



**THE INDONESIAN FOOD AND DRUG AUTHORITY
OF THE REPUBLIC OF INDONESIA**

DISCLAIMER:

The Original document is written in Bahasa Indonesia, and subsequently translated into English. In the event of a discrepancy between the two versions, Bahasa Indonesia version shall take precedence.

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY

NUMBER 15 OF 2020

ON

AMENDMENT TO THE REGULATION OF THE INDONESIAN FOOD AND
DRUG AUTHORITY NUMBER 30 OF 2017

ON

THE SURVEILLANCE OF DRUGS AND FOOD IMPORTED INTO THE
TERRITORY OF INDONESIA

BY THE BLESSINGS OF ALMIGHTY GOD

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

- Considering :
- a. that in order to guarantee safety, efficacy/benefit, quality of Drugs and Food imported into the territory of Indonesia, there is a necessity of establishing a Regulation on the Surveillance of Drugs and Food Imported into the Territory of Indonesia;
 - b. that several provisions regarding the surveillance of the imported Drugs and Food as regulated in Regulation of the Indonesian Food and Drug Authority Number 30 of 2017 on the Surveillance of Drugs and Food Imported to the Territory of Indonesia need to be adjusted to legal needs as well as developments in science and technology in the field of Drug and Food surveillance;

- c. that based on the considerations as referred to in point a and point b, it is necessary to issue a Regulation of the Indonesian Food and Drug Authority on the Amendment to the Regulation of the Indonesian Food and Drug Authority Control Number 30 Of 2017 on the Surveillance of Drugs and Food Imported to the Territory of Indonesia;

- Observing
- : 1. Government Regulation Number 24 of 2018 on Electronically Integrated Business Licensing Services (State Gazette of the Republic of Indonesia Number 90 of 2018, Supplement to the State Gazette of the Republic of Indonesia Number 6215);
 2. Government Regulation Number 86 of 2019 on Food Security (State Gazette of the Republic of Indonesia of 2019 Number 249, Supplement to the State Gazette Number 6442);
 3. Presidential Regulation Number 80 Of 2017 on the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia of 2017 Number 180);
 4. Regulation of the Indonesian Food and Drug Authority Number 26 of 2017 on the Organization and the Governance the Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2017 Number 1745);
 5. The Regulation of the the Indonesian Food and Drug Authority Control Number 12 Of 2018 on the Organization and the Governance of Technical Implementing Units within the the Indonesian Food and Drug Authority Environment (State Bulletin of the Republic of Indonesia Of 2017 Number 784) as has been amended by the Regulation of the Indonesian Food and Drug Authority Number 29 Of 2019 on the Amendment to the Regulation of the the Indonesian Food and

Drug Authority Number 12 Of 2018 on the Organization and the Governance of Technical Implementing Units within the the Indonesian Food and Drug Authority Environment (State Gazette of the Republic of Indonesia Of 2017 Number 1274);

6. The Regulation of the the Indonesian Food and Drug Authority Number 26 Of 2018 on Electronically Integrated Business Licensing Services in the Drugs and Food Sector (State Bulletin of the Republic of Indonesia of 2018 Number 1131);

HAS DECIDED:

To issue : THE REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON THE AMENDMENTS TO THE REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY CONTROL NUMBER 30 OF 2017 ON THE SURVEILLANCE OF DRUGS AND FOOD IMPORTED TO THE TERRITORY OF INDONESIA.

ARTICLE I

Several Provisions the Regulation of the Indonesian Food and Drug Authority Number 30 Of 2017 on the Surveillance of Drugs and Food Imported to the Territory of Indonesia (State Bulletin of the Republic of Indonesia Of 2017 Number 1843) are amended as follows:

1. The Provisions of Article 1 are amended, so that it reads as follow:

Article 1

In this Agency Regulation:

1. Drug and Food mean Drugs, Traditional Medicines, Quasi-Medicines, Cosmetics, Health Supplements, and Processed Food.

2. Importation of Drugs and Food means the importation of Drugs and Food into the territory of Indonesia.
3. Import Certificate of Border (Surat Keterangan Impor Border) hereinafter abbreviated as SKI Border refers to a letter of approval for the import of Drugs and Traditional Medicines into the territory of Indonesia in the framework of distribution surveillance of Drugs and Food.
4. Import certificate of Post Border (Surat Keterangan Impor Post Border) hereinafter abbreviated as SKI Post Border refers to a letter of approval for the import of Traditional Medicines in the form of Quasi Drugs, Cosmetics, Health Supplements, and Processed Food into the territory of Indonesia in the framework of distribution surveillance of Drugs and Food.
5. The applicant of SKI Border refers to a company which holds a Marketing Authorization or an importer that is authorized by a company which holds Marketing Authorization to apply for the import of Medicines and Traditional Medicines into the territory of Indonesia.
6. The applicant of SKI Post Border refers to a company which holds a Marketing Authorization or an importer that is authorized by a company which holds a Marketing Authorization to apply for approval allowing the import of Traditional Medicines in the form of Quasi Drugs, Cosmetics, Health Supplements, and Processed Food to the distribution.
7. Drug means a finished medicine including Biological Products, which is an ingredient or combination of ingredients 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.
8. Biological Products refer to products that contain biological materials derived from humans, animals or microorganisms which are made in conventional ways

including extraction, fractionation, reproduction, cultivation, or through biotechnological methods which include fermentation, genetic engineering, cloning, including but not limited to enzymes, monoclonal antibodies, hormones, stem cells, gene therapy, vaccines, blood products, recombinant DNA products and immunosera.

9. Traditional Medicine means materials or ingredients in the form of vegetable materials, animal materials, mineral materials, dosage form extracts (galenic), or a mixture of those materials which have been used hereditarily for medication purposes, and which can be administered in accordance with norms prevailing in society.
10. Quasi drugs refer preparations containing active ingredients with pharmacological effects to treat minor complaints.
11. Cosmetic means a material or dosage form designed for topical use on the human body (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.
12. 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.
13. Processed Food means food or beverage that is processed in a certain way or method with or without food additives.
14. Bulk products refers to materials that have been processed and only require packaging to be considered as products.

15. Business Registration Number, hereinafter referred to as BRN, refers to a business identifier issued by the Online Single Submission Body after the business conduct Registration.
16. Aju number refers to the number that the system assigns to each application of SKI Border or SKI Post Border.
17. Marketing Authorization means a form of agreement to have Food and Drugs registered for marketing in Indonesian territory. Marketing Authorization
18. Expiry date refers to a date before which, the drugs and food is proper for consumption and comes in the form of date, month and year, or month and year.
19. The Technical Implementing Unit (Unit Pelaksana Teknis) within the the Indonesian Food and Drug Authority Environment hereinafter abbreviated as UPT BPOM refers to a work unit that is independent in nature that carries out certain technical operational tasks and/or certain supporting technical tasks in the field of Drug and Food control.
20. Deputy refers to the Deputy in the the Indonesian Food and Drug Authority Environment.
21. Chairperson of the Agency refers to the Chairperson of the Indonesian Food and Drug Authority.
22. Day refers to calender days.
23. Hour refers to business hours.

2. Between section (3) and section (4) of Article 3, 4 (four) section are inserted, namely section (3a), section (3b), section (3c), and section (3d), so that Article 3 reads as follows:

Article 3

- (1) Apart from fulfilling the provisions as referred to in Article 2, the importation of Drugs and Food must also obtain approval from the Chairperson of the Agency.
- (2) The approval from the Chairperson of the Agency as referred to in section (1) are in the forms of:
 - a. SKI Border; or
 - b. SKI Post Border.
- (3) SKI Border or SKI Post Border as referred to in section (2) shall only be valid for 1 (one) time importation.
- (3a) Business actors importing Drugs and/or Traditional Medicines in the framework of border are obligated to hold SKI Border at the time of submitting an import notification of goods issued by the competent authority.
- (3b) Business actors importing Traditional Medicines in the form of Quasi Drugs, Cosmetics, Health Supplements, and/or Processed Food in the framework of post border are obligated to hold SKI Post Border no later than 7 (seven) days as from the date of the approval letter issuance for releasing the goods.
- (3c) The applicant of SKI Post Border may apply for SKI Post Border before obtaining the number and date of registration regarding the import notification of goods.
- (3d) Excluded from the provisions in section (1), the importation of Drugs in the form of narcotics, psychotropic substances, or precursors must meet the following requirements:
 - a. analysis of the surveillance results; and
 - b. the approval letter of import,in accordance with the provisions of legislation.

