

# AMENDMENT TO REGULATION OF THE HEAD OF THE DRUG AND FOOD CONTROL AGENCY NO. HK.03.1.5.12.11.09956 OF 2011 ON THE PROCEDURE OF REGISTERING PROCESSED FOODS (Regulation of the Head of the Drug and Food Control Agency No. 43/2013 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 :

To adjust provisions on the registration of processed foods, it is necessary 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.03.1.5.12.11.09956 of 2011 on the Procedure of Registering 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. Regulation  
to be continued

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**AMENDMENT TO REGULATION OF THE HEAD OF  
THE DRUG AND FOOD CONTROL AGENCY  
NO. HK.03.1.5.12.11.09956 OF 2011 ON THE  
PROCEDURE OF REGISTERING PROCESSED FOODS  
(Regulation of the Head of the Drug and Food Control  
Agency No. 43/2013 dated June 28, 2013)  
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8. 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 as already amended by Regulation of the Head of the Drug and Food Control Agency No. 42/ 2013 (State Gazette of 2013 No. 963);
9. Regulation of the Head of the Drug and Food Control Agency No. HK.03.1.5.12.11.09956 of 2011 on the Procedure of Registering Processed Foods (State Gazette of 2011 No. 811).

**D E C I D E S :**

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.03.1.5.12.11.09956 OF 2011 ON THE PROCEDURE OF REGISTERING PROCESSED FOODS.

**Article I**

Several provisions in Regulation of the Head of the Drug and Food Control Agency No. HK.03.1.5.12.11.09956 of 2011 on the Procedure of Registering 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 the 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. Register is a company or party which is given authority by company to register processed food to receive a registration approval.

12. Evaluation and registration fees are fees which are imposed within the framework of evaluating processed food according to the legislation.

13. Director is the Director of Food Security Evaluation.

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

15. Day is working day.

2. The title of Part Two, Chapter II, the Procedure of Registering Processed Foods is amended so that it reads as follows:

## **Part Two**

### **Variation Registration**

3. Article 13 is amended so that it reads as follows :

#### **Article 13**

- (1) A change in processed foods that have received registration approval shall be reported to the Agency Head through variation registration mechanism.
- (2) To obtain approval of data change, companies shall file written applications to the Agency Head through the Director.

4. In-between Articles 13 and 14, one new article, namely Article 13A is inserted as follows:

**Article 13A**

- (1) Variation registration with minor change shall be proposed by filling the form as contained in Attachment 7 and enclosing variation registration documents according to the change proposed.
- (2) If the form and variation registration documents as referred to in paragraph (1) are complete and correct, no later than 10 (ten) working days, the Agency Head shall issue variation registration approval.
- (3) Without having to await the variation registration approval as referred to in paragraph (2), registers can start making the change as referred to in paragraph (1) after submitting variation registration documents along with a receipt of bank payment.

5. Article 14 is amended so that it reads as follows:

**Article 14**

- (1) Variation registration with major change shall be proposed by filling the form as contained in Attachment 7 and enclosing variation registration documents according to the change proposed.
- (2) The documents as referred to in paragraph (1) shall be audited and evaluation and registration fees shall be set.
- (3) The results of the audit of application documents

as referred to in Article 13 paragraph (1) may come in the form of:

- a. being accepted for further evaluation;
- b. being returned to be completed; or
- c. being rejected.

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

**Article 18**

- (1) Approval of data change or rejection of data change as referred to in Article 17 for :
  - a. certain processed foods are issued no later than 60 (sixty) days;
  - b. functional foods/foods with claim, foods with herb are issued no later than 45 (forty five) days;
  - c. Irradiation foods, genetically engineered foods, BTP, organic foods, and other foods are issued no later than 30 (thirty) days.
- (2) Other foods as referred to in paragraph (1) letter c cover types of foods other than those referred to in paragraph (1) letters a and b, irradiation foods, genetically engineered foods, BTP, and organic foods.
- (3) The period of time as referred to in paragraph (1) and Article 13A paragraph (2) starts from the receipt of applications for data change as referred to in Article 16.
- (4) If the results of further evaluation need additional data and/or further study, the calculation of time as referred to in paragraph (1) shall be temporarily halted starting from the

date of application for additional data.

- (5) The temporarily halted calculation of time as referred to in paragraph (4) will be continued after the receipt date of letter fulfilling additional data.

7. The title of CHAPTER VI is changed so that it reads as follows:

CHAPTER VI  
REPEAT REGISTRATION

8. Article 25 is amended so that it reads as follows:

Article 25

- (1) The repeat registration of processed foods can only be done to processed foods which are the same as those approved previously.
- (2) If processed foods which are registered again have changed, the company shall make variation registration first.
- (3) The repeat registration of processed foods can only be done in 6 (six) months at the earliest and 10 (ten) working days at the latest before the validity date of registration approval ends.

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