1) letter a may come in the form of :

- a. a change in label design;
- b. inclusion and/or alteration of nutrition score information;
- c. alteration and/or addition of claims; and/or
- d. a change in composition;

- (3) The change in minor data as referred to in paragraph (1) letter b may come in the form of :

- a. a change in the name of company;
- b. a change in the name of importer and/or distributor;
- c. a change in trade name;
- d. alteration and/or addition of net weight/content;
- e. inclusion of halal text; and/or
- f. a change in promotion interests in certain time.

6. The title of CHAPTER IX is amended so that it reads as follows:

CHAPTER IX

REPEAT REGISTRATION

7. Article 34 is amended so that it reads as follows:

Article 34

(1) The repeat registration of processed foods can be done only to processed foods similar to those approved previously.

(2) If processed foods that are registered again have changed, the companies shall make variation registration first.

8. Article 39 is amended so that it reads as follows:

Article 39

(1) Violators of this Regulation may be liable to administrative sanctions in the form of :

- a. written warning;
- b. temporary ban on circulation;
- c. suspended registration of processed foods;
- d. temporary suspension of activities; or
- e. revocation of registration approval.

(2) The administrative sanctions as referred to in paragraph (1) letter d may be imposed based on or in case of :

- a. matters which do not meet security requirements are found during re-evaluation;
- b. processed foods in circulation do not accord with the data approved at the time of receiving registration approval or data change approval;
- c. the result of audit and/or test of processed foods in circulation does not meet the criteria as referred to in Article 7.
- d. advertised processed foods violate the legislation;
- e. court verdict with fixed legal force is re-

lated to processed foods;

- f. the company violates provisions on food production and/or distribution;
- g. the importer or distributor holding registration approval is no longer appointed by the original factory abroad;
- h. food industrial business permit, import permit, and/or distribution permit are revoked;
- i. the location of importer does not accord with that contained in the registration approval or data change approval;
- j. the location of production facilities does not accord with that contained in the registration approval or data change approval; and/or
- k. at the request of registration approval holder.

(3) Administrative sanctions in the form of suspended registration of processed foods are imposed on companies committing the violation as referred to in paragraph (2) letter f.

(4) Companies are responsible for processed foods that are still in circulation but their registration approval has been revoked.

(5) The trade name of processed foods whose registration approval has been revoked cannot be used for the same processed foods.

Article II

This Regulation shall come into force as from

the date of promulgation.

For public cognizance, this Regulation shall be promulgated by placing it in the State Gazette of the Republic of Indonesia

Stipulated in Jakarta

On June 28, 2013

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

sgd.

LUCKY S. SLAMET

Promulgated in Jakarta

On July 23, 2013

THE LAW AND HUMAN RIGHTS MINISTER
OR THE REPUBLIC OF INDONESIA,

sgd.

AMIR SYAMSUDIN

STATE GAZETTE OF THE REPUBLIC OF INDONESIA
OF 2013 NO.963

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