Predpisy notifikované v Dohode o technických prekážkach obchodu (TBT WTO)
19. týždeň roku 2025

Číslo/Dátum	Notifikujúca strana	Charakteristika notifikácie	Pripomienková doba
G/TBT/N/ARM/107 06/05/2025	Armenia	*Materials, reagents, equipment for water treatment and water purification* **Eurasian Economic Commission Collegium Draft Decision on amendments to the Section 11 of the Chapter II of the Common sanitary-epidemiological and hygienic requirements for products subject to sanitary-epidemiological supervision (control);** The draft provides for the updating of the Section 11 of the Chapter II of the Common Sanitary-Epidemiological and Hygienic Requirements for Products (Goods) Subject to Sanitary-Epidemiological Supervision (Control) which regulates the requirements for products and items that are sources of ionizing radiation, including those that are generating, as well as items and goods containing radioactive substances.	30.05.2025
G/TBT/N/BRA/1591 06/05/2025	Brazil	*FOOTWEAR, GAITERS AND THE LIKE; PARTS OF SUCH ARTICLES (HS code(s): 64); Footwear (ICS code(s): 61.060)* **Public Consultation N° 12, 5 May 2025** Proposal for Technical Regulation for Shoe LabelingComments must be presented on the Participa + Brasil Platform at:https://www.gov.br/participamaisbrasil/inmetro-diretoria-de-avaliacao-da-conformidade	24.06.2025
G/TBT/N/IND/361 06/05/2025	India	*Reinforcement Couplers* **Reinforcement Couplers for Mechanical Splices (Quality Control) Order, 2025** Reinforcement Couplers for Mechanical Splices (Quality Control) Order, 2025Reinforcement Coupler — Coupling sleeve or threaded coupler or hybrid coupler for mechanical splices of reinforcement bars for the purpose of providing transfer of axial tensile force and compressive force from one bar to the other. They are used to join reinforcement bars in concrete structure, offering a strong and reliable alternative to traditional lap splices.	05.07.2025
G/TBT/N/PHL/344 06/05/2025	Philippines	*Pharmaceutics (ICS code(s): 11.120)* **Implementing Guidelines on the Registration of Biological Pharmaceutical Products for Human Use Applied for Marketing Authorization in accordance with Administrative Order No. 2024-0013 "General Rules and Regulations on the Registration of Pharmaceutical Products and Active Pharmaceutical Ingredients Intended for Human Use** This Circular aims to provide the specific guidelines, procedures, standards for evaluation, and requirements for the registration of biological pharmaceutical products seeking marketing authorization from the FDA, in accordance with AO No. 2024-0013.	09.05.2025
G/TBT/N/RUS/170 06/05/2025	Russian Federation	*Veterinary medicinal products*	05.07.2025

		Eurasian Economic Commission Council Draft Decision on amendments to the Eurasian Economic Commission Council Decision No. 1 of January 21, 2022 The draft provides for:-- extending the transition period until December 31, 2030, to allow for the continued circulation within the Union of veterinary medicinal products registered in the member states of the Union according to national procedures;- maintaining the possibility for veterinary medicinal products registered in accordance with the legislation of the Member States of the Union before the entry into force of the Rules for the Regulation of Circulation of Veterinary Medicinal Products in the Customs Territory of the Eurasian Economic Union, as approved by the Decision of the Council of the Eurasian Economic Commission No. 1 of January 21, 2022 (hereinafter referred to as the Union Rules), to continue circulation within the Customs Territory of the Union until the end of the transition period, i.e., until December 31, 2030, in the event of amendments to the registration dossier of these veterinary medicinal products;- adjustments of certain provisions of the Union Rules of a clarifying and technical nature.	
