

THE MINISTER OF HEALTH OF THE
REPUBLIC OF INDONESIA
REGULATION NO: 382/MENKES/PER/VI/1989

ON
FOOD REGISTRATON
THE MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA

Considering:

- a. That the registration of food is undertaken in order to protect the public against food which does not meet the health requirements and to further guarantee the safety and quality of food in distribution;
- b. That in support of the development of the food industry, the registration of food need to be simplified without disregarding the purpose and objectives of the food registration;
- c. That based on consideration of a and b above the Regulation of the Minister of Health of the Republic of Indonesia No. 330/Menkes/Per/Xii/76 on the compulsory Registration of food needs to be adjusted and rearranged in the Regulation of the Minister of Health on food Registration.

In view of:

1. Law No. 9, 1960 on Basic Health (State Gazette of the Republic of Indonesia No. 131, 1960; Supplement to the State Gazette of the Republic of Indonesia No. 2068)
2. Regulation of the Minister of Health of the Republic of Indonesia No. 329/Menkes/Per/Xii/76 on food Production and Distribution;
3. Regulation of the Minister of Health of the republic of Indonesia No. 722/Menkes/Per/IX/88 on Food Additives.

DECIDES:

To promulgate:

THE REGULATION OF THE MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA ON FOOD REGISTRATION.

CHAPTER 1
GENERAL PROVISION

For the purpose of this Regulation:

Food: Means any article used as food or drink for human consumption including all materials used in the production of food and beverages

- a. Process food: means food made of raw material, with or without addition of food additives and/or processing aids
- b. Registration: means the evaluation process of food prior to approval for distribution in conformity with the established criteria
- c. Company: means the food company that according to the laws and regulations is obliged to obtain an industrial license to be registered.
- d. Director General: means the Director General responsible for the registration of food.

CHAPTER II
REGISTRATION

Article 2

1. The manufacturer or importer shall register the food produced or imported
2. The manufacturer or importer shall guarantee that the registered food is safe and wholesome, and is honestly labeled.

Article 3

1. The food obliged to be registered is processed food, both produced domestically as well as imported, which is distributed in labeled retail package.
2. Processed food produced domestically specified in paragraph (1) refers to food processed by a company.
3. Imported processed food shall meet the health requirements and other existing regulations.

Article 4

1. Besides joining the extension programmed, home industry shall register the following product:
 - a. Milk and milk products;
 - b. Food for infants;
 - c. Commercially sterilized canned food;
 - d. Alcoholic beverages.
2. Home Industry which has not joined the extension programmed shall register his entire Product.
3. The extension programmed provided to home food industries as specified in paragraph (1) and (2) shall conform to existing regulation.

Article 5

1. Food exempted from the obligation to be registered are:
 - a. Processed food with the shelf life does not exceed seven days at room temperature;
 - b. Processed food produced by home industry which has joined extension programmed;
 - c. Processed food which imported as donation to the Indonesian Government or Social Institutions;
 - d. Processed food, which imported in small quantities for certain purposes.
2. Processed food, which donated as, specified in paragraph (1) sub c, its container or package should bear statement that it is donation.
3. Processed food imported in small quantities specified in paragraph (1) sub d are only for the following purposes:
 - a. Registration with the Department of Health of the Republic of Indonesia;
 - b. Scientific activities;
 - c. Self-consumption.

Article 6

The company registering their processed food shall already hold an industrial license or be registered in conformity with the existing laws and Regulation.

Article 7

The company or home industry registering their food specified in article 3 and article 4 shall be ready for inspection by the officers appointed by the Director General.

Article 8

1. The application for the registration of domestically produced food specified in article 3 and article 4 shall be submitted by the responsible officer of the company.
2. *The application for the registration of imported food specified in article 3 shall be submitted by the food importer, or representative of the foreign factory in Indonesia appointed or authorized by the original factory.*

Article 9

The responsible officer shall render the correct information at the time of registration.

Article 10

No fees in whatever form shall be imposed on such registration.

Article 11

The procedure of the registration is determined by the Director General

CHAPTER III REGISTRATION APPROVAL

Article 12

The approval for the registration of food is granted by the Minister of Health, in this matter on his behalf by the Director General or an appointed officer.

Article 13

1. Based on the result of evaluation, the Director General or the appointed officer may determine:
 - a. Registration approval; or
 - b. Conditional approval; or
 - c. Rejection of the registration.
2. The decision on registration application specified in paragraph (1) shall be given at the latest 3 (three) months as from receipt of the registration application by the Directorate General using the model forms M1, M2 or M3.

Article 14

The registration approval specified in article 13 shall prevail forever insofar as the product meets the requirements.

Article 15

1. In the approval specified in article 14 the label of the food is included.
2. The label of the registered food shall be similar and shall not deviate from the label specified in paragraph (1).

