

REGULATION OF
THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 28 OF 2023
ON

AMENDMENT TO REGULATION OF THE INDONESIAN FOOD AND DRUG
AUTHORITY NUMBER 27 OF 2022 ON
IMPORTATION CONTROL OF FOOD AND DRUGS
INTO THE TERRITORY OF INDONESIA

BY THE BLESSINGS OF ALMIGHTY GOD

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

- Considering :
- a. that the administration of importation control of food and drugs as regulated in Regulation of the Indonesian Food and Drug Authority Number 27 of 2022 on Importation Control of Food and Drugs into the Territory of Indonesia is no longer in line with the legal needs, so it is necessary to be amended;
 - b. that based on the provisions of Article 3 section (1) point d of Presidential Regulation Number 80 of 2017 on Indonesian Food and Drug Authority, the Indonesian Food and Drug Authority has a controlling function prior to the circulation and during circulation;
 - c. that based on the considerations as referred to in point a and point b, it is necessary to issue Regulation of the Indonesian Food and Drug Authority on Amendment to Regulation of the Indonesian Food and Drug Authority

- d. Number 27 of 2022 on Importation Control of Food and Drugs into the Territory of Indonesia;

- Observing : 1. Law Number 10 of 1995 on Customs (State Gazette of the Republic of Indonesia of 1995 Number 75, Supplement to the State Gazette of the Republic of Indonesia Number 3612) as amended by Law Number 17 of 2006 on Amendment to Law Number 10 of 1995 on Customs (State Gazette of the Republic of Indonesia of 2006 Number 93, Supplement to the State Gazette of the Republic of Indonesia Number 4661);
- 2. Presidential Regulation Number 80 of 2017 on Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia of 2017 Number 180);
 - 3. Regulation of the Indonesian Food and Drug Authority Number 21 of 2020 on Organization and Work Procedures of Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2020 Number 1002) as amended by Regulation of the Indonesian Food and Drug Authority Number 13 of 2022 on Amendment to Regulation of the Indonesian Food and Drug Authority Number 21 of 2020 on Organization and Work Procedures of Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2022 Number 629);
 - 4. Regulation of the Indonesian Food and Drug Authority Number 23 of 2020 on Organization and Work Procedures of Technical Implementation Units within National Food and Drug Testing Development Center of Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2020 Number 1004);
 - 5. Regulation of the Indonesian Food and Drug Authority Number 10 of 2021 on Standards for Business Activities and Products on Implementation of Risk-Based Business Licensing for Food and Drug Sector (State Bulletin of the Republic of Indonesia of 2021 Number 292);

6. Regulation of the Indonesian Food and Drug Authority Number 27 of 2022 on Importation Control of Food and Drugs into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2022 Number 1154);
7. Regulation of the Indonesian Food and Drug Authority Number 19 of 2023 on Organization and Work Procedures of Technical Implementation Units within Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2023 Number 611);

HAS DECIDED:

To issue : REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON AMENDMENT TO REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY NUMBER 27 OF 2022 ON IMPORTATION CONTROL OF FOOD AND DRUGS INTO THE TERRITORY OF INDONESIA.

Article I

Some provisions in Regulation of the Indonesian Food and Drug Authority Number 27 of 2022 on Importation Control of Food and Drugs into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2022 Number 1154), are amended as follows:

1. Provisions of Article 1 are amended so that Article 1 reads as follows:

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Authority Regulation:

1. Food and Drugs mean Drugs, Natural Medicinal Products, Quasi Drugs, Cosmetics, Health Supplements, and Processed Food.
2. Importation of Food and Drugs means importation of Food and Drugs into the territory of Indonesia.