- (4) SKI Border or SKI Post Border as referred to in section (2) shall use the format as contained in Annex I which is an integral part of this Agency Regulations.
3. The provisions of section (1) are amended and between section (1) and section (2) of Article 8 2 (two) section are inserted, namely section (1a) and section (1b), so that Article 8 reads as follows:

Article 8

- (1) The applicant of SKI Border or SKI Post Border must have NIB by means of Online Single Submission to obtain the services of SKI Border or SKI Post Border.
- (1a) The applicant of SKI Border or SKI Post Border must select the permit code of SKI Border or SKI Post Border of the Indonesian Food and Drug Authority on the Online Single Submission system.
- (1b) The applicant of SKI Border or SKI Post Border as referred to in section (1a) must register to obtain a user name and password by means of a single sign on mechanism on the official service page of SKI Border or SKI Post Border of the Indonesian Food and Drug Authority or the official page of national single window agency.
- (2) The registration by means of the single sign on mechanism as referred to in section (1b) is made to gain login access in the Indonesian Food and Drug Authority inhouse, including UPT BPOM and the official site of national single window agency.
- (3) In the event that the application is submitted by means of a proxy, the proxy holder must obtain the proxy which has been legalized by a notary.

4. The Provisions of Article 9 are amended, so that the Article 9 reads as follows:

Article 9

- (1) The applicant of SKI Border or SKI Post Border shall perform the entry data online and upload the supporting documents on the official service site of SKI Border or SKI Post Border of the the Indonesian Food and Drug Authority or the official site of the national single window agency.
- (2) Supporting Documents as referred to in section (1) consists of the result of scanning process:
 - a. the original letter of application signed by the director or the proxies of the board of directors which is sufficiently stamped;
 - b. the original letter of statement of person in charge which is sufficiently stamped;
 - c. the original NIB;
 - d. the original proxy for import made in the form of a general deed by a notary, should the SKI Border Applicant or SKI Post Border Applicant be a business actor whose company receives the authority to import; and
 - e. the list of HS Code commodities to be imported.
- (3) In addition to fulfilling the requirements as intended in section (2), the SKI Border or SKI Post Border Applicants must clearly state the address of the warehouse where the products are stored.
- (4) Regarding the application of SKI Border for Drugs, in addition to meeting the requirements as intended in section (3), it must be accompanied by a scan of the original document:
 - a. pharmaceutical industry business license or pharmaceutical wholesaler business license in accordance with the provisions of legislation; and

- b. Good Drug Distribution Method (CDOB) certificate which applies to pharmaceutical wholesalers.
- (5) Against the application for registration as referred to in section (2), section (3), and section (4), the verification is made online.
 - (6) If necessary, officers may verify such documents manually.
 - (7) In the the verification results be declared complete and correct, the Applicant of SKI Border or the Applicant of SKI Post Border will get a user name and password to login into the official service site of the SKI Border or SKI Post Border of the Indonesian Food and Drug Authority or the official site of the national single window agency.
5. The Provisions of Article 10 are amended, that the Article 10 reads as follows:

Article 10

- (1) The Registration of the Applicant of SKI Border or the Applicant of SKI Post Border as referred to in Article 8 shall only be conducted 1 (one) time.
- (2) The Applicant of SKI Border or the Applicant of SKI Post Border may change the data of the Applicant of SKI Border or the Applicant of SKI Post Border provided that it is not related to NIB.
- (3) Should there be any change in data as referred to in section (2), the Applicant of SKI Border or the Applicant of SKI Post Border are obligated to change data online by means of the official service site of SKI Border or SKI Post Border of the the Indonesian Food and Drug Authority or the official service site of the national single window agency by attaching supporting data related to the changed data.

- (4) Against the amendment referred to in section (3), verification is performed by the the Indonesian Food and Drug Authority.
 - (5) Based on the results of the verification as referred to in section (4), the the Indonesian Food and Drug Authority shall grant approval or reject data changes submitted by the Applicant of SKI Border or the Applicant of SKI Post Border.
 - (6) In the event of data changes related to NIB, the Applicant of SKI Border or the Applicant of SKI Post Border are obligated to apply for re-registration online.
6. Between Article 10 and Article 11 are inserted 1 (one) article, namely Article 10A so as to read as follows:

Article 10A

- (1) In the event the Applicant of SKI Border or the Applicant of SKI Post Border can not to login into the official service site of SKI Border or SKI Post Border of the Indonesian Food and Drug Authority or the official service site of the national single window agency, the facility "forget the password" may be used.
- (2) In the event that the Applicant of SKI Border or the Applicant of SKI Post Border can not use the "forgot password" facility, to avoid misuse of user names, the Applicant of SKI Border or the Applicant of SKI Post Border must submit an application letter regarding the change in identity to the Indonesian Food and Drug Authority manually subject to the following provisions:
 - a. The Applicant of SKI Border or the Applicant of SKI Post Border presents the original proxy from the director of the company;
 - b. the original application letter that contains the company letterhead on which the sufficient stamp duty is dully signed by the director of the company;and

c. the photocopy, accompanied by the presence of the original NIB document.

(3) The approval of amendments will be issued in not later than 2 (two) work days since the date of receipt of the application letter as referred to in section (2) when it is declared complete and correct.

7. The Provisions of Article 11 are amended, so that the Article 11 reads as follows:

Article 11

The registration procedure of the Applicant of SKI Border or the Applicant of SKI Post Border and the change in data of the Applicant of SKI Border or the Applicant of SKI Post Border is outlined in the guideline of use online in the official service site of SKI Border or SKI Post Border of the the Indonesian Food and Drug Authority or the official service site of the national single window agency.

8. The Provisions of Article 12 are amended, so that the Article 12 reads as follows:

Article 12

Application for Certificate of Import is carried out in accordance with the provision of the Regulation of the the Indonesian Food and Drug Authority which regulates the Electronically Integrated Business Licensing Service for the Drug and Food Sector.

9. The Provisions of Article 13 are amended, so that the Article 13 reads as follows:

Article 13

- (1) The application of SKI Border or SKI Post Border is conducted online.
- (2) Any UPT BPOM in the entire territory of Indonesia that has not been connected to the official website of national single window agency shall apply for SKI Border or SKI Post Border manually.

10. Article 14 is deleted.

11. The Provisions of Article 15 are amended, so that the Article 15 reads as follows:

Article 15

- (1) The application of SKI Border or SKI Post Border as referred to in Article 13 section (1) must be equipped with electronic documents as follows:
 - a. Marketing Authorization approval;
 - b. analysis certificates or Product Certificates regarding the Use of Indonesian National Standard (SNI) Marks for mandatory SNI Food; and
 - c. invoices.
- (2) In the event of the Marketing Authorization validity period being less than 3 (three) months or based on the product re-registration, the application of SKI Border or SKI Post Border must also be accompanied by proof of acceptance of re-registration.
- (3) The import of Drugs, Traditional Medicines, Cosmetics, and Health Supplements in the form of Bulk Products, must attach a Marketing Authorization approval.

- (4) Analysis certificate as intended in section(1) letter b must contain at least:
 - a. product name;
 - b. the test parameters in accordance with the provisions;
 - c. test results;
 - d. analysis method;
 - e. batch number/lot number/production code;
 - f. production dates; and
 - g. expiration date.
- (5) In the event of the issuer of the analysis certificate is different from the producer, the name of the producer must be stated on the certificate of analysis as referred to in section (1) point b.
- (6) If necessary, the Indonesian Food and Drug Authority may take samples and conduct evaluation for testing in an accredited laboratory.
- (7) The financing for testing as referred to in section (6) is incurred by the Applicant of SKI Border or the Applicant of SKI Post Border.
- (8) Should the security and quality be necessary, the National Indonesian Food and Drug Authority may request that the Applicant of SKI Border or the Applicant of SKI Post Border attach other supporting documents in accordance with the provisions of legislation.

12. The Provisions of Article 20 are amended, so that the Article 20 reads as follows:

Article 20

The application of SKI Border for Traditional medicine or SKI Post Border for Quasi Drugs, Cosmetics, and Health Supplements, in addition to fulfilling the provisions as referred to in Article 15, must also meet the following requirements:

- a. the name of the product, package, and the package size listed on the invoice must correspond to the name of the product, packaging, and the package size listed on the Marketing Authorization
- b. In the event that the name of the product as referred to in point a does not match the name stated in the Marketing Authorization, it must be completed with a certificate from the manufacturer; and/or
- c. certificates/other letters of information required in accordance with the provisions of legislation.

13. The Provisions of Article 22 are amended, so that the Article 22 reads as follows:

Article 22

- (1) The Applicant of SKI Border or the Applicant of SKI Post Border are obligated to complete the application documents correctly and legally to be uploaded in the official service site of SKI Border or SKI Post Border of the Indonesian Food and Drug Authority or the official service site of the national single window agency.
- (2) The Applicant of SKI Border or the Applicant of SKI Post Border is prohibited from circulating, transferring, and/or using Drugs and Food before SKI Border or SKI Post Border is issued.

14. The Provisions of Article 23 are amended, so that the Article 23 reads as follows:

Article 23

- (1) Within a maximum period of 6 (six) hours after the documents are received completely according to the requirements and after making payment of non-tax state revenue, the application documents as referred to in Article 15 to Article 21 is evaluated to determine the fulfillment of administrative requirements and safety,

efficacy/usefulness, and quality requirements for the issuance of approval or rejection.

