

**THE INCLUSION OF INFORMATION ON
THE ORIGIN OF CERTAIN MATERIALS,
ALCOHOLIC CONTENT AND EXPIRY DATE ON
THE LABELS OF DRUGS, TRADITIONAL DRUGS,
FOOD SUPPLEMENTS AND FOODS
(Regulation of the Head of the Food and Drug Supervisory
Board No. HK.03.1.23.06.10.5166 dated June 30, 2010)**

BY THE GRACE OF ALMIGHTY GOD
THE HEAD OF THE FOOD AND DRUG SUPERVISORY BOARD OF THE REPUBLIC OF INDONESIA,

Considering :

- a. that to protect public health, drugs, traditional drugs, food supplements and foods must meet security, restorative power/benefit, and quality requirements;
- b. that information on security, restorative power/benefit and quality requirements put on the labels of drugs, traditional drugs, food supplements and foods must be objective and complete and must not be misleading;
- b. that in addition to the information as referred to in letter b, the public are also entitled to receive information on the origin of certain materials, alcoholic content and expiry date put on the labels

GOVERNMENT REGULATIONS

of drugs, traditional drugs, food supplements, and foods;

- d. that based on the considerations as referred to in letter a, letter b and letter c, it is necessary to stipulate Regulation of the Head of the Food and Drug Supervisory Board on the Inclusion of Information on the Origin of Certain Materials, Alcoholic Content, and Expiry Date on the Labels of Drugs, Traditional Drugs, Food Supplements and Foods;

In view of :

1. Law No. 7/1996 on Food (Statute Book of 1996 No. 99, Supplement to Statute Book No. 3656);
2. Law No. 8/1999 on Consumer Protection (Statute Book of 1999 No. 42, Supplement to Statute Book No. 3821);
3. Law No. 36/2009 on Health (Statute Book of 2009 No. 14, Supplement to Statute Book No. 5063);
4. Government Regulation No. 72/1988 on the Safeguarding of Pharmaceutical Preparations and Health Instruments (Statute Book of 1998 No. 138, Supplement to Statute Book No. 3781);
5. Government Regulation No. 69/1999 on Food Label and Advertisement (Statute Book of 1999 No. 131, Supplement to Statute Book No.3867);
6. Government Regulation No. 28/2004 on Food Security, Quality and Nutrition (Statute Book of 2004 No. 107, Supplement to Statute Book No. 4424);
7. Presidential Decree No. 103/2001 on the Position, Task, Function, Authority, Organizational Structure and Working Mechanism of Non Ministerial Government Institutes as already several times amended the latest by Presidential Decree No. 64/2005;
8. Presidential Decree No. 110/2001 on the Organizational Unit and Tasks of Echelon I Officials of Non-Ministry Government Institute as already several times amended the latest by Presidential Regulation No.52/2005;
9. Decision of the Head of the Food and Drug Supervisory Board No. 02001/SK/KBPOM/2001 on the Organization and Work Mechanism of the Food and Drug Supervisory Board as already amended by Decision of the Head of the Food and Drug Supervisory Board No. HK.00.05.21.4231/2004;

D E C I D E S :

To stipulate :

REGULATION OF THE HEAD OF THE FOOD AND DRUG SUPERVISORY BOARD ON THE INCLUSION OF INFORMATION ON THE ORIGIN OF CERTAIN MATERIALS, ALCOHOLIC CONTENT AND EXPIRY DATE ON THE LABELS OF DRUGS, TRADITIONAL DRUGS, FOOD SUPPLEMENTS AND FOODS.

CHAPTER I

GENERAL PROVISIONS

Article 1

Referred to in this Regulation as :

1. Certain material is a material originating or containing or originating from animals, either in a singular or mixture form or processed product or its derivatives.
2. Alcohol is ethyl alcohol with a chemical formula of C₂H₅OH.
3. Expiry date is a piece of information on the expiry date of drugs, traditional drugs, food supplements, and foods fit for consumption in the form of date, month, and year or month and year.
4. Label is any information on product in the form of picture, written statement or a combination of picture and written statement or other form attached to, incorporated with, stuck on, or part of product package.

Article 2

The certain materials as referred to in Article 1 point 1 can come in the form of gelatin, glicerine,

GOVERNMENT REGULATIONS

enzyme, fat, collagen, colostrum, embryo extract, blood extract, hydrolyzed haemoglobin, keratin, hair extract, placenta, protein, thymus extract, thymus hydrolisate, stomach extract, oil, rosetti fat (shortening), condenser, emulsifier, stabilizer, l-sistein, monogliseride, digliseride, or trigliseride.