3. Border Import Certificate (*Surat Keterangan Impor Border*), hereinafter referred to as SKI Border, means an approval letter of importation of goods into the territory of Indonesia which is fulfilled before the goods are released from the customs area in the framework of controlling the circulation of Food and Drugs.
4. Post Border Import Certificate (*Surat Keterangan Impor Post Border*), hereinafter referred to as SKI Post Border, means an approval letter of importation of goods into the territory of Indonesia which is fulfilled before or after the goods are released from the customs area in the framework of controlling the circulation of Food and Drugs.
5. Marketing Authorization means a registration approval for Drugs, Natural Medicinal Products, Quasi Drugs, Health Supplements, and Processed Food or an approval in the form of notice that the Cosmetics has been notified, commitment compliance of processed food and an approval of processed food to be circulated in the territory of Indonesia.
6. Emergency Use Authorization, hereinafter abbreviated as EUA, means an approval for Drug use during the public health emergency for Drugs that have not obtained the Marketing Authorization or Drugs that have obtained a Marketing Authorization with different indications for use/new indications.
7. SKI Border Applicant means a company of Marketing Authorization holder, or a government institution and an importer authorized by the Marketing Authorization holder, to apply for the importation of Drugs, Natural Medicinal Products, Quasi Drugs, Health Supplements, and Cosmetics into the territory of Indonesia.
8. SKI Post Border Applicant means the company holding the Marketing Authorization or an importer authorized by the company holding the Marketing Authorization, to apply for the importation of Processed Food into the territory of Indonesia.

9. Drug means an ingredient or combination of ingredients, including Biological Products, which is used to influence or investigate the physiological system or state of pathology in order to establish diagnosis, prevention, healing, recovery, and improvement of health and contraception, for humans.
10. Biological Product means a product containing biological materials derived from a human, animal, or microorganism prepared in a conventional way, including extraction, fractionation, reproduction, cultivation, or through biotechnology methods, among others fermentation genetic engineering, cloning, including but not limited to enzymes, monoclonal antibodies, hormones, stem cells, gene therapy, vaccines, blood products, DNA recombinant products, and immunosuppressants.
11. Natural Medicinal Products means materials, ingredients, or products originating from natural resources in the form of plants, animals, microorganisms, minerals, or other materials from natural resources, or a mixture of those materials which have been used from generation to generation, or have been proven efficacious, safe, and of good quality, used for health care, health improvement, disease prevention, treatment, and/or health recovery based on empirical and/or scientific evidence.
12. Quasi Drugs means dosage with active ingredients with pharmacological effect that has non-systemic or local characteristics for minor complaints.
13. Health Supplement means a product designed to supplement nutrient intake, to maintain, to increase, and/or to improve health functions, to have nutritional value and/or a physiological effect, to contain one or more materials in the form of vitamins, minerals, amino acids and/or other non-plant materials combinable with plants.

14. Cosmetic means a material or dosage form designed for topical use on the human body, e.g. epidermis, hair, nails, lips, and external genital organs, or teeth and the oral mucosa mainly to clean, to perfume, to alter the appearance, and/or to improve body odor or to protect or to maintain the body in good condition.
15. Processed Food means food or beverage that is processed in a certain way or method with or without food additives.
16. Bulk Product means an ingredient having been processed and only requiring packaging to become finished products.
17. Business Identification Number (*Nomor Induk Berusaha*), hereinafter abbreviated as NIB, means the identity of a business actor issued by the Online Single Submission Institution after the business actor submits a registration.
18. Aju Number means a number given by the system for every application of SKI Border or SKI Post Border.
19. Expiration means information on the ending period of time of Food and Drugs are edible for consumption in the form of date, month, and year, or month and year.
20. Indonesia National Single Window System (*Sistem Indonesia National Single Window*), hereinafter abbreviated as SINSW, means an electronic system that integrates systems and/or information relating to the process of handling customs documents, quarantine, licensing documents, port/airport documents, and other documents, related to exports, imports, national logistics documents, and/or the transportation of certain goods, which ensures data and information security and integrates the flow and process of information between internal systems automatically.
21. Technical Implementation Unit (*Unit Pelaksana Teknis*) within the Indonesian Food and Drug Authority, hereinafter abbreviated as UPT of the Indonesian FDA,

means an independent work unit that carries out certain operational technical duties and/or certain supporting technical duties in the field of Food and Drug control.