- (2) the Indonesian Food and Drug Authority shall conduct evaluation by means of continue (clock on) and stop (clock off) mechanisms against the completion of requirements as referred to in section (1).
- (3) In the event of the evaluation results be in the form of improvements to the fulfillment of requirements as referred to in section (1) then the calculation of the time period as referred to in section (1) is discontinued (clock off) until the Applicant of SKI Border or the Applicant of SKI Post Border submits the additional data.
- (4) The Applicant of SKI Border or the Applicant of SKI Post Border submits additional data no more than 3 (three) times within a time limit of 30 (thirty) Days as from the date the Aju Number is issued.
- (5) The calculation of evaluation time will continue (clock on) after the Applicant of SKI Border or the Applicant of SKI Post Border submit additional data completely and correctly within the period as intended in section (4).
- (6) In the event that the Applicant of SKI Border or the Applicant of SKI Post Border can not submit additional data within the time limit as referred to in section (4) or obtain a decision of rejection then:
 - a. the application is declared canceled and fees that have been paid may not be refunded; and
 - b. The Applicant of SKI Border or the Applicant of SKI Post Border must submit a new application by paying non-tax state revenue.

15. The Provisions of Article 24 are amended, so that Article 24 reads as follows:

Article 24

- (1) The approval for the application of SKI Border or SKI Post Border as referred to in Article 23 section (1) is issued in electronic form, and it does not require a wet stamp and signature.
- (2) SKI Border or SKI Post Border as referred to in section (1) is issued in not later than 6 (six) hours since the date the application is received completely and meets the requirements.
- (3) In the event that the application of SKI Border or SKI Post Border as referred to in Article 23 section 1) is rejected, the rejection is informed online by means of the official service site of SKI Border or SKI Post Border of the Indonesian Food and Drug Authority or the official service site of the national single window agency.
- (4) SKI Border or SKI Post Border may be printed by the Applicant of SKI Border or the Applicant of SKI Post Border or other relevant agencies through the official website of national single window agency.
- (5) In the event that there be technical issues, SKI Border or SKI Post Border may be issued not later than 6 (six) hours or manually.
- (6) Any UPT BPOM in the entire regions of Indonesia that has not been connected to the official service site of SKI Border or SKI Post Border of the Indonesian Food and Drug Authority Control shall conduct the issuance of SKI Border or SKI Post Border manually.

16. Between Article 24 and Article 25 are inserted 3 (three) articles, namely Article 24A, 24B, and Article 24C so as to read as follows:

Article 24A

- (1) The issuance of SKI Border or SKI Post Border may be provided with accelerated services for the purposes of overcoming epidemics/pandemics and/or public health emergencies in accordance with the provisions legislation.
- (2) The acceleration service as referred to in section (1) is determined by the Chairperson of the Agency.

Article 24B

- (1) Pharmaceutical industries or pharmaceutical wholesalers carrying out Drug importation activities are obligated to submit reports on the implementation of drug importation.
- (2) The reporting on the importation of Drugs as referred to in section (1) is carried out periodically, in the form of reports on the import and distribution of Drugs.
- (3) Excluded from the provisions as referred to in section (2), the reporting on the importation of drugs in the form of narcotics, psychotropic substances and precursors is carried out in each importation process.
- (4) The reports as referred to in section (2) and section(3) are submitted to the Chairperson of the Agency c.q. Relevant directors who are in charge of Drug importation.

Article 24C

The Applicant of SKI Border or the Applicant of SKI Post Border is obligated to submit the report of the Drug and Food import to the Chairperson of the Agency on the official service site of SKI Border or SKI Post Border of the Indonesian Food and Drug Authority or the official service site of the national single window agency as referred to in Article 9 section (1) within the time limit not later than 7 (seven) Days after the goods are released.

17. The Provisions of section (1), section (2), section (3) Article 26 are amended, so that the Article 26 reads:

Article 26

- (1) The Applicant of SKI Border or the Applicant of SKI Post Border shall incur a fee for each importation as non-tax state revenue in accordance with the provisions of legislation.
- (2) The Payment of non-tax state revenue as referred to in section (1) is made by means of an electronic payment mechanism.
- (3) In the event of any urgent situation or UPT has not been connected online to the official service site of SKI Border or SKI Post Border of the Indonesian Food and Drug Authority, the payment of non-tax state revenue may be done manually.
- (4) In the event that the application as referred to in section (1) is rejected, the fee that has been paid may not be refunded.

18. Between Article 26 and Article 27 are inserted 2 (two) articles, namely Article 26A and Article 26B so as to read as follows:

Article 26A

- (1) The payment of non-tax state revenue is made within a maximum period of 3 (three) days since the date the Applicant of SKI Border or the Applicant of SKI Post Border submitted the application on the official service site of SKI Border or SKI Post Border of the Indonesian Food and Drug Authority or the official service site of the national single window agency.
- (2) Aju numbers is issued since the document was first created on the official service site of SKI Border or SKI Post Border of the Indonesian Food and Drug Authority or the official service site of the national single window

agency as a starting point for calculating the period of the submission number.

- (3) Service Level Arrangement is calculated since the payment has been made in the official service site of SKI Border or SKI Post Border of the Indonesian Food and Drug Authority or the official service site of the national single window agency.
- (4) The Service Level Arrangement as referred to in section (3) is the service level at the time when the approval or rejection decision regarding the SKI Border or SKI Post Border of importation of Drugs and Food is issued.
- (5) 1 (one) Aju Number may contain a maximum of 20 (twenty) product items.

Article 26B

The application of SKI Border for Medicines and Traditional Medicines and SKI Post Border for Quasi Drugs, Cosmetics, and Health Supplements, in addition to fulfilling the provisions as referred to in Article 15, Article 16, Article 20, and Article 21 must also comply with the provisions referred to in Article 26A.

19. The Provisions of Article 28 are amended, so that the Article 28 reads as follows:

Article 28

- (1) Excluded from the provisions as regulated in this Agency Regulation for Drugs and Food without a Marketing Authorization from the Indonesian Food and Drug Authority, may be imported into the territory of Indonesia.
- (2) Drugs and Food as referred to in section (1) are Drugs and Food which are imported for:
 - a. individual/personal use with or without consideration of health workers;
 - b. research;

- c. product and/or scientific development;
 - d. donations;
 - e. samples for registration/registration of Marketing Authorizations;
 - f. clinical trials for registration requirements, product development, and/or science;
 - g. government programs;
 - h. urgent national interest;
 - i. special use for health services that are not domestically available; and
 - j. exhibitions.
- (3) Research and product development as referred to in section (2) point b and point c are not intended for market testing.
- (4) The exhibition as referred to in section (2) point j only applies to products of Traditional Medicines, Health Supplements, Cosmetics, and/or Processed Food.
- (5) The import of Drugs and Food into Indonesian territory as referred to in section (2) is carried out through a special route mechanism/Special Access Scheme.
- (6) Importation of Drugs and Food into Indonesian territory as referred to in section (2) may be allowed through:
- a. shipping/transportation services; or
 - b. passenger luggage.
- (7) Importation of Drugs and Food into Indonesian territory for personal/individual use, research, product development, science (research), samples for registration, and/or exhibitions as referred to in section (2) must meet the following requirements:
- a. not for sale; and
 - b. in limited quantities as required.
- (8) Limits on the number of Drugs and Food that are imported through delivery/transportation services or passenger luggage for the purpose as referred to in section (2) point a, point b, point e and/or point j are in

accordance with the provisions listed in Annex IV which is an integral part of this Agency Regulation.

- (9) Further provisions regarding limits on the number, requirements, and the procedures for the application for Special Access Scheme as referred to in section (2) point c, point d, point f, point g, point h, and point i, are carried out in accordance with the provisions of legislation on the importation of Drugs and Food through Special Access Scheme.

20. The Provisions of Article 29 are amended, so that the Article 29 reads as follows:

Article 29

- (1) The application for the import of Drugs and Food into the territory of Indonesia as referred to in Article 28 section (2) is submitted to the Chairperson of the Indonesian Food and Drug Authority.
- (2) The Surveillance of Drugs and Food imported into Indonesian territory for the purpose as referred to in Article 28 section (2) point a is carried out by the Directorate General of Customs and Excise in accordance with the provisions of legislation.
- (3) In the event of based on the surveillance as referred to in section (2), it is found that the import of Drugs and Food is not in accordance with the provisions as referred to in Article 28 section (7), the Directorate General of Customs and Excise may carry out the destruction and it is carried out in accordance with the provisions of legislation.
- (4) The surveillance as referred to in section (2) is carried out by using:
 - a. the form and filling instructions as contained in Annex III to this Agency Regulation; and

b. the official service site of SKI Border or SKI Post Border of t the Indonesian Food and Drug Authority.

(5) In the event that the surveillance as referred to in section (3) result in Drugs and Food which may allegedly be not in accordance with the provisions of the legislation, the Directorate General of Customs and Excise may coordinate with the Indonesian Food and Drug Authority.

