



THE AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA

REGULATION OF THE HEAD OF THE AGENCY OF DRUG AND FOOD CONTROL

REPUBLIC OF INDONESIA

NUMBER 27 YEAR 2013

CONCERNING

IMPORTATION CONTROL OF DRUG AND FOOD

INTO THE TERRITORY OF INDONESIA

BY THE GRACE OF GOD ALMIGHTY

THE HEAD OF THE AGENCY OF DRUG AND FOOD CONTROL

REPUBLIC OF INDONESIA,

Considering:

- a. that Drug and Food imported into the territory of Indonesia must have circulation permit number and meet the provisions of the regulating legislation on import;
- b. that control arrangements of the importation of Drug and Food that has been stipulated by Regulation of the Head of the Agency of Drug and Food Control Number HK.000.05.23.1455 Year 2008 concerning Importation Control of Processed Food, Regulation of the Head of the Agency of Drug and Food Control Number HK.00.05.42.2996 Year 2008 concerning Importation Control of Traditional Medicine, Regulation of the Head of the Agency of Drug and Food Control Number HK.03.1.23.04.11.03724 Year 2011 concerning Importation Control of Cosmetics, Regulation of the Head of the Agency of Drug and Food Control Number HK.03.1.3.12.11.10692 Year 2011 concerning Importation Control of Imported Drugs, need to be adjusted to current provisions on import;
- c. that based on the consideration as intended in item a and item b necessitate the stipulation of Regulation of the Head of the Agency of Drug and Food



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Control concerning Importation Control of Drug and Food into the Territory of Indonesia;

In view of:

1. Law Number 8 Year 1999 concerning Consumer Protection (State Gazette Year 1999 Number 42, Addendum Number 3821);
2. Law Number 36 Year 2009 concerning Health (State Gazette Year 2009 Number 144, Addendum Number 5063);
3. Law Number 18 Year 2012 concerning Food (State Gazette of the Republic of Indonesia Year 2012 Number 227, Addendum Number 5360);
4. Government Regulation Number 72 Year 1998 concerning Securing Pharmaceutical Preparations and Health Devices (State Gazette of the Republic of Indonesia Year 1998 Number 138, Addendum Number 3781);
5. Government Regulation Number 69 Year 1999 concerning Food Label and Advertisement (State Gazette of the Republic of Indonesia Year 1999 Number 131, Addendum Number 3867);
6. Government Regulation Number 28 Year 2004 concerning Food Safety, Quality and Nutrition (State Gazette of the Republic of Indonesia Year 2004 Number 107, Addendum Number 4244);
7. Government Regulation Number 48 Year 2010 concerning Type and Tariff on Non-tax State Revenue Applicable to Drug and Food Control (State Gazette Year 2010 Number 67, Addendum Number 5131);
8. Government Regulation Number 10 Year 2012 concerning Customs, Taxation, and Excise Treatment as well as Procedures of Importation and Exportation of Goods To and From as well as In an Area Stipulated as Free Trade and Free Port Area (State Gazette Year 2012 Number 17, Addendum Number 5277);
9. Presidential Regulation Number 10 Year 2008 concerning Utilization of Electronic System in the Context of Indonesia National Single Window as amended by Presidential Regulation Number 35 Year 2012;
10. Presidential Decree Number 103 Year 2001 concerning Position, Task, Function, Authority, Organizational Structure, and Work Procedure of



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Non-Department Government Institutions as amended several times, lastly by Presidential Regulation Number 3 Year 2013;

11. Presidential Decree Number 110 Year 2001 concerning Organization and Task Unit of Echelon I Non-Department Government Institutions as amended several times, lastly by Presidential Regulation Number 4 Year 2013;
12. Regulation of the Minister of Health Number 1010/Menkes/Per/XI/2008 concerning Drug Registration as amended by Regulation of the Minister of Health Number 1120/Menkes/Per/XII/2008;
13. Regulation of the Minister of Health Number 1176/Menkes/Per/VIII/2010 Year 2010 concerning Cosmetics Notification;
14. Regulation of the Minister of Health Number 1799/Menkes/Per/XII/2010 concerning Pharmaceutical Industry;
15. Regulation of the Minister of Finance Number 213/PMK.011/2011 Year 2011 concerning Establishment of Classification System of Goods and Imposition of Import Tariff Duty on Imported Goods;
16. Regulation of the Minister of Health Number 1148/Menkes/Per/VI/2011 concerning Pharmaceutical Wholesaler;
17. Regulation of the Minister of Health Number 007 Year 2012 concerning Traditional Medicine Registration;
18. Regulation of the Minister of Health Number 033 Year 2012 concerning Food Additive;
19. Decree of the Head of the Agency of Drug and Food Control Number 02001/SK/KBPOM Year 2001 concerning Organization and Work Procedure of the Agency of Drug and Food Control as amended by Decree of the Head of the Agency of Drug and Food Control Number HK.00.05.21.4231 Year 2004;
20. Regulation of the Head of the Agency of Drug and Food Control Number HK.00.05.41.1384 Year 2005 concerning Criteria and Managing Registration of Traditional Medicine, Standardized Herbal Medicine and Phytopharmaca;



