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 28 YEAR 2013

CONCERNING

IMPORTATION CONTROL OF DRUG MATERIAL, TRADITIONAL MEDICINE MATERIAL, HEALTH SUPPLEMENT MATERIAL, AND FOOD MATERIAL 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 Material, Traditional Medicine Material, Health Supplement Material, and Food Material imported into the territory of Indonesia must meet the requirements of safety, special virtue/benefit and quality, as well as fulfilling the provisions of the regulating legislation on import;
b. that the arrangement of importation control of Drug Material, Traditional Medicine Material, and Food Material that has been stipulated by 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, Regulation of the Head of the Agency of Drug and Food Control Number HK.00.05.1.42.0115 Year 2009 concerning Importation Control of Traditional Medicine Raw Material, Regulation of the Head of the Agency of Drug and Food Control Number HK.03.1.3.12.11.10693 Year 2011 concerning Importation Control of Drug Material, need to be adjusted with 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 Control concerning Importation Control of Drug Material, Traditional Drug Material, Health Supplement Material, and Food Material into the Territory of Indonesia;

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In view of:

1. Law Number 8 Year 1999 concerning Consumer Protection (State Gazette of the Republic of Indonesia Year 1999 Number 42, Addendum Number 3821);
2. Law Number 36 Year 2009 concerning Health (State Gazette of the Republic of Indonesia 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 28 Year 2004 concerning Food Safety, Quality, and Nutrition (State Gazette of the Republic of Indonesia Year 2004 Number 107, Addendum Number 4244);
6. 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);
7. 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);
8. Presidential Decree Number 103 Year 2001 concerning Position, Task, Function, Authority, Organizational Structure, and Work Procedure of Non-Department Government Institutions as amended several times, lastly by Presidential Regulation Number 3 Year 2013;
9. 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;

10. 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;
11. Regulation of the Minister of Health Number 1799/Menkes/Per/XII/2010 concerning Pharmaceutical Industry;
12. 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;
13. Regulation of the Minister of Health Number 1148/Menkes/Per/VI/2011 concerning Pharmaceutical Wholesaler;
14. Regulation of the Minister of Health Number 033 Year 2012 concerning Food Additive;
15. 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;
16. 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;
17. Decree of the Head of the Agency of Drug and Food Control Number HK.00.05.23.4416 Year 2008 concerning Service Level Arrangement in the Agency of Drug and Food Control Environment in the Context of Indonesia National Single Window;

DECIDES:

To stipulate: REGULATION OF THE HEAD OF THE AGENCY OF DRUG AND FOOD CONTROL CONCERNING IMPORTATION CONTROL OF DRUG MATERIAL, TRADITIONAL MEDICINE MATERIAL, HEALTH SUPPLEMENT MATERIAL, AND FOOD MATERIAL INTO THE TERRITORY OF INDONESIA.

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CHAPTER I

GENERAL PROVISIONS

Article 1

In this Regulation what is referred to as:

1. Importation of Drug Material, Traditional Medicine Material, Health Supplement Material, and Food Material is the importation of Drug Material, Traditional Medicine Material, Health Supplement Material, and Food Material into the territory of Indonesia.
2. Import Information Letter, hereinafter referred to as SKI, is an information letter for the importation of Drug Material, Traditional Medicine Material, Health Supplement Material, and Food Material into the territory of Indonesia.
3. Information Letter of Non-Drug and Food Commodity, hereinafter referred to as SKK-NOM, is an information letter for the importation of Raw Materials that are not intended as Drug Material, Traditional Medicine Material, Health Supplement Material, and Food Material.
4. Drug Material is a material that either has special virtue or no special virtue used in drug processing with the standard and quality as pharmaceutical raw material including reference material, not including raw materials in the form of narcotics, psychotropic, and precursors.
5. Traditional Medicine Material is crude drugs or galenic preparations used in the production of traditional medicine and not in packaging that are ready for use by consumers.
6. Health Supplement Material is material intended for the production of health supplement, containing one or more materials in the form of vitamin, mineral, amino acid or other materials (originating from plant or non-plant) that have nutritional value and/or physiological effect, which in not meant as food.
7. Food is everything which originate from biological source of products from agriculture, plantation, forestry, fishery, animal husbandry, aquatic, and water, both processed or not, intended as food or beverage for human consumption including food

additive, food raw material, and other materials used in the preparation, processing, and/or manufacturing of food or beverage.