21. The Provisions of section (4) Article 30 are amended, so that the Article 30 reads as follows:

Article 30

- (1) The surveillance of the import of Drugs and Food is carried out through inspection of products and facilities in accordance with the provisions of legislation.
- (2) The surveillance as referred to in section (1) is carried out to ensure:
 - a. the suitability of Drugs and Food imported into Indonesian territory with the data contained in the import documents; and
 - b. compliance with legislation.
- (3) The surveillance of the import of Drugs and Food may be carried out based on a risk analysis.
- (4) The risk analysis as referred to in sectionsection (3) may be carried out based on data on the realization of the import of Drugs and Food which is delivered through the official website of the national single window agency.
- (5) The surveillance of the import of Drugs and food is carried out in coordination with the relevant Ministries/Agencies.

22. The Provisions of Article 31 are amended, so that the Article 31 reads as follows:

Article 31

- (1) Business actors who violate the provisions of Article 3 section (3a), section (3b), Article 10 section (3), section (6), Article 22, and Article 24B, is subject to administrative sanctions in the form of:
 - a. written warning;
 - b. temporary cessation of import and/or distribution activities;
 - c. closure of online access to application of SKI Border or SKI Post Border for the products, no later than 1 (one) year;
 - d. the recall of Drug and Food products from circulation;
 - e. the destruction or return shipping to the country of re-export origin;
 - f. the Marketing Authorization suspension; and/or
 - g. revocation of Marketing Authorization.
- (2) The administrative sanctions as referred to in section (1) may be forwarded to the related Ministries/Agencies.
- (3) Administrative sanctions as referred to in section (1) to section (2) are imposed by the Chairperson of the Agency.

23. Between Article 31 and Article 32 are inserted 1 (one) article, namely Article 31A so as to read as follows:

Article 31A

The procedure for the imposition of administrative sanctions as referred to in Article 31 is implemented in accordance with Decision of the Chairperson of the Agency which regulates the follow-up to the results of surveillance.

24. Several provisions in Annex I, Annex II, Annex III are amended and to which 1 (one) Annex is added namely Annex IV therefore, those become as listed in Annex I, Annex II, Annex III, and Annex IV which is an integral part of this Agency Regulation.

ARTICLE II

This Agency Regulation comes into force on the date of its promulgation.

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

Issued in Jakarta
on 9 July 2020

CHAIRPERSON OF THE INDONESIAN FOOD AND
DRUG AUTHORITY,

signed

PENNY K. LUKITO

Promulgated in Jakarta
on 13 July 2020

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

signed.

WIDODO EKATJAHJANA

STATE BULLETIN OF THE REPUBLIC OF INDONESIA OF 2020 NUMBER 754

ANNEX I
 THE REGULATION OF THE INDONESIAN FOOD AND
 DRUG AUTHORITY NUMBER 15 YEAR 2020
 CONCERNING
 THE AMENDMENTS TO THE REGULATION OF THE
 INDONESIAN FOOD AND DRUG AUTHORITY NUMBER 30
 YEAR 2017 CONCERNING THE SURVEILLANCE OF DRUGS
 AND FOOD IMPORTED TO THE TERRITORY OF INDONESIA

THE FORMAT OF IMPORT CERTIFICATE

Name of Importer	:	
Office Address	:	
TIN	:	
API/NIB	:	
Exporter's Name	:	
Country of Origin of Exporters	:	

No	The Name of the Product	Packaging	No. Marketing Authorization	Number of Goods	No. Lot/Batch	HS Code
Manufacturers						
The Country of Manufacturers						

THE CHAIRPERSON OF THE INDONESIAN FOOD
AND DRUG AUTHORITY,

sign.

PENNY K. LUKITO.

ANNEX II
THE REGULATION OF THE INDONESIAN FOOD AND
DRUG AUTHORITY NUMBER 15 YEAR 2020
CONCERNING
THE AMENDMENTS TO THE REGULATION OF THE INDONESIAN
FOOD AND DRUG AUTHORITY NUMBER 30 YEAR 2017
CONCERNING THE SURVEILLANCE OF DRUGS AND FOOD
IMPORTED TO THE TERRITORY OF INDONESIA

1. DRUGS AND FOOD OF WHICH IMPORTATION SHALL BE RESTRICTED INTO INDONESIAN AREA AT THE BORDER

A. ANNEX OF HS CODE OF DRUGS

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
	30.02	Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic purposes; parts of blood and other immunological products, whether or not modified or obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeast) and products alike	

		Antiserum, blood fractions and other immunological products whether or not modified or obtained by biotechnological processes:	
1			Epoetin alfa (Cas Number 113427-24-0)
3	3002.20.20	- - Vaccines for pertussis, measles, meningitis or polio	
	30.03	Medicines (excluding articles of heading 30.02, 30.05 or 30.06) consist of two or more constituents which have been mixed together for therapeutic or prophylactic purposes, which are not prepared in specific doses or not in packages for retail sale.	
	3003.10	- Containing penicillin or its derivatives, with the structure of penicillanic acid, or streptomycin or its derivatives:	
5	3003.10.10	- - Containing amoxicillin (INN) or its salt	
6	3003.10.20	- - Containing ampicillin (INN) or its salts	
		- Others, containing hormones or other products of heading 29.37:	
		- Others, containing alkaloids or their derivatives:	
12	3003.60.00	- Others, contain active antimalarial substances as described in Subheading Note 2 to this Chapter	Including medicines containing artemisinin (INN) for digestion by mouth in combination with other active pharmaceutical ingredients, or containing one of the following active substances, in combination with other active pharmaceutical ingredients: amodiakuin (INN); artelinic acid or its salts; arteminol (INN); artemotil (INN); artemeter (INN); artesunate (INN); chloroquine (INN); dihydroartemisinin (INN); lumefantrine (INN); mefloquine (INN); piperakuin (INN); primetamine (INN) or sulfadoxine (INN).
	30.04	Medicines (excluding articles of heading 30.02, 30.05 or 30.06) despite their consisting of mixed products for therapeutic or prophylactic purposes, are prepared in specific doses (including in the form of a transdermal administration system) or in the forms or packages for retail sale.	
	3004.10	- Containing penicillin or its derivatives, with the structure of penicillanic acid, or streptomycin or its derivatives:	
14	3004.10.15	- - - Containing penicillin G (excluding penicillin G benzathine), phenoxymethyl penicillin or their salts	

No	HS CODE	DESCRIPTION OF GOODS	
15	3004.10.16	- - - Containing ampicillin, amoxicillin or its salt, that of oral use type	
		- - - Containing streptomycin or its derivatives:	

19	3004.20.10	- - - Containing gentamicin, lincomycin, sulfamethoxazole or their derivatives, that of the type taken orally or in the form of an ointment	
		- - - Containing erythromycin or its derivatives:	
		- - - Containing tetracyclines or chloramphenicol or their derivatives:	
23	3004.20.71	- - - That of the oral use type or in the form of an ointment	
25	3004.20.91	- - - That of the oral use type or in the form of an ointment	
		- Others, containing hormones or other products of heading 29.37:	
28	3004.32.10	- - - Containing dexamethasone or its derivatives	
	3004.32	- - - Containing corticosteroid hormones, derivatives or analogous structures:	
29	3004.32.40	- - - Containing hydrocortisone sodium succinate or fluokinolone acetoneide	
32	3004.49.50	- - - Containing papaverine or berberine, that of the oral use type	
33	3004.49.60	- - - Containing theopilin, that of the oral use type	
35	3004.49.80	- - - Containing kinin hydrochloride or kinin dihydrochloride, for injection, containing kinin sulfate or kinin bisulfate, that of the oral use type	
	3004.50	- Others, containing vitamins or other products of heading 29.36:	
37	3004.50.10	- - - That in suitable type for children, in the form of a syrup	
		- - - Other, Containing more than one vitamins:	

	3004.60	- Others, contain active antimalarial substances as described in Subheading Note 2 to this Chapter :
42	3004.60.10	- - Containing Artemisin in combination with other active pharmaceutical ingredients
45	3004.90.10	- - Transdermal therapeutic patch system for the treatment of cancer or heart disease
46	3004.90.20	- - Closed sterile water for inhalation, pharmaceutical grade
		- - Analgesics, antipyretics and other drugs for the treatment of coughs or colds whether or not with antihistamines:
50	3004.90.51	- - - - Containing acetylsalicylic acid, paracetamol or dipyron (INN) from that of the oral use type
52	3004.90.53	- - - - Containing diclofenac from that of the oral use type
53	3004.90.54	- - - - Containing piroxicam (INN) or ibuprofen

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
		- - Antimalaria :	
57	3004.90.64	- - - - Containing artemisin in addition to subpost 3004.60.10	
59	3004.90.71	- - - - Containing piperazine or mebendazol (INN)	
		- - Other drugs for the treatment of cancer, HIV/AIDS or other serious diseases:	
61	3004.90.81	- - - - Containing deferoxamine, for injection	
64	3004.90.91	- - - - Containing sodium chloride or glucose, for infusion	
65	3004.90.92	- - - - Containing sorbitol or salbutamol, for infusion	
66	3004.90.93	- - - - Containing sorbitol or salbutamol, in other forms	
67	3004.90.94	- - - - Containing cimetidine (INN) or ranitidine (INN) other than those used for injection	