G/TBT/N/UKR/340 06/05/2025	Ukraine	*Medicines* **Draft Resolution of the Cabinet of Ministers of Ukraine "On Amendment to the Procedure for State Quality Control of Medicines Imported to Ukraine"** The draft Resolution proposes excluding from the scope of the Procedure for State Quality Control of Medicines Imported to Ukraine medicines imported in accordance with the Laws of Ukraine "On Humanitarian Aid," "On Charitable Activities and Charitable Organizations," and "On the Implementation of Global Fund Programs to Fight AIDS, Tuberculosis, and Malaria in Ukraine." The simplified procedure for import of medicines as humanitarian aid is important in light of the need to ensure access to essential medicines under martial law and to meet the urgent demand for appropriate treatment and quality medical care.	05.07.2025
G/TBT/N/VNM/347 06/05/2025	Viet Nam	*Commercial natural gas, including PNG, CNG and LNG* **Draft National technical regulation on commercial natural gas** This draft technical regulation prescribes the limits for technical criteria related to safety, health, environment and quality management requirements for commercial natural gas, including pipeline natural gas (PNG), compressed natural gas (CNG) and liquefied natural gas (LNG) with HS codes specified in the List of export and import goods issued by the Ministry of Finance under Circular No. 31/2022/TT-BTC dated June 8, 2022 (see Appendix A).This draft technical regulation applies to agencies, organizations and individuals that involve the production, trading, processing, blending, import and distribution of commercial natural gas in Vietnam.	05.07.2025
G/TBT/N/VNM/348 06/05/2025	Viet Nam	*LED lighting products* **Draft National technical regulation on safety and electromagnetic compatibility (EMC) of LED lighting products**	05.07.2025

		This draft technical regulation specifies safety, electromagnetic compatibility and management requirements for LED lighting products listed in Appendix A of this technical regulation. This regulation only applies to LED lighting products within the scope of application of the corresponding safety standards listed in Appendix A of this regulation.This technical regulation does not apply to:LED lighting products in traffic lighting projects, urban centers, concentrated residential areas and public spaces (public entertainment areas, squares, parks and flower gardens);LED lighting products for means of transport;Explosion-proof LED lighting products.This draft technical regulation applies to organizations and individuals that manufacture, import and commercialize LED lighting products (hereinafter referred to as Enterprises) listed in Appendix A of this technical regulation, conformity assessment organizations, state management agencies and other relevant organizations and individuals.	
G/TBT/N/CPV/4 07/05/2025	Cabo Verde	*Television sets (HS code: 8528)* **Ordonnance conjointe nº 70/2020 du 21 décembre, concernant la certification et les exigences minimales pour les téléviseurs (Joint Order No. 70/2020 of 21 December on certification and minimum requirements for television sets) (6 pages, in Portuguese)** The notified Order establishes the requirements for the labelling and the provision of supplementary information for television sets, including:(a) the definition of energy efficiency classes for television sets;(b) the minimum conditions for importation and marketing (minimum class D);(c) energy labelling obligations and technical requirements;(d) test methods and certification of compliant models;(e) conditions for the award of the Energy Efficiency Guarantee Seal;(f) rules for verification and market monitoring.G/TBT/N/CPV/4- 2 -	
G/TBT/N/CPV/5 07/05/2025	Cabo Verde	*Machines à laver le linge pour usage domestique (SH: 8450)* **Ordonnance conjointe nº 69/2020 du 21 décembre 2020, concernant la certification et les exigences minimales pour les machines à laver le linge domestiques.** La réglementation fixe les exigences applicables à l'étiquetage et à la fourniture d'informations supplémentaires concernant les téléviseurs, notamment: a) définition des classes d'efficacité énergétique des machines à laver le linge; b) conditions minimales d'importation et de commercialisation (minimum classe A); c) obligations d'étiquetage énergétique et exigences techniques; d) méthodes de test et certification des modèles conformes; e) conditions pour l'attribution du Sceau de Garantie d'Efficacité Énergétique.	21.12.2020
G/TBT/N/CPV/6 07/05/2025	Cabo Verde	*Butane for the domestic market (HS code(s): 2711.13)* **Ordonnance conjointe nº 73/2005 du 26 décembre 2005, établissant les spécifications techniques du butane (Joint Order No. 73/2005 of 26 December 2005 establishing technical specifications for butane) (5 pages, in Portuguese)** The notified Order establishes the technical requirements for butane, including: Physico-chemical properties:- Density at 15°C (min. 0.560 kg/m³, ISO standard 3993)- Composition	

		(C4 ≥ 85% molar mass, EN 27941)- Maximum total sulphur content (50 mg/kg, EN 24260)Safety and quality:- Vapour pressure at 40°C (max. 520 kPa, EN ISO 24256)- Copper strip corrosion (max. 1, ASTM D 1838).- Absence of water, separated or in suspension (visual inspection)Energy performance: Net calorific value (min. 10,000 kcal/kg, ASTM D 3588)Test methods: ISO, EN, ASTM and NP standards specified for each parameterG/TBT/N/CPV/6- 2 -
G/TBT/N/CPV/7 07/05/2025	Cabo Verde	*Combustibles pour véhicules et usage industriel (Code (s) du SH: 2710* **Ordonnance conjointe nº 11/2006 du 6 février 2006, réglementant l'introduction des combustibles pour consommation** La réglementation fixe les exigences techniques pour les combustibles, notamment : Propriétés physico-chimiques: - Essence (EN 228:1999) : Indice d'octane (RON min. 95), teneur en soufre (max. 50 mg/kg), stabilité à l'oxydation. - Diesel (EN 590:1999) : Indice de cétane (min. 51), point d'éclair (min. 55°C), teneur en soufre (max. 10 mg/kg). Sécurité et qualité: - Contrôle des additifs (interdiction de composés métalliques). - Limitation des impuretés (eau, sédiments). Méthodes d'essai:Normes européennes (EN) ou méthodes équivalentes approuvées par la DGIE.