22. Chairperson of the Authority means the Chairperson of the Indonesian Food and Drug Authority.
 23. Deputy means the Deputy within the Indonesian Food and Drug Authority.
 24. Day means a calendar day.
 25. Hour means a work hour.
2. Provisions of section (2), section (4), and section (5) of Article 3 are amended, so that Article 3 reads as follows:

Article 3

- (1) In addition to fulfilling the provisions as referred to in Article 2, the Importation of Food and Drugs is also required to obtain an approval from Chairperson of the Authority.
- (2) The approval from Chairperson of the Authority as referred to in section (1) is in the form of:
 - a. SKI Border, for the importation of Drugs, Natural Medicinal Products, Quasi Drugs, Health Supplements, and Cosmetics into the territory of Indonesia; or
 - b. SKI Post Border, for the importation of Processed Food into the territory of Indonesia.
- (3) The SKI Border or the SKI Post Border as referred to in section (2) is only valid for 1 (one)-time importation.
- (4) Drugs, Natural Medicinal Products, Quasi Drugs, Health Supplements, or Cosmetics that are imported into the territory of Indonesia are required to obtain the SKI Border when applying for the import notification issued by the authorized institution.
- (5) Processed Food imported into the territory of Indonesia is required to obtain an SKI Post Border not later than

- 7 (seven) Days as of the issuance date of goods release letter.
- (6) The SKI Border Applicant can apply for the SKI Post Border before getting a registration number and date of import notification of goods.
 - (7) Exempted from the provisions as referred to in section (1), the importation of Drugs in the form of narcotics, psychotropics or pharmaceutical precursors must meet the following requirements:
 - a. control analysis; and
 - b. import authorization, in accordance with the provisions of legislation.
 - (8) The SKI Border or the SKI Post Border as referred to in section (2) uses a format of import certificate as set out in Annex I as an integral part of this Authority Regulation.
3. Provisions of section (1) point b of Article 4 are amended, so that Article 4 reads as follows:

Article 4

- (1) To obtain the SKI Border or the SKI Post Border as referred to in Article 3 section (2), Food and Drugs imported into the territory of Indonesia at the time of submitting the application for SKI Border or SKI Post Border must have the shelf life of at least:
 - a. 9 (nine) months before the Expiration, for Drugs in the form of Biological Products;
 - b. 2/3 (two thirds) of the shelf life, for Drugs other than Biological Products, Natural Medicinal Products, Quasi Drugs, Health Supplements, and/or Processed Food;
 - c. 1/3 (one third) of the shelf life for Cosmetics; or
 - d. 2 (two) years before the Expiration, for Drugs intended for donation purposes.
- (2) Exempted from the provisions as referred to in section (1), are Food and Drugs in the form of:

- a. Drugs that have EUA in accordance with the provisions of legislation; and
 - b. Processed Food that has no Expiration in accordance with the provisions of legislation.
- (3) Exempted from the provisions as referred to in section (1) point d, for donation Drugs with Expiration period of 2 (two) years must have the remaining shelf life of at least 2/3 (two thirds) of the expiration period.
4. Provisions in section (2) of Article 10 are amended and inserted 1 (section), namely section (2a), so that Article 10 reads as follows:

Article 10

- (1) In addition to meeting the requirements as referred to in Article 9 section (2), the application for the SKI Post Border for Processed Food must also be completed with the scanning of original document of Processed Food Safety Management System Certificate at the circulation facility.
- (2) The provisions as referred to in Article 8 section (5) and Article 9 section (2) point c are exempted for government institutions submitting the SKI Border application in the event of an emergency condition in the form of scarcity and/or shortage of Drugs, Natural Medicinal Products, Quasi Drugs, Health Supplements, and/or Cosmetics.
- (2a) The government institution as referred to in section (2) may use an appointment letter as an import executor from the Marketing Authorization Holder as the recipient of the power of attorney in submitting the SKI Border application.
- (3) The registration application as referred to in Article 9 section (1) to section (6) is verified electronically or if necessary, the verification can be carried out non-electronically.

