

**Predpisy notifikované v Dohode o technických prekážkach obchodu (TBT WTO)  
37. týždeň roku 2022**

Číslo/Dátum	Notifikujúca strana	Charakteristika notifikácie	Pripomienková doba
<a href="#">G/TBT/N/EU/921</a> 12/09/2022	European Union	<p><i>Chemical substances classified as drug precursors</i></p> <p><b>Draft Commission Delegated Regulation amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of certain drug precursors in the list of scheduled substances</b></p> <p>This draft Commission Regulation adds 4-AP, 1-boc-4-AP, norfentanyl, DEPAPD and PMK ethyl glycidate to Category 1 of the list of scheduled substances in Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors. Operators engaged in import, export or intermediary activities involving scheduled substances listed in Category 1 of the Annex have the obligation to hold a licence. Special labelling requirements apply for any packaging containing these substances according to Article 5 of the Regulation.</p>	11/11/2022
<a href="#">G/TBT/N/ARG/437</a> 13/09/2022	Argentina	<p><i>(Código(s) del SA: 2209)</i></p> <p><b>Proyecto de Resolución Conjunta "Código Alimentario Argentino (CAA) -Capítulo XVI "Correctivos y coadyuvantes –Aceto Balsámico y Aceto Balsámico Tradicional";</b></p> <p>El Proyecto, elaborado por la Comisión Nacional de Alimentos, (CONAL) incorpora los artículos 1334 tris y quarter que fija los patrones de identidad y calidad del aceto balsámico y aceto balsámico tradicional, respectivamente.</p>	12/11/2022
<a href="#">G/TBT/N/ARG/438</a> 13/09/2022	Argentina	<p><i>Conservas vegetales. (Código(s) de la ICS: 67.230)</i></p> <p><b>Proyecto de Resolución Conjunta "Código Alimentario Argentino –Capítulo XI Alimentos Vegetales: Conservas vegetales –Artículo 926";</b></p> <p>El Proyecto, elaborado por la Comisión Nacional de Alimentos (CONAL) contiene la modificación de su Artículo 926 añadiendo la definición, tratamiento térmico y criterios microbiológicos de las conservas elaboradas con frutas y hortalizas.</p>	12/11/2022
<a href="#">G/TBT/N/ARG/439</a> 13/09/2022	Argentina	<p><i>Harina de arroz (Código(s) del SA: 11)</i></p> <p><b>Proyecto de Resolución Conjunta "Código Alimentario Argentino –Capítulo IX Alimentos farináceos -Cereales, Harinas y Derivados –Artículo 696: Harina de arroz ";</b></p> <p>El Proyecto elaborado por la Comisión Nacional de Alimentos (CONAL) propone la modificación del porcentaje de humedad de la harina de arroz e incorpora los criterios microbiológicos aplicables a la misma.</p>	12/11/2022
<a href="#">G/TBT/N/AUS/145</a> 13/09/2022	Australia	<p><i>Medical Devices supplied into Australia under the Therapeutic Goods Administration's regulatory framework.</i></p> <p><b>Unique Device Identification (UDI) Consultation 3 - Detailed considerations for implementing the proposed Australian medical device UDI regulatory framework;</b></p> <p>The Australian Government is undertaking a significant program of reform to the regulation of therapeutic goods in</p>	11/10/2022

Australia. The reforms will continue to improve the safety, performance, and quality of medical devices in Australia and improve health outcomes for patients who require medical devices. As part of the Australian Government Department of Health and Aged Care, the Therapeutic Goods Administration (TGA) regulates therapeutic goods, and is responsible for implementing the Government's reforms, including the introduction of a unique device identification (UDI) system for medical devices supplied in Australia. Changes to the Therapeutic Goods Act 1989 were passed by the Australian parliament in February 2021, to allow for the establishment of the UDI database and the introduction of related requirements. For the system to be operational, there is a need to provide for the establishment of the UDI database and for setting out of related requirements, in the Therapeutic Goods (Medical Devices) Regulations 2002 (the MD Regulations). This consultation relates to the details of the proposed regulatory framework, including seeking feedback on:

- the impact of accepting both European and USA compliant labels
- acceleration of delivered benefits through a phased implementation approach
- scope and exemptions in applying the UDI
- providing and maintaining data over the full life of the device
- UDI related fees and charges
- UDI labelling and supporting documentation
- any potential regulatory burden
- adoption and use in the broader healthcare setting

<a href="#">G/TBT/N/EU/922</a> 13/09/2022	European Union	<i>Food</i> <b>Draft Commission Regulation amending Annex II to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards nicotinamide riboside chloride added to foods;</b> This draft Commission Delegated Regulation concerns the authorisation of the addition of nicotinamide riboside chloride, as a source of niacin to foods in line with EFSA's relevant scientific opinion.	12/11/2022
<a href="#">G/TBT/N/EU/923</a> 13/09/2022	European Union	<i>Food</i> <b>Draft Commission Delegated Regulation amending Commission Delegated Regulation (EU) 2016/127 as regards the protein requirements for infant and follow-on formula manufactured from protein hydrolysates.;</b> This delegated Regulation aims to amend Delegated Regulation (EU) 2016/127 by amending the compositional requirements set out by that Regulation for the protein content, protein source, protein processing and protein quality for infant and follow-on formula manufactured from hydrolysates based on the relevant EFSA scientific opinion.	12/11/2022
<a href="#">G/TBT/N/TPKM/504</a> 13/09/2022	Chinese Taipei	-Other switches (HS code(s): 853650); -Other (HS code(s): 853669); -Fitted with connectors (HS code(s): 854442)	12/11/2022

