

MEDICINE, TRADITIONAL MEDICINE, COSMETICS, FOOD SUPPLEMENT AND FOOD PRODUCTS FROM, CONTAINING OR ORIGINATING FROM CERTAIN SUBSTANCES AND/OR CONTAINING ALCOHOL

(Regulation of the Head of R.I. Drug and Food Products Control Agency

No. HK.00.05.1.23.3516, dated August 31, 2009)

WITH THE BLESSING OF THE ONE AND ONLY GOD,
HEAD OF DRUG AND FOOD PRODUCTS CONTROL
AGENCY OF THE REPUBLIC OF INDONESIA,

Considering :

- a. that the public is required to be protected from the use of medicine, traditional medicine, cosmetics, food supplement, and food products which scientifically do not meet requirements on safety, quality, and benefit
- b. that there are medicine, traditional medicine, cosmetics, food supplement and food products from certain substances, containing or originating from certain substances which according to Islamic law (syariah) contain substances not allowed and not commonly used by the Indonesian community, where the majority are Muslims;
- c. that in order to exercise control on medicine and food, it is necessary to regulate the circulation permits of medicine, traditional medicine, cosmetics, food supplement and food products from certain substances, containing or originating from certain substances and/or containing alcohol;
- d. that Decision of the Head of Drug and Food Products Control Agency No. HK.00.05.23.0131 Year 2003 concerning Inclusion of the Origin of Certain Substance, Alcohol Content, and Expiry Date on Labels of Medicine, Traditional medicine, Food supplement, and Food is no more suitable with the development of science and technology, therefore it is required to be perfected;

- e. that based on the considerations referred to in letter a thru letter d, it is necessary to stipulate a regulation of the Head of Drug and Food Products Control Agency concerning circulation permit of medicine, traditional medicine, cosmetics, food supplement, and food products containing or originating from certain substances and/or containing alcohol;

In view of:

1. Law No. 23 Year 1992 (***BN No. 6320 page 16A and so on***) concerning Health (Statute Book of the Republic of Indonesia Year 1992 No. 100, Supplement to Statute Book No. 3495);
2. Law No. 7 Year 1996 concerning Food (Statute Book of the Republic of Indonesia Year 1996 No. 99, Supplement to Statute Book No. 3656);
3. Law No. 8 Year 1999 (***BN No. 6321 pages 1A-7A and so on***) concerning Protection of Consumers (Statute Book of the Republic of Indonesia Year 1999 No. 42, Supplement to Statute Book No. 3821);
4. Government Regulation No. 72 Year 1998 concerning Securing the Supply of Pharmacy and Health instruments (Statute Book Year 1998 No. 138, Supplement to Statute Book No. 3781);
5. Government Regulation No. 69 Year 1999 (***BN No. 6370 pages 14A-15A and so on***) concerning Food Label and Advertisement (Statute Book Year 1999 No. 131 Supplement to Statute Book No. 3867);

6. Government Regulation No. 28 Year 2004 concerning Food Safety, Quality and Nutrient (Statute Book Year 2004 No. 107 Supplement to Statute Book No. 4424);
7. Presidential Decree No. 103 Year 2000 concerning Position, Mission, Functions, Authority, Organization Structure, and Work Mechanism of Non-Department Government Agencies having been amended several times, lastly by Presidential Regulation No. 64 Year 2005;
8. R.I. Health Minister Decision No. 82/MENKES/SK/I/1996 concerning Inclusion of the inscription "Halal" on Food Product Labels;

DECIDES:

To stipulate:

REGULATION OF THE HEAD OF DRUG AND FOOD PRODUCTS CONTROL AGENCY OF THE REPUBLIC OF INDONESIA CONCERNING CIRCULATION PERMIT ON MEDICINE, TRADITIONAL MEDICINE, COSMETICS, FOOD SUPPLEMENT AND FOOD PRODUCTS FROM CERTAIN SUBSTANCES, CONTAINING CERTAIN SUBSTANCES AND/OR CONTAINING ALCOHOL

CHAPTER I

GENERAL PROVISIONS

Article 1

In this Regulation, definitions of terms used are:

1. Circulation permit is a form of registration approval for medicine, traditional medicine, cosmetics, food supplement, and food products issued by the Drug and Food Control Agency of the Republic of Indonesia so that the products can be legally circulated within the territory of Indonesia.
2. Medicine is finished medicine, including biological products, solely or mixture of active substances, including narcotics and psycho-tropics, additional substances, contraception and health instruments containing medicine.
3. Additional substance in medicine is medicine component used as substance for filler, solvent, coating, aid, propellant, and substances meant to enhance its benefit, stability, preservation or as coloring substance, and having no pharmacology effect.
4. Traditional medicine is substance or ingredients in the form of vegetation substance, animal substance, mineral substance, galenic supply or mixture of those substances which traditionally are used for medical treatment based on experience.
5. Cosmetics is the substance or supply purported to be used on human outer parts (epidermis, hair, nails, lips, outer parts of genital organ) or teeth and mouth mucosa, particularly to clean, perfume, change the appearance, and/or improve body odor or protect or maintain the body to be in good condition.
6. Food supplement is concentrate products containing one or more vitamins and/or minerals, consumed in measured small amount, and not in the form of general food products, and marketed in the form of among others capsule, tablet, powder or liquid, purported to fulfill intake of vitamin and/or mineral of normal diet.
7. Food products and/or drinks are processed food achieved from a process using certain methods with or without additional substances.
8. Certain substances are substances containing or originating from animals or other living beings solely by itself or a mixture or processed product or its derivative excluding bee honey, or in its process, got in contact with certain substances.
9. Alcohol is ethanol with chemical formula C_2H_5OH

