

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 26 OF 2022
ON
IMPORTATION CONTROL OF FOOD AND DRUG SUBSTANCES
INTO THE TERRITORY OF INDONESIA

BY THE BLESSINGS OF ALMIGHTY GOD

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

- Considering :
- a. that the public is needed to be protected from the importation of food and drug substances which do not meet the requirements of safety, efficacy/benefit and quality into the territory of Indonesia;
 - 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 the administration of importation control of food and drug Substances as regulated in Regulation of the Indonesian Food and Drug Authority Number 29 of 2017 on Importation Control of Food and Drug Substances into the Territory of Indonesia as amended by Regulation of the Indonesian Food and Drug Authority Number 14 of 2020 on Amendment to Regulation of the Indonesian Food and Drug Authority Number 29 of 2017 on Importation Control of Food and Drug Substances into the Territory of Indonesia is no longer in line with the legal requirements, so it is necessary to be replaced;
 - d. that based on the consideration as referred to in point a, point b, and point c, it is necessary to establish Regulation of the Indonesian Food and Drug Authority on Importation Control of Food and Drug Substances 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 22 of 2020 on Organization and Work Procedures of Technical Implementation Units within Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2020 Number 1003) as amended several times and last by Regulation of the Indonesian Food and Drug Authority Number 24 of 2022 on Second Amendment to Regulation of the Indonesian Food and Drug Authority Number 22 of 2020 on Organization and Work Procedures of Technical Implementation Units within Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2022 Number 1111);
5. 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 2021 Number 1004);
6. 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);

HAS DECIDED:

To issue : REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON IMPORTATION CONTROL OF FOOD AND DRUG SUBSTANCES INTO THE TERRITORY OF INDONESIA.

CHAPTER I GENERAL PROVISIONS

Article 1

In this Authority Regulation:

1. Food and Drug Substances mean drug substances, traditional medicine substances, quasi medicine substances, health supplement substances, cosmetic substances, and food substances.

2. Importation of Food and Drug Substances means importation of Food and Drug Substances into the territory of Indonesia.
3. Border Import Certificate (*Surat Keterangan Impor Border*), hereinafter referred to as SKI Border, means an approval 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 Drug Substances.
4. Post Border Import Certificate (*Surat Keterangan Impor Post Border*), hereinafter referred to as SKI Post Border, means an approval 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 Drug Substances.
5. Priority Service means service of SKI Border or SKI Post Border for the importation of Food and Drug Substances into the territory of Indonesia through automatic recommendation process by the system.
6. SKI Border Applicant means the company or the importer authorized by the company to apply for the importation of drug substances and traditional medicine substances into the territory of Indonesia.
7. SKI Post Border Applicant means the company or the importer authorized by the company, to apply for the importation of quasi medicine substances, cosmetic substances, health supplement substances, and food substances into the territory of Indonesia.
8. Drug Substances mean efficacious or non-efficacious substances used in drug processing with the standard and quality as pharmaceutical raw materials including reference substances.
9. Traditional Medicine Substances mean active substances in the form of crude drugs or galenic preparations as well as additional substances used in the manufacture of traditional medicines and not in the ready-to-use packaging for consumers.
10. Quasi Medicine Substances mean active substances which have efficacy as well as additional substances used in the manufacture of quasi medicines.
11. Cosmetic Substances mean ingredients or mixture of ingredients which are derived from nature and/or have synthetic characteristics serving as cosmetic components.
12. Health Supplement Substances mean active substances which have efficacy/benefit as well as additional substances used in the manufacture of health supplements.
13. Food Substances mean raw materials intended for the production of food and beverages not in ready-to-use retail packaging, including food additives, processing aids, and other materials.
14. Food Additives (*Bahan Tambahan Pangan*), hereinafter referred to as BTP, mean any substances added to food in

- order to affect the nature and form of the food.
15. 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.
 16. Aju Number means a number given by the system for every application of import certificate.
 17. 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.
 18. 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.
 19. Chairperson of the Authority means the Chairperson of the Indonesian Food and Drug Authority.
 20. Deputy means the Deputy within the Indonesian Food and Drug Authority.
 21. Day means a calendar day.
 22. Hour means a work hour.

Article 2

- (1) Food and Drug Substances that can be imported into the territory of Indonesia are required to fulfill the requirements of safety, efficacy/benefit, and quality.
- (2) The Food and Drug Substances as referred to in section (1) include Drug Substances used in the Drug processing with emergency use authorization.
- (3) In addition to fulfilling the requirements of safety, efficacy/benefit, and quality as referred to in section (1), the importation of Food and Drug Substances into the territory of Indonesia must also meet all the provisions of legislation.

Article 3

The Importation of Food and Drug Substances is conducted by a company or an importer in the field of Food and Drugs in accordance with the provisions of legislation.