68	3004.90.96	- - - Nasal drops contains naphazoline, xylometazoline or oxymetazoline	
	30.06	Pharmaceutical articles shall be detailed in Note 4 to this Chapter	
	3006.30	- Opacity preparations for X-ray examination; diagnostic reagents designed to be administered to patients:	
71	3006.60.00	- Chemical contraceptive preparations based on hormones, other products of heading 29.37 or spermicides	

B. ANNEX OF HS CODE OF TRADITIONAL MEDICINE

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
	20.09	Fruit juices (including grape must) and vegetable juices, are not fermented and do not contain added alcohol, whether or not containing added sugar or other sweeteners.	
		- Juice from one type of fruit or another vegetable:	
	21.06	Processed food not specified or included in other headings.	
		- - Other food supplements; fortificant premixes :	
3	2106.90.72	- - - Other food supplements	
	30.04	Medicines (excluding articles of heading 30.02, 30.05 or 30.06) despite their consisting of mixed products for therapeutic or prophylactic purposes, are prepared in specific doses (including in the form of a transdermal administration system) or in the forms or packages for retail sale.	
4	3004.90.65	- - - Herbal Medication	Traditional medicine as an antimalarial
5	3004.90.72	- - - Herbal Medication	Traditional medicine as an anthelmintic

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
6	3004.90.98	- - - Herbal Medication	
7	3004.90.99	- - - Others	

33.01	Essential oils (whether containing terpenes or not), including that of concrete and absolute property; resinoids; oleoresin extract; essential oil concentrate in fat, in fixed oil, in wax or the like, obtained by enfleurage or maceration; inclusion products are terpenes in the process of removing terpenes from essential oils; distilled with water and aqueous solutions of essential oils.	
8lex 3301.29.90	- - - Others	Traditional medicine used topically

2. DRUGS AND FOOD OF WHICH IMPORTATION SHALL BE RESTRICTED INTO INDONESIAN AREA AT THE POST BORDER

A. ANNEX OF HS CODE OF COSMETICS

No	HS CODE	DESCRIPTION OF GOODS	TYPES OF GOODS
1	3303.00.00	Perfume and fragrance.	Baby cologne, Eau de cologne, Eau de toilette, Body fragrance perfume
	33.04	Beauty or make-up preparations and preparations for the skin case (other than medicines), including preparations for sunscreen or skin protection; manicure or pedicure preparations.	
2	3304.10.00	- Lip makeup preparations	Lip care Lip color Lip gloss Lip liner Lip shine
3	3304.20.00	- Eye makeup preparations	Eye foundation. Eye shadow Eye cream Mascara Other eye makeup preparations)
4	3304.30.00	- Manicure and pedicure preparations	Base coat Cuticle remover/softener Nail dryer Nail extender/Nail elongator Nail Nail strengthener Nail polish remover, Foot care Nail color, Top coat

5	3304.91.00	-- Powder, whether or not compacted	Body Powder Antiseptic body powder Baby powder Compact powder, Face powder, Mask Eye mask, Peeling Beauty or make-up preparations and Preparations for the skin case (other than medicines), including preparations for skin covering or protection against the sun
6	3304.99.20	--- Anti-acne preparations	

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
7	3304.99.30	--- Other creams and lotions for face or skin	Foundation, Anti aging, Baby cream, Baby lotion Liquid powder, Cold cream Make up Base, Antiwrinkle Night cream, Day cream Eye mask, Nutritive cream, Peeling Moisturizer, Skin freshener Skin care, body and hand Vanishing cream Eye moisturizer, Wrinkle smoothing remover Whitening eye cream Massage cream, Skin lightener Preparations for tanning skin without sunbathing (in the form of creams and lotions)

8	3304.99.90	- - - Others	<p>Massage gel, Scrub Mangir make-up kit Mask (gel sample) Eye mask (gel sample) Massage oil, Peeling Facial cleanser does not contain soap/surfactants Skin freshener (does not contain surfactants) Skin freshener for the face Eye makeup remover, Preparation to darken the skin without sunbathing, Baby oil Wrinkle smoothing remover "Stage" make-up, "bridal" make-up, Feminine hygiene Astringent Beauty or make-up preparations and preparations for the skin case (other than medicines), including other preparations for sunscreen or skin protection</p>
9	Ex 3305.10.10	- - Containing anti-fungal properties	Dandruff shampoo
10	Ex 3305.10.90	- - Others	Baby shampoo
11	3305.20.00	- Permanent curling or straightening preparations	Neutralizer Hair straightener, Hair curling iron (Permanent wave)
12	3305.30.00	- Hair lacquer	Hair styling
13	Ex 3305.90.00	- Others	Hair dye activator, Hair creambath Hair conditioner, Hair dressing Fantasy hairdo, Hair tonic
	33.06	Oral or dental hygiene preparations, including artificial tooth-strengthening pastes and powders; floss for cleaning between the teeth (dental floss), in separate packages for retail sales.	
14	ex3306.10.10	- - Powders and pastes for dental prophylaxis	Toothpaste (Dentrifices)
15	Ex 3306.10.90	- - Others	Toothpaste (Dentrifices)
16	3306.90.00	- Others	Mouth washes Mouth freshener, Other oral hygiene preparations

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
	33.07	Preparations used before shaving, while shaving or after shaving, deodorants, bath preparations, depilatory preparations and fragrance preparations, cosmetics or make-up preparations, not specified or included in other headings; room deodorizing preparations, whether or not scented or containing disinfectant.	
17	3307.10.00	- Preparations used before shaving, while shaving or after shaving	
18	3307.20.00	- Deodorants and antiperspirants	
19	3307.30.00	- Fragrance salts and other preparations for bathing	Bath salt, Bath oil Bath powder, Bath foam Other bath preparations
20	3307.90.30	- - Paper and tissue, impregnated, or coated with fragrances or cosmetics	Facial skin cleanser (tissue) Other cosmetics in the form of tissue coated with fragrances/cosmetics
21	ex3307.90.40	- - Other fragrances or cosmetics, including depilatory drugs	Depilatories
	34.01	Soap; organic surface-active products and preparations for use as soap, in the form of bars, cakes, molded pieces or shapes, whether or not containing soap; organic surface active products and preparations for cleaning the skin in the form of liquids or creams and prepared for retail sale, whether or not containing soap; paper, wadding, felt and nonwovens, impregnated, coated or covered with soap or detergent.	
		- Soap and organic surface active products and preparations, in the form of bars, cakes, molded pieces or shapes, and paper, wadding, felt or nonwovens, impregnated, coated or covered with soap or detergent:	
	3401.11	- - For toilet purposes (including medicinal products):	
22	Ex 3401.11.40	- - - Soap contains medicine including disinfectant soap	Antiseptic bath soap (solid)
23	Ex 3401.11.50	- - - Other soaps including bath soap	Baby bath soap (solid), Bath soap (solid)
24	3401.11.60	- - - Others, of felt or nonwovens, impregnated, coated or covered with soap or detergent	Facial cleanser
25	3401.11.90	- - - Others	
26	3401.19.10	- - - Of felt or nonwovens, impregnated, coated or covered with soap or detergent	
27	3401.19.90	- - - Others	
28	3401.20.20	- - Soap chips	

29	Ex 3401.20.99	- - - Others	Antiseptic soap Baby bath soap Bath soap
30	Ex 3401.30.00	- Organic surface-active products and preparations for cleaning the skin, in liquid or cream form which are prepared for retail sale, whether or not containing soap	Antiseptic soap Baby bath soap Bath soap Handwash (Contains Surfactants) in liquidcream form

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
	38.08	Insecticides, rodenticides, fungicides, herbicides, anti-sprouting and plant growth regulating products, disinfectants and products alike, which are prepared in certain forms or packages for retail sale or as preparations or goods (for example, ribbons, wicks and wax treated with sulfur, and fly paper).	
31	Ex 3808.94.90	- - - Others	Facial cleanser (tissue), Feminine hygiene (tissue)

B. ANNEX OF HS CODE OF HEALTH SUPPLEMENTS

No	HS CODE	DESCRIPTION OF GOODS	TYPES OF GOODS
	21.06	Processed food not specified or included in other headings.	
		- - Other food supplements; fortificant premixes :	
1	2106.90.71	- - - Food supplements contain ginseng	
2	2106.90.72	- - - Other food supplements	Health supplements
3	2106.90.96	- - - Other medical food	Health supplements
	22.02	Water, including mineral water and sparkling water, containing added sugar or other sweetening or flavoring agents, and other non-alcoholic beverages, excluding fruit or vegetable juices of heading 20.09.	
	2202.10	- Water, including mineral water and sparkling water, contains added sugar or other sweetening or flavoring:	
4	2202.10.10	- - Sparkling mineral water or sparkling water, flavored	Health supplements in the form of health drinks
5	2202.10.90	- - Others	Health supplements in the form of health drinks
	35.07	Enzyme; prepared enzymes not specified or included in other headings.	
6	Ex 3507.90.00	- Others	Health supplements containing enzymes

