WORLD TRADE ORGANIZATION

G/TBT/N/PHL/346

27 August 2025

(25-5366)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** PHILIPPINES **If applicable, name of local government involved (Articles 3.2 and 7.2):**
2.	**Agency responsible:** ATTY. PAOLO S. TESTON Director General Food and Drug Administration DEPARTMENT OF HEALTH Email: cchuhsrr@fda.gov.ph; cchuhsrr-policy@fda.gov.ph; ntru@fda.gov.ph; bps.smd@dti.gov.ph www.fda.gov.ph
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 codes or national tariff lines. ICS numbers may be provided in addition, where applicable):** Tobacco, tobacco products and related equipment (ICS code(s): 65.160)
5.	**Details of notified document(s) (title, number of pages and languages, means of access):** Licensing Guidelines for Tobacco Product Manufacturers and Importers under the Food and Drug Administration (FDA); (26 page(s), in English) **Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request:** https://members.wto.org/crnattachments/2025/TBT/PHL/25_05696_00_e.pdf https://www.fda.gov.ph/draft-for-comments-submission-of-position-papers-on-the-draft-licensing-guidelines-for-tobacco-product-manufacturers-and-importers-under-the-food-and-drug-administration-fda/ Engr. Ana Trinidad F. Rivera, MSc Director IV Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research DEPARTMENT OF HEALTH Email: cchuhsrr@fda.gov.ph; cchuhsrr-policy@fda.gov.ph; ntru@fda.gov.ph; bps.smd@dti.gov.ph
6.	**Description of content:** The proposed issuance aims to provide the guidelines for the licensing of manufacturers and importers of tobacco products.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Under Book II article III of the IRR of RA No. 9711 Section 1, the FDA has jurisdiction over the regulation of health products. Pursuant to Section 10 (ff) of Republic Act No. 9711 "Health Products" is defined as food, drugs, cosmetics, devices, biologicals, in-vitro diagnostics reagents and household/urban hazardous substances and/or

	combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA. Furthermore, as stated under the Supreme Court Decision Gr No. 200431, the Supreme Court has recognized the FDA's authority to exercise its jurisdiction over the health aspect of tobacco products, which is not covered by any specialized laws such as RA No. 9211. In this regard, the Philippine FDA is proposing the imposition of requirements for the licensing of tobacco product manufacturers and importers. This proposed policy will establish traceability and accountability of legitimate tobacco manufacturers and importers which would help ensure that products comply with FDA regulations and protect the public. It would also help minimize or prevent the manufacture and distribution of tobacco products contaminated with foreign substances such as, but not limited to metal, glass, and plastics.; Protection of human health or safety
8.	**Relevant documents:** • Republic Act (RA) No. 9211 and its Implementing Rules and Regulations (IRR) : Tobacco Regulations Act of 2003 • RA No. 11900 and its IRR: Vaporized Nicotine and Non-Nicotine Product Regulations Act • RA No. 9711 and its IRR: The Food and Drug Administration (FDA) Act of 2009
9.	**Proposed date of adoption:** To be determined **Proposed date of entry into force:** This issuance shall take effect fifteen (15) days after publication to the Official Gazette or a newspaper of general circulation, with three (3) copies to be filed with the U.P. Law Center pursuant to Section 3, Chapter 3, Book VII of Executive Order No. 292, Series of 1987 through this Department's records officer or its equivalent functionary.
10.	**Provision of comments** **Final date for comments:** 19 September 2025 **[ ] 60 days from notification** **Contact details of agency or authority designated to handle comments regarding the notification:** Mr. Neil P. Catajay Director Bureau of Philippine Standards Department of Trade and Industry 3F Trade and Industry Building 361 Sen. Gil Puyat Avenue Makati City Philippines 1200 Tel: (632) 751 4700; (632) 7913128 Email: bps@dti.gov.ph Website: http://www.bps.dti.gov.ph