Article 4

- (1) In addition to fulfilling the provisions as referred to in Article 2 and Article 3, the Importation of Food and Drug Substances 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 Drug Substances and Traditional Medicine Substances into the territory of Indonesia; or
 - b. SKI Post Border, for the importation of Quasi Medicine Substances, Cosmetic Substances, Health Supplement Substances, and Food Substances 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) Drug Substances and/or Traditional Medicine Substances that are imported into the territory of Indonesia must obtain the SKI Border when applying for the import notification issued by the authorized institution.
- (5) Health Supplement Substances, Quasi Medicine Substances, Cosmetic Substances, and/or Food Substances that are imported into the territory of Indonesia are required to obtain an SKI Post Border not later than 7 (seven) Days as of the issuance date of goods release letter issued by the authorized institution.
- (6) Exempted from the provisions as referred to in section (1), the importation of Drug Substances in the form of narcotics, psychotropics or pharmaceutical precursors must meet the following requirements:
 - a. control analysis of monitoring results; and
 - b. import authorization,in accordance with the provisions of legislation.
- (7) The SKI Border or SKI Post Border as referred to in section (2) uses a format of import certificate as set out in the Annex as an integral part of this Authority Regulation.

Article 5

The SKI Border or the SKI Post Border as referred to in Article 4 section (2) also applies for the Importation of Food and Drug Substances into the free trade zones and free ports, special economic zones and bonded storage.

Article 6

- (1) The list of Food and Drug Substances of which importation is limited into the territory of Indonesia is issued by Chairperson of the Authority.
- (2) Exempted from the provisions as referred to in section (1), is Food and Drug Substances of which the importation is not to be used in Food and Drugs.
- (3) In the event that the HS Code listed in the SKI as referred to in Article 4 section (2) is different from the HS Code stipulated by the authorized institution in customs, the eligible HS Code is the one stipulated by the authorized institution in accordance with the provisions of legislation.

CHAPTER II
APPLICATION PROCEDURES

Part One

Applicant Registration of SKI Border or SKI Post Border

Article 7

- (1) The SKI Border Applicant or the SKI Post Border Applicant must obtain an NIB through Online Single Submission in order to receive the SKI Border or the SKI Post Border service.
- (2) The SKI Border Applicant or the SKI Post Border Applicant must choose an authorization code of the SKI Border or the SKI Post Border of the Indonesian Food and Drug Authority in the Online Single Submission system.
- (3) The SKI Border Applicant or the SKI Post Border Applicant as referred to in section (2) must submit a registration in order to get a username and a password with single sign on mechanism on the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or through SINSW.
- (4) The registration through single sign on mechanism as referred to in section (3) is carried out in order to obtain the login access at in-house Indonesian Food and Drug Authority, including UPT of the Indonesian FDA and SINSW.
- (5) In the event that the application is submitted by the proxy, then the proxy must obtain the power of attorney certified by a notary.

Article 8

- (1) The SKI Border Applicant or the SKI Post Border Applicant submits a registration through data entry electronically and uploads the supporting documents to the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW.
- (2) The supporting documents as referred to in section (1) consist of the scanning of:
 - a. original application letter signed by the director or the proxy of board of directors;
 - b. duly stamped, original statement letter of the responsible person;
 - c. original import power of attorney in the form of a general deed by a notary if the SKI Border Applicant or the SKI Post Border Applicant is the recipient of the power of attorney in importation; and
 - d. list of HS Code of commodities which will be imported;
 - e. original of Resident Identity Card (KTP) of the responsible person; and
 - f. front view and back view photos of the warehouse and office.
- (3) In the event that the commodity type of Food and Drugs with intended use is not in line with the list of HS Code of

commodities as referred to in section (2) point d, the application procedures follow the commodity type of Food and Drugs that becomes the intended use.

- (4) In the event that there are differences in determining the HS Code between the SKI Border Applicant or the SKI Post Border Applicant and the Indonesian Food and Drug Authority for the commodity to be imported, then the Indonesian Food and Drug Authority may request the SKI Border Applicant or the SKI Post Border Applicant to attach a Pre-Import Classification Settlement (*Penetapan Klasifikasi Sebelum Impor*, PKSI) from the authorized institution in the field of customs in accordance with the provisions of legislation.
- (5) In addition to fulfilling the requirements as referred to in section (2), the SKI Border Applicant or the SKI Post Border Applicant must clearly state the address of the warehouse where the Food and Drug Substances are stored.
- (6) In the event of warehouses as referred to in section (5) are more than 1 (one), the SKI Border Applicant or the SKI Post Border Applicant must include all addresses of warehouses where Food and Drug Substances are stored, including the temporary/rental/contract warehouses.
- (7) In addition to fulfilling the requirements as referred to in section (2) and section (5), SKI Border applications in the form of Drug Substances must also be completed with the scanning of original documents of:
 - a. pharmaceutical industry business license or pharmaceutical wholesaler business license in accordance with the provisions of legislation; and
 - b. certificate of Good Distribution Practice (*Cara Distribusi Obat yang Baik*, CDOB) for pharmaceutical wholesalers.
- (8) The registration application as referred to in section (1) is verified electronically or if necessary, the verification may be carried out non-electronically.
- (9) In the event that the verification results are declared complete and correct, the SKI Border Applicant or the SKI Post Border Applicant receives the registration approval in the form of a username 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.