G/TBT/N/CPV/8 07/05/2025	Cabo Verde	*Combustibles pour véhicules et usage industriel (Code (s) du SH: 2710)* **Ordonnance conjointe nº 11/2006 du 6 février 2006, réglementant l'introduction des combustibles pour consommation** La réglementation fixe les exigences techniques pour les combustibles, notamment : Propriétés physico-chimiques: - Essence (EN 228:1999) : Indice d'octane (RON min. 95), teneur en soufre (max. 50 mg/kg), stabilité à l'oxydation. - Diesel (EN 590:1999) : Indice de cétane (min. 51), point d'éclair (min. 55°C), teneur en soufre (max. 10 mg/kg). Sécurité et qualité: - Contrôle des additifs (interdiction de composés métalliques). - Limitation des impuretés (eau, sédiments). Méthodes d'essai:Normes européennes (EN) ou méthodes équivalentes approuvées par la DGIE.
G/TBT/N/CPV/9 07/05/2025	Cabo Verde	*Gaz de pétrole liquéfiés (GPL) (Code(s) du SH : 2711.19)* **Ordonnance conjointe nº 3/2011 du 17 janvier 2011, approuvant le Règlement de sécurité pour les installations de stockage de GPL (capacité ≤ 200 m³ par récipient)** La réglementation fixe les exigences techniques pour le stockage sécurisé des GPL, notamment : Classification des installations : - Postes de bouteilles (≤ 150 dm³) et postes de réservoirs (≤ 200 m³). - Distinction entre réservoirs superficiels, enterrés et recouverts. Exigences techniques : - Distances de sécurité (voir tableau I de l'annexe) : - 1,5 m minimum des limites de propriété. - 3 à 15 m des sources d'allumition (selon la capacité). - Ventilation : Aérations permanentes pour les cabines de bouteilles (≥ 2,5 % de la surface totale). - Matériaux : Structures incombustibles (résistance au feu ≥ 120 minutes). Équipements obligatoires : - Válvulas de sécurité avec tubage vertical (≥ 2 m pour les réservoirs ≥ 7,5 m³). - Systèmes de détection de gaz et d'incendie. - Extincteurs (poudre ABC 6 kg pour les réservoirs ≥ 2,5 m³). Interdictions : - Stockage en caves ou

		zones non ventilées. - Utilisation de vaporisateurs à flamme directe.	