Article 16

1. Food, which registration is approved based on the evaluation, shall be given registration number.
2. The domestic product registration number proceeded by MD, and imported product registration number proceeded by ML.
3. Registration number shall be put on the label of the food in such a manner that it is clearly legible.

Article 17

1. Every 4 (four) year after obtaining the registration number the applicant shall submit a report to the Director General or the appointed officer using the model form M4.
2. Copies of the report specified in paragraph (1) shall be submitted to the head of the Regional Office of the Department of Health and the Head of the Office of Drug Food Control.

Article 18

1. Registration number may be revoked:
 - a. At the request of applicant;
 - b. If applicant violates the provision of article 17;
 - c. If the product is not in conformity with the requirement.
2. Registration number is cancelled if:
 - a. The trade name used has been validly registered by another company with the Department of justice;
 - b. The food concerned is no longer produced.

CHAPTER IV RE-EVALUATION

Article 19

Food which registration has been approved may be re-evaluated whenever necessary, in the light of scientific and technological developments.

CHAPTER V SANCTIONS

Article 20

1. The company or importer violating article 9 or article 15 of this Regulation, or, if the food produced or distributed is found to be hazardous or harmful to health, shall recall such food from distribution and report the implementation to the Director General or the appointed officer using the model form M6.
2. The sanction specified in paragraph (1) shall be determined by the Director General using the model form M5.
3. If within a period of 2 (two) month the company or importer has not executed the sanction specified in paragraph (1), he shall be subject to the revocation of the registration number or another penalty according to the existing laws and Regulations.
4. The sanction specified in paragraph (3) shall be determined by the Director general using the model form M7.
5. The sanction specified above shall be announced to the public.

CHAPTER VI TRANSITIONAL PROVISION

Article 21

1. Food which has obtained a registration number before the enactment of this Regulation shall be allowed to be distributed for a period of 1 (one) year after this Regulation comes into force.
2. The company or importer is give 1 (one) year time to comply with this regulation.

CHAPTER VII CLOSING PROVISION

Article 22

As this regulation comes into force, the Regulation of the Minister of Health No 330/Menkes/Per/XII/1976 on the Compulsory Registration of Food is hereby revoked.

Article 23

Technical matters which are not arranged in this Regulation will be further regulated by the Director General.

Article 24

This Regulation shall come into force as from the date of its enactment.

For public cognizance, this Regulation shall be published in the State Gazette of the Republic of Indonesia.

Jakarta, 2 June 1989

THE MINISTER OF HEALTH
OF THE REPUBLIC OF INDONESIA

signed
Dr. ADHYATMA, MPH

THE DIRECTOR GENERAL OF DRUG AND
FOOD CONTROL
DECREE NO :03537/B/SK/VI/89
ON

THE GUIDELINES ON THE IMPLEMENTATION OF THE REGULATION OF THE MINISTER OF HEALTH OF THE REPUBLIC OF
INDONESIA NO.382/MENKES/PER/VI/89
ON FOOD REGISTRATION
THE DIRECTOR GENERAL OF DRUG AND FOOD CONTROL

Considering:

That to implement the Regulation of the Minister of Health of the Republic of Indonesia No. 382/Menkes/Per/VI/89 on the food Registration, it is deemed necessary to promulgate the decree of the Director General of Drug and Food Control on the guidelines on its implementation.

In view of:

1. The Regulation of the Minister of Health of the republic of Indonesia No. 382/Menkes/Per/VI/89 on Food registration;
2. The Regulation of the Minister of Health of the Republic of Indonesia No. 146/Menkes/SK/IV/78 on the Organization Structure and the Work Procedure of the Office of Drug and Food Control which has been amended based on the Decree of the Minister of Health of the Republic of Indonesia No. 783/Menkes/SK/XI/86 on the Amendment of the Position of Technical Unit in the Department of health;
3. The Decree of the Minister of Health of the Republic of Indonesia No. 558/Menkes/SK/1984 on the Organization Structure and the Work Procedure of the Department of Health

DECIDES

To promulgate:

THE DECREE OF THE DIRECTOR GENERAL OF DRUG AND FOOD CONTROL ON THE GUIDELINES ON THE IMPLEMENTATION OF THE REGULATION OF THE MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA NO. 382/MENKES/PER/VI/89 ON FOOD REGISTRATION

CHAPTER I
THE REGISTRATION PROCEDURE

Article 1

1. For food registration, the applicant shall submit or send a registration application to the Director General of Drug and Food Control
2. The registration application specified in paragraph (1) shall be submitted in 3 (three) copies except for label in 10 (ten) copies.