Article 9

- (1) The registration of the SKI Border Applicant or the SKI Post Border Applicant as referred to in Article 8 can only be conducted 1 (one) time.
- (2) The SKI Border Applicant or the SKI Post Border Applicant may change the registration data that has been approved.
- (3) In the event of data changes as referred to in section (2), the SKI Border Applicant or the SKI Post Order Applicant is required to change the data through the official website of SKI Border or SKI Post Border service of the

Indonesian Food and Drug Authority service or SINSW by attaching the supporting data related to the data being changed.

- (4) To the data changes as referred to in section (3), verification is carried out by the Indonesian Food and Drug Authority.
- (5) Based on the verification results as referred to in section (4), the Indonesian Food and Drug Authority gives an approval or rejection to the data changes submitted by the SKI Border Applicant or the SKI Post Border Applicant not later than 2 (two) work days since the SKI Border Applicant or the SKI Post Border Applicant submits the data changes.
- (6) The issuance of the approval or rejection of data changes as referred to in section (5) is conducted with time to respond mechanism.
- (7) The time to respond mechanism as referred to in section (6) is conducted in accordance with the following provisions:
 - a. the calculation of the evaluation period in order to give an approval or rejection as referred to in section (5) is stopped if additional data is required based on the evaluation results; and
 - b. the calculation of the evaluation period in order to give an approval or rejection as referred to in section (5) restarts from the beginning after the SKI Border Applicant or the SKI Post Border Applicant submits additional data.

Article 10

- (1) In the event that the SKI Border Applicant or the SKI Post Border Applicant fails to log into the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW, the 'forget password' facility can be applied.
- (2) In the event that the SKI Border Applicant or the SKI Post Border Applicant fails to use the 'forget password' facility, the SKI Border Applicant or SKI Post Border Applicant may submit application letter of identity updates to the Indonesian Food and Drug Authority manually with the following requirements:
 - a. the SKI Border Applicant or the SKI Post Border Applicant shows the original power of attorney from the company director;
 - b. the original of application letter uses the company letterhead, is duly stamped, and signed by the company director;
 - c. the copy of NIB and shows the original document; and
 - d. the copy of company director's Resident Identity Card.
- (3) The approval of changes will be issued not later than 2 (two) work days as of the receipt of the application letter as referred to in section (2) is declared complete and correct.

Article 11

The registration procedures of the SKI Border Applicant or the SKI Post Border Applicant and data changes of the SKI Border Applicant or the SKI Post Border Applicant are included in the usage instructions online on the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW.

Article 12

The application for import certificates is carried out in accordance with the provisions of Regulation of the Indonesian Food and Drug Authority which regulates electronically integrated business licensing services in Food and Drug sector.

Part Two

Application Submission of SKI Border or SKI Post Border

Article 13

The application of SKI Border or SKI Post Border is carried out online.

Article 14

- (1) The application of SKI Border or SKI Post Border as referred to in Article 13 must be completed with the following electronic documents of:
 - a. a certificate of analysis or a 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 Substances (*Bahan Pangan Standar Nasional Indonesia*);
 - b. material safety data sheet and/or material specifications letter;
 - c. a duly stamped statement letter of the designation/distribution purposes; and
 - d. invoice.
- (2) The certificate of analysis as referred to in section (1) point a is issued by the manufacturer.
- (3) 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 a can only be issued by an accredited laboratory.
- (4) Exempted from the provision as referred to in section (3), the certificate of analysis as referred to in section (1) point a for Drug Substances, apart from being issued by the manufacturer, can also be issued by other pharmaceutical industries, distributors, repackers, or laboratories that carry out testing for and on behalf of the manufacturer or distributor of the repacker.
- (5) In the event that the certificate of analysis of Drug Substances as referred to in section (4) is issued by a repacker or a laboratory that conducts testing for and on behalf of the repacker, the SKI Border Applicant must attach a certificate of origin analysis issued by the manufacturer.