**Proposal for Amendments to the Legal Inspection Requirements for Plugs and Socket-Outlets for Fixed Wiring and 7 Other Power Distribution Products;**

Plugs and socket outlets for fixed wiring are having more and more diversified functions, e.g., wireless control, timing control, and induction control. Household switches for fixed wiring are gradually being replaced by electronic switches. As a result of risk assessment, BSMI proposes to add 8 products for fixed wiring with wireless control, wired network control, timing control, voice control, motion sensing, light sensing, and electricity calculation functions into the scope of legal inspection.

[G/TBT/N/MEX/516](#)  
13/09/2022

Mexico

*Transporte de mercancías peligrosas*

12/11/2022

**PROYECTO de Norma Oficial Mexicana PROY-NOM-006-SCT2/2022, Aspectos básicos para la revisión ocular de la unidad destinada al transporte de mercancías peligrosas.;**

PROYECTO de Norma Oficial Mexicana PROY-NOM-006-SCT2/2022, Aspectos básicos para la revisión ocular de la unidad destinada al transporte de mercancías peligrosas

[G/TBT/N/NZL/115](#)  
13/09/2022

New Zealand

*Mineral transport fuels and biofuels, this includes the following:*

12/11/2022

*2709 -Petroleum oils and oils obtained from bituminous minerals, crude*

*2710 -Petroleum oils and oils obtained from bituminous minerals (other than crude) and preparations not elsewhere specified, containing by weight 70 % or more of petroleum oils or of oils obtained from bituminous minerals, these oils being the basic constituents of the preparations; waste oils*

**Cabinet Paper - Sustainable Biofuels Obligation: Final policy design**

**The Sustainable Biofuels Obligation: proposals for regulations**

The Sustainable Biofuels Obligation will require importers and domestic producers of liquid transport fuels to reduce the emissions intensity of their fuel supply by a set percentage each year through the deployment of biofuels. Biofuels used to meet the Obligation will be assessed using a lifecycle emissions analysis methodology to determine their GHG emissions intensity.

The obligation will apply to all transport fuels, excluding domestic aviation fuel. An aviation-based obligation will be developed over a longer timeframe. The Obligation is currently scheduled to enter into force from 1 April 2023.

The timing of this proposed measure may be subject to change, in which case an addendum notification will be issued. Only biofuels that are determined to be sustainable will be eligible under the Obligation. Methodologies to determine the sustainability of biofuels will be set out in supporting regulations. This could include the use of existing sustainability certifications schemes such as the International Sustainability and Carbon Certification Plus Standard. Regulations may also place limits or restrictions on the extent to which an obligated party may meet their obligation by means of a particular type of biofuel, particularly with respect to feedstocks, to address issues of indirect land use change. The supporting regulatory framework will be developed in late 2022 and will

provide further detail on the methodology for determining the sustainability of biofuels, and limits or restrictions on particular types of biofuels. An addendum notification will be issued once this detail is available.

[G/TBT/N/SVN/120](#)  
13/09/2022

Slovenia

*Road engineering (ICS code(s): 93.080)*

12/11/2022

**TSPI PGV.06.325 : 2022 Stabilized bearinglayers of the pavement structure made by cold process**

TSPI indicate the parameters for determining the suitability of road sections for this type of rehabilitation and the selection of the most appropriate stabilization technology. Design procedures, execution of work, quality control and state the requirements for the quality characteristics of the materials used, the produced mixture, the embedded layer and the frequency of testing are also defined.

[G/TBT/N/UKR/227](#)  
13/09/2022

Ukraine

*Medical devices, in vitro diagnostic medical devices, active implantable medical devices*

13/10/2022

**Draft Resolution of the Cabinet of Ministers of Ukraine "On Amendments to Some Resolutions of the Cabinet of Ministers of Ukraine on the Recognition of Conformity Assessment Results";**