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21. Decree of the Head of the Agency of Drug and Food Control Number HK.00.05.23.4415 Year 2008 concerning The Enactment of Electronic System in the Context of Indonesia National Single Window in the Agency of Drug and Food Control Environment;
22. Decree of the Head of the Agency of Drug and Food Control Number HK.00.0g.23.4416 Year 2008 concerning Service Level Arrangement in the Agency of Drug and Food Control Environment in the Context of Indonesia National Single Window;
23. Regulation of the Head of the Agency of Drug and Food Control Number HK.03.1.23.10.11.08481 Year 2011 concerning Criteria and Managing of Drug Registration;
24. Regulation of the Head of the Agency of Drug and Food Control Number HK.03.1.5.12.11.09955 Year 2011 concerning Processed Food Registration;
25. Regulation of the Head of the Agency of Drug and Food Control Number HK.03.1.5.12.11.09956 Year 2011 concerning Criteria and Managing of Processed Food Registration;

DECIDES:

To stipulate: REGULATION OF THE HEAD OF THE AGENCY OF DRUG AND FOOD CONTROL CONCERNING IMPORTATION CONTROL OF DRUG AND FOOD INTO THE TERRITORY OF INDONESIA

CHAPTER I

GENERAL PROVISIONS

Article 1

What is referred to in this Regulation as:

1. Drug and Food is drug, traditional medicine, quasi medicine, cosmetics, health supplement, and processed food.
2. Importation of Drug and Food is importation of Drug and Food into the territory of Indonesia.



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3. Import Information Letter, hereinafter referred to as SKI, is an information letter for the importation of Drug and Food into the territory of Indonesia.
4. Drug is finished drug including biological product that is an ingredient or mixture of ingredients utilized for affecting/examining physiological system or pathological condition in order to determine diagnosis, prevention, treatment, recovery and improvement of health and contraception for human.
5. Biological Product is vaccine, antibody, antigen, hormone, enzyme, blood product and other fermentation product (including monoclonal antibodies and product originating from DNA recombinant technology) utilized to affect/inspect physiological system or pathological condition in order to prevent, treat, recover and improve health.
6. Traditional Medicine is an ingredient or mixture of ingredients in the form of plant material, animal material, mineral material, essence preparation (galenic), or mixture of those materials which for generations has been used for medication, and can be implemented according to public norms.
7. Quasi Medicine is medicine with active ingredients with pharmacological effect for minor complaints.
8. Cosmetics is ingredient or preparation intended for used on the outer human body (epidermis, hair, nail, lips and outer genital organ) or teeth and mucous membrane in the mouth specifically to clean, perfume, alter the appearance and or improve body odor or protect or maintain the body in good condition.
9. Health Supplement is product that is meant to complement the nutritional need, maintain, increase and improve health function, containing one or more ingredients in the form of vitamin, mineral, amino acid or other ingredient (originating from plant or non-plant) that have nutritional value and/or physiological effect, not intended as food.
10. Processed Food is food or beverage resulting from a process in a certain way or method with or without added ingredient.
11. Circulation Permit is a form of Drug and Food approval given by the Head of the Agency for circulation in the territory of Indonesia.



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12. Expiration limit is information of the time period of drug, traditional medicine, health supplement, and food fit for consumption in the form of date, month, and year, or month and year.
13. The Head of the Agency is the Head of the Agency responsible in Drug and Food Control.

CHAPTER II

REQUIREMENTS

Article 2

- (1) Drug and Food that can be imported into the territory of Indonesia for circulation is Food and Drug that has obtained circulation permit.
- (2) In addition to obtaining circulation permit as intended in paragraph (1), also have to fulfill the provisions of the regulating legislation on import.

Article 3

- (1) In addition to fulfilling the provisions as intended in Article 2, importation of Drug and Food also has to obtain approval from the Head of the Agency.
- (2) Approval from the Head of the Agency as intended in paragraph (1) is in the form of SKI.
- (3) SKI as intended in paragraph (2) is only valid for one-time importation.
- (4) SKI as intended in paragraph (2) use a format as listed in Attachment I which is an integral part of this Regulation.