- (6) The certificate of analysis as referred to in section (1) point a must at least contain:
 - a. name and address of the manufacturer;
 - b. name of substances;
 - c. testing parameter based on the provisions;
 - d. test results;
 - e. analysis method;
 - f. batch number/lot number/production code;
 - g. production date; and
 - h. expiration date.
- (7) The Indonesian Food and Drug Authority may carry out sampling and testing at an accredited laboratory to ensure the validity and legality of certificate of analysis as referred to in section (6).
- (8) The financing for the testing as referred to in section (7) is borne by the SKI Border Applicant or the SKI Post Border Applicant.
- (9) In the event that it is necessary to ensure compliance with the safety, quality and data integrity aspects, the Indonesian Food and Drug Authority may request the SKI Border Applicant or the SKI Post Border Applicant to attach supporting documents other than those as referred to in section (1) in accordance with the provisions of legislation.

Part Three

Application Submission of Drug Substances

Article 15

- (1) The importation of Drug Substances can only be conducted by the SKI Border Applicant that has already obtained an approval as the SKI Border Applicant.
- (2) The SKI Border Applicant as referred to in section (1) consists of:
 - a. pharmaceutical industries; and
 - b. pharmaceutical wholesalers.
- (3) The importation of Drug Substances by the pharmaceutical industries as referred to in section (1) point a is only intended for in-house production needs and not for general distribution.
- (4) In addition to fulfilling the provisions as referred to in Article 14, the SKI Border application of Drug Substances also needs to be completed with the following documents:
 - a. active pharmaceutical substances, completed with Good Manufacturing Practice (CPOB) owned by the manufacturer of Drug Substances which is still valid or other similar documents issued by the local authorities and/or the authorities of other countries;
 - b. Drug Substances derived from biological products and from animals, completed with the information of the originality; and
 - c. in addition to meeting the provisions as referred to in point b, Drug Substances derived from biological products in the form of vaccine substances must also be completed with the summary batch/lot protocol issued by the manufacturer.

Part Four
Application Submission of Traditional Medicine Substances
and Health Supplement Substances

Article 16

In addition to fulfilling the provisions as referred to in Article 14, the application submission for the SKI Border for Traditional Medicine Substances and the SKI Post Border for Health Supplement Substances must also be completed with the following documents:

- a. a health certificate and/or a certificate of free sale from the government/authorized institution in the country of origin that is still valid;
- b. a certificate of origin of substances, for Traditional Medicine Substances and Health Supplement Substances of animal origin;
- c. reporting on the distribution of previously imported Traditional Medicine Substances and Health Supplement Substances; and/or
- d. other required certificates/reference letters in accordance with the provisions of legislation.

Part Five
Application Submission of Quasi Medicine Substances

Article 17

In addition to fulfilling the provisions as referred to in Article 14, the application submission for the SKI Post Border for Quasi Medicine Substances must also be completed with the following documents:

- a. a health certificate and/or a certificate of free sale from the government/authorized institution in the country of origin that is still valid;
- b. reporting on the distribution of previously imported Quasi Medicine Substances and Health Supplement Substances; and/or
- c. other required certificates/reference letters in accordance with the provisions of legislation.

Part Six
Application Submission of Cosmetic Substances

Article 18

In addition to fulfilling the provisions as referred to in Article 14, the application submission for the SKI Post Border for Cosmetic Substances must also be completed with the following documents:

- a. a statement letter issued by the fragrance manufacturer, stating that the fragrance is manufactured in accordance with guidelines of International Fragrance Association (IFRA) for Cosmetic Substances in the form of fragrance ingredients;
- b. reporting on the distribution of previously imported fragrance ingredients; and/or
- c. other required certificates/reference letters in accordance with the provisions of legislation.

Part Seven
Application Submission of Food Substances

Article 19

In addition to fulfilling the provisions as referred to in Article 14, the application submission for the SKI Post Border for Food Substances must also be completed with the following documents:

- a. a health certificate which includes a statement ensuring that the Food Substances are safe for humans consumption and/or a certificate of free sale stating that the product is traded/ freely sold in the country of origin for human consumption from the government/authorized institution in the country of origin that is still valid;
- b. reporting on the distribution of previously imported BTP;
- c. a certificate from the manufacturer of the country of origin, if the exporter is different from the manufacturer;
- d. other required certificates/reference letters in accordance with the provisions of legislation; and/or
- e. intended use/distribution purpose of Food Substances which are further processed for hotels, restaurants, food outlets, cafes or other similar businesses must attach an order letter and photo of the smallest packaging.