8. Food Material is basic material used to produce food and beverage not in retail packaging ready for use by consumer, including food additive material, support material, and other materials.
9. Food Additive Material, hereinafter referred to as BTP, is material added into food to influence its characteristics or food shape.
10. The Head of the Agency is the Head of the Agency responsible in drug and food control.

CHAPTER II

REQUIREMENTS

Article 2

(1) Drug Material, Traditional Medicine Material, Health Supplement Material, and Food Material that can be imported into the territory of Indonesia must fulfill the requirements of safety, special virtue/benefit, and quality.
(2) In addition must also meet the provisions of safety, special virtue/benefit, and quality requirements as intended in paragraph (1), it also must meet the provisions of the regulating legislation on import.

Article 3

Importation of Drug Material, Traditional Medicine Material, Health Supplement Material, and Food Material is performed by industry or importer of Drug and Food according to provisions of the regulating legislation.

Article 4

(1) In addition to fulfilling the provisions as intended in Article 3, importation of Drug Material, Traditional Medicine Material, Health Supplement Material, and Food Material must also 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 is only valid for 1 (one) time importation.

(4) SKI as intended in paragraph (2) uses the format stated in Attachment I which is an integral part of this Regulation.

Article 5

SKI as intended in Article 4, is valid for the importation of Drug Material, Traditional Medicine Material, Health Supplement Material, and Food Material in the Free Trade and Free Port Area.

Article 6

(1) The list of Drug Material, Traditional Medicine Material, Health Supplement Material, and Food Material with regulated importation is included in Attachment II which is an integral part of this Regulation.
(2) In case the SKK-NOM application is not intended as Drug Material, Traditional Medicine Material, Health Supplement Material, and Food Material but has the same Harmonized System Code (HS Code) as those listed in Attachment II as intended in paragraph (1), The Head of the Agency can issue a non-transactional SKK-NOM.

Article 7

(1) SKK-NOM as intended in Article 6 paragraph (2) can be issued with the following provisions:
    a. issued only once with a validity period of 2 (two) years as long as there is no change in the name of the raw material, HS Code, exporter name, and importer name; and
    b. if deemed necessary, the Agency of Drug and Food Control at any time can conduct random inspection of the correctness of the SKK-NOM implementation at the importer’s warehouse and/or distribution channel.
(2) If the inspection result as intended in paragraph (1) item b found that the raw material imported based on the SKK-NOM is distributed and/or utilized for the manufacturing or production of Drug, Traditional Medicine, Health Supplement, and Food, then it will be subject to administrative sanctions.

(3) SKK-NOM as intended in paragraph (1) use the format as listed in Attachment III which is an integral part of this Regulation.

CHAPTER III

APPLICATION PROCEDURES

Part One

Applicant Registration

Article 8

(1) Applicant that will apply for SKI must register using the Single Sign On mechanism to obtain an account in the form of user ID and password.
(2) The Single Sign On mechanism as intended in paragraph (1) is to obtain login access to the Agency of Drug and Food Control in-house (including Main Office/POM Office) and the Indonesia National Single Window portal.
(3) In the case of application submitted by the proxy, then the proxy must obtain letter of authorization that must be certified by notary.

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 data entry electronically and submits the supporting documents by uploading it into 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. PBF permit, for PBF that has been authorized by the pharmaceutical industry to conduct importation of drug;
h. 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) For verification purposes as intended in paragraph (4), the applicant must show the original documents as intended in paragraph (3).
(6) In case the verification result is complete and correct, applicant will be given a user ID and password.

Article 10

(1) Registration of applicant as intended in Article 8 only need to be performed 1 (one) time, as long as there is no change in applicant data.
(2) If change occurs in applicant data, applicant must submit data change notification or submit re-application.

Article 11

Registration procedures of applicant and applicant data change are included in the User Manual which can be accessed through the e-bpom application.

Article 12

(1) User ID and password as intended in Article 9 paragraph (4) is Company secret data.
(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 equipped with the following electronic documents:
   a. certificate of analysis;
   b. safety and/or material specification data sheet;
   c. statement letter of intended use;
   d. invoice
   e. packing list;
   f. Bill of lading or Air Way Bill; and
   g. proof of payment of Non-Tax State Revenue (PNPB).