Article 3

- (1) In addition to fulfilling the law and regulation, the labels of drugs, traditional drugs, food supplements and foods shall also carry information on the origin of certain materials, alcoholic content and expiry date as stipulated in this Regulation.
- (2) If the origin of certain materials as referred to in paragraph (1) and/or products containing the origin of certain materials have received a certificate from the authorized agency, information on the relevant certificate shall be put on the label.
- (3) If information on the certificate as referred to in paragraph (2) comes in the form of halal label, it shall be put in the label according to that contained in the relevant certificate.

CHAPTER II

CERTAIN MATERIALS

Article 4

- (1) The labels of drugs, traditional drugs, food supplements and foods containing certain materials shall carry information on the content of the certain materials on the labels.
- (2) In addition to the information as referred to in paragraph (1), the labels of drugs, traditional drugs, and food supplements containing certain materials originating from pork shall carry special mark in the form of words "Containing Pork" written in black inside a black box on white base like the following example:

CONTAINING PORK

- (3) The special mark as referred to in paragraph (2)

for drugs whose production process touches on certain materials originating from pork shall carry a written statement "In its production process it touches on material originating from pork".

- (4) The statement as referred to in paragraph (3) shall be written in black inside a black box on white base like the following example:

In its production process it touches on materials originating from pork.

- (5) The information as referred to in paragraph (2) for foods shall contain special mark in the form of written statement "containing pork + (picture of pig)" in red inside a red box on white base like the following example :

CONTAINING PORK



- (6) The written statement as referred to in paragraph (5) shall measure at least 1.5 mm, shall be read clearly, and shall be in proportion to the size of label.

CHAPTER III

ALCOHOLIC CONTENT

Article 5

- (1) The labels of drugs, traditional drugs, food supplements and foods containing alcohol shall carry information on alcoholic content.
- (2) The alcoholic content as referred to in paragraph (1) shall be expressed in percentage.

CHAPTER IV

EXPIRY DATE

Article 6

- (1) The labels of drugs, traditional drugs, food supplements and foods shall carry the expiry date.

GOVERNMENT REGULATIONS

- (2) The expiry date as referred to in paragraph (1) shall be stuck on the label clearly so that it can easily be seen and read.

Article 7

- (1) The expiry date of drugs, traditional drugs, food supplements and foods shall be written by mentioning month and year.
- (2) The expiry date of foods with a storage period of less than 3 (three) months shall be written by mentioning date, month and year.

Article 8

- (1) Excepted to provisions in Article 6 shall be traditional drugs that must not be registered.
- (2) Excepted to provisions in Article 6 for foods in the form of :
- a. alcoholic drink made of wine;
 - b. drinks containing alcohol of more than 10 (ten) percent;
 - c. vinegar;
 - d. sugar (sucrose); and
 - e. bread and cake with a storage period of less than or equal to 24 (twenty-four) hours.

**CHAPTER V
ADMINISTRATIVE SANCTIONS**

Article 9

Violators of this regulation can be liable to administrative sanctions in the form of :

- a. Written warning;
- b. Order to withdraw and/or destroy products;
- c. The freezing of circulation permit/registration approval; or
- d. Other administrative sanctions according to the law and regulation.

**CHAPTER VI
TRANSITIONAL PROVISIONS**

Article 10

The labels of drugs, traditional drugs, food supplements, and foods that have secured a circulation permit/registration approval before this regulation is put into force shall adjust to this regulation no later than 1 (one) year after this regulation has been stipulated.

**CHAPTER VII
CONCLUSION**

Article 11

When this Regulation begins to take effect, Regulation of the Head of the Food and Drug Supervisory Board No. HK.00.05.1.23.3516 on the Circulation Permits of Drugs, Traditional Drugs, Cosmetics, Food Supplements and Foods Originating and Containing Certain Materials and/or Containing Alcohol shall be declared null and void.

Article 12

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 30, 2010

THE HEAD OF THE FOOD AND DRUG SUPERVISORY BOARD OF

THE REPUBLIC OF INDONESIA,

sgd.

DRA. KUSTANTINAH, APT., M.APP.SC

Promulgated in Jakarta

On July 5, 2010

THE LAW AND HUMAN RIGHTS MINISTER

sgd.

PATRIALIS AKBAR, SH, MH

**STATE GAZETTE OF THE REPUBLIC OF INDONESIA
OF 2010 NO.328**

(S)