Part Eight
Responsibilities of Applicant

Article 20

- (1) The SKI Border Applicant or the SKI Post Border Applicant is obligated to complete the application documents correctly and legally which are uploaded on the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW.
- (2) The SKI Border Applicant or the SKI Post Border Applicant is obligated to ensure that the Food and Drug Substances imported into the territory of Indonesia are in accordance with the approval of the SKI Border or the SKI Post Border.
- (3) The SKI Border Applicant or the SKI Post Border Applicant is prohibited from importing the Food and Drug Substances other than those stated in the approval of the SKI Border or the SKI Post Border.
- (4) The SKI Border Applicant or the SKI Post Border Applicant is prohibited from distributing, transferring, and/or using Food and Drug Substances prior to the issuance of the SKI Border or the SKI Post Border.
- (5) The SKI Post Border Applicant for Food Substances with the intended use/distribution purpose as referred to in Article 14 section (1) point c for hotels, restaurants, food outlets, cafes or other similar businesses is prohibited from directly trading/circulating to consumers and re-packing without a marketing authorization for processed food in accordance with the provisions of legislation.

CHAPTER III
IMPORTATION APPROVAL

Article 21

- (1) Within a maximum period of 6 (six) Hours after the documents are received in full according to the requirements and after the payment of non-tax state revenue, the application documents as referred to in Article 14 to Article 19 are evaluated to determine fulfillment of the administrative requirements and requirements for safety, efficacy/benefit, and quality to issue an approval or rejection.
- (2) The Indonesian Food and Drug Authority conducts an evaluation using a clock-on and clock-off mechanism for the fulfillment of the requirements as referred to in section (1).
- (3) In the event that the evaluation result is in the form of revision to the fulfillment of the requirements as referred to in section (1), then the calculation of the period as referred to in section (1) is clocked off until the SKI Border Applicant or the SKI Post Border Applicant submits additional data.
- (4) The SKI Border Applicant or the SKI Post Border Applicant submits additional data for a maximum of 3 (three) times within a time limit of not later than 30 (thirty) Days as of the date of the Aju Number is issued.
- (5) The calculation of the evaluation period will be clocked on after the SKI Border Applicant or the SKI Post Border Applicant submits additional data completely and correctly within the time limit as referred to in section (4).
- (6) In the event that the SKI Border Applicant or the SKI Post Border Applicant fails to submit additional data within the time limit as referred to in section (4) or receives a rejection, then:
 - a. the application is considered invalid and the fees paid are non-refundable; and
 - b. the SKI Border Applicant or the SKI Post Border applicant must submit a new application by paying a non-tax state revenue.

Article 22

- (1) The application approval of the SKI Border or the SKI Post Border as referred to in Article 21 section (1) is issued electronically, and does not require stamp and signature.
- (2) The SKI Border or the SKI Post Border as referred to in section (1) is issued for a maximum of 6 (six) Hours after the application has been completely received and has fulfilled the requirements.
- (3) In the event that the application of SKI Border or SKI Post Border as referred to in Article 21 section (1) is rejected, then the rejection is announced online through the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW.

- (4) The SKI Border or the SKI Post Border may be printed by the SKI Border Applicant or the SKI Post Border Applicant or other corresponding institutions through SINSW.

CHAPTER IV SKI ISSUANCE SERVICE

Article 23

- (1) The issuance of the SKI Border or the SKI Post Border may also receive a Priority Service.
- (2) The Priority Service as referred to in section (1) is only given to the SKI Border Applicant or the SKI Post Border Applicant that meet the following criteria:
 - a. has a good track record, in accordance with the technical guidelines of track record evaluation; and
 - b. has conducted an importation activity for the last 6 (six) months with particular frequency and volume.
- (3) In addition to fulfilling the criteria as referred to in section (2), the Priority Service of the SKI Border and the SKI Post Border Issuance is only provided based on the results of a risk assessment with the consideration, among other things, the level of risk that is not a high risk category.
- (4) The SKI Border Applicant or the SKI Post Border Applicant that fulfills the provisions as referred to in section (2) is stipulated by the Deputy and evaluated periodically.
- (5) The Priority Service as referred to in section (1) is valid for the period of 1 (one) year as long as the SKI Border Applicant or the SKI Post Border Applicant meet the criteria in accordance with the periodic evaluation.

Article 24

- (1) Issuance of the SKI Border or the SKI Post Border can be provided with an accelerated service for the purposes of overcoming outbreaks/pandemic and/or public health emergencies in accordance with the provisions of legislation.
- (2) The accelerated service as referred to in section (1) is stipulated by Chairperson of the Authority.

Article 25

To the SKI Border Applicant or the SKI Post Border Applicant who is eligible for obtaining a Priority Service as referred to in Article 23, the application will be automatically evaluated through the official website of the SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority.

CHAPTER V
IMPORTATION OF TRADITIONAL MEDICINE SUBSTANCES,
QUASI MEDICINE SUBSTANCES, COSMETIC SUBSTANCES,
AND/OR FOOD SUBSTANCES BY SMALL
AND MEDIUM-SCALE INDUSTRIES

Article 26

- (1) The importation of Traditional Medicine Substances, Quasi Medicine Substances, Cosmetic Substances, and Food Substances for small and medium-scale industrial purposes can be conducted by:
 - a. small and medium-scale industries; or
 - b. a company or an importer.
- (2) The small and medium-scale industries as referred to in section (1) point a must have already been registered in corresponding Ministries or Institutions.