Article 4

In addition to fulfilling the requirements as intended in Article 2 and Article 3, Drug and Food imported into the territory of Indonesia must have a shelf life of at least:

- a. 1/3 (one-third) of the shelf life for Drug, Traditional Medicine, Quasi Medicine, Health Supplement, and Cosmetics;
- b. 9 (nine) months prior to Expiration Limit, for Biological Product;
- c. 2/3 (two-third) of the shelf life, for Processed Food.



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Article 5

SKI as intended in Article 3, also applies for the importation of Drug and Food into the Free Trade and Free Trade Area.

Article 6

- (1) Importation of Drug and Food can only be performed by the holder of Circulation Permit or its proxy.
- (2) In case the importation is performed by the proxy as intended in paragraph (1), then the proxy must have a permit according to provisions of the regulating legislation.

Article 7

- (1) The List of Drug and Food with regulated importation is as stated in Attachment II which is an integral part of this Regulation.
- (2) In case there is an SKI application not designated for Drug and Food but has Harmonized System Code (HS Code) that is the same as the one listed on Attachment II as intended in paragraph (1), the Head of the Agency shall issue the SKI.

CHAPTER III

APPLICATION PROCEDURES

Part One

Applicant Registration

Article 8

- (1) Applicant who will submit SKI application must perform the registration using the Single Sign On mechanism to obtain registration account in the form of user ID and password.
- (2) Single Sign On mechanism as intended in paragraph (1) is to obtain login access at the Agency of Drug and Food Control in-house (including Main Office/POM Office) and Indonesia National Single Window Portal.
- (3) In case the application is submitted by the proxy, then the proxy has to obtain authorization letter certified by public notary.



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Article 9

- (1) Registration as intended in Article 8 is conducted through the website of the Agency of Drug and Food Control at <http://www.pom.go.id> or through the sub site <http://www.e-bpom.pom.go.id>.
- (2) Applicant performs the data entry electronically and submits the supporting documents by uploading it to the e-bpom application.
- (3) Supporting documents as intended in paragraph (2) consists of:
 - a. Original Application Letter signed by the Director or the Proxy of Director and duly stamped;
 - b. duly stamped Original Letter of Statement of the Responsible Person;
 - c. Photocopy of Import Identification Number (API);
 - d. Photocopy of Trading Business Permit (SIUP);
 - e. Photocopy of the Tax Identification Number (NPWP);
 - f. Photocopy of Importation Letter of Authorization in the form of General Certificate by Notary, in the case where the application is a company that has been authorized for import;
 - g. Pharmaceutical Industry Permit in case of Drug importation;
 - h. PBF permit, for PBF that has been authorized by the pharmaceutical industry to conduct importation of drug;
 - i. List of HS Code that will be imported.
- (4) To the registration application as intended in paragraph (2) and paragraph (3), verification is conducted.
- (5) In case the verification result is complete and correct, applicant will be given a user ID and password.

Article 10

- (1) Applicant registration as intended in Article 8 can only be conducted 1 (one) time, as long as there is no change in the applicant data.
- (2) If data changes occur, applicant must submit a data change notification or filed for readmission.



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Article 11

Applicant registration procedures and data change of applicant is found in the User Manual which can be accessed at e-bpom application.

Article 12

- (1) User ID and password as intended in Article 9 paragraph (4) is a Company secret.
- (2) Misuse of user ID and password is the full responsibility of the Company.

Part Two

Submission of Application

Article 13

- (1) SKI is issued based on application.
- (2) SKI application as intended in paragraph (1) must be equipped with the following electronic documents:
 - a. approval of Circulation Permit;
 - b. certificate of analysis;
 - c. invoice;
 - d. packing list;
 - e. Bill of lading or Air Way Bill; and
 - f. proof of payment of Non-Tax State Revenue (PNPB).
- (3) In case the validity period of the circulation permit is less than 1 (one) month, then SKI application must also be equipped with proof of application for re-registration.
- (4) Specifically for importation of drug in the form of bulk product, then in addition of attaching the approval of circulation permit as intended in paragraph (2) item a, also has to be equipped with bulk product import approval letter.
- (5) certificate of analysis as intended in paragraph (2) item b must at least contain the batch number/lot number/production code and date of production and/or expiration date.
- (6) In case the issuer of the certificate of analysis is different than the producer, then the name of the producer must also be stated in the certificate of analysis as intended in paragraph (5).