At the beginning of Russia's military aggression against Ukraine, there was a risk of complicating the work of designated bodies for conformity assessment of products with the requirements of technical regulations. The possible suspension of their work would have to a delay or blockage of imports to Ukraine of certain groups of goods that were subject to the conformity assessment procedure with the requirements of Ukrainian technical regulations with the involvement of designated conformity assessment bodies. Therefore, on March 29, 2022 the Resolution of the Cabinet of Ministers of Ukraine No 389 "On Amendments to Some Resolutions of the Cabinet of Ministers of Ukraine on the Recognition of Conformity Assessment Results" was adopted providing for the possibility (for the duration of martial law) to recognize by a designated conformity assessment body of the results of conformity assessment of medical devices, in vitro diagnostic medical devices and active implantable medical devices carried out by foreign accredited bodies (G/TBT/N/UKR/162/Add.1 ). To date, the majority of Ukrainian designated conformity assessment bodies have confirmed their ability to carry out conformity assessment activities and provide appropriate services to Ukrainian and foreign enterprises under martial law. Also, during the martial law period, the Ministry of Health of Ukraine has not received any applications from businesses about cases of inability of Ukrainian designated conformity assessment bodies to provide them with relevant services. Consequently, the Ukrainian infrastructure of designated conformity assessment bodies today continues to function and is able to provide business entities with the full range of services required to assess compliance with the requirements of technical regulations. In this regard, the draft Resolution of the Cabinet of Ministers of Ukraine "On Amendments to Some Resolutions of the Cabinet of Ministers of Ukraine on the Recognition of Conformity Assessment Results" was developed to exclude provisions allowing for the recognition by a designated conformity assessment body

		of the results of conformity assessment of medical devices, in vitro diagnostic medical devices and active implantable medical devices carried out by foreign accredited conformity assessment bodies.	
<a href="#">G/TBT/N/GBR/53</a> 13/09/2022	United Kingdom	<p><i>Pesticide active substances; Pesticides and other agrochemicals (ICS code(s): 65.100)</i></p> <p><b>The Great Britain Pesticides Approvals Register;</b> For the purposes of transparency, the United Kingdom is signposting Members to the public register, which provides the list of approved active substances to be included in plant protection products in Great Britain, together with details on the specific conditions of approval.</p>	
<a href="#">G/TBT/N/USA/1916</a> 13/09/2022	United States of America	<p><i>Class 7 radioactive materials; Quality (ICS code(s): 03.120); Transport (ICS code(s): 03.220); Environmental protection (ICS code(s): 13.020); Radiation protection (ICS code(s): 13.280); Protection against dangerous goods (ICS code(s): 13.300); Test conditions and procedures in general (ICS code(s):19.020)</i></p> <p><b>Hazardous Materials: Compatibility With the Regulations of the International Atomic Energy Agency;</b> Notice of proposed rulemaking -PHMSA, in coordination with the Nuclear Regulatory Commission, proposes to amend the Hazardous Materials Regulations to maintain alignment with international regulations and standards governing the transportation of Class 7 radioactive materials. Specifically, PHMSA proposes to adopt changes contained in the International Atomic Energy Agency standards. Additionally, PHMSA proposes regulatory amendments identified through internal regulatory review processes to update, clarify, correct, or streamline certain regulatory requirements applicable to the transportation of Class 7 (radioactive) materials.</p>	12/12/2022
<a href="#">G/TBT/N/URY/67</a> 13/09/2022	Uruguay	<p><i>Vehículos de las categorías M, N y O</i></p> <p><b>Proyecto de Reglamento Técnico MERCOSUR de Instalación de Dispositivos de Iluminación y Señalización Lumínica;</b> Se actualiza la Resolución MERCOSUR/GMC/RES N° 83/94 mediante la aprobación de un nuevo Reglamento Técnico MERCOSUR, en el que se establecen los requisitos relacionados con la instalación de dispositivos de iluminación y señalización luminosa de vehículos que circulan en los Estados Parte del bloque, con el propósito de mejorar la seguridad vial en el MERCOSUR. Para ello, se toman como base el Reglamento UNECE N° 48 y la norma "Federal Motor Vehicle Safety Standard" (FMVSS) N° 108.</p>	12/11/2022
<a href="#">G/TBT/N/VNM/237</a> 13/09/2022	Vietnam	<p><i>Products of the chemical industry (ICS 71.100)</i></p> <p><b>Draft of Circular guiding measures to distinguish industrial alcohol from food alcohol;</b> This Circular guides measures to distinguish industrial alcohol not used in food from food alcohol in order to prevent the preparation of alcohol from industrial alcohol not used in food. This draft of Circular applies to organizations and individuals producing, trading and using industrial alcohol in the territory of the Socialist Republic of Vietnam and other relevant agencies, organizations and individuals.</p>	12/11/2022

<a href="#">G/TBT/N/BRA/1444</a> 14/09/2022	Brazil	<p><i>Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale. (HS code(s): 3003); Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale. (HS code(s): 3004)</i></p> <p><b>Resolution -RDC number 750, 06 September 2022;</b> This Resolution establishes a temporary optimized analysis procedure, in which the analyzes conducted by an Equivalent Foreign Regulatory Authority are used for the verified analysis of the market authorization and post-market authorization petitions of medicines, biological products and their inputs, and the letter of adequacy of the pharmaceutical ingredient dossier active. This Resolution is valid for 180 (one hundred and eighty) days from the date of its entry into force.</p>	
<a href="#">G/TBT/N/BRA/1445</a> 14/09/2022	Brazil	<p><i>Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale. (HS code(s): 3003); Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale. (HS code(s): 3004)</i></p> <p><b>Normative Instruction 182, 05 September 2022;