



03 July 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 22 to 28 June 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from Japan, Brazil, Republic of Korea and Japan:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/J PN/816	Japan	Date of Distribution: 26 June 2024 Deadline for Comments: 26 July 2024	Biological products	The Minimum Requirements for Biological Products will be amended as follows: Regarding the standard for “Freeze-dried Live Attenuated Rubella Vaccine” and “Freeze-dried Live Attenuated Measles-Rubella Combined Vaccine”, the requirements in case of using human diploid cells will be added. The Public Notice on National Release Testing will be amended as follows: The criterion for “Freeze-dried Live Attenuated Rubella Vaccine” and “Freeze-dried Live Attenuated Measles-Rubella Combined Vaccine” will be partially amended.
G/TBT/N/B RA/1410/A dd.1	Brazil	Date of Distribution: 25 June 2024 Deadline for Comments: Not indicated	Herbal medicines and traditional herbal products - Addendum	Resolution - RDC number 708, 01 July 2022 - previously notified through G/TBT/N/BRA/1410 - which contains provisions on post - approval changes of herbal medicines and traditional herbal products, was changed by Resolution 882, 14 June 2024.
G/TBT/N/K OR/1215	Republic of Korea	Date of Distribution: 25 June 2024 Deadline for Comments: 24 August 2024	In vitro diagnostic medical devices	The proposed amendments to the Regulation on In Vitro Diagnostic Medical Device Group and Class by Group is as follows: - Establishment of 6 new items (IVD reagents for concentrating hematopoietic cell, etc.)
G/TBT/N/K OR/1216	Republic of Korea	Date of Distribution: 25 June 2024 Deadline for	In vitro diagnostic medical devices	The proposed amendments to the “Regulation on In Vitro Diagnostic Medical Device Approval/Report/Review, etc.” are as follows: A. Allow occasional reporting of minor matters of in vitro diagnostic medical

BUREAU OF PHILIPPINE STANDARDS

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)



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 Para Sa Bagong Pilipinas



		Comments: 24 August 2024		devices and extend the quarterly reporting period. B. After changing in vitro diagnostic medical devices, it was not possible to manufacture (import) the existing devices, but if the change was not due to side effects, manufacture (import) of the existing devices is allowed for six (6) months.
G/TBT/N/J PN/815	Japan	Date of Distribution: 24 June 2024 Deadline for Comments: 23 July 2024	Narcotics	Under the provision of the Narcotics and Psychotropics Control Act, Ministry of Health, Labour and Welfare designates a substance as Narcotics

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

BUREAU OF PHILIPPINE STANDARDS

3/F Trade and Industry Building
 361 Sen. Gil Puyat Avenue, Makati City, 1200 Philippines
 Phone: (632) 7791.3125 / 7791.3126
 E-mail: bps@dti.gov.ph • Website: www.bps.dti.gov.ph

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