(3) Certificate of analysis as intended in paragraph (2) item a must at least contain batch number/lot number/production code and production date and/or expiration date.

(4) In case the issuer of the certificate of analysis is different than the producer, then the name of the producer must also be stated on the certificate of analysis as intended in paragraph (2) item a.

Part Three

Submission of Drug Material Application

Article 14

Specific to SKI application for:

a. Drug Material of special virtue, in addition to fulfilling the provisions as intended in Article 13, it must also be equipped with Good Manufacturing of Drug Certificate (CPOB) that is still valid from the local Authorized Agency.
b. Drug Materials Originating from Biological Product, in addition to fulfilling the provisions as intended in Article 13, must also be equipped with information of the origin of the material.
c. Drug Material origination from Biological Product in the form of vaccine, in addition to fulfilling the provisions as intended in item b, must also be equipped with summary batch/lot protocol issued by the producer.

Part Four

Submission of Traditional Medicine Material and Health Supplement Material Application

Article 15

Specific to SKI application for Traditional Medicine Material and Health Supplement Material, in addition to fulfilling the provisions as intended in Article 13, must also be equipped with importation letter of recommendation from the Ministry of Agriculture for Traditional Medicine Material and Health Supplement Material of animal origin.

Part Five

Submission of Food Material Application

Article 16

Specific to SKI application for Food Material, in addition to fulfilling the provisions as intended in Article 13, must also be equipped with the following documents:

a. Health certificate and/or certificate of free sale that is still valid from government/authorized agency in the country of origin;
b. Distribution report of BTP that was imported previously; and/or
c. Other certificate/information letter that is required according to provisions of the regulating legislation.

CHAPTER IV

IMPORTATION APPROVAL

Article 17

(1) Application documents as intended in Article 13, Article 14, Article 15, and Article 16 is evaluated through several evaluation stages to fulfill the administrative requirements and safety, special virtue/benefit, and quality requirements.
(2) The evaluation result can be in the form of approval or rejection.
(3) In case the evaluation result is in the form of rejection because of lack of data, in a maximum period of 30 (thirty) days, the applicant can submit re-application free of charge.
(4) If re-application as intended in paragraph (3) is submitted after the 30 (thirty) days period, applicant can submit the application as new application.
(5) SKI and SKK-NOM are issued at the latest 1 (one) working day after all of the application documents are complete and correct.

(6) SKI and SKK-NOM are issued in the electronic form and do not require wet stamp or signature (paperless).

(7) Rejection of application is delivered electronically through e-bpom.

(8) SKI and SKK-NOM can be printed by the applicant or other interested agencies through the Indonesia National Single Window (INSW).

(9) In case of force majeure, SKI and SKK-NOM are issued manually.

(10) Specifically for the Main Office/POM Office throughout the territory of Indonesia that is not yet facilitated with the Indonesia National Single Window (INSW) system, SKI and SKK-NOM is issued manually.

CHAPTER V

DOCUMENTATION

Article 18

(1) Importation documents of Drug Material, Traditional Medicine Material, Health Supplement Material, and Food Material must be well documented by the Drug and Food manufacturer and importer so inspection can be easily conducted.

(2) The documents as intended in paragraph (1) can be checked at any time by the officer from the Agency of Drug and Food Control.

CHAPTER VI

FEE

Article 19

(1) The SKI and SKK-NOM application is subject to fee as Non-Tax State Revenue according to provisions of the regulating legislation.

(2) In case the application as intended in paragraph (1) is rejected, the fee that has been paid cannot be refunded.

CHAPTER VII

RE-IMPORTATION

Article 20

Drug Material, Traditional Medicine Material, Health Supplement Material, and Food Material that have been exported from the territory of Indonesia or exported based on export information letter issued by the Agency of Drug and Food Control because of some specific reason must re-enter the territory of Indonesia, still has to submit importation application by attaching the export information letter issued by the Agency of Drug and Food Control and the reason for re-entering.

CHAPTER VIII

SANCTION

Article 21

(1) Violation of provisions in this Regulation is subject to administrative sanction in the form of:
   a. written reprimand;
   b. temporary suspension of importation and/or distribution; and/or
   c. extermination/re-export.