- (4) In the event that the verification results are declared complete and correct, the SKI Border Applicant or the Post Border Applicant receives the registration approval in the form of a user name and password in order to log into the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW.
5. Provisions of section (5) and section (6) of Article 16 are amended, so that Article 16 reads as follows:

Article 16

- (1) The application of SKI Border or SKI Post Border as referred to in Article 15 must be completed with the following electronic documents:
 - a. Marketing Authorization approval;
 - b. certificate of analysis or Certificate of Indonesian National Standard Marking on Product/SNI Marking on Product (*Sertifikat Produk Penggunaan Tanda Standar Nasional Indonesia - SPPT SNI*) for Compulsory SNI Food (*Pangan Standar Nasional Indonesia*); and
 - c. invoice.
- (2) In the event that the validity period of the Marketing Authorization is less than 3 (three) months, the SKI Border or the SKI Post Border applications must also be supported by the re-registration receipt.
- (3) The importation of Food and Drugs in the form of Bulk Products must attach the Marketing Authorization approval of Food and Drugs in accordance with the provisions of legislation.
- (4) The certificate of analysis as referred to in section (1) point b is issued by the manufacturer.
- (5) In the event that certificate of analysis is not issued by the manufacturer, then the certificate of analysis as referred to in section (1) point b for the importation of Natural Medicinal Products, Quasi Drugs, Health

Supplements, Cosmetics, and Processed Food can only be issued by an accredited laboratory.

- (6) Further provisions regarding the testing by an accredited laboratory as referred to in section (5) for the importation of Natural Medicinal Products, Quasi Drugs, Health Supplements, and Cosmetics use testing parameters according to the technical instructions issued by Chairperson of the Authority.

6. The Title of Part Four is amended to read as follows:

Part Four

Application Submission of Natural Medicinal Products, Quasi
Drugs, Health Supplements, and Cosmetics

7. Provisions in Article 25 are amended, so that Article 25 reads as follows:

Article 25

In addition to fulfilling the provisions as referred to in Article 15, Article 16, and Article 17, the application submission for the SKI Border for Natural Medicinal Products, . Quasi Drugs, Health Supplements, or Cosmetics must also be completed with the following documents:

- a. product name, packaging, and packaging size listed on the invoice must match the product name, packaging, and packaging size listed on the Marketing Authorization;
 - b. in the event that the product name as referred to in point a does not match the name listed in the Marketing Authorization, the application must be supported with the reference letter from the manufacturer; and/or
 - c. other required certificates/reference letters in accordance with the provisions of legislation.
8. Provisions in section (2), section (3), and section (7) of Article 38 are amended, so that Article 38 reads as follows:

Article 38

- (1) The research, product development, and exhibition as referred to in Article 37 section (2) point b, point c and point j are not intended for market testing.
 - (2) The donation as referred to in Article 37 section (2) point d only applies to Drugs, Natural Medicinal Products, Health Supplements, Quasi Drugs and Processed Food.
 - (3) The clinical trials for registration requirement, product development, and/or science as referred to in Article 37 section (2) point f, emergency national interests as referred to in Article 37 section (2) point h, and special use for health service which can not be produced domestically as referred to in Article 37 section (2) point i only apply for Drugs, Natural Medicinal Products, Quasi Drugs, Health Supplements, and Processed Food.
 - (4) The clinical trials as referred to in Article 37 section (2) point f, include test drugs with the expanded access program approval.
 - (5) Further provisions regarding the expanded access program as referred to in section (4) are determined by the Chairperson of the Authority.
 - (6) The Government Program as referred to in Article 37 section (2) point g only applies for Drugs.
 - (7) The Exhibition as referred to in Article 37 section (2) point j only applies for Natural Medicinal Products, Quasi Drugs, Health Supplements, Cosmetics, and/or Processed Food.
9. Provisions regarding import form of food and drugs through transport services for personal use and import form of goods for personal use in point A and point C of Annex II to Regulation of the Indonesian Food and Drug Authority Number 27 of 2022 on Importation Control of Food and Drugs into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2022 Number 1154) are amended

to read as in Annex II which is an integral part of this Authority Regulation.

