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台灣醫療暨生技器材工業同業公會
收 114. 2. 10 文
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經濟部國際貿易署　函

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受文者：台灣醫療暨生技器材工業同業公會

發文日期：中華民國114年2月6日
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主旨：有關土耳其修正玩具、衛生用品及菸酒類產品2025年進口管理規定，請查照並惠轉知會員廠商。

說明：依據駐土耳其代表處經濟組本（114）年1月28日土耳經字第1140010055號函（如附件）辦理。

訂

正本：財團法人中華民國對外貿易發展協會、台北市進出口商業同業公會、高雄市進出口商業同業公會、臺灣省進出口商業同業公會聯合會、中華民國全國工業總會、台灣區玩具暨孕嬰童用品工業同業公會、台灣區教育用品工業同業公會、臺灣自行車輸出業同業公會、台灣醫療暨生技器材工業同業公會、台灣保健營養食品工業同業公會、臺灣糖菓餅乾麵食工業同業公會、臺灣區麵粉工業同業公會、台灣菸酒股份有限公司
副本：駐土耳其代表處經濟組

線

署長 劉盛廉

檔號		保存年限
	/ /	

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訂

主旨：有關土耳其修正玩具、衛生用品及菸酒類產品2025年進口管理規定事，報請鑒察。

說明：

一、依據土耳其113年12月31日第32769(2025/10；2025/19；2025/20)號政府公報辦理。

經濟部貿易署

二、土國政府公告修正旨述產品進口管理規定，相關規定均自2025年1月1日起實施:

(一)玩具進口管理規定(2025/10)：

1、貨物進口前需透過土國線上風險管理系統TAREKS申請獲得參考號碼；範圍涵蓋玩具染料、兒童遊戲黏土、玩具文具及特定規格自行車等共56項產品，進口商需在報關前完成相關程序。

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國際貿易署　114/02/02
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2、業者於2025年1月1日生效前已完成出口運送文件或已向土國海關申報之產品，在進口商申請下，可於2025年2月28日(含當天)依原規定辦理。

(二)醫療衛生產品進口管理規定(2025/20)：

1、進口產品需取得土耳其衛生部核發之管制證明，有效期12個月；進口時需檢附原產地衛生證明及分析報告；特殊情況則可申請緊急進口許可。主要管制品涵蓋人用藥品、原料藥、特殊醫療用途食品及包裝飲用水等項目。

2、業者於2025年1月1日生效前已完成出口運送文件或已向土國海關申報之產品，可於生效後45天內依原規定辦理；至原核發之管制證明於有效期內仍然有效。

(三)菸酒類產品進口管理規定(2025/19)：

1、進口產品需取得土耳其農林部菸酒局核發之符合性證明，酒精類產品則需另做進口申報。管制範圍涵蓋乙醇、菸草及其製品、菸紙、菸嘴，以及供零售的酒類飲品。除特別規定外(如純酒精得在海關特殊監管程序下進口、特定菸草得以研究測試為目的進口等)，所有產品必須包裝完整、可直接零售方可進口。

2、本修正規定自2025年1月1日生效，未訂定過渡期。

三、檢送上述土國政府公報與其附件(管制產品清單)原文，以及本組摘譯之英文版1份如附，併請鑒察。

正本：經濟部國際貿易署
副本：電子公文交換章 2025/02/02 11:55:07

TUESDAY, 31 December 2024 Official Gazette Number: 32769 (4. Duplicate)

NOTIFICATION

From the Ministry of Trade:

NOTIFICATION ON IMPORT INSPECTION OF TOYS

(PRODUCT SAFETY AND INSPECTION: 2025/10)

Purpose and Scope

ARTICLE 1- (1) The purpose of this Communiqué is to regulate the procedures and principles regarding the inspection of compliance of the products listed in Annex-1 with the Toy Safety Regulation published in the Official Gazette dated 4/10/2016 and numbered 29847.

(2) This Communiqué covers products subject to the Release for Free Circulation Regime.

(3) This Communiqué does not cover goods exported under the Inward Processing Regime and returned.

Basis

ARTICLE 2- (1) This Communiqué has been prepared based on Article 455 of Presidential Decree No. 1 on the Presidential Organization, the Product Safety and Technical Regulations Law No. 7223 dated 5/3/2020, the Technical Regulations Regime Decision enacted by Presidential Decision No. 6038 dated 14/9/2022, and the Regulation on Technical Regulations in Foreign Trade published in the Official Gazette dated 16/8/2023 and numbered 32281.

Definitions

ARTICLE 3- (1) In this Communiqué:

a) A.TR Circulation Certificate: A document issued and endorsed by the customs administration or authorized institutions to ensure that goods in free circulation in Turkey or the European Union benefit from preferential treatment under the Customs Union.

b) Ministry: The Ministry of Trade.

c) Inspection Unit: The Product Safety Inspections Directorates under the Regional Directorates of the Ministry responsible for product safety inspections.

ç) Foreign Trade Risk-Based Control System (TAREKS): An internet-based application established to conduct inspections, conformity, and authorization processes electronically and based on risk analysis in accordance with the Product Safety and Technical Regulations Legislation.

d) Physical Inspection: One or more of document control, marking control, physical examination, and laboratory testing.

e) Returned goods: Previously exported goods that have been returned for the reasons defined in Article 446, Paragraph 1, Subparagraphs (a), (b), and (c) of the Customs Regulation published in the Official Gazette dated 7/10/2009 and numbered 27369.

f) Out of scope: Products that fall under the GTIP listed in Annex-1 but are not covered by the Toy Safety Regulation or are not targeted for inspection under this Communiqué by the Ministry.

g) User: Persons authorized to perform transactions on behalf of companies via TAREKS.

ğ) Risk: The possibility that products within the scope of this Communiqué do not comply with the Toy Safety Regulation.

h) Risk analysis: The process carried out in TAREKS to determine the risk level of products listed in Annex-1 and whether they should be directed to physical inspection based on company information, past import inspections, market surveillance and inspection results, manufacturer or importer company or user, customs entry, product type, brand, model, price, quantity, country of origin, dispatch, or trade, and other available data for risk assessment.

TAREKS and Company Registration

ARTICLE 4- (1) All transactions related to the import inspection of toys are conducted via TAREKS and based on risk analysis.