C. ANNEX OF HS CODE OF QUASI DRUGS

No	HS CODE	DESCRIPTION OF GOODS	TYPES OF GOODS
	30.04	Medicines (excluding articles of heading 30.02, 30.05 or 30.06) despite their consisting of mixed products for therapeutic or prophylactic purposes, are prepared in specific doses (including in the form of a transdermal administration system) or in the forms or packages for retail sale.	
1	Ex 3004.90.99	- - - Other	Quasi preparation for external/topical use
	21.06	Processed food not specified or included in other headings.	
2	Ex 2106.90.99	- - - Others	Quasi preparation for oral use

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
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D. ANNEX OF HS CODE OF PROCESSED FOOD

No	HS CODE	DESCRIPTION OF GOODS	TYPES OF GOODS
	04.01	Milk and Milk skin, not concentrated or containing additional sugar or other sweetening ingredients.	
	0401.10	- With a fat content not exceeding 1% by weight:	
	0401.20	- With a fat content exceeding 1% but not exceeding 6% by weight:	
	0401.40	- With a fat content exceeding 6 % but not exceeding 10 % by weight:	
	0401.50	- With a fat content exceeding 10% by weight:	
	04.02	Milk and Milk skin, concentrated or containing additional sugar or other sweetening ingredients.	
	0402.10	- In powder, granular or other solid form, with a fat content not exceeding 1.5	
		- - Does not contain added sugar or other sweetening ingredients:	
8	0402.10.42	- - - In packages with a net weight of 2 kg or less	

10	0402.10.92	- - - In packages with a net weight of 2 kg or less
		- In powder, granular or other solid form, with a fat content exceeding 1.5% by weight:
	0402.21	- - Does not contain added sugar or other sweetening ingredients:
12	0402.21.30	- - - In packages with a net weight of 2 kg or less
14	0402.29.30	- - - In packages with a net weight of 2 kg or less
16	0402.91.00	- - Does not contain added sugar or other sweetening ingredients
	04.03	Thickened butter, concentrated milk and milk skin, yogurt, kefir and other fermented or acidified milk and milk skin, concentrated or containing additional sugar or other sweeteners or flavored with or containing added fruit, nuts or cocoa or not.
		- - In liquid form, whether or not thickened:
18	0403.10.21	Flavored with or containing added fruit (including pulp and jam), nuts or cocoa
20	0403.10.91	- - - Flavored with or containing added fruit (including pulp and jam), nuts or cocoa

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
	04.04	Whey, whether or not concentrated or containing additional sugar or other sweetening matter; the product consists of natural milk as the main ingredient, whether or not it contains additional sugar, other sweeteners, not specified or included in other headings.	
	0404.10	- Whey and Whey that are modified, concentrated or whether containing added sugar or other sweetening ingredients or not:	
	04.05	Butter and other fats and oils obtained from milk; dairy spreads.	

	0406.10	- Fresh cheeses (uncooked or not preserved) including whey cheese and milk curd:	
32	0406.10.10	- - Fresh cheese (uncooked or not preserved), including whey cheese	
	0406.20	- Grated cheese or powder cheese, of all types:	
	09.01	Coffee, whether roasted or decaffeinated; coffee husks and skins; coffee substitutes contain coffee in any proportion.	

	12.12	Carob nuts, seaweed and other algae, sugar beet and sugarcane, fresh, chilled, frozen or dried, whether or not crushed; hard skin of fruit and kernels and other vegetable products (including unroasted chicory root of the Cichorium intybus sativum variety) of a kind mainly used for human consumption, not specified or included in other headings.	
42	1212.21.14	- - - Gelidium spp.	
	13.01	Lacquer; natural gums, resins, gum-resin, and oleoresins (for example, gums of balm).	
	13.02	Vegetable saps and extracts; pectic, pectinic and pectic substances; Gelatin and mucilages in addition to other thickening agents, whether or not modified, are derived from vegetable products.	
		- Mucilages and thickeners, whether or not modified, derived from vegetable products:	
48	1302.32.00	- - Mucilages and thickeners, whether or not modified, derived from locust beans, locust beans or guar seeds	

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No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
	15.01	Pork fat (including lard) and poultry fat, other than heading 02.09 or 15.03.	
	15.07	Soybean oil and its fractions, whether or not refined, but not chemically modified.	
56	1507.90.10	-- The fraction of unrefined soybean oil	
	15.09	Olive oil and its fractions, whether or not refined, but not chemically modified.	
58	1509.10.10	-- In packages with a net weight not exceeding 30 kg	
		-- Others :	
	15.12	Sunflower, safflower or cottonseed oil and fractions thereof, whether or not refined, but not chemically modified.	
60	1512.19.10	-- Fractions from unrefined sunflower seed oil or safflower oil	
	15.13	Coconut oil (copra), palm kernel oil, or babassu oil and their fractions, whether or not refined, but not chemically modified.	
	15.14	Rapeseed oil, colza or mustard oil and their fractions, whether or not refined, but not chemically modified.	
		- Colza or rapeseed oil contains low erucic acid and its fractions:	
	15.15	Other certain vegetable fats and oils (including jojoba oil) and their fractions, whether or not refined, but not chemically modified.	

	15.16	Animal or vegetable fats and oils and their fractions, partially or completely hydrogenated, inter-esterified, re-esterified or elidized, whether or not refined, but not further processed.
69	1516.20.54	- - From peanuts, palm oil or coconut
70	1516.20.98	- - From peanuts, palm oil or coconut

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
	15.17	Margarine; mixtures or edible preparations of animal or vegetable fats or oils or of different fractions of fats or oils in this chapter, other than edible fats or oils or their fractions of heading 15.16.	
71	1517.10.10	- - In airtight packaging for retail	
74	1517.90.30	- - Of a kind used as mold release preparations	
77	1517.90.50	- - Mixtures or other solid preparations of fat or vegetable oil or of their fractions	
		- - Mixtures or other liquid preparations of fat or vegetable oil or of their fractions :	
78	1517.90.62	- - The main ingredient is crude palm oil	
79	1517.90.63	- - With other main ingredients of palm oil, in packages with a net weight not exceeding 25 kg	
80	1517.90.64	- - With other main ingredients of palm oil, in packages with a net weight exceeding 25 kg	
81	1517.90.67	- - With the main ingredients of soybean oil or coconut oil	
	16.01	Sausages and similar products, of meat, leftover meat or blood; processed food derived from this product.	
83	1601.00.10	- - In airtight packaging for retail	

	16.02	Meat, other leftover meat or blood that is processed or preserved.	
85	1602.10.10	- - Containing pork, in airtight packaging for retail sale	
	16.02	Meat, other leftover meat or blood that is processed or preserved.	
88	1602.31.10	- - - In airtight packaging for retail	
89	1602.31.91	- - - Meat separated of stripped from by machining	
91	1602.32.10	- - -Chicken curry, in airtight packaging for retail sale	
94	1602.41.10	- - - In airtight packaging for retail	
96	1602.42.10	- - - In airtight packaging for retail	

98	1602.49.11	- - - - In airtight packaging for retail	
100	1602.49.91	- - - - In airtight packaging for retail	
	1602.90	- Others, including preparations from animal blood :	
103	1602.90.10	- - Lamb curry, in airtight packaging for retail sale	

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
105	1603.00.00	Extracts and juices of meat, fish or crustaceans, molluscs or other aquatic invertebrates.	
	16.04	Fish processed or preserved; caviar and caviar substitutes prepared from fish eggs.	
		- Fish, whole or in chunks, but not chopped:	

106	1604.11.10	- - - In airtight packaging for retail	
108	1604.12.10	- - - In airtight packaging for retail	
110	1604.13.11	- - - - In airtight packaging for retail	
112	1604.13.91	- - - - In airtight packaging for retail	
		- - - In airtight packaging for retail :	
116	1604.15.10	- - - In airtight packaging for retail	
118	1604.16.10	- - - In airtight packaging for retail	
120	1604.17.10	- - - In airtight packaging for retail	
123	1604.18.91	- - - - In airtight packaging for retail	
125	1604.19.20	- - - Horse mackerel, in airtight packaging for retail sale	
126	1604.19.30	- - - Others, in airtight packaging for retail sale	
131	1604.20.91	- - - In airtight packaging for retail	
	16.05	Crustaceans, molluscs and other aquatic invertebrates, prepared or preserved.	
134	1605.10.10	- - In airtight packaging for retail	

	17.03	The drops result from the extraction or refining of sugar.	
163	1703.10.10	-- Containing additional flavoring or coloring agents	
	17.04	Confectionery (including white chocolate), does not contain cocoa.	
	18.03	Cocoa paste, whether or not defatted.	
170	1803.20.00	Defatted partially or completely	
172	1805.00.00	Cocoa powder, not containing added sugar or other sweeteners.	
	18.06	Chocolate and other food preparations containing cocoa.	
173	1806.10.00	Cocoa powder, containing added sugar or other sweetening ingredients	
	1806.20	- Other preparations in the form of blocks, plates or sticks weighing more than 2 kg or in the form of liquid, paste, powder, granules or other bulk forms in direct packages or wraps, with contents exceeding 2 kg:	
174	1806.20.10	-- Chocolate confectionery in the form of blocks, plates or bars	
		- Others, in the form of blocks, plates or bars	
178	1806.90.10	-- Chocolate confectionery in tablet or pastiles form	

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
	19.01	Malt extract; processed food from flour, groats, crude flour, starch or malt extract, not containing cocoa or containing less than 40% cocoa by weight calculated on the basis of cocoa defatted, not specified or included in other headings; food preparations from headings 04.01 to 04.04, not containing cocoa or containing less than 5% cocoa by weight calculated on the basis of defatted cocoa, not specified or included in other headings.	