10. Provisions regarding quantity limit of imported goods without Marketing Authorization through special access in Annex III to Regulation of the Indonesian Food and Drug Authority Number 27 of 2022 on Importation Control of Food and Drugs into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2022 Number 1154) are amended to read as in Annex III which is as an integral part of this Authority Regulation.

Article II

This Authority Regulation comes into force after 30 (thirty) Days as of the date of its promulgation.

In order that every person may know hereof, it is ordered to promulgate this Authority Regulation by its placement in the State Bulletin of the Republic of Indonesia.

Issued in Jakarta
on 3 November 2023

CHAIRPERSON OF THE INDONESIAN FOOD AND
DRUG AUTHORITY,

signed

PENNY K. LUKITO

Promulgated in Jakarta
on 8 November 2023

DIRECTOR GENERAL OF LEGISLATION OF THE MINISTER OF LAW AND
HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA,

signed

ASEP N. MULYANA

Jakarta, 25 September 2024
Has been translated as an Official Translation
on behalf of Minister of Law and Human Rights
of the Republic of Indonesia
DIRECTOR GENERAL OF LEGISLATION AD INTERIM,



ANNEX I TO
REGULATION OF THE INDONESIAN FOOD AND DRUG
AUTHORITY NUMBER 28 OF 2023
ON
AMENDMENT TO REGULATION OF THE INDONESIAN
FOOD AND DRUG AUTHORITY NUMBER 27 OF 2022 ON
IMPORTATION CONTROL OF FOOD AND DRUGS
INTO THE TERRITORY OF INDONESIA

IMPORT CERTIFICATE FORMAT

IMPORT CERTIFICATE
FOOD AND DRUG COMMODITIES

Number: ST

Chairperson of the Indonesian Food and Drug Authority of the Republic of
Indonesia has granted the approval to:

Importer's Name :
Office Address :
NPWP (Taxpayer Identification Number :
APIP/APIU Number :
Exporter's Name :
Exporter's Country of Origin :

To receive:

No	Product Name	Packaging	MA Number	Quantity	Lot/Batch Number	HS Code
	Manufacturer					
	Manufacturer's Country of Origin					

No. and Date of Invoice :

Through : Office of Customs and Excise Service

With the provisions:

1. The above product must meet the provisions of legislation in the field of Food and Drugs.
2. This Import Certificate can be directly accessed through the official website of SKI Border or SKI Post Border of the Indonesian Food and Drug Authority or SINSW.

Thus, we truly make this Import Certificate in order to be used accordingly.

Jakarta,

On behalf of Chairperson of the Indonesian Food and
Drug Authority of the Republic of Indonesia
Director of

signed.

(Full Name)

NIP

This document is official, and issued electronically through the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority; thus, it does not require stamp and signature.

CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

ANNEX II TO
REGULATION OF THE INDONESIAN FOOD AND DRUG
AUTHORITY NUMBER 28 OF 2023
ON
AMENDMENT TO REGULATION OF THE INDONESIAN
FOOD AND DRUG AUTHORITY NUMBER 27 OF 2022 ON
IMPORTATION CONTROL OF FOOD AND DRUGS
INTO THE TERRITORY OF INDONESIA

