

15 May 2023

NOTICE TO RELEVANT STAKEHOLDERS

Dear Sir/Ma'am:

This refers to the draft regulations distributed through the World Trade Organization – Technical Barriers to Trade (WTO-TBT) website (www.epingalert.org) from 29 April to 05 May 2023.

Relative thereto, we respectfully invite stakeholders to comment on the six (6) notified draft technical regulations from European Union, Indonesia, and United States:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/EU/977	European Union	Date of Distribution: 04 May 2023 Deadline for Comments: 13 May 2023	Substance bis(2-ethylhexyl) phthalate (DEHP) in medical devices	Commission Regulation (EU) 2021/2045 of 23 November 2021 (notified under G/TBT/N/EU/760) amended Annex XIV to Regulation (EC) No 1907/2006 (REACH) by giving a Latest application date (LAD) regarding uses of Bis(2-ethylhexyl) phthalate (DEHP) in medical devices until 27 November 2023 and a Sunset date (SD) until 27 May 2025.
G/TBT/N/IDN/153	Indonesia	Date of Distribution: 04 May 2023 Deadline for Comments: 02 July 2023	Drug and food materials	This regulation is the amendments to Indonesian FDA Regulation No. 29 of 2017 on Supervision of the Importation of Drug and Food Materials into Indonesian Territory. New provisions changed on this regulation include: a. Additional regulation on the entry of certain drug materials (Propylene Glycol, Polyethylene Glycol and other materials with limited levels of Ethylene Glycol and Diethylene Glycol for pharmaceutical grade) through Post Border Import Notification Letter (Surat Keterangan Impor) mechanism. b. The amendment of the operational definition of Border Import Notification Letter and Post Border Import Notification Letter.

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Membership:

- International Organization for Standardization (ISO)
- International Electrotechnical Commission (IEC)
- World Trade Organization (WTO) Technical Barriers to Trade (TBT)
 - National Enquiry Point (NEP)
 - National Notification Authority (NNA)

				<p>c. The adjustment of Special Access Scheme mechanism under Indonesia FDA supervision such as for Biological Products; Research Drugs (excluding Biological Products, narcotics, psychotropics and pharmaceutical precursors); and Drug Materials.</p> <p>d. The amendment of the provision of importation realization report submitted by business actors.</p> <p>e. The addition of several drug materials to the list of drug materials attachments which is supervised by Indonesia FDA.</p>
G/TBT/N/IDN/154	Indonesia	<p>Date of Distribution: 04 May 2023</p> <p>Deadline for Comments: 02 July 2023</p>	Drugs and food	<p>This regulation is the amendments to Indonesian FDA Regulation No. 30 of 2017 on Supervision of the Importation of Drug and Food into Indonesian Territory. New provisions changed on this regulation include:</p> <p>a. Additional Petitioners to accommodate the need for the imported drug by the Indonesian government.</p> <p>b. Additional Import Notification Letter provisions for drug entry into Special Economic Zones.</p> <p>c. The amendment of the shelf life of drugs intended for donation purposes, namely 2 (two) years before the expiration date.</p> <p>d. The amendment of the provisions for reporting the realization of imports by business actors.</p> <p>e. The amendment of the provisions for the entry of drugs and food for personal use.</p> <p>f. The addition of several drugs to the list of drug attachments under Indonesia FDA supervision.</p>

G/TBT/N/IDN/155	Indonesia	Date of Distribution: 04 May 2023 Deadline for Comments: 02 July 2023	Drug and food materials	<p>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.</p> <p>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.</p> <p>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>
G/TBT/N/IDN/156	Indonesia	Date of Distribution: 04 May 2023 Deadline for Comments: 02 July 2023	Drug and food	<p>a. This decree is the implementing regulation of Indonesian FDA Regulation No. 27 of 2022 on Supervision of the Importation of Drug and Food into Indonesian Territory.</p> <p>b. The list of restricted drug and food importation into the territory of Indonesia which is supervised by the Indonesian FDA through the Border Import Notification Letter and the Post Border Import Notification Letter scheme.</p>

G/TBT/N/US/1058/R/ev.1/Add.3	United States	Date of Distribution: 02 May 2023 Deadline for Comments: Not Indicated	Hearing aids - Addendum	In this document, the Wireless Telecommunications Bureau (Bureau) of the Federal Communications Commission (Commission) extends the enforcement of the technical standard transition period for hearing aid compatibility by six months from 5 June 2023 to 5 December 2023.
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To access the notification form, right click the document symbol to open the hyperlink. Should you have any queries on this matter or request for full text of draft regulation in English, please do not hesitate to email us at BPS@dti.gov.ph copy bps.smd@dti.gov.ph.

Thank you.

Sincerely,

NEIL P. CATAJAY
Director