(2) Companies intending to import products within the scope of this Communiqué must be registered in TAREKS under the Foreign Trade Risk-Based Control System Communiqué (Product Safety and Inspection: 2011/53) published in the Official Gazette dated 29/12/2011 and numbered 28157, and at least one user must be authorized to conduct transactions on behalf of the company in TAREKS.

Importer Application

ARTICLE 5- (1) Inspections within the scope of this Communiqué are conducted before the registration of the customs declaration under Article 181, Paragraph 4 of the Customs Regulation.

(2) The user submits an application via TAREKS by entering information about the import consignment and uploading the documents specified in Article 1 and 2 of Annex-2 through the "Foreign Trade Risk-Based Control System (TAREKS) Application" section on the Ministry's website or via the e-Government portal.

(3) Upon application, TAREKS assigns an application number to the company to track its processes with the relevant inspection unit.

(4) The company and the user are responsible for the accuracy, completeness, and timely submission of the declared information and documents.

Exemptions and Exceptions

ARTICLE 6- (1) For products declared by the user in TAREKS with an A.TR Circulation Certificate, a TAREKS reference number confirming the product's import eligibility is directly generated.

(2) No application is required through TAREKS for returned goods previously exported for the reasons defined in Article 446, Paragraph 1, Subparagraphs (a), (b), and (c) of the Customs Regulation, and import procedures are concluded in accordance with Article 11.

(3) No application is required through TAREKS for the import of goods specified in Part Five of the Decision on the Implementation of Certain Provisions of the Customs Law No. 4458, enacted by the Council of Ministers Decision No. 2009/15481 dated 29/9/2009, and import procedures are concluded in accordance with Article 11.

(4) Products within the scope of Paragraph 1 may also be directed to physical inspection based on risk analysis.

Scope Exclusion

ARTICLE 7- (1) The declaration of scope exclusion for the subject import batch shall be submitted by the importing company to the relevant customs administration. The assessment of the scope exclusion decision is primarily conducted by the relevant customs administration.

(2) If the relevant customs administration determines that the subject import batch falls within the scope of this Communiqué, the scope evaluation may also be determined based on the technical examination conducted by the relevant inspection unit.

Risk Analysis

ARTICLE 8- (1) Products directed for physical inspection are determined based on risk analysis within the framework of the information declared by users through TAREKS.

(2) The criteria to be used in risk analysis shall be determined by the Ministry, taking into account the opinions of other relevant parties when deemed necessary.

(3) With the provision of data flow between TAREKS and the National Market Surveillance and Inspection Information System (PGDBİS), data related to market surveillance and inspection of products within the scope of this Communiqué, as well as import inspections, shall be transmitted to PGDBİS.

(4) For products not directed for physical inspection as a result of risk analysis, a TAREKS reference number indicating their eligibility for import shall be generated directly.

Physical Inspection

ARTICLE 9- (1) The documents specified in Articles 3, 4, 5, and 6 of Annex-2 for products directed for physical inspection shall be uploaded to TAREKS electronically within twenty working days, including the application date. Additional time may be granted by the system if requested. If the relevant documents are not uploaded within the specified period, the application will result in a negative outcome.

(2) Additional information and documents may be requested from companies.

(3) If no non-compliance with the relevant legislation is detected during the physical inspection or if the product is determined to be out of scope, a TAREKS reference number indicating the product's eligibility for import is generated.

(4) If non-compliance with the relevant legislation is detected or the requested additional information and documents are not uploaded to TAREKS within the given time, the physical inspection will result in a negative outcome.

(5) If it is determined that the Declaration of Conformity, test report, or other documents requested by the inspection unit uploaded to TAREKS were not issued by the relevant party, the physical inspection will result in a negative outcome even if other conditions are met.

Notifications to the User

ARTICLE 10- (1) Inquiries related to the inspection process and results shall be conducted through TAREKS.

(2) Notifications regarding the inspection process and results shall be sent to the email address provided by users in the "Authorization Applications" section under the Communiqué on Risk-Based Control System in Foreign Trade (Product Safety and Inspection: 2011/53). The Ministry is not responsible for notifications that do not reach the user.

(3) In case of non-compliance with the legislation during the inspection, the situation shall also be notified in writing and through the system to the relevant customs administration.

Declaration of TAREKS Reference Number to Customs

ARTICLE 11- (1) It is mandatory for the importing company to record the TAREKS reference number indicating the product's eligibility for import in box 44 of the customs declaration.

(2) The TAREKS reference number is valid for one year from the date of issuance.

(3) For products declared to customs as out of scope, the 23-digit TAREKS reference number 18100099222013015773484 shall be recorded in box 44 of the customs declaration by the importing company. If such products are directed for inspection by the relevant customs administration while under customs supervision, an application shall be submitted via TAREKS within the framework of Article 5.

(4) If it is determined that products listed in the annex to this Communiqué as a result of a GTIP change are under customs supervision, an application shall be submitted via TAREKS within the framework of Article 5.

(5) For imports of goods specified in the fifth section of the Decision on the Implementation of Certain Articles of Customs Law No. 4458, the 23-digit TAREKS reference number 18100099110115014436576 shall be recorded in box 44 of the customs declaration.

(6) For the import of returned goods, the 23-digit TAREKS reference number 24100099910333534943036 shall be recorded in box 44 of the customs declaration.

Responsibility of the Importer

ARTICLE 12- (1) Whether subject to inspection under this Communiqué or not, the importer is responsible for ensuring that imported products comply with all relevant legislation, including the Toy Safety Regulation, and are safe, and for the accuracy of accompanying documents under Law No. 7223.

(2) The permission for the import of a product or the issuance of a TAREKS reference number does not imply compliance with legislation and/or safety.

(3) The TAREKS reference number issued for the product under this Communiqué cannot be used for purposes other than import processing or as proof of the product's compliance and safety.

(4) If it is determined through subsequent inspections that the GTIP of the imported product is listed in Annex-1, the situation shall be reported to the Ministry's Directorate General for Consumer Protection and Market Surveillance by the relevant customs administration. If the relevant unit determines that the product is unsafe and notifies the customs administration, it will be considered non-compliant.