**A. IMPORT FORM OF FOOD AND DRUG THROUGH TRANSPORT
SERVICES FOR PERSONAL USE**

IMPORT FORM OF FOOD AND DRUGS
THROUGH TRANSPORT SERVICES FOR PERSONAL USE

Name :
Phone Number and E-mail :
Date of Birth (DD/MM/YYYY) :
Address :
ID number/passport number :
Receipt :
Shipping Receipt Number :
Shipper Name and Address :
Country of Origin :

Product Description

No.	Product Name and Brand	Package Size	The Amount of (pcs)	Remarks*

*For Drugs: please attach Doctor's prescription/Hospital recommendation for prescription drug

Notes:

1. On the Remarks column, state the amount of use per day. For prescription drug, please state the amount according to Doctor's prescription/Hospital recommendation;
2. The above-mentioned product(s) is solely for personal use and not for sale;
3. Directorate General of Customs and Excise is not responsible for the risks of using the above-mentioned product;
4. If a violation occurs, it will be subject to sanctions in accordance with the provisions of legislation.

Jakarta, (dd/mm/yyyy)

Applicant,

(name and signature)

Technical Documents:

1. Recommendation and data support form the doctor*
2. Justification of the number of needs

B. IMPORT FORM OF FOOD AND DRUGS THROUGH PERSONAL BELONGINGS, CREW OF CARGO AND CROSS BORDER FOR PERSONAL USE

IMPORT FORM OF DRUG AND FOOD THROUGH PERSONAL BELONGINGS,
CREW OF CARGO AND CROSS BORDER FOR PERSONAL USE

Name :
Phone Number and E-mail :
Date of Birth (DD/MM/YYYY) :
Address :
ID Number/Passport Number :
Country of Origin :

Flight/Voyage Number :

Date of Arrival :

Product Description

No.	Product Name and Brand	Package Size	The Amount of Products (pcs)	Remarks*

*For Drugs: please attach Doctor's prescription/Hospital recommendation for prescription drug

Notes:

1. On the Remarks column, state the amount of use per day. For prescription drug, please state the amount according to Doctor's prescription/Hospital recommendation;
2. The above-mentioned product(s) is solely for personal use and not for sale;
3. Directorate General of Customs and Excise is not responsible for the risks of using the above-mentioned product;
4. If a violation occurs, it will be subject to sanctions in accordance with the provisions of legislation.

Jakarta, (dd/mm/yyyy)

Applicant,

(name and signature)

C. INSTRUCTIONS FOR FILLING THE FORM OF THE IMPORT OF GOODS FOR PERSONAL USE

Column on the Form	Filling Instructions
Name	: Filled with full name according to ID Card/Passport of the passenger or consignee
Phone Number and E-mail	: Filled with contactable telephone number and email
Date of Birth (DD/MM/YYYY)	: Filled with place and date of birth with the format (Day/Month/Year) of the passenger or consignee
Address	: Filled with domicile address of the passenger or consignee
ID Number/ Passport Number	: Filled with identification number of the passenger or consignee based on the ID Card/Passport
Flight/Voyage Number	: Filled with airline name/flight number used by the passenger
Date of Arrival	: Filled with date of arrival of the passenger
Receipt	: Filled with number and date of receipt
Shipping Receipt Number	: Filled with shipping receipt number
Shipper Name and Address	: Filled with shipper name and address
Country of Origin	: Filled with country of origin of the goods
Product Description	
Product Name and Brand	: <ol style="list-style-type: none"> 1. For Drugs, filled with the name of active ingredients followed by the brand (if generics, filled with active ingredients only), for example: Paracetamol drug "Pasemol". 2. Filled with brand name and product type, e.g.: <ol style="list-style-type: none"> a. Natural Medicinal Products "Tolak Pegel Linu" b. Quasi Drug "Balsam X" c. Health Supplement "Energi Oke" d. Cosmetics "BMZ Lipstick Shine 0" e. "SUPER LEZAT" instant noodles (Product type: instant noodles, brand: SUPER LEZAT)