G/TBT/N/AUS/181 08/05/2025	Australia	*Decabromodiphenyl ethane (DBDPE)Mercury and mercury compounds* **Proposed management standards for high-risk industrial chemicals:Proposed standard – Decabromodiphenyl ethane (DBDPE)Chemical profile (DBDPE)Proposed standard – Mercury and mercury compoundsChemical profile (Mercury and mercury compounds)** The Industrial Chemicals Environmental Management Standard (IChEMS) has been developed by all Australian governments to efficiently and effectively manage the risks of industrial chemicals to the environment, while providing consistent requirements for businesses across Australia. The IChEMS Register records standards for the environmental management of chemicals, including risk management measures for specific industrial uses. In turn, the Australian federal government and each state and territory government will enact legislation to implement the standards in their jurisdictions. The proposed standards will assign the following chemicals, and mixtures and articles containing the chemicals, to Schedule 6 of the IChEMS Register. This will prohibit their import, manufacture, use and export in Australia, with exceptions for specific essential uses, unintentional trace contamination, research, environmentally sound disposal, and for articles in use prior to the standards' date of entry into force.Decabromodiphenyl ethane (DBDPE)Mercury and mercury compoundsAs a Party to the Minamata Convention on Mercury, Australia adheres to controls on mercury added products as prescribed by Article 4 of the Minamata Convention on Mercury. As advised in G/TBT/N/AUS/134/Add.1, the Recycling and Waste Reduction (Mandatory Product Stewardship – Mercury-added Products) Rules 2021 (the Rules), prohibit the manufacture, import and export of products containing mercury, with some exemptions for essential products. As at 25 April 2025, the Rules automatically incorporated the changes made to Annex A of the Minamata Convention on Mercury by the Fifth Conference of the Parties.	28.05.2025
G/TBT/N/THA/779 08/05/2025	Thailand	*Medical Devices* **Draft Notification of the Ministry of Public Health Re: Rules, Procedures and Conditions for Labeling and Instructions for Use of Medical Devices B.E. ….** The Minister of Public Health hereby issues the draft notification of the Ministry of Public Health Re: Rules, Procedures, and Conditions for Labeling and Instructions for Use of Medical Devices, including the following:This draft notification repeals the Notification of the Ministry of Public Health RE: Rules, Procedures and Conditions on Display of Labels and Medical Device Package Inserts, B.E. 2563 (2020)This draft notification shall not apply to the following cases: Medical devices of which specific labeling and instructions for use requirements have already been prescribed by other notifications; Medical devices of which manufacturing or importation is granted exemption under section 27 of the Medical Devices Act, B.E. 2551 (2008) as amended;Medical devices manufactured or imported solely for export outside Thailand.This draft notification specifies	07.07.2025

		the following:Definitions of 'Home Use Medical Device' and 'Professional Use Medical Device'.Requirements for labeling and instructions for use.Specific requirements for labeling and instructions for use of medical devices of software, applications, or other similar types without physical form.Specific requirements for labeling and instructions for use of medical devices for surgical and dental instruments or equipment designed or manufactured for reuse, as well as accessories.Requirement for labeling at customs inspection.Transition period for labeling and instructions for use of medical devices implementing in accordance with the Notification of the Ministry of Public Health RE: Rules, Procedures and Conditions on Display of Labels and Medical Device Package Inserts, B.E. 2563 (2020)	
G/TBT/N/GBR/102 08/05/2025	United Kingdom	*ESSENTIAL OILS AND RESINOIDS; PERFUMERY, COSMETIC OR TOILET PREPARATIONS (HS code(s): 33)* **The Cosmetic Products (Restriction of Chemical Substances) Regulations 2025.** This measure will amend Regulation (EC) No 1223/2009 ("the Cosmetics Regulation") as it applies in Great Britain to restrict the use of benzophenone-3 in a number of cosmetic products.	07.07.2025
G/TBT/N/USA/2195 08/05/2025	United States of America	*Equipment and systems used by the Public Safety Answering Points (PSAPs); Telecommunication systems (ICS code(s): 33.040); Telecommunication terminal equipment (ICS code(s): 33.050); Radiocommunications (ICS code(s): 33.060); Mobile services (ICS code(s):* **Wireless E911 Location Accuracy Requirements** Proposed rule - In this document, the Federal Communications Commission (the FCC or Commission) proposes rules to strengthen wireless 911 location accuracy rules and to put more actionable location information in the hands of Public Safety Answering Points (PSAPs) and first responders.	07.07.2025