Article 27

The Traditional Medicine Substances, Quasi Medicine Substances, Cosmetic Substances, and/or Food Substances for small and medium-scale industrial purposes as referred to in Article 26 section (1) point a may only be used for personal purposes and not for sale.

Article 28

- (1) The Importation of Traditional Medicine Substances, Quasi Medicine Substances, Cosmetic Substances, and/or Food Substances for small and medium-scale industrial purposes is proposed by an importer acting as the SKI Border Applicant or the SKI Post Border Applicant.
- (2) In addition to fulfilling the provisions as referred to in Article 2, Article 3, Article 8, Article 9, and Article 14, the SKI Border Applicant or the SKI Post Border Applicant as referred to in section 1 must also have a cooperation agreement for the import of goods with the respective owner.
- (3) Provisions regarding the procedures for submitting applications for the SKI Border or the SKI Post Border as referred to in Article 7 to Article 19 apply mutatis mutandis to the import of Traditional Medicine Substances, Quasi Medicine Substances, Cosmetic Substances, and/or Food Substances by the importer for the product owner that does not have an NIB that also applies as an importer's identification number.

Article 29

- (1) The Importation of Traditional Medicine Substances, Quasi Medicine Substances, Cosmetic Substances, and Food Substances for small and medium-scale industrial purposes without an import notification number may be conducted by another company or importer that meets the provisions of legislation in imports.
- (2) The Importation of Traditional Medicine Substances, Quasi Medicine Substances, Cosmetic Substances, and

Food Substances as referred to in section (1) is only designated for the product owner.

- (3) The product owner as referred to in section (2) is the small and medium-scale industries.
- (4) The small and medium-scale industries as referred to in section (3) must have already been registered in the corresponding Ministries or Institutions.

Article 30

The Traditional Medicine Substances, Quasi Medicine Substances, Cosmetic Substances, and Food Substances for small and medium-scale industrial purposes which are imported into the territory of Indonesia as referred to in Article 29 section (2) may only be used for personal purposes and not for sale.

Article 31

- (1) The Importation of Traditional Medicine Substances, Quasi Medicine Substances, Cosmetic Substances, and Food Substances for small and medium-scale industrial purposes are proposed by an importer acting as the SKI Border Applicant or the SKI Post Border Applicant.
- (2) In addition to fulfilling the provisions as referred to in Article 2, Article 3, Article 7 section (1), Article 8, Article 9, Article 14, Article 16, Article 17, Article 18, and Article 19, the SKI Border Applicant or the SKI Post Border Applicant as referred to in section (1) must also complete the cooperation agreement for the import of goods with the respective owner.
- (3) The procedures for submitting applications for the Importation of Traditional Medicine Substances, Quasi Medicine Substances, Cosmetic Substances, and Food Substances by the importer for the product owner that does not have an NIB refers to the procedures for submitting the application for the SKI Border or the SKI Post Border as referred to in Article 7 to Article 20.

Article 32

The importer as referred to in Article 26 section (1) point b is obligated to submit a report on the distribution and the use of imported raw materials to the Indonesian Food and Drug Authority every 3 (three) months.

Article 33

The Indonesian Food and Drug Authority can conduct a research, an inspection on the importation implementation of Food and Drug Substances to the importers or Industrial facilities of the small and medium-scale industries.

Article 34

The list of Traditional Medicine Substances, Quasi Medicine Substances, Cosmetic Substances, and Food Substances which can be classified into small and medium-scale industrial purposes as referred to in Article 29 are stipulated by Chairperson of the Authority.

CHAPTER VI
DOCUMENTATION

Article 35

- (1) The Importation document of Food and Drug Substances must be properly documented at least for 3 (three) years by the company or importer granted a proxy by the company, which submits the application of the SKI Border or the SKI Post Border.
- (2) The Indonesian Food and Drug Authority, during the issuance process of the SKI Border and the SKI Post Border, may conduct a random checking on the validity and legality of the SKI Border and the SKI Post Border documents at the premises of the SKI Border Applicant and the SKI Post Border Applicant.

CHAPTER VII
FEES

Article 36

- (1) The SKI Border Applicant or the SKI Post Border Applicant is subject to fees for every importation as non-tax state revenue in accordance with the provisions of legislation.
- (2) The non-tax state revenue as referred to in section (1) is conducted with online payment mechanism.
- (3) In case of emergencies, the payment of non-tax state revenue can be settled manually.
- (4) In the event that such application as referred to in section (1) is rejected, then such fees already paid are non-refundable.