Column on the Form	Filling Instructions
Package Size	: Filled with individual size of product package, e.g.: a. 100 grams (a net weight/product nett) b. Box, bottle @ 60 capsules @ 500 mg c. Box, 6 sachets @ 4 grams d. Box, 10 strips @ 10 capsules @ 500 mg e. Tube Box, 3.5 grams
The Amount of Products (pcs)	: 1. Filled with the amount of products sent per product type, for example: 5 pieces (amount of products is subject to each primary package) 2. Specifically for Drug, it is filled with the smallest unit of use (e.g.: 30 tablets/capsules, 250 milliliters of syrup, 100 grams of cream, 10 units of single dose)
Remarks*	: Filled with the information regarding the doctor's prescription attached (amount of usage per day, for example: 3 tablets per day, 15 milliliters of syrup per day, 1 single dose per day)
Applicant, Name and Signature	: Filled with the name and signature of the passenger or consignee

CHAIRPERSON OF THE INDONESIAN FOOD
AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

ANNEX III TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 28 OF 2023
ON
AMENDMENT TO REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 27 OF 2022 ON IMPORTATION CONTROL OF FOOD AND DRUGS
INTO THE TERRITORY OF INDONESIA

QUANTITY LIMIT OF IMPORTED GOODS WITHOUT MARKETING AUTHORIZATION
THROUGH SPECIAL CHANNELS

Commodity	Quantity Limit of Importation of Goods		
	Personal/Individual Use Purpose	Sample Purpose for Registration/Application	Display Purpose
Drugs:	1. Personal goods of passengers/personal goods of crew of cargo/personal goods of border crossers: <ul style="list-style-type: none">• Solid dosage forms	-	-

Commodity	Quantity Limit of Importation of Goods		
	Personal/Individual Use Purpose	Sample Purpose for Registration/Application	Display Purpose
	<p>(tablets/caplets/capsules/pills/and others): 30 pcs per person for each type/item of product;</p> <ul style="list-style-type: none"> • Semisolid dosage forms (cream/ointment/gel/suppository/and others) 3 pcs per person for each product type/item; • Liquid dosage forms (syrup/emulsion/suspension/and others): 3 pcs per person for each type/item of product; • Aerosol dosage forms: 3 pcs per person for each type/item of product; or • According to the doctor's prescription for the requirement of maximum 90-day treatment. <p>2. Goods of carrier transportation/postal</p>		

Commodity	Quantity Limit of Importation of Goods		
	Personal/Individual Use Purpose	Sample Purpose for Registration/Application	Display Purpose
	service: according to the doctor's prescription for the requirement of maximum 90-day treatment.		
Natural Medicinal Products	Maximum 5pcs* per passenger/recipient for each product type/item. *) Notes: For tablet/capsule dosage forms in strips/blisters/bottles and packaged in	Maximum 2 pcs/items of Natural Medicinal Products products for each package or according to sample requirements for testing.	Maximum 10 pcs/items of products for each package.
Quasi Drugs	small boxes, the permitted quantity is 5 small boxes.	Maximum 2 pcs/items of Quasi Drug products for each package or according to sample requirements for testing.	Maximum 10 pcs/items of products for each package.
Health Supplements		Maximum 2 pcs/items of Health Supplement products for each package or according to sample requirements for testing.	Maximum 10 pcs/items of products for each package.

Commodity	Quantity Limit of Importation of Goods		
	Personal/Individual Use Purpose	Sample Purpose for Registration/Application	Display Purpose
Cosmetics	Maximum 20 pcs per passenger/recipient.	Maximum 2 pcs/items of Cosmetic products for each package or according to sample requirements for testing.	Maximum 10 pcs/items of products for each package.
Food: a. Food for Special Nutritional Needs	According to the doctor's prescription.	-	-
b. Other Processed Food, excluding Alcoholic Beverages	5 Kilograms per passenger/recipient.	-	-

CHAIRPERSON OF THE INDONESIAN FOOD AND
DRUG AUTHORITY,

signed

PENNY K. LUKITO