



4 May 2023

(23-3141)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>INDONESIA</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Indonesian Food and Drug Authority (FDA) Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: Bureau for Cooperation and Public Relations Indonesian Food and Drug Authority (FDA) Jl. Percetakan Negara No.23 Jakarta 10560 – Indonesia Telephone : +(62-21) 42875379 Facsimile : +(62-21) 42875379 Email : kerjasama@pom.go.id Website : http://www.pom.go.id Directorate of Implementation System for Standards and Conformity Assessment National Standardization Agency of the Republic of Indonesia (BSN) TBT WTO Notification and Enquiry Point of Indonesia Gedung 2 Laboratorium SNSU BSN, Komplek Puspiptek, Muncul, Tangerang Selatan, Banten 15314 Email: tbt.indonesia@bsn.go.id and tbt.indonesia@gmail.com Website: http://www.bsn.go.id
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Drug Materials, Traditional Drug Materials, Cosmetic Materials, Health Supplement Materials, Food Materials.
5. Title, number of pages and language(s) of the notified document: Decree of The Head of Indonesian FDA No. 246 of 2022 on the List of Restricted Drug and Food Materials Importation into The Territory of Indonesia and Drug and Food in the Form of Traditional Drug Materials, Quasi Drug Materials, Cosmetic Materials, And Food Materials Entered into the Territory of Indonesian for Small and Medium Industries; (174 page(s), in Indonesian)

<p>6. Description of content:</p> <ol style="list-style-type: none"> a. This decree is the implementing regulation of Indonesian FDA Regulation No. 26 of 2022 on Supervision of the Importation of Drug and Food Materials into Indonesian Territory. b. The list of restricted drug and food materials importation into the territory of Indonesia and drug and food in the form of traditional drug materials, quasi drug materials, cosmetic materials, and food materials entered into the territory of Indonesia for small and medium industries in accordance with the harmonized system (HS) code. The importation of those drug and food materials is supervised by the Indonesian FDA through the Border Import Notification Letter and the Post Border Import Notification Letter scheme. c. This decree also accommodates the importation of Propylene Glycol, Polyethylene Glycol and other pharmaceutical grade solvents such as Butylene glycol and Hydrogenated starch hydrolysate through the Post Border Import Notification Letter scheme.
<p>7. Objective and rationale, including the nature of urgent problems where applicable: As guidelines for The Importation of Drug and Food Materials into Indonesian Territory; Protection of human health or safety</p>
<p>8. Relevant documents:</p> <ol style="list-style-type: none"> 1. Presidential Regulation Number 80 of 2017 concerning the Drug and Food Control Agency (State Gazette of the Republic of Indonesia year 2017 Number 180); 2. Indonesian FDA Regulation Number 21 of 2020 on the Organization and Work Procedure of Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia year 2020 Number 1002) as amended by Indonesian FDA Regulation Number 13 of 2022 on the amendments to Indonesian FDA Regulation Number 21 of 2020 on the Organization and Work Procedure of Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia Year 2022 Number 629); 3. Indonesian FDA Regulation Number 22 of 2020 on the Organization and Working procedure of Technical Implementation Unit within the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia Year 2020 Number 1003) as amended several times, the latest by Indonesian FDA Regulation Number 24 of 2022 on the second amendments to Indonesian FDA Regulation Number 22 Year 2020 the Organization and Working procedure of Technical Implementation Unit within the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia Year 2022 Number 1111); 4. Indonesian FDA Regulation No. 26 of 2022 on Supervision of the Importation of Drug and Food Materials into Indonesian Territory (State Gazette of the Republic of Indonesia Year 2022 Number 1153).
<p>9. Proposed date of adoption: 14 November 2022 Proposed date of entry into force: 14 December 2022</p>
<p>10. Final date for comments: 60 days from notification</p>
<p>11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body: https://members.wto.org/crnattachments/2023/TBT/IDN/23_09449_00_x.pdf</p>