Article 2

The registration application specified in article 1 includes:

- a. Application forms for registration consists of Form A, B, C, D and E which have been filled in completely and honestly in compliance with the guidelines;
- b. Sample food;
- c. Label and brochure, if any; Other than stated in item a. b, and c;
- d. For food which domestically produced: a copy of the license or Registration Letter from the Department of Industry, or license from the Capital Investment Coordination Board in line with the existing regulation;
- e. For repacking product, item d and a recommendation letter from the factory of origin;
- f. For food produced based on license: item d and the license from foreign factory.
- g. For imported product: a letter of certification from the foreign factory, certificate of Health/free sale and a Radiation-Free Certificate in line with the existing regulation.

Article 3

1. The registration application specified in article 2 includes:
 - a. Form A, contains general information on food, name and address of the applicant, including the factory or the company;
 - b. Form B, contains the information on composition including the quality of the raw material, package and the closure;
 - b. Form C, contains the information on the production method, including the method of cleaning the package and the closure;
 - c. Form D, contains the information on the quality control system and the method of the finished product testing;
 - d. Form E, contains the complete list of the application forms which has been submitted by the applicant.
2. The specimen of the forms for the registration application are attached to this Decree.

Article 4

Other than specified in article 2, when it is deemed necessary the applicant may includes other document in 3 (three) copies, which can support the evaluation of the application.

Article 5

1. The complete registration application specified in article 2 will be examined right after the application is received, and to the applicant whose application by using the model form M8 will be given, and for the uncompleted application, a letter or rejection will be given by using the model Form M9;
2. The rejected application forms can be withdrawn at the latest 3 (three) months from the date of notification.

CHAPTER II EVALUATION

Article 6

1. Evaluation of the application is carried out based on the Regulation and the guidelines determined by the evaluation team assigned by the Director General;
2. Based on the result of the evaluation, the head of the Directorate of Food Control will take a decision on behalf of the Director General.

Article 7

1. Decision specified in article 6 paragraph (2) can be in the form of approval, conditional approval or rejection;
2. For food product which has obtained the approval, a registration number will be given by using the model Form M1;
3. If food product obtained conditional approval, the applicant will be given a written notification on the requirement which shall be fulfilled to obtain the approval by using the model Form M2;
4. The requirement specified in paragraph (3) can be in the form of inspection or examination by the Office of Drug and Food Control to check the premises or the product;
5. Decision to the application which obtained conditional approval will be determined at the latest 6 (six) months since the notification specified in paragraph 3;
6. Decision to the rejection of the application will be notified in written to the applicant along with the reason for rejection by using the model Form M3.

Article 8

Applicant who intends to change his product after obtaining the registration number shall submit a written application to the Director General c.q. Head of Directorate of Food Control by using the model form M10.

CHAPTER III CLOSING PROVISION

Article 9

This decree shall come into force as from the date promulgation

Jakarta, 23 June 1989
DIRECTOR GENERAL OF DRUG
AND FOOD CONTROL

signed
DRS. SLAMET SOESILO
NIP. 140 051 341

THE DIRECTOR GENERAL OF DRUG AND
FOOD CONTROL
DECREE NO: 02593/B/SK/VIII/91
ON
FOOD ADDITIVE PRODUCT AND FOOD ADDITIVE PRODUCER REGISTRATION
THE DIRECTOR GENERAL OF DRUG AND
FOOD CONTROL

Considering:

- a. That to protect the public from the usage of food additives which are not in compliance with the requirements, it is necessary to strengthen the control of companies which produced food additive;
- b. That in conjunction with the above consideration and for the implementation of article 7 and 8 of the regulation of the Minister of health No. 722/Menkes/Per/IX/1988 on Food Additives, it is necessary to promulgate the Decree of the Director General of Drug and Food Control on Food Additive Product and Food Additive Producer Registration.

In view of:

1. The regulation of the minister of Health of the Republic of Indonesia No. 722/Menkes/Per/IX/1988 on Food Additives.
2. The Regulation of the Minister of Health of the Republic of Indonesia No. 382/Menkes/Per/VI/89 on Food registration.
3. The Decree of the Director General of Drug and Food Control No. 02987/B/SK/XII/90 on the Registration of Certain Food Additives.

DECIDES

To promulgate:

THE DECREE OF THE DIRECTOR GENERAL OF DRUG AND FOOD CONTROL ON FOOD ADDITIVE PRODUCT AND FOOD ADDITIVE PRODUCER REGISTRATION.

CHAPTER I
THE REGISTRATION PROCEDURE
First Part
Producer Registration

Article 1

1. For producer registration the applicant shall submit or send a registration application to the Directorate General of Drug and Food control;
2. The registration application specified in paragraph (1) is submit in 3 (three) copies.