(2) In addition to administrative sanction as intended in paragraph (1) the violator can also be subject to criminal sanction according to provisions of the regulating legislation.

CHAPTER IX

TRANSITIONAL PROVISIONS

Article 22

(1) At the time this Regulation comes into effect, SKI applications that are being submitted and have not obtain approval, are 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.03.1.3.12.11.10693 Year 2011 concerning Importation Control of Drug Material;

c. Regulation of the Head of the Agency of Drug and Food Control Number HK.00.05.1.42.0115 Year 2009 concerning Importation Control of Traditional Medicine Raw Material; and
d. Regulation of the Head of the Agency of Drug and Food Control Number HK.00.05.1.55.1621 Year 2008 concerning Importation Control of Food Packaging Material.

(2) All provisions of the regulating legislation relating to the importation of Drug Material, Traditional Medicine Material, Health Supplement Material, and Food Material that already exist still remain valid as long as not contrary to and or have not been replaced based on this regulation.

CHAPTER X

CLOSING PROVISIONS

Article 23

At the time this Regulation comes into effect:

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.00.05.1.55.1621 Year 2008 concerning Importation Control of Food Packaging Material;
c. Regulation of the Head of the Agency of Drug and Food Control Number HK.00.05.1.42.0115 Year 2009 concerning Importation Control of Traditional Medicine Material; and
d. Regulation of the Head of the Agency of Drug and Food Control Number HK.03.1.3.12.11.10693 Year 2011 concerning Importation Control of Drug Material.

are revoked and declared invalid.

Article 24

This Regulation shall come into effect on the date of its legislation.

THE AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA

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
THE MINISTER OF JUSTICE AND HUMAN RIGHT
REPUBLIC OF INDONESIA,

AMIR SYAMSUDIN

STATE GAZETTE OF THE REPUBLIC OF INDONESIA YEAR 2013 NUMBER 739

THE AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA

ATTACHMENT I
REGULATION OF THE HEAD OF THE AGENCY OF DRUG AND FOOD CONTROL
REPUBULIC OF INDONESIA
NUMBER 28 YEAR 2013
CONCERNING
IMPORTATION CONTROL OF DRUG MATERIAL, TRADITIONAL MEDICINE MATERIAL, HEALTH SUPPLEMENT MATERIAL, AND FOOD MATERIAL 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	Raw Material Name	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 goods cannot be sold at retails to consumer but can only be used as material ... (Drug/Drug Additive/Reference Material/Traditional Drug/Quasi Material/Food Supplement/ Food/Food Additive) the Type of Commodity choice in the system is according to the requirement, specifically for food additive there is an additional format.
2. This Import Information Letter can be accessed directly through INSW e-bpom.

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

THE AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA

ATTACHMENT III
REGULATION OF THE HEAD OF THE AGENCY OF DRUG AND FOOD CONTROL
REPUBULIC OF INDONESIA
NUMBER 28 YEAR 2013
CONCERNING
IMPORTATION CONTROL OF DRUG MATERIAL, TRADITIONAL MEDICINE MATERIAL, HEALTH SUPPLEMENT MATERIAL, AND FOOD MATERIAL INTO THE TERRITORY OF INDONESIA

FORMAT OF NON DRUG AND FOOD COMMODITY INFORMATION LETTER

INFORMATION LETTER
NON DRUG AND FOOD COMMODITY

Number :

The Head of the Agency of Drug and Food Control R.I. grants approval to :

Importer Name :
Office Address :
NPWP :
No. APIP/APIU :
Exporter Name :
Exporter Country of Origin :

To receive :

No.	Raw Material Name	HS Code	Producer	Country of Producer

With the following provisions :

1. This Information Letter is issued only once witht valisity period of 2 (two) years as long as there is no change in Raw Material Name, HS code, Exporter Name, dan Importer Name.
2. This Information Letter can be accessed directly through INSW e-bpom system.

THE AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA

Jakarta, ...

on behalf of the Head of the Agency of Drug and Food Control R.I.
Director of PT and PKRT Distribution Control,

Signed

(Full Name)
NIP

This document is valid, issued electronically through INSW e-bpom system so it does not require w

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

signed.

LUCKY S. SLAMET