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

Article 2

Animals or other living beings referred to in Article 1 number 8 cover:

- a. pig, dog and offspring born from their inter-marriage;
- b. Corpse, including dead animals not due to being slaughtered in accordance with Islamic method, except fish and grasshoppers;
- c. Any animal deemed and felt as disgusting to be eaten in accordance with human nature such as worms, lice, leech, and the like;
- d. Any animal with tusk/fangs;
- e. Any animal with claws, and devouring its prey by pouncing or swooping and seizing;
- f. Animals prohibited by Islam to be killed, such as bees, Hud-hud bird, frogs, and ants;
- g. Meat cut from a permitted (hala) animal whereas the animal is still alive;
- h. Any poisonous animal and disadvantageous if eaten;
- i. Any animal lying in two natures, such as turtle, crocodile, alligator, and the like; and
- j. Blood, urine, faeces, and placenta.

CHAPTER II

MEDICINE PRODUCTS

Article 3

- (1) Medicine products originating from, containing or during its production process got in contact with certain substances may be provided with a circulation permit if it has an emergency nature.

- (2) Circulation permit for the products referred to in paragraph (1) shall be given based on an evaluation on safety, benefit, quality, and recommendation from the Inter-Sector Team on Permissiveness (Kehalalan) and Emergency.
- (3) Membership of the Inter-Sector Team referred to in paragraph (2) consist of:
 - a. Health Department;
 - b. Drug and Food Products Control Agency;
 - c. Indonesia Muslim Leader (Ulama) Council ;
 - d. Group of related expert doctors.
- (4) The Team referred to in paragraph (3) is stipulated by the Head of the Agency and has an ad hoc nature.
- (5) The alcohol level of medicine products containing alcohol shall be stated on the composition label.
- (6) The alcohol level referred to in paragraph (3) shall be stated in percentage.
- (7) Information on medicine products and bio-products originating from pigs/porcine shall be stated in its box with the inscription "Originating from Pig" in red color on a white color base as shown in the sample.

ORIGINATING FROM PIG

- (8) Information on medicine products and bio-products which in its production process got in contact with substances originating from pig/porcine shall be stated in its box in red color on a white color base as shown in the following sample:

During production process, got in contact with substances originating from pig and had been purified, hence undetected on the end products.

CHAPTER III
TRADITIONAL MEDICINE, COSMETICS, AND FOOD
SUPPLEMENT PRODUCTS

Article 4

- (1) Traditional medicine, cosmetics, and food supplement products generally do not have an emergency nature.
- (2) If the products referred to in paragraph (1) contain or originate from such substances, it shall not be given a circulation permit.

Article 5

- (1) The alcohol level of traditional medicine, cosmetics and food supplement products containing alcohol not included in the provisions meant in Article 4 paragraph (2), must be stated in the composition on the label.
- (2) The level of alcohol referred to in paragraph (1) shall be stated in percentage.

CHAPTER IV
FOOD PRODUCTS AND DRINK PRODUCTS

Article 6

- (1) Food products and drink products from, containing or originating from certain substances shall not be given a circulation permit.
- (2) Exempted from the provisions referred to in paragraph (1), food products and drink products from, containing, or originating from pig may be provided with a circulation permit on condition it must meet requirements on safety, quality, and nutrient, and labels of the food products are also required to include the inscription and picture "containing pig + picture of pig" in its box in red color on a white color base as shown in the sample:



- (3) The inscription "CONTAINING PIG" referred to in paragraph (2) must meet the following provisions:

Minimum Measurement of Surface Width of Main Part of Label

30 cm² or less than 1,5 mm

More than 30 cm² but not more than 160 cm² 3 mm

More than 160 cm² but not more than 645 cm² 4,5 mm

More than 645 cm² but not more than 2580 cm² 6 mm

More than 2580 cm² 12,5 mm

- (4) Level of alcohol contained in food products and drink products containing alcohol must be stated in the composition on the label.
- (5) The level of alcohol referred to in paragraph (3) shall be stated in percentage.

CHAPTER V

SANCTIONS

Article 7

- (1) Any violation on provisions of this Regulation may be imposed to administrative sanctions in the form of:
 - a. written warning for three (3) times;
 - b. temporary cessation of production and distribution activities;
 - c. freezing and/or cancellation of Approval Letter;
 - d. withdrawal of all products from circulation and destruction.
- (2) Besides being imposed to the administrative sanction referred to in paragraph (1), criminal sanctions can also be imposed in accordance with provisions of prevailing legislations.

CHAPTER VI
TRANSITIONAL PROVISIONS

Article 7

- (1) By the time this Regulation of the Agency Head commences to come to effect, decision of the Head of Drug and Food Products Control Agency No. HK.00.05.23.0131 Year 2003 is revoked and declared as no more in effect.
- (2) Medicine, traditional medicine, cosmetics, food supplement and food products that had received a circulation permit and produced before the stipulation of this Regulation are obligated to be adjusted within one (1) year at the latest from the stipulation of this Regulation.

CHAPTER VII
CLOSING PROVISIONS

Article 8

This Regulation comes to effect from the dated of stipulation.

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

Stipulated in Jakarta

On August 31, 2009

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

Sgd

Dr. Husniah Rubiana Thamrin Akib, MS., M.Kes, Sp.FK

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