Article 37

- (1) The payment of non-tax state revenue is settled not later than 3 (three) work days after the SKI Border Applicant or the SKI Post Border Applicant sends the application through the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW.
- (2) The Aju Number is issued since the document was firstly created on the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW as the starting point for calculating the submission number.
- (3) The service level arrangement is calculated since the payment has been updated to the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW.
- (4) The service level arrangement as referred to in section (3) is the service level of issuance of an approval or rejection of the SKI Border or the SKI Post Border of Importation of Food and Drug Substances.
- (5) Each 1 (one) Aju Number can contain a maximum of 20 (twenty) product items.

Article 38

- (1) In addition to fulfilling the provisions as referred to in Article 14 to Article 19, the submission of applications for SKI Border or SKI Post Border must also fulfill the provisions as referred to in Article 37.
- (2) In addition to fulfilling the provisions as referred to in Article 28 section (2), the importer acting as the SKI Border Applicant or the SKI Post Border Applicant submitting applications for the importation of Traditional Medicine Substances, Cosmetic Substances, and/or Food Substances for small and medium-scale industrial purposes must also fulfill the provisions as referred to in Article 36.

CHAPTER VIII
RE-IMPORTATION

Article 39

- (1) The SKI Border Applicant and/or the SKI Post Border Applicant with the intention of conducting a re-importation of Food and Drug Substances into the territory of Indonesia must submit a re-importation application to Chairperson of the Authority.
- (2) The re-importation of Food and Drug Substances into the territory of Indonesia as referred to in section (1) must attach the following documents:
 - a. export documents, and/or other documents from corresponding institutions confirming that the Food and Drug Substances are originally from the territory of Indonesia;
 - b. an export certificate issued by the Indonesian Food and Drug Authority, if any;
 - c. a re-importation reasoning letter, if necessary can be completed with chronological details of release and re-importation of products; and
 - d. a follow-up action plan for products being re-imported.
- (3) The procedures of re-importation of Food and Drug Substances as referred to in section (1) are in accordance with the provisions of application procedures of the SKI Border or SKI Post Border as referred to in Article 7 to Article 19.

CHAPTER IX
REPORTING

Article 40

- (1) The SKI Border Applicant is obligated to submit importation data in the form of import notification on the official website of SKI Border service of the Indonesian Food and Drug Authority through SINSW.
- (2) The importation data as referred to in section (1) can be used as a report on the implementation of importation that has been carried out by the SKI Border Applicant.

Article 41

The SKI Post Border Applicant must submit the approval data of the SKI Post Border through the official website of SKI Post Border Service of the Indonesian Food and Drug Authority which is integrated with SINSW within a maximum period of 7 (seven) Days after the release of the goods.

Article 42

Specifically for reporting Cosmetic Substances, the SKI Post Border Applicant is obligated to submit reports on the distribution of Cosmetic Substances every 3 (three) months to the Chairperson of the Authority c.q. corresponding Director who handles the importation of Cosmetic Substances.

CHAPTER X
IMPORTATION OF FOOD AND DRUG SUBSTANCES FOR
SPECIFIC PURPOSES

Article 43

- (1) In the event that the Food and Drug Substances are imported into the territory of Indonesia for specific purposes, the importation is conducted through a special access scheme.
- (2) The specific purposes as referred to in section (1) include:
 - a. a research;
 - b. a product development and/or science; and/or
 - c. a donation.
- (3) The importation through the special access scheme as referred to in section (1) must obtain an approval from Chairperson of the Authority.
- (4) The importation of Food and Drug Substances as referred to in section (1) must meet the following conditions:
 - a. carried out through delivery/cargo services;
 - b. not for sale; and
 - c. in limited quantities as needed.
- (5) Further provisions regarding the requirements, application procedures, and control of the Importation of Food and Drug Substances through the special access scheme are in accordance with the provisions of legislation governing the Importation of Food and Drug Substances through the special access scheme.

CHAPTER XI
CONTROL

Article 44

- (1) The Importation Control of Food and Drug Substances is conducted through the product and facility inspection in accordance with the provisions of legislation.
- (2) The control as referred to in section (1) is conducted to ensure:
 - a. the compatibility of Food and Drug Substances imported into the territory of Indonesia with the data listed in the import documents; and
 - b. the compliance to the legislation.

- (3) The Importation Control of Food and Drug Substances is conducted based on risk analysis.
- (4) The risk analysis as referred to in section (3) is conducted in accordance with importation realization data of Food and Drugs sent through the SINSW.
- (5) The Importation Control of Food and Drug Substances is conducted in coordination with corresponding Ministries/Institutions.