213	1903.00.00	Tapioca and its substitutes prepared from starch, in the form of flakes, grains, pearls, sieves or any form alike.	
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No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
	19.04	Processed foods produce by inflating or roasting cereals or cereal products (for example, corn chips); cereals (other than corn), in the form of grains or flakes or grains that have been processed otherwise (except flour, groats and coarse flour), which have not been cooked or otherwise processed, not specified or included in other headings.	

	1904.10	- Processed foods obtained by inflating or roasting cereals or cereal products:	
	1904.20	- Processed foods obtained from unroasted cereal chips or unroasted mixed cereal chips with roasted cereal chips or inflated cereal:	
216	1904.20.10	- - Processed food taken from unroasted cereal chips	
	19.05	Bread, pastries, cookies, biscuits and other bakery products, whether or not containing cocoa; communion wafers, empty casings of a kind suitable for pharmaceutical use, sealing wafers, rice paper and products alike.	
	1905.40	- Rusk, toast and similar baked products:	
225	1905.40.10	- - Not containing additional sugar, honey, eggs, fat, cheese or fruit	
232	1905.90.60	- - Empty casings of a kind suitable for pharmaceutical purposes	
233	1905.90.70	- - Communion wafers, sealing wafers, rice paper and products alike	

20.01	Vegetables, fruit, nuts and other plant parts which are not edible. prepared or preserved with vinegar or acetic acid.
20.02	Tomatoes processed or preserved in addition to vinegar or acetic acid.
20.03	Mushrooms and fungi, processed or preserved other than with vinegar or acetic acid.
20.04	Other vegetables processed or preserved other than with vinegar or acetic acid, frozen, other than products of heading 20.06.
20.05	Other vegetables processed or preserved other than with vinegar or acetic acid, not frozen, other than products of heading 20.06.

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
247	2005.10.10	- - In airtight packaging for retail	
249	2005.20.11	- - - In airtight packaging for retail	
251	2005.20.91	- - - In airtight packaging for retail	

255	2005.59.10	- - - In airtight packaging for retail	
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261	2005.99.10	- - - In airtight packaging for retail
263	2006.00.00	Vegetables, fruit, nuts, fruit skins and other parts of the plant, preserved with sugar (dry, shiny or crystalline).
	20.07	Jams, fruit jellies, marmalades, fruit or nut purees and pastes, obtained from cooking, whether or not containing additional sugar or other sweeteners.
266	2007.99.10	- - - Fruit pellets and pastes other than mango, pineapple or strawberry
	20.08	Fruits, nuts and other plant parts that are edible, otherwise processed or preserved, whether or not containing additional sugar or other sweetening substances or alcohol, not specified or included in other headings.
		- Nuts, peanuts and other nuts, whether or not mixed:
275	2008.20.10	- - In airtight packaging for retail
277	2008.30.10	- - Containing added sugar or other sweetening ingredients or alcohol
281	2008.60.10	- - Containing added sugar or other sweetening ingredients or alcohol
283	2008.70.10	- - Containing added sugar or other sweetening ingredients or alcohol
	2008.93	- - Cranberry (<i>Vaccinium macrocarpon</i> , <i>Vaccinium oxycoccos</i> , <i>Vaccinium vitis-idaea</i>) :
286	2008.93.10	- - Containing added sugar or other sweetening ingredients or alcohol

	21.01	Extracts, essences and concentrates, from coffee, tea or mats and preparations on the basis of this product or	
		- Extracts, essences and concentrates, from coffee, as well as preparations based on coffee extracts, essences or concentrates or coffee based preparations:	
	2101.12	- - Processed products based on extracts, essence, or concentrate or coffee based processed products :	
320	2101.12.91	- - - Processed coffee based on extracts, essences or concentrates, containing added sugar, whether or not containing creamer	
321	2101.12.92	- - - - Processed coffee based on ground roasted coffee containing added sugar, whether or not containing creamer	
	2101.20	- Extracts, essences and concentrates, from tea or mats and preparations based on extracts, essences or tea concentrates or processed products based on a tea or mat basis:	
323	2101.20.20	- - Tea extract for the production of processed tea, in powder form	

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
324	2101.20.30	- - Processed tea consisting of a mixture of tea, milk powder and sugar	
	21.02	Yeast (active or inactive); other single-celled micro-organisms, dead (but not including vaccines of heading 30.02); baking powder.	
	21.03	Sauces and its processed products; mixture of spices and mixture of flavoring ingredients; mustard flour and mustard powder and processed mustard.	
329	2103.30.00	- Mustard flour and mustard powder and processed mustard	

	21.04	Soups and broths as well as the processed products; homogeneous mixed food processed products.	

	22.01	Water, including natural or artificial mineral water and sparkling water, not containing added sugar or other sweeteners or flavorings; ice and snow.	
	22.02	Water, including mineral water and sparkling water, containing added sugar or other sweetening or flavoring agents, and other non-alcoholic beverages, excluding fruit or vegetable juices of heading 20.09.	
	2202.10	- Water, including mineral water and sparkling water, contains added sugar or other sweetening or flavoring:	
369	2202.10.10	- - Sparkling mineral water or sparkling water, flavored	
372	2202.99.10	- - - Drinks with flavored UHT milk as the base ingredient	
374	2202.99.40	- - - Drinks with coffee based ingredients or coffee flavor	
375	2202.99.50	- - - Drinks not containing soda that is ready for immediate consumption	

377	2203.00.11	- - With an alcohol content not exceeding 5.8% by volume	
378	2203.00.19	- - With an alcohol content exceeding 5.8% by volume	
379	2203.00.91	- - With an alcohol content not exceeding 5.8% by volume	
380	2203.00.99	- - With an alcohol content exceeding 5.8% by volume	
	22.04	Fermented drinks (Wine) from fresh grapes, including fortified fermented drinks (wine); grape must other than heading 20.09.	
		- Other fermented drinks (wine); grape must in which fermentation is prevented or stopped by the addition of alcohol :	
382	2204.21.11	- - - With an alcohol content not exceeding 15% by volume	
383	2204.21.13	- - - With an alcohol content exceeding 15% but not exceeding 23% by volume	
384	2204.21.14	- - - With an alcohol content exceeding 23% by volume	

		- - - Grape must whose fermentation is prevented or stopped by the addition of alcohol:	
385	2204.21.21	- - - - Grape must in which fermentation is prevented or stopped by the addition of alcohol, in packs of 2L or less, with an alcohol content not exceeding 15% by volume	
386	2204.21.22	- - - - Grape must in which fermentation is prevented or stopped by the addition of alcohol, in packs of 2L or less, with an alcohol content exceeding 15% by volume	
	2204.22	- - In packs of more than 2 l but not more than 10 l:	
387	2204.22.11	- - - - With an alcohol content not exceeding 15% by volume	
388	2204.22.12	- - - - With an alcohol content exceeding 15% but not exceeding 23% by volume	
389	2204.22.13	- - - - With an alcohol content exceeding 23% by volume	
No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
		- - - Grape must whose fermentation is prevented or stopped by the addition of alcohol:	
390	2204.22.22	- - - - With an alcohol content exceeding 15% by volume	
391	2204.29.11	- - - - With an alcohol content not exceeding 15% by volume	
392	2204.29.13	- - - - With an alcohol content exceeding 15% but not exceeding 23% by volume	
393	2204.29.14	- - - - With an alcohol content exceeding 23% by volume	
		- - - Grape must whose fermentation is prevented or stopped by the addition of alcohol:	
394	2204.29.21	- - - - With an alcohol content not exceeding 15% by volume	
395	2204.29.22	- - - - With an alcohol content exceeding 15% by volume	
396	2204.30.10	- - With an alcohol content not exceeding 15% by volume	
397	2204.30.20	- - With an alcohol content of more than 15% by volume	
	22.05	Vermouth and other fermented drinks made from fresh grapes that are flavored with vegetable or flavored substances.	
398	2205.10.10	- - With an alcohol content not exceeding 15% by volume	
399	2205.10.20	- - With an alcohol content exceeding 15% by volume	
400	2205.90.10	- - With an alcohol content not exceeding 15% by volume	
401	2205.90.20	- - With an alcohol content exceeding 15% by volume	