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Part Three

Submission of Vaccine and Serum Application

Article 14

- (1) Specifically for the application of SKI in the form of vaccine, in addition to fulfilling the provisions as intended in Article 13, also must be equipped with the following documents:
 - a. batch/lot release certificate from the Authorized Agency in the country of origin where the vaccine is released for every importation; and
 - b. summary batch/lot protocol issued by the producer.
- (2) Specifically for application of SKI in the form of serum, in addition to fulfilling the provisions as intended in Article 13, also had to be equipped with certificate of analysis stating the source of the source of the active substance.

Article 15

- (1) Vaccine that has obtained SKI, can be circulated after sampling, evaluating, and testing is conducted as well as the results meeting the requirements.
- (2) Sampling, evaluating, and testing as intended in paragraph (1) is performed by the Agency of Drug and Food Control.
- (3) All expenses of sampling, evaluating, and testing are the responsibility of the applicant.

Article 16

- (1) Vaccine that has obtain batch/lot release certificate from the Authorized Agency in the country of origin where the vaccine is released shall be:
 - a. evaluated against the summary batch/lot protocol, certificate of analysis and label;
and
 - b. descriptive testing.
- (2) Evaluation and testing result as intended in paragraph (1) is the release certificate.
- (3) Release certificate as intended in paragraph (2) is issued at the maximum 10 (ten) working days, after the document is complete and the sample is received at the



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laboratory of the National Testing Center of Drug and Food (PPOMN), at the Agency of Drug and Food Control.

Article 17

- (1) Vaccine that has not obtain batch/lot release certificate from the Authorized Agency in the country of origin where the vaccine is released shall be:
 - a. evaluated against the summary batch/lot protocol, certificate of analysis and label;
 - b. descriptive testing; and
 - c. potential testing and/or other testing that have been determined.
- (2) Evaluation and testing result as intended in paragraph (1) is in the form of release certificate and testing certificate.
- (3) release certificate and testing certificate as intended in paragraph (2) is issued at the maximum 65 (sixty five) calendar days after the document is complete and sample is received in the laboratory of the National Testing Center of Drug and Food (PPOMN), at the Agency of Drug and Food Control.

Part Four

Submission of Application for Traditional Medicine, Quasi Medicine, Cosmetics, and Health Supplement

Article 18

Specifically for application of SKI for Traditional Medicine, Quasi Medicine, Cosmetics, and Health Supplement, in addition of fulfilling the provisions as intended in Article 13, also has to fulfill the following requirements:

- a. product name stated on the invoice has to be the same as the product name stated on the Circulation Permit, except for cosmetics;
- b. In the case of cosmetics as intended in item a does not have to be the same as the name stated in the Circulation Permit, hence it must be equipped with information letter from the producer.

Part Five

Submission of Application for Processed Food



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Article 19

Specifically for the application of SKI for Processed Food, in addition of fulfilling the provisions as intended in Article 13, also has to fulfill the following requirements:

- a. approved label at the time of application;
- b. information letter from the producer at the country of origin, if the exporter is different than the producer;
- c. importation recommendation letter from the Ministry of Agriculture for Processed Food of animal origin;
- d. for Processed Food name on the import document that is not the same as the one stated on the Circulation Permit, shall be equipped with information letter from the producer;
- e. Other certificates/letters that is required according to provisions of the regulating legislation.

CHAPTER IV

IMPORTATION APPROVAL

Article 20

- (1) Application documents as intended in Article 13, Article 14, Article 15, Article 16, Article 17, Article 18, and Article 19 is evaluated through several stages of evaluation to fulfill the administrative requirements and safety, efficacy/benefit and quality requirements.
- (2) Evaluation result is in the form of approval or rejection.
- (3) In case the evaluation result is rejection because of lack of data, after a time period of a maximum of 30 (thirty) days, the applicant can submit re-application free of charge.
- (4) If the re-application as intended in paragraph (3) is submitted after the 30(thirty) days period has passed, applicant can submit the application as new application.
- (5) SKI is issued at the longest 1 (one) working day after all the application documents are complete and correct.
- (6) SKI is issued electronically and does not require stamp and signature (paperless).
- (7) Rejection of application is delivered electronically through e-bpom.



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- (8) SKI can be printed by the applicant of other interested agencies through the Indonesia National Single Window (INSW) system.
- (9) In case of force majeure, SKI is issued manually.
- (10) Specifically for Main Office/POM Office throughout the territory of Indonesia that has not been facilitated with the Indonesia National Single Window (INSW) system, the SKI is issued manually.

