16 May 2024

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 4 -10 May 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from the United States:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/USA/2054/Add.1	United States	**Date of Distribution:** 7 May 2024 **Deadline for Comments:** Not indicated	In vitro diagnostic test systems - Addendum	The Food and Drug Administration is issuing a final rule to amend its regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. In conjunction with this amendment, the Food and Drug Administration is phasing out its general enforcement discretion approach for laboratory developed tests (LDTs) so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs. This phaseout policy includes enforcement discretion policies for specific categories of IVDs manufactured by a laboratory, including currently marketed IVDs offered as LDTs and LDTs for unmet needs. This phaseout policy is intended to better protect the public health by helping to assure the safety and effectiveness of IVDs offered as LDTs, while also accounting for other important public health considerations such as patient access and reliance.This rule is effective 5 July 2024.
G/TBT/N/BRA/1468/Add.1	Brazil	**Date of Distribution:** 6 May 2024 **Deadline for Comments:** Not indicated	Active pharmaceutical ingredients, cannabis products for medicinal purposes, medicines and biological	Draft resolution number 1135, 23 December 2022 - previously notified through G/TBT/N/BRA/1468 - which is regarded to a regulatory proposal for the establishment of specific criteria and procedures for defining the Equivalent Foreign Regulatory Authorities of the sanitary inspection process of manufacturers of active pharmaceutical ingredients, Cannabis products for medicinal purposes, medicines and biological products, was adopted

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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)

			products - Addendum	as Normative Instruction 292, 02 May 2024.
G/TBT/N/BRA/1535	Brazil	**Date of Distribution:** 6 May 2024 **Deadline for Comments:** 16 June 2024	Accreditation and monitoring of laboratories	Public consultation that establishes the criteria and requirements for the accreditation and monitoring of laboratories by the Ministry of Agriculture and Livestock.

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,

Digitally signed by
Catajay Neil Pinuela

NEIL P. CATAJAY
Director