Article 2

1. The registration application specified in article 1 includes:
 - a. Form PBTM 01 contains information among others name and address of the company and also the responsible person;
 - b. Form PBTM 02 contains information on the location and the lay out of the factory;
 - c. Form PBTM 03 contains information on the production equipment;
 - d. Form PBTM 04 contains information on food additives which will be produced and the quality requirement;
 - e. Photocopy of license owned by the producer.
2. The model form for the registration application of producer is attached to this Decree

Part Two
Food additive registration

Article 3

1. For the registration of certain food additive, the applicant shall submit or send a complete registration application to the Directorate General of Drug and Food Control;
2. The complete registration application specified in paragraph (1) is submitted in 3 (three) copies.

Article 4

The complete application for certain food additive registration specified in article 3 includes the following:

- a. Application for registration consists of Form BT01, BT02, BT03, BT04 and BT 05 which have been filled in completely and honestly in compliance with the guidelines;
- b. Sample of food additives concerned;
- c. Label and brochure, if any; Other than stated in item a, b and c;
- d. For repacking product: recommendation letter from the factory of origin and producer registration number for domestic product;
- e. For product produced based on license: recommendation letter or license from foreign factory and producer registration number for domestic product;

- f. For imported products: letter describing the legal use of food additive from authorized agency of country of origin.

Article 5

1. Application for food additive registration specified in article 4 consists of:
 - a. Form BT01, contains general information on food additive, name and address of the applicant, including the factory or the company;
 - b. Form BT02, contains information on food additive including composition, if food additive is in a preparation form along with its ingredient and quality of each substance;
 - c. Form BT03, contains information on the production procedure of food additive;
 - d. Form BT04, contains information on quality control system and the procedure for testing of quality;
 - e. Form BT05, contains the list of documents and other, which attached to application.
2. The model form for the registration application of product is attached to this decree.

Article 6

Other than specified in article 5, when it is deemed necessary the applicant may include other documents in 3 (three) copies, which can support the evaluation of the application.

CHAPTER II EVALUATION OF REGISTRATION APPLICATION

Article 7

1. The application specified in article 2 and 4 will be examined right after the application is received, and to the applicant whose application has already completed a receipt for application by using the model Form PBTM 05 will be given for producer registration, and Form BT06 for food additive registration;
2. For the uncompleted application. A letter of rejection will be given by using the model Form PBTM 06 for producer registration and Form BT 07 for food additive registration;
3. The rejected application forms can be withdrawn at the latest 3 (three) months from the date of notification.

Article 8

1. The evaluation of the application is carried out based on the Regulation and the guidelines determined by the evaluation team assigned by the Director General;
2. Based on the result of the evaluation, the Head of the Directorate of Food Control on behalf of the Director General may determine:
 - a. Registration approval; or
 - b. Conditional approval; or
 - c. Rejection of registration.

Article 9

1. For producer or food additive product which obtained the approval, a registration number will be given by using the model Form PBTM07 for producer registration and Form BT08 for food additive product registration;
2. If a producer of food additive product obtained conditional approval, the applicant will be given a written notification on the requirements which shall be fulfilled to obtain the approval by using the model Form PBTM08 for producer registration and Form BT09 for food additive product registration;
3. The requirement specified in paragraph (2) can be in the form of inspection by the office of Drug and Food Control to check the premises or the product;
4. Decision to the application which obtained conditional approval will be determined at the latest 6 months since the notification specified in paragraph (3);
5. Decision to the rejection of the application will be notified in written to the applicant along with the reason for rejection by using the model Form PBTM09 for producer registration and Form BT10 for food additive product registration.

Article 10

The approval for the registration of the producer and registration of food additive is granted by the Minister of Health, in this matter on his behalf by the Director General or an appointed Officer.

Article 11

The registration approval specified in article 10 shall prevail forever insofar as the producer or the product meets the requirements.

Article 12

Producer or food additive product which registration is approved based on the evaluation shall be given a registration number

Article 13

1. Registration number specified in article 12 may be revoked:
 - a. At the request of applicant;
 - b. If the producer or product is not in conformity with the requirements.

2. Registration number is cancelled if:

- a. The trade name used has been validly registered by another company with the Department of Justice;
- b. The producer had ended its activity or the food additive concerned is no longer produced.

Article 14

Applicant who intends to make a change after obtaining the registration number shall submit a written application to the Director General c.q Head of the Directorate of Food Control by using the model Form PBTM10 for producer and Form BT11 for food additive product.

CHAPTER III
CLOSING PROVISION

Article 15

Technical matters which are not sufficiently arranged in this Decree will be further decided by the Director General of Drug and Food control

Article 16

The Decree shall come into force as from the date of its promulgation.

Jakarta, 14 August 1991

THE DIRECTOR GENERAL OF DRUG AND FOOD CONTROL
signed

SLAMET SOESILO

Nip. 140 051 341

CHART OF FOOD REGISTRATION