CHAPTER V

DOCUMENTATION

Article 21

- (1) Importation document of Drug and Food must be properly documented by the holder of the Circulation Permit.
- (2) The document as intended in paragraph (1) can be inspected at any time by officers of the Agency of Drug and Food Control.

CHAPTER VI

FEE

Article 22

- (1) the SKI application is subject to fee as Non-Tax State Revenue according to provisions of the regulating legislation.
- (2) In cases the application as intended in paragraph (1) is rejected, the fee that has been paid cannot be refunded.

CHAPTER VII

RE-IMPORTATION

Food and Drug that has been exported from the territory of Indonesia or exported based on the export information letter issued by the Agency of Drug and Food Control that because of a particular reason has to re-enter the territory of Indonesia, still have to submit importation application by attaching the export information letter issued by the Agency of Drug and Food Control and the reason for the re-entry.



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CHAPTER VIII

SANCTION

Article 24

- (1) Violation of provisions in this Regulation is subject to administrative sanction in the form of:
- a. writer reprimand;
 - b. temporary suspension of importation and/or circulation activities;
 - c. extermination or re-export;
 - d. freezing of circulation permit; and/or
 - e. cancellation of circulation permit;
- (2) In addition to administrative sanction as intended in paragraph (1) , criminal sanctions can be imposed according to provisions of the regulating legislation.

CHAPTER IX

TRANSITIONAL PROVISIONS

Article 25

- (1) At the time this Regulation comes into effect, SKI application that is being submitted and has not received approval, is still processed based on:
- a. Regulation of the Head of the Agency of Drug and Food Control Number HK.00.05.23.1455 Year 2008 concerning Importation Control of Processed Food;
 - b. Regulation of the Head of the Agency of Drug and Food Control Number HK.03.1.23.04.11.03724 Year 2011 concerning Importation Control of Cosmetics; and
 - c. Regulation of the Head of the Agency of Drug and Food Control Number HK.03.1.3.12.11.10692 Year 2011 concerning Importation Control of Imported Drug.
- (2) All provisions related to importation of Drug and Food are still in effect as long as not contradicting and/or has not been change based on this regulation.

CHAPTER X



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CLOSING PROVISIONS

Article 26

At the time this Regulation comes into effect:

1. Regulation of the Head of the Agency of Drug and Food Control Number HK.00.05.23.1455 Year 2008 concerning Importation Control of Processed Food;
2. Regulation of the Head of the Agency of Drug and Food Control Number HK.03.1.23.04.11.03724 Year 2011 concerning Importation Control of Cosmetics;
and
3. Regulation of the Head of the Agency of Drug and Food Control Number HK.03.1.3.12.11.10692 Year 2011 concerning Importation Control of Imported Drug.

are revoked and declared invalid.

Article 27

This Regulation comes into effect on the date of its legislation.

For public cognizance, ordering the promulgation of this Regulation by including it in the State Gazette of the Republic of Indonesia.

Stipulated in Jakarta
on 6 May 2013
THE HEAD OF THE AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA,

LUCKY S. SLAMET

Legislated in Jakarta
on 28 May 2013
MINISTER OF JUSTICE AND HUMAN RIGHT
REPUBLIC OF INDONESIA,

AMIR SYAMSUDIN

STATE GAZETTE OF THE REPUBLIC OF INDONESIA YEAR 2013 NUMBER 738

ATTACHMENT I
REGULATION OF THE HEAD OF THE AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NUMBER 27 YEAR 2013
CONCERNING
IMPORTATION CONTROL OF DRUG AND FOOD
INTO THE TERRITORY OF INDONESIA

FORMAT OF IMPORT INFORMATION LETTER

IMPORT INFORMATION LETTER
DRUG AND FOOD COMMODITY
Number : PO

The Head of the Agency of Drug and Food Control RI grant approval to:

Name of Importer :
Office Address :
NPWP :
APIP/APIU Number :
Exporter Name :
Exporter Country of Origin :

To receive :

No	Product Name	Packaging	Circulation Permit Number	Amount of Goods	Batch/Lot Number	HS Code
	Producer					
	Country of Producer					

No. & Date of BL/AWB :
No. & Date of Invoice :
Through : Office of Customs and Excise Service ...

With the provisions:

1. The above product must fulfill the provisions of legislation in Drug and Food
 2. This Import Information Letter can be directly accessed through INSW e-bpom system.
- Thus this Import Information Letter is made to be used properly.

Jakarta, ...

on behalf of The Head of the Agency of Drug and Food Control R.I.
Director of Food Inspection and Certification

(Full Name)
NIP

this document is issued electronically through the INSW e-bpom system thus it does not require stamp and signature.

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

LUCKY S. SLAMET