	22.06	Other fermented drinks (for example, fermented apples, pears, honey in water solution, sake); mixtures of fermented drinks and mixture of fermented drinks with non-alcohol drinks, not specified or included in other headings.
402	2206.00.10	- Fermented apples and fermented pears
406	2206.00.41	- - With an alcohol content not exceeding 1.14% by volume
408	2206.00.91	- - Other fermented rice drinks (including medicated fermented rice drinks)
	22.08	Undenatured ethyl alcohol with an alcohol content of less than 80% by volume; alcohol, liqueur and other alcoholic beverages.
	2208.20	- Alcohol obtained from the distillation of fermented grape or grape marc drinks:
412	2208.40.00	- Rum and other alcohols obtained by refining fermented cane sugar products
415	2208.70.10	- - With an alcohol content not exceeding 57% by volume
416	2208.70.90	- - With an alcohol content exceeding 57% by volume
417	2208.90.20	- - Samsu contains drugs with an alcohol content of more than 40% by volume

No	HS CODE	DESCRIPTION OF GOODS	CALLOUTS
418	2208.90.50	- - Pineapple wine or alcohol with an alcohol content not exceeding 40% by volume	
419	2208.90.60	- - Pineapple wine or alcohol with an alcohol content exceeding 40% by volume	
420	2208.90.91	- - - With an alcohol content not exceeding 1.14% by volume	
	28.53	Phosphide, whether or not with own chemical formula, not including ferrophosphorus; other inorganic compounds (including distilled water or conductivity water and water of similar purity); liquefied air (whether or not primed gas has been removed); compressed air; amalgam, other than amalgam of precious metals.	

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THE CHAIRPERSON OF THE INDONESIAN FOOD AND
DRUG AUTHORITY,

sign.

PENNY K. LUKITO.

ANNEX III
THE REGULATION OF THE INDONESIAN
FOOD AND DRUG AUTHORITY NUMBER 15
YEAR 2020
CONCERNING
THE AMENDMENTS TO THE REGULATION OF THE
INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 30 YEAR 2017 CONCERNING THE
SURVEILLANCE OF DRUGS AND FOOD IMPORTED
TO THE TERRITORY OF INDONESIA

A. FORM IMPORT INFORMATION OF DRUG AND FOOD FOR PERSONAL USE

FORM

FORM IMPORT INFORMATION OF DRUG AND FOOD FOR PERSONAL USE

Full Name	:	
Phone Number and E-mail	:	
Date of Birth (DD/MM/YYYY)	:	.../.../...
Address	:	
ID number/passport number	:	
Name/Flight (voyage) number	:	
Date of Arrival	:	

Product Description:

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

For Drug: please attach Doctor's prescription/Hospital recommendation)

Note:

1. Such Products with the name and the quantity may only be for personal use and shall not be marketed or traded. (*The above-mentioned product(s) is solely for personal use and not for sale.*)
2. Customs and Excise shall not be responsible for the risks arising from the use of the products mentioned above. (*Directorate General of Customs and Exercise does not responsible for the risks of using the above-mentioned product.*)
3. If a violation occurs, it will be subject to sanctions in accordance with the provision of the legislation. .

Applicant,

Officer,

Jakarta, (dd/mm/yyyy)

name and signature signature and stamp

B. FORM IMPORT INFORMATION OF DRUG AND FOOD THROUGH TRANSPORT SERVICES FOR PERSONAL USE

FORM IMPORT INFORMATION OF DRUG AND FOOD THROUGH TRANSPORT SERVICES FOR PERSONAL USE

Full Name	:	
Phone Number and E-mail	:	
Date of Birth (<i>DD/MM/YYYY</i>)	:	<i>.../.../...</i>
Address	:	
ID number/passport number	:	
Receipt of Purchase	:	
Shipping receipt number	:	
Shipper Name and address	:	
Country of Origin	:	

Product Description

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

* (For Drugs: please Attach Doctor's prescription/Hospital

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e) :

1. Such Products with the name and the quantity may only be for personal use and shall not be marketed or traded. (*The above-mentioned product(s) is solely for personal use and not for sale.*);
2. Customs and Excise shall not be responsible for the risks arising from the use of the products mentioned above. (*Directorate General of Customs and Exercise does not responsible for the risks of using the above-mentioned product*);
3. If a violation occurs, it will be subject to sanctions in accordance with the provision of the legislation. .

Jakarta, (dd/mm/yyyy)

Applicant,

name and signature
Officer,

signature and stamp

Technical Documents:

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

C. FILLING INSTRUCTIONS OF PRODUCT ENTRY FOR PERSONAL USE

Columns in the Forms	Filling Instruction
Full Name	: Filled with the full name according to the Id Card/Passport Id of the passengers or consignees

Phone Number and E-mail	: Filled with telephone number and email that can be contacted
Date of Birth (DD/MM/YYYY)	: Filled with place and date of birth with the format (Day/Month/Year) of the passengers or the consignee
Address	: To be completed with the domicile address of the passenger or the consignee
ID number/passport number	: Filled with identification number of the passenger or the goods consignee in accordance with Id Card/Passport Id
Name/Flight (voyage) number	: Fill in the name of the aircraft/flight number used by the passenger
Date of Arrival	: Filled with the date of arrival of the passenger
Receipt of Purchase	: Filled with number and date of proof of purchase of goods
Shipping receipt number	: Filled with goods delivery receipt number
Shipper Name and address	: Filled with the name and address of the sender of the goods
Country of Origin	: Filled with the country of origin of the consignment
Product Description	
Product Name and Brand	: Filled in the brand name and type of goods, for example:

	<p>a. Instant noodle “SUPER LEZAT” (Type of instant noodle brands: SUPER LEZAT)</p> <p>b. Health Supplement “Energi Oke”</p> <p>c. Traditional Medicine “Tolak Pegel Linu”</p> <p>d. Cosmetics "BMZ Lipstick Shine 0”</p>
Package Size	<p>: Filled with the individual size of the item packaging, for example:</p> <p>a. 100 grams (the net weight of the product)</p> <p>b. Box, bottle @ 60 capsules @ 500 mg</p> <p>c. Box, 6 sachets @ 4 grams</p> <p>d. Box, 10 strips @10 capsules @ 500 mg</p> <p>e. Box tube, 3.5 grams</p>
The Amount of Products) (pcs)	<p>: Filled with the number of items sent per product type, for example:</p> <p>a. 5 pieces (number of items according to each primary pack)</p>
Remarks*	<p>: Filled with a description of the doctor's prescription as attached (sample dose)</p>
Applicant, name and signature	<p>: Filled with name and signature of the passenger or the consignee</p>
Officer, (Signature and stamp)(name)	<p>: Filled with name, signature and stamp of the local Customs and Excise officer</p>

THE CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY,

sign.

PENNY K. LUKITO

ANNEX IV
THE REGULATION OF THE INDONESIAN FOOD AND DRUG
AUTHORITY NUMBER 15 YEAR 2020

CONCERNING
THE AMENDMENTS TO THE REGULATION OF THE INDONESIAN FOOD AND
DRUG AUTHORITY NUMBER 30 YEAR 2017 CONCERNING THE
SURVEILLANCE OF DRUGS AND FOOD IMPORTED TO THE TERRITORY OF
INDONESIA

LIMITATION OF THE AMOUNT OF IMPORTED GOODS WITHOUT MARKETING
AUTHORIZATIONS THROUGH SPECIAL LINE

* Limitations in the table below, refer to the provisions for the entry of Drugs and Food as referred to in
Article 28

Com modi ties	Limits on the amount of imported goods			
	For individual/ personal use with or without considerati on of health workers (Per Day)	Each Objectives (per day)	Sample Purpose for Registrati on/enroll ment (Per day)	Exhibi tion Purpo se (Per day)
Drugs	In accordance with the doctor's prescription	-	-	-

Traditional medicine	Maximum of 5pcs* per passenger/receiver for each type/item of product.	In accordance with the research proposal/protocol.	At most 2 pcs/item of Traditional Medicines products for each packaging accordingly	Not more than 10 pcs/items of products for each packaging.
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	*) Note: For tablets/capsules inside strips/blisters/bottles and packaged in small boxes, then the limit of the number allowed is 5 small boxes.		with sample requirements for testing.	
Health supplements		In accordance with the research proposal/protocol.	At most 2 pcs/items of Health Supplement products for each packaging or according to sample requirements for testing.	Not more than 10 pcs/items of products for each packaging.
Cosmetics	Maximum of 20 pcs per passenger/receiver.	In accordance with the research proposal/protocol.	At most 2 pcs/items of Cosmetics products for each packaging or according to sample requirements	Not more than 10 pcs/items of products for each packaging.

			nts for testing.	
Food: Food Products for special nutritional needs	In accordance with the doctor's prescription			

b. Processed Food others, except alcoholic drinks.	5 Kilograms per passenger/ receiver of
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THE CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

sign.

PENNY K. LUKITO