G/TBT/N/BLZ/19 09/05/2025	Belize	*HS Codes 280440; 281121; 280430* **Draft Belize Standard Code of Good Manufacturing Practices for Medical Gases** This code of good manufacturing practices for medical gases provides requirements for the production, storage and distribution of medical gases namely for Oxygen; Nitrogen; Carbon dioxide; Nitrous Oxide; Compressed Air and any other medical gases, classified as drugs. The standard is not intended to be used in hospitals or at home for personal use. Atmospheric air contains a large variety of trace constituents. It is impractical to set individual limits for many of these; however, this specification qualifies certain grades of air by limiting the concentrations of specific trace constituents.	27.06.2025
G/TBT/N/BLZ/20 09/05/2025	Belize	*Nitrogen (HS code(s): 280430); Oxygen (HS code(s): 280440); Carbon dioxide (HS code(s): 281121)* **Draft Belize Standard Specification for Medical Gases - General Requirements** This standard describes the properties of common medical gases, medical gas containers, and safe practices and handling of these gases.	27.06.2025

G/TBT/N/KOR/1292 09/05/2025	Korea, Republic of	*In Vitro Diagnostic Medical Devices* **Proposed amendments to the "Regulation on In Vitro Diagnostic Medical Device Approval/Report/Review etc."** The Korean Ministry of Food and Drug Safety is proposing the amendments of the "Regulation on In Vitro Diagnostic Medical Device Approval/Report/Review etc." as follows: 1)Addition of "Performance Evaluation Report" to the clinical performance study documentation required for in vitro diagnostic medical devices (IVDs)2) Establishment of definitions and dossier requirements for 'cybersecurity' regarding IVDs that use wired or wireless communication technologies, as part of the regulatory approval process3) Inclusion of newly developed IVDs in the scope of expedited review, with restrictions on equivalence comparison during the post-market surveillance period4) Centralization of the identical product review of Class II IVD to the "National Institute of Medical Device Safety Information" which is responsible for Class II certification5) Clarification of administrative procedures for Class I IVDs, etc.	08.07.2025
G/TBT/N/KOR/1293 09/05/2025	Korea, Republic of	*Medical Devices* **Proposed amendments to the "Regulation on the Permission, Notification, Review, etc of Medical Devices"** The Korean Ministry of Food and Drug Safety is proposing the amendments of the "Regulation on the Permission, Notification, Review, etc of Medical Devices" as follows: 1) Add clinical evaluation data to the types of clinical trial data and provide a guidance on how to fill out each item.2) A person who wishes to receive confirmation that the product is identical to a Class 2 medical device that has already been certified should submit relevant materials to the head of the National Institute of Medical Device Safety Information.3) Stipulate the procedure for accepting a manufacture/import notification of a medical device in accordance with the Enforcement Rule of the Medical Devices Act, as amended on 7 August 2024.4) Establish a new definition of medical device cybersecurity and require related information to be included in the application. 5) Add newly developed medical devices to the list of products subject to expedited review and restrict the exemption from submission of clinical test data through equivalence review for newly developed medical devices during the post-marketing surveillance period. 6) Provide examples requiring the submission of clinical test data for clarification of the scope of submitted materials.	08.07.2025
G/TBT/N/CHE/294 09/05/2025	Switzerland	*Medicinal products for human use* **Draft Ordinance on unique identifiers and anti-tampering devices on the outer packaging of medicinal products for human use** This Draft Ordinance on unique identifiers and anti-tampering devices establishes rules for the mandatory implementation of safety features to prevent falsified medicines from entering the legal supply chain in Switzerland.A unique identifier in the form of a 2D Data Matrix code on the outer packaging ensures the identification of each individual package by uploading the relevant information into a database hosted by the Swiss Medicines Verfication Organisation (SMVO). Additionally, an anti-tampering device, such as a tamper-evident seal, indicates whether a package has been opened. These measures help	08.07.2025

verify the authenticity of medicines, ensuring that counterfeit products are identified before they reach patients.The ordinance mandates the establishment of an “end-to-end” verification system for safety features, supplemented by risk-based checks at the wholesale level. In practice, the safety features placed on a medicine pack by the manufacturer or marketing authorization holder are systematically verified for authenticity at the end of the supply chain, before that pack is dispensed to a patient (e.g.: by pharmacies or hospitals).Furthermore, the ordinance regulates the setting up, management and supervision of a repositories system where legitimate unique identifiers are stored. This system, managed by stakeholders under the supervision of the competent authorities, serves as a reference for verifying the authenticity of medicinal products. In Switzerland, the operation of the database system will be entrusted to a non-profit private organization, the SMVO, which has been founded by the manufacturers and marketing authorization holders of medicinal products labeled with unique identifiers.