Sanctions

ARTICLE 13- (1) Those who act contrary to this Communiqué, make false or misleading declarations, falsify or submit falsified documents specified in Annex-2 or requested during the inspection process, shall be subject to the provisions of Law No. 7223, Customs Law No. 4458 dated 27/10/1999, the Technical Regulations Regime Decision, and other relevant legislation.

(2) In inspections conducted via TAREKS, the authorization of users acting contrary to the legislation, the provisions of this Communiqué, and its implementations shall be suspended for 3 to 12 months depending on the severity of the violation; the company's inspection applications shall be directed to physical inspection for 6 to 12 months. These sanctions shall be determined by considering factors such as the frequency of applications, previous violations, and the nature of the product.

Authority

ARTICLE 14- (1) The Directorate General of Product Safety and Inspection of the Ministry is authorized to take measures and make regulations regarding the implementation of the issues covered in this Communiqué.

Repealed Communiqué

ARTICLE 15- (1) The Communiqué on Import Inspection of Toys (Product Safety and Inspection: 2024/10), published in the Official Gazette No. 32416 dated 31/12/2023, is repealed.

Effective Date

ARTICLE 16- (1) This Communiqué shall enter into force on 1/1/2025.

Execution

ARTICLE 17- (1) The provisions of this Communiqué shall be executed by the Minister of Trade.

ANNEX-1
LIST OF PRODUCTS SUBJECT TO INSPECTION UNDER THE TOY SAFETY REGULATION

Customs Tariff Statistical Position	Product Definition
3213.10.00.00.00	Paint sets (excluding those for artistic activities and professional products)
3213.90.00.00.00	Others (excluding those for artistic activities and professional products)
3407.00.00.90.12	Modeling pastes (only those prepared for children's play)
3924.10.00.00.39	Others (only toy-like ones)
3926.10.00.00.00	School and office supplies (only toy-like ones)
4016.92.00.00.00	Erasers (only toy-like ones)
4202.22.10.00.00	Made of plastic sheets (only toy-like ones)
4202.22.90.90.00	Others (only toy-like ones)
4202.32.10.00.00	Made of plastic sheets (only toy-like ones)
4202.32.90.90.00	Others (only toy-like ones)
4820.10.90.00.11	School notebooks (only toy-like ones)
7323.93.00.00.00	Made of stainless steel (only toy-like ones)
8213.00.00.10.19	Others (only toy-like ones)
8214.10.00.00.12	Pencil sharpeners (only toy-like ones)
8472.90.80.90.12	Hole punchers or staplers (only toy-like ones)
8505.11.10.00.00	Containing neodymium, praseodymium, dysprosium, or samarium (only toy magnets)
8505.11.90.00.00	Others (only toy magnets)
8505.19.10.00.00	Permanent magnets made of agglomerated ferrite (only toy magnets)
8505.19.90.00.00	Others (only toy magnets)
8712.00.30.00.00	Bicycles with ball bearings (seat height less than 435 mm)
8712.00.70.00.11	Without ball bearings (seat height less than 435 mm)
8712.00.70.00.19	Others (seat height less than 435 mm)
9503.00.10.11.00	Strollers for dolls
9503.00.10.12.00	Tricycles
9503.00.10.19.11	Scooters
9503.00.10.19.19	Others
9503.00.21.00.00	Dolls
9503.00.29.00.00	Components, parts, and accessories

Customs Tariff Statistical Position	Product Definition
9503.00.30.00.00	Electric trains (including tracks, signals, and other accessories)
9503.00.35.00.00	Made of plastic materials
9503.00.39.00.00	Made of other materials
9503.00.41.00.00	Stuffed toys
9503.00.49.00.00	Others (excluding swimming seats)
9503.00.55.00.00	Toy musical instruments and devices
9503.00.61.00.00	Made of wood
9503.00.69.00.00	Others
9503.00.70.00.00	Other toys (sets or kits)
9503.00.75.00.00	Made of plastic materials
9503.00.79.00.00	Made of other materials
9503.00.81.00.00	Toy guns
9503.00.85.00.00	Molded miniature metal models
9503.00.87.00.00	Portable interactive electronic educational devices primarily designed for children
9503.00.95.00.00	Made of plastic materials (excluding swimming seats)
9503.00.99.00.00	Others
9504.90.10.00.00	Electric racing cars in sets (with racing game features)
9504.90.80.00.00	Others
9506.70.30.00.00	Roller skates
9608.10.10.10.00	Made of plastic materials (only toy-like ones)
9608.10.10.90.00	Others (only toy-like ones)
9608.20.00.10.00	Made of plastic materials (only toy-like ones)
9609.10.10.00.00	"Leads" made of graphite (only toy-like ones)
9609.10.90.00.00	Others (only lead pencils)
9609.20.00.00.00	Black or colored pencil leads (only toy-like ones)
9609.90.10.00.00	Pastels and charcoal pencils (only pastel paints)
9609.90.90.00.00	Others (only chalks for children's use)
9617.00.00.00.12	Thermos flasks and other vacuum containers (only toy-like ones)

ANNEX-2
DOCUMENTS TO BE UPLOADED TO TAREKS

1. Customs documents applicable to the goods (*):

- Summary Declaration, TIR Carnet, Transit Accompanying Document, or Transport Document (Bill of Lading, CMR Document, CIM Transport Document), in cases where the goods are under temporary storage or subject to simplified procedures.
- Free Zone Transaction Form, Status Document (if the goods are in the Free Zone).
- Previous customs regime-related Customs Declaration (e.g., warehouse and temporary importation).
- Customs Declaration (if deemed necessary under Articles 11, paragraphs three and four).
- Invoice or proforma invoice (*).
- EU Declaration of Conformity (if issued in other languages, accompanied by an approved Turkish translation) (*).
- Test reports proving compliance with the Toy Safety Regulation published by the Ministry of Commerce on October 4, 2016, in the Official Gazette No. 29847, either the original reports issued by an accredited laboratory or copies approved by the testing laboratory.
- Test reports demonstrating compliance with chemicals restrictions in toys as per the Regulation on the Registration, Evaluation, Authorization, and Restriction of Chemicals published on June 23, 2017, in the Official Gazette No. 30105, either the original reports issued by an accredited laboratory or copies approved by the testing laboratory.
- Photographs of the imported product taken in the customs area.

- The originals or certified copies of the documents must be submitted upon request by the relevant inspection authority.

TUESDAY, 31 December 2024 Official Gazette Number: 32769 (4. Duplicate)

NOTIFICATION

From the Ministry of Trade:

NOTIFICATION ON IMPORT INSPECTION OF SOME PRODUCTS INSPECTED BY THE MINISTRY OF HEALTH

(PRODUCT SAFETY AND INSPECTION: 2025/20)

Purpose

Article 1 - (1) The purpose of this Communiqué is to regulate the procedures and principles for conformity inspections in terms of human health and safety during the importation of the products listed in Annex-1/A, Annex-1/B, Annex-1/C, and Annex-2.

Scope

Article 2 - (1) This Communiqué covers the procedures and principles regarding the importation of the products listed in Annex-1/A, Annex-1/B, Annex-1/C, and Annex-2 that are subject to the Free Circulation Regime.

Legal Basis

Article 3 - (1) This Communiqué has been prepared based on Article 455 of Presidential Decree No. 1 on the Presidential Organization, the Technical Regulations Regime Decision enforced by Presidential Decision No. 6038 dated 14/9/2022, and the Regulation on Technical Regulations in Foreign Trade published in the Official Gazette No. 32281 dated 16/8/2023.

Import Inspection and Certification

Article 4 –(1) For products listed in Annex-1/A, Annex-1/B, Annex-1/C, and Annex-2, if imported for the purposes specified for them, compliance with human health and safety is documented with a Control Certificate based on documents submitted to the Ministry of Health.

(2) The Control Certificate for the products within the scope of this Communiqué must be presented to the relevant customs authority by the importer or their representative at the time of registration of the customs declaration.

(3) The validity of the Control Certificate is twelve months. However, it may be canceled before its expiration upon the request of the certificate holder or under circumstances prescribed by the relevant legislation of the Ministry of Health.

(4) For products listed in Annex-1/A that require special permits after review by the Ministry of Health (Turkish Medicines and Medical Devices Agency), the provisions of the Import Inspection Communiqué for Substances Subject to Special Permits of the Ministry of Health (Product Safety and Inspection: 2025/4) apply.

(5) Applications for vaccines, antidotes, and serums necessary for sustaining public health services and supplied free of charge may be submitted to the General Directorate of Public Health only for finished products.

Application

Article 5 –(1) To obtain a Control Certificate, the following documents must be submitted to the Ministry of Health before importation:

a. Application letter.

b. Control Certificate form (in triplicate) for products listed in Annex-2, as per Annex-3.

c. Proforma invoice or invoice.

ç. Analysis certificate for products listed in Annex-1/C and Annex-2.

d. Health certificate approved by the competent authority of the country of origin, along with its translation, for products listed in Annex-1/C and Annex-2.

(2) The Control Certificate can be issued electronically through the Single Window System in line with Circular No. 2016/16 published by the Ministry of Trade.

(3) For subsequent imports of products listed in Annex-1/C and Annex-2 that share the same specifications, country of origin, and exporting company as a previously certified product, the health certificate submitted for the earlier Control Certificate will apply. However, the Ministry may request renewal of the health certificate if deemed necessary.

(4) The Ministry of Health may require additional information and documents for the importation of products within the scope of this Communiqué as necessary.

Information Form

Article 6 –(1) Pharmaceutical manufacturers or suppliers importing raw or starting materials for medicinal preparations used in the pharmaceutical industry must submit copies of the customs declaration and invoice along with an electronic import feedback form to the Turkish Medicines and Medical Devices Agency within 30 days after importation.

(2) For medicinal preparations/products listed in Annex-1/A, Annex-1/B, and Annex-1/C, importers must submit copies of the customs declaration and invoice via the electronic import feedback form to the Turkish Medicines and Medical Devices Agency within 15 days after importation.

(3) Manufacturers importing raw and auxiliary materials for Special Medical Purpose Foods (ÖTAG) must submit copies of the customs declaration and invoice along with an electronic import feedback form to the Turkish Medicines and Medical Devices Agency within 30 days after importation.

Exemptions and Exceptions

Article 7 – (1) This Communiqué does not apply to the following personal items, samples, and returned goods:

a. Personal items: Products that, given their purpose and quantity, are not deemed to be imported for commercial purposes and are intended solely to meet a personal need unrelated to professional or commercial activities. For these products, reference number 2517199991712379051288 3 must be recorded by the importer in field 44 of the Customs Declaration.

b. Samples: Items representing a specific type or quality of goods that, by their presentation or quantity, cannot be used for purposes other than placing an order. For these products, reference number 2527299992712478041289 2 must be recorded by the importer in field 44 of the Customs Declaration. For pesticides and pesticide-like substances used in public health, sample quantities are limited to 10 kg/L.

c. Returned goods: Exported goods returned to the Turkish Customs Region for reasons such as:

1) Being unable to enter free circulation or be placed on the market in the destination country due to prevailing regulations.

2) Being rejected by the buyer due to defects or non-compliance with contract terms.

3) Being unable to fulfill its intended purpose due to reasons beyond the exporter's control.

Evidence for these situations must be provided to the customs authority with documents obtained from the buyer or relevant authorities outside the Turkish Customs Region. For these products, reference number 2537399993712577031287 1 must be recorded by the importer in field 44 of the Customs Declaration.

Customs Procedures

Article 8 - (1) The Control Certificate issued by the Ministry of Health is recorded in the customs declaration at the time of registration. The importer or their representative is responsible for submitting the Control Certificate to the relevant customs authority.

(2) In procedures under the first paragraph, the declaration by the importer or their representative is essential. If it is determined that false or misleading information has been provided, the provisions of Article 9 shall apply.

Sanctions

Article 9 - (1) Those who act in violation of this Communiqué, provide false or misleading declarations, use, present, or falsify fraudulent documents are subject to the provisions of the Product Safety and Technical Regulations Law No. 7223 dated 5/3/2020, the Customs Law No. 4458 dated 27/10/1999, the relevant provisions of the Technical Regulations Regime Decision, the related regulations published by the Ministry of Health, and other applicable legislation.

Data Notification

Article 10 – (1) Information and documents regarding the importation of products within the scope of this Communiqué may be requested by the Ministry of Health from the Ministry of Trade if deemed necessary.

Measures for Implementation

Article 11 – (1) The General Directorate of Product Safety and Inspection of the Ministry of Trade is authorized to take measures and make arrangements regarding the implementation of matters stated in this Communiqué.

Repealed Communiqué

Article 12 –(1) The Communiqué on Import Inspection of Certain Products Monitored by the Ministry of Health (Product Safety and Inspection: 2024/20), published in the Official Gazette No. 32416 (Fourth Repetition) dated 31/12/2023, has been repealed.

Transition Period

Provisional Article 1 –(1) For products for which a transport document has been issued in the country of origin for export purposes or submitted to customs authorities under customs legislation before the effective date of this Communiqué, their importation will be subject to the provisions of the repealed Communiqué on Import Inspection of Certain Products Monitored by the Ministry of Health (Product Safety and Inspection: 2024/20) for a period of forty-five days from the effective date of this Communiqué. However, the favorable provisions of this Communiqué shall apply to such transactions.

(2) Control Certificates obtained under the repealed Communiqué on Import Inspection of Certain Products Monitored by the Ministry of Health (Product Safety and Inspection: 2024/20) will remain valid for the duration specified in that Communiqué, starting from the date they were issued.

Entry into Force

Article 13 –(1) This Communiqué enters into force on 1/1/2025.

Execution

Article 14 –(1) The provisions of this Communiqué shall be executed by the Minister of Trade.

Annex-1/A

Relevant Unit: Turkish Medicines and Medical Devices Agency

No	Customs Tariff Position (CTP)	Substance Name	Purpose of Use
1	1211.20.00.00.00	Ginseng root	Solely for medical and pharmaceutical products, intermediary products used in human health as "natural (plant-based, animal-based, mineral, etc.) and other pharmaceutical products that are auxiliary in treatment and protective for health" (excluding those used for laboratory analysis or for medicinal research purposes).
2	1504.10.10.10.00	Used in medicine	Same as above.
3	1504.10.10.90.00	Others	Same as above.
4	1504.20.90.00.00	Others	Same as above.
5	2106.10.20.00.19	Others	Same as above.
6	2106.90.92.00.00	Solid milk fat, sucrose, isoglucose, starch, or glucose content < specified thresholds	Same as above, excluding products under the Medical Devices Regulation.
7	2106.90.98.00.19	Others	Same as above.
8	2404.91.10.00.00	Nicotine-containing products to aid tobacco cessation	Solely human medicinal products, excluding those for laboratory analysis or under the Medical Devices Regulation.
9	2404.92.00.00.00	For transdermal use	Same as above.
10	3002.12.00.00.1P	Snake serum	Only anti-serum used in the human body, excluding for laboratory analysis or medicinal research purposes.
11	3002.12.00.00.19	Others	Same as above.
12	3002.12.00.00.22a	Blood globulins	Same as above.
13	3002.12.00.00.29	Others	Only medicinal products based on blood components applied to the human body, excluding for laboratory analysis or research purposes.
14	3002.15.00.00.00	Packaged/Prepared Immunological Products	Same as above.
15	3002.41.10.00.00	SARS-related coronavirus vaccines (SARS-CoV types)	Solely vaccines applied to the human body, excluding for laboratory analysis or medicinal research purposes.

No	Customs Tariff Position (CTP)	Substance Name	Purpose of Use
16	3002.41.90.10.00	Polio vaccines	Same as above.
17	3002.41.90.20.11	Measles vaccines	Same as above.
18	3002.41.90.20.12	Mumps vaccines	Same as above.
19	3002.41.90.20.13	BCG vaccines	Same as above.
20	3002.41.90.20.14	DPT combination vaccines	Same as above.
21	3002.41.90.20.15	Cholera vaccines	Same as above.
22	3002.41.90.20.16	Typhoid vaccines	Same as above.
23	3002.41.90.20.19	Others	Same as above.

Note: For products under the supervision of the Ministry of Agriculture and Forestry, there is no need to apply to the Ministry of Health under this Communiqué.

Ministry of Agriculture and Forestry Note: For products under the supervision of the Ministry of Agriculture and Forestry, there is no need to apply to the Ministry of Health under this Communiqué.

No	Customs Tariff Position (CTP)	Substance Name	Purpose of Use
24	3002.49.00.00.00a	Others	Only human medicinal products and intermediary products used in human health, "other pharmaceutical products that aid in treatment and protect health" (excluding products under the Medical Devices Regulation or those for laboratory analysis or research purposes).
25	30.03a	Medicinal mixtures for treatment or prevention, containing two or more elements (excluding those under CTP 30.02, 30.05, or 30.06) (not pre-dosed or packaged for retail).	Only combinations of substances used in human medicinal products (excluding products under the Medical Devices Regulation or those for laboratory analysis or research purposes).
26	30.04	Medicinal products, mixed or not, for treatment or prevention (excluding items under CTP 30.02, 30.05, or	Only human medicinal products (excluding products under the Medical Devices Regulation or those for laboratory analysis or research

No	Customs Tariff Position (CTP)	Substance Name	Purpose of Use
		30.06) (including transdermal administration systems), pre-dosed or packaged for retail.	purposes).
27	3006.30.00.00.11	Diagnostic reagents prepared for application to patients	Only human medicinal products (excluding products for laboratory analysis or research purposes, or those under the Medical Devices Regulation).
28	3006.30.00.00.12	Preparations opaque to X-rays for radiographic examinations	Same as above.
29	3006.60.00.00.00	Hormone-based contraceptives and spermicides	Only human medicinal products applied to the body (excluding products for laboratory analysis or research purposes, or those under the Medical Devices Regulation).
30	3301.90.90.90.00a	Others	Only medical and pharmaceutical products, intermediary products used in human health as "natural and other pharmaceutical products that aid in treatment and protect health" (excluding products under the Medical Devices Regulation or those for laboratory analysis or research purposes).

Annex 1/B

Relevant Unit: Turkish Medicines and Medical Devices Agency

No	Customs Tariff Position (CTP)	Substance Name	Purpose of Use
1	28.44	Radioactive chemical elements and isotopes, mixtures, or residues containing them	Only human medicinal products and combinations of substances used in human medicinal products (excluding products under the Medical Devices Regulation).
2	2918.99.90.00.14	Misoprostol	Only substances used in human medicinal products.
3	2921.49.00.00.39	Other aromatic monoamines and derivatives; salts (only Sibutramine)	Same as above.
4	2922.19.00.00.21	Bornaprine	Same as above.

No	Customs Tariff Position (CTP)	Substance Name	Purpose of Use
5	2922.19.00.00.22	Cyclopentolate	Same as above.
6	2922.19.00.00.23	Cyclopentolate hydrochloride	Same as above.
7	2922.19.00.00.28a	Others (only Dapoxetine, Diphenhydramine)	Same as above.
8	2922.49.85.90.36a	Gabapentin	Same as above.
9	2922.50.00.90.19	Others (only Phenylephrine)	Same as above.
10	2924.29.70.00.24	Acetophenetidin (p-ethoxyacetanilide, phenacetin)	Same as above.
11	2930.90.95.90.68	Others (only Armodafinil)	Same as above.
12	2933.39.99.00.22	Tropicamide	Same as above.

Products Monitored by the Ministry of Agriculture and Forestry

For the products within the scope of this notification, there is no need to apply to the Ministry of Health separately.

Table of Substances for Human Medicinal Products:

No	HS Code	Substance Name	Purpose of Use
13	2933.59.95.00.34	Buspirone (INN)	Substances used solely in human medicinal products
14	2933.59.95.00.38	Others (Only Avanafil)	Substances used solely in human medicinal products
15	2933.99.80.90.43	Benzydamine	Substances used solely in human medicinal products
16	2933.99.80.90.44	Benzydamine Hydrochloride	Substances used solely in human medicinal products
17	2934.99.90.90.27	Others (Only Tadalafil)	Substances used solely in human medicinal products
18	2935.90.90.00.29	Others (Only Sildenafil, Vardenafil, Udenafil)	Substances used solely in human medicinal products
19	2937.29.00.00.19a	Others (Only Mifepristone)	Substances used solely in human medicinal products
20	2937.50.00.00.00a	Prostaglandins, Thromboxanes, and Leukotrienes (Only Alprostadil)	Substances used solely in human medicinal products

No	HS Code	Substance Name	Purpose of Use
21	2938.90.90.90.19	Others (Only Modafinil)	Substances used solely in human medicinal products
22	2939.59.00.00.12	Dimenhydrinate	Substances used solely in human medicinal products
23	2939.79.90.90.17a	Hyoscine (Scopolamine)	Substances used solely in human medicinal products
24	2939.79.90.90.29	Others (Only Yohimbine)	Substances used solely in human medicinal products

Special Medical Purpose Foods:

For products monitored by the Ministry of Agriculture and Forestry, there is no need to apply to the Ministry of Health separately.

No	HS Code	Substance Name	Purpose of Use
1	1108.12.00.90.00	Others	Special medical purpose foods
2	1516.10.10.00.19	Others	Special medical purpose foods
3	1702.30.90.00.00	Others	Special medical purpose foods
4	1702.90.50.00.19a	Others	Special medical purpose foods
5	18.06a	Chocolate and other cocoa-based food preparations	Special medical purpose foods
6	1901.10.00.11.00	Dietary formulas	Special medical purpose foods
7	1901.10.00.19.00	Others	Special medical purpose foods
8	1901.10.00.90.00	Others	Special medical purpose foods
9	1901.90.99.90.11	Low-protein flour for phenylketonuria patients	Special medical purpose foods
10	1901.90.99.90.12	Low-protein rice for phenylketonuria patients	Special medical purpose foods
11	1901.90.99.90.13	Egg substitute for phenylketonuria patients	Special medical purpose foods
12	1901.90.99.90.19a	Others	Special medical purpose foods

No	HS Code	Substance Name	Purpose of Use
13	1902.19.10.00.11	Low-protein pasta for phenylketonuria patients	Special medical purpose foods
14	1902.19.90.00.13	Low-protein pasta for phenylketonuria patients	Special medical purpose foods
15	1905.31.99.00.13	Low-protein biscuits for phenylketonuria patients	Special medical purpose foods
16	1905.32.99.00.11	Low-protein wafers for phenylketonuria patients	Special medical purpose foods
17	1905.90.55.00.00	Flavored or salted products	Special medical purpose foods
18	1905.90.70.00.17	Low-protein products for phenylketonuria patients	Special medical purpose foods
19	1905.90.70.00.19a	Others	Special medical purpose foods
20	1905.90.80.00.13a	Low-protein products for phenylketonuria patients	Special medical purpose foods
21	1905.90.80.00.19a	Others	Special medical purpose foods
22	2104.10.00.00.12	Soups	Special medical purpose foods
23	2106.10.20.00.11	Dietary formulas	Special medical purpose foods
24	2106.10.20.00.19	Others	Special medical purpose foods
25	2106.10.80.00.11	Dietary formulas	Special medical purpose foods
26	2106.10.80.00.19	Others	Special medical purpose foods
27	2106.90.92.00.00	Products with limited milk fat, sugar, or starch content	Special medical purpose foods
28	2106.90.98.00.16a	Dietary formulas	Special medical purpose foods
29	2106.90.98.00.19	Others	Special medical purpose foods

Products Monitored by the Ministry of Agriculture and Forestry

For products under the scope of this notification, it is not necessary to apply separately to the Ministry of Health.

Table of Substances for Special Medical Purpose Foods:

No	HS Code	Substance Name	Purpose of Use
30	2202.99.11.00.00a	Others	Special medical purpose foods
31	2202.99.15.00.00a	Others	Special medical purpose foods
32	2202.99.19.00.00a	Others	Special medical purpose foods
33	2202.99.91.00.00a	Others	Special medical purpose foods
34	2202.99.95.00.00	Others	Special medical purpose foods
35	2202.99.99.00.00a	Others	Special medical purpose foods
36	2924.19.00.00.17a	Glutamine	Special medical purpose foods
37	3504.00.10.00.00	Concentrated milk proteins (as defined in Chapter Note 1)	Special medical purpose foods
38	3505.10.50.00.00a	Esterified or etherified starches	Special medical purpose foods
39	3505.10.90.00.19a	Others	Special medical purpose foods

Annex-2

Responsible Unit: Directorate General of Public Health

No	HS Code	Substance Name	Purpose of Use
1	22.01b	Water (including natural or artificial mineral waters and carbonated waters, not containing added sugar or other sweeteners, nor flavored); ice and snow (excluding ice and snow)	For human consumption

Note: Products or goods under the monitoring scope of the Ministry of Agriculture and Forestry are excluded.

Annex-3: CONTROL CERTIFICATE

Republic of Turkey
Ministry of Health

Control Certificate

Field	Description
Substance Name (1):	...
Goods HS Code (2):	...
List the goods belong to:	...
Importer's trade name, address, phone number:	...
Importer's tax office and registration number:	...
Exporter's trade name and address:	...
Place of use for the goods:	...
Quantity of the goods:	...
Country of origin of the goods:	...
Country where goods will be shipped:	...
Customs entry location:	...
Trade name, address, phone number of the using company:	...

Select the applicable specifications by circling the respective letter(s):

- A: European Union specifications
- B: FDA specifications
- C: World Health Organization specifications
- D: Complies with the provisions of Law No. 5996 on Veterinary Services, Plant Health, Food, and Feed

Additional Notes:

- If the proforma invoice covers multiple products under a single name, their original names must be specified separately.
- The determination of the HS Code is not the responsibility of the Ministry of Health.

We hereby declare that the information provided in this form is accurate and complete. We commit to conducting the import process in accordance with the provisions of the Import Inspection Communiqué (Product Safety and Inspection: 2025/20) and certify the health and safety compliance of the products covered by the attached approved invoice.

| Company Seal | Name and Surname of Authorized Person | Signature |

The inspection carried out under the relevant communiqué provisions concludes that the importation of the substance covered by the attached approved invoice is deemed suitable.

This document is prepared for submission to the relevant customs office.

| Signature and Seal | Date |

TUESDAY, 31 December 2024 Official Gazette Number: 32769 (4. Duplicate)

NOTIFICATION

From the Ministry of Trade:

NOTIFICATION ON IMPORT CONTROL OF TOBACCO, TOBACCO PRODUCTS, ALCOHOL AND ALCOHOLIC BEVERAGES

(PRODUCT SAFETY AND CONTROL: 2025/19)

Purpose

Article 1 – (1) The purpose of this Communiqué is to establish the procedures and principles regarding the documentation of compliance of the products listed in Annex-1 with the relevant technical regulations, the notification of the products listed in Annex-2, and their inspection.

Scope

Article 2 – (1) This Communiqué covers the procedures and principles related to the importation of substances listed in the attached schedules under the Customs Procedures for Release for Free Circulation, Inward Processing Regime, Outward Processing Regime, Processing Under Customs Control, and Temporary Importation Regime.

Legal Basis

Article 3 – (1) This Communiqué has been prepared based on Article 455 of the Presidential Decree No. 1 on the Presidential Organization, the Technical Regulations Regime Decision enacted by Presidential Decision No. 6038 dated 14/9/2022, and the Regulation on Technical Regulations in Foreign Trade published in the Official Gazette No. 32281 dated 16/8/2023.

Compliance Inspection and Certification

Article 4 – (1) With the Decision on the Procedures and Principles Regarding the Importation of Cigars and Cigarillos, Determination of Their Prices and Domestic Marketing of the products listed in the Annexes, put into effect by the Decision of the Council of Ministers dated 31/3/2008 and numbered 2008/13482; Products listed in the annexed schedules must comply with the provisions of:

a) The Regulation on the Domestic and Foreign Trade of Alcohol and Alcoholic Beverages, published in the Official Gazette No. 25130 dated 6/6/2003;

b) The Regulation on the Production, Processing, and Domestic and Foreign Trade of Tobacco, published in the Official Gazette No. 27637 dated 10/7/2010;

c) The Regulation on Determining Rules for the Nominal Filling Quantity of Prepackaged Products (2007/45/EC), published in the Official Gazette No. 27662 dated 4/8/2010;

ç) The Regulation on the Production and Trade of Tobacco Products, published in the Official Gazette No. 27749 dated 4/11/2010;

d) The Regulation on the Production and Trade of Ethanol and Methanol, published in the Official Gazette No. 28100 dated 30/10/2011;
e) The Communiqué on Warning Messages to be Placed on Alcoholic Beverage Packaging, published in the Official Gazette No. 28732 dated 11/8/2013;
f) The Regulation on the Production and Trade of Filter Tubes, published in the Official Gazette No. 29044 dated 28/6/2014;

g) The Regulation on the Production and Trade of Rolling Tobacco Paper, published in the Official Gazette No. 29868 dated 25/10/2016;

ğ) The Communiqué on Registering Cigarette Filter Producers (Communiqué No. 2021/13), published in the Official Gazette No. 31434 dated 25/3/2021;

h) The Technical Regulation Communiqué on Cigars and Cigarillos (Communiqué No. 2023/12), published in the Official Gazette No. 32323 dated 28/9/2023;

ı) the Technical Regulation Communiqué on Hookah Tobacco Products (Communiqué No. 2023/13), published in the Official Gazette No. 32323 dated 28/9/2023;

i) The Technical Regulation Communiqué on Rolling Tobacco Products (Communiqué No. 2023/14), published in the Official Gazette No. 32323 dated 28/9/2023;

j) The Technical Regulation Communiqué on Pipe Tobacco Products (Communiqué No. 2023/15), published in the Official Gazette No. 32323 dated 28/9/2023;

k) The Communiqué on Determining Compliance of Filter Tubes with Technical Regulations (Communiqué No. 2023/60), published in the Official Gazette No. 32453 dated 7/2/2024.

Certificate of Compliance

Article 5 – (1) A Certificate of Compliance is issued by the Directorate of Tobacco and Alcohol Affairs of the Ministry of Agriculture and Forestry for the importation of ethyl alcohol, methanol, tobacco, tobacco products, cigarette paper, filter tubes, and cigarette filters listed in Annex-1.

(2) The Certificate of Compliance can also be issued electronically as an e-document through the Single Window System managed by the Ministry of Trade.

Notification

Article 6 – (1) For the importation of alcoholic beverages specified in Annex-2 to be placed on the market, it is mandatory for the importer to notify the Directorate of Tobacco and Alcohol Affairs of the Ministry of Agriculture and Forestry within the framework of the relevant legislation.

Products That Cannot Be Imported

Article 7 – (1) The release for free circulation and importation of bulk alcoholic beverages, mixed alcoholic beverages originating from alcoholic drinks, agricultural-origin distillates that can be used in the production of alcoholic beverages, products containing tobacco or reconstituted tobacco, and concentrated beverages that can be used in the preparation of alcoholic drinks by adding water, food alcohol, or other raw materials/additives, are prohibited. However, exceptions are granted for products imported for testing, sampling, research and development purposes, and Oriental-type tobacco and tobacco powder intended for processing in tobacco facilities.

Exclusions

Article 8 – (1) For products listed in Annex-1 that are determined not to fall within the jurisdiction of the Directorate of Tobacco and Alcohol Affairs of the Ministry of Agriculture and Forestry based on their Customs Tariff Statistical Position, an Exclusion Letter provided in Annex-4 is issued to the importer.

(2) The Exclusion Letter may also be issued electronically as an e-document through the Single Window System managed by the Ministry of Trade.

Customs Procedures

Article 9 – (1) For the importation of products listed in Annex-1, the Certificate of Compliance or the Exclusion Letter issued by the Directorate of Tobacco and Alcohol Affairs of the Ministry of Agriculture and Forestry must be submitted to customs authorities at the time of the declaration registration.

(2) The importer is responsible for the inspection of the products to be imported and for the declaration of excluded items.

Responsibility

Article 10 – (1) The importer is responsible for ensuring that the imported products comply with the legislation specified in Article 4 and for fulfilling their obligations under the Product Safety and Technical Regulations Law No. 7223, dated 5/3/2020.

Authority

Article 11 – (1) The Directorate General of Product Safety and Inspection under the Ministry of Trade is authorized to take measures and issue regulations for the implementation of matters covered in this Communiqué.

Repealed Communiqué

Article 12 – (1) The Tobacco, Tobacco Products, Alcohol, and Alcoholic Beverages Import Inspection Communiqué (Product Safety and Inspection: 2024/19), published in the fourth repeated issue of the Official Gazette No. 32416, dated 31/12/2023, has been repealed.

(2) References made to the Tobacco, Tobacco Products, Alcohol, and Alcoholic Beverages Import Inspection Communiqué (Product Safety and Inspection: 2024/19) in other legislation shall be deemed as references to this Communiqué.

Entry into Force

Article 13 – (1) This Communiqué shall enter into force on 1/1/2025.

Execution

Article 14 – (1) The provisions of this Communiqué shall be executed by the Minister of Trade.

Annex-1

Products Subject to a Certificate of Compliance in Importation

HS Code	Product Name
2207.10.00.10.11	Bulk ethyl alcohol
2207.10.00.10.12	Packaged ethyl alcohol
2207.10.00.90.12	Packaged ethyl alcohol
2207.20.00.10.01	Purity 99% or higher
2207.20.00.10.09	Others
2207.20.00.10.14	Packaged ethyl alcohol
2207.20.00.90.13	Bulk ethyl alcohol
2207.20.00.90.14	Packaged ethyl alcohol
2208.90.91.10.00	Derived from agricultural products
2208.90.91.90.00	Others
2208.90.99.10.00	Derived from agricultural products
2208.90.99.90.00	Others
2401	Leaf tobacco and tobacco waste
2402	Cigars, cheroots, cigarillos, and cigarettes made from tobacco or tobacco substitutes
2403	Other manufactured tobacco, "homogenized" or reconstituted tobacco, tobacco extracts, and essences
2905.11	Methanol (methyl alcohol)
4813	Cigarette paper (whether cut to size, in booklets, or in rolls)
5601.22.10.00.11	Cigarette filters
5601.22.90.00.11	Cigarette filters with a diameter over 8mm

Annex-2

Products Subject to Notification in Importation

HS Code	Product Name
2203.00	Beers made from malt (ready for retail sale)
2204	Fresh grape wine (including fortified wine) and grape must (excluding those under HS Code 20.09) (ready for retail sale)
2205	Vermouth and other wines of fresh grapes flavored with plants or aromatic substances (ready for retail sale)

HS Code	Product Name
2206.00	Other fermented beverages (e.g., cider, perry, mead, sake), mixtures of fermented beverages not elsewhere classified, and mixtures of fermented and non-alcoholic beverages (ready for retail sale)
2908	Undenatured ethyl alcohol with an alcohol content by volume of less than 80%, spirits, liqueurs, and other alcoholic beverages obtained by distillation (ready for retail sale) (excluding undenatured ethyl alcohol with an alcohol content by volume of less than 80%)

Annex-3

Products That Cannot Be Imported

HS Code	Product Name
2203.00	Beers made from malt (bulk)
2204	Fresh grape wine (including fortified wine) (bulk)
2204.30	Other grape must (bulk)
2205	Vermouth and other wines of fresh grapes flavored with plants or aromatic substances (bulk)
2206.00	Other fermented beverages and mixtures of fermented and non-alcoholic beverages (bulk)
2207.10.00.90.11	Bulk ethyl alcohol (except those imported under Customs Processing Regime)
2207.20.00.10.15	Alcoholic beverages
2207.20.00.90.15	Alcoholic beverages
2401.10.60.00.00	Oriental sun-cured tobacco (unstripped, undried, or stemmed, except for those imported for testing, sampling, R&D, or tobacco processing facilities)
2401.20.60.00.00	Oriental sun-cured tobacco (partially or fully stripped, except for those imported for testing, sampling, R&D, or tobacco processing facilities)
2401.30.00.00.19	Others (falling through a sieve with a mesh size of 3mm)
2404.11.00.00.00	Products containing tobacco or reconstituted tobacco (new tobacco products)

Annex-4

OUT OF SCOPE LETTER

T.R.

MINISTRY OF AGRICULTURE AND FORESTRY

Date

Number:
Subject:

To the Relevant Company,

The product(s) declared for importation by your company and specified in this document are outside the scope of Annex-1 of the Tobacco, Tobacco Products, Alcohol, and Alcoholic Beverages Import Inspection Communiqué (Product Safety and Inspection: 2025/19) pursuant to the regulations outlined below.

Sincerely,

Document Type	**Document Date**	**Document Number**	**HS Code**
Invoice Date	Invoice Number	Quantity	Relevant Legislation