CHAPTER XII PROHIBITION

Article 45

- (1) In order to protect the public from Food and Drug Substances containing hazardous substances, or from the abuse of Food and Drug Substances, specific Food and Drug Substances are prohibited from being imported into the territory of Indonesia.
- (2) The specific Food and Drug Substances as referred to in section (1) are in accordance with the provisions of legislation governing goods prohibited from importation.

CHAPTER XIII SANCTIONS

Article 46

- (1) The SKI Border Applicant and/or the SKI Post Border Applicant that violates the provisions in Article 2 section (1), Article 2 section (3), Article 4 section (1), Article 4 section (4), Article 4 section (5), Article 9 section (3), Article 15 section (1), Article 20, Article 27, Article 30, Article 32, Article 40, Article 41, Article 42, and/or Article 45 is subject to administrative sanctions.
- (2) The administrative sanctions as referred to in section (1) are in form of:
 - a. a written warning;
 - b. a temporary discontinuation of importation and/or distribution activity;
 - c. a termination of priority services for 2 (two) years;
 - d. an online access blocking to submit applications for the SKI Border and the SKI Post Border for the product for a maximum of 1 (one) year; and/or
 - e. a destruction or re-delivery/re-export.
- (3) The administrative sanctions as referred to in section (1) can be copied to the corresponding Ministries/Institutions.
- (4) The administrative sanctions as referred to in section (1) are imposed by Chairperson of the Authority.

Article 47

The procedures for imposing administrative sanctions as referred to in Article 46 are carried out in accordance with Regulations of the Indonesian Food and Drug Authority which regulate follow-up of the control results.

CHAPTER XIV
TRANSITIONAL PROVISION

Article 48

- (1) Applications for the SKI Border or the SKI Post Border that have been submitted prior to the enforcement of this Authority Regulation, will still be processed based on Regulation of the Indonesian Food and Drug Authority Number 29 of 2017 on Importation Control of Food and Drug Substances into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2017 Number 1842) as amended by Regulation of the Indonesian Food and Drug Authority Number 14 of 2020 on Amendment to Regulation of the Indonesian Food and Drug Authority Number 29 of 2017 on Importation Control of Food and Drug Substances into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2020 Number 753).
- (2) The approval for the SKI Border or the SKI Post Border that has been issued based on Regulation of the Indonesian Food and Drug Authority Number 29 of 2017 on Importation Control of Food and Drug Substances into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2017 Number 1842) as amended by Regulation of the Indonesian Food and Drug Authority Number 14 of 2020 on Amendment to Regulation of the Indonesian Food and Drug Authority Number 29 of 2017 on Importation Control of Food and Drug Substances into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2020 Number 753) is still declared in effect until the Food and Drug Substances have been imported into the territory of Indonesia.

CHAPTER XV
CLOSING PROVISIONS

Article 49

At the time this Authority Regulation comes into force, Regulation of the Indonesian Food and Drug Authority Number 29 of 2017 on Importation Control of Food and Drug Substances into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2017 Number 1842) as amended by Regulation of the Indonesian Food and Drug Authority Number 29 of 2017 on Importation Control of Food and Drug Substances into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2020 Number 753) is repealed and declared ineffective.

Article 50

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

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

Issued in Jakarta
on 14 November 2022

CHAIRPERSON OF THE INDONESIAN FOOD
AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

Promulgated in Jakarta
on 14 November 2022

MINISTER OF LAW AND HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA,

signed

YASONNA H. LAOLY

STATE BULLETIN OF THE REPUBLIC OF INDONESIA OF 2022 NUMBER 1153

Jakarta, 10 July 2023

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,



ANNEX TO
REGULATION OF THE INDONESIAN FOOD AND DRUG
AUTHORITY
NUMBER 26 OF 2022
ON
IMPORTATION CONTROL OF FOOD AND DRUG SUBSTANCES
INTO THE TERRITORY OF INDONESIA

IMPORT CERTIFICATE FORMAT

IMPORT CERTIFICATE FOOD AND DRUG SUBSTANCES COMMODITY Number: PO						
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) :						
API/NIB :						
Exporter's Name :						
Exporter's Country of Origin :						
To receive:						
No.	Raw Material	Quantity	Lot / Batch Number	HS Code	Manufacturer	Manufacturer's Country of Origin
No. and Date of Invoice :						
Through : Office of Customs and Excises Service...						
With the provisions:						
1. The above product is not put on retail to the customers, and only be used as (Drug/Drug Excipient/Reference Material/Traditional Medicine/Quasi Drug Reference Substance/Health Supplement/Cosmetic/Food/Food Additives) substances → the option of Commodity Type in the system is based on the needs; Food Additive option has an additional format.						
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						
signature						
(Full Name)						
NIP						
<i>This document is 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.</i>						

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY
OF THE REPUBLIC OF INDONESIA,

signed

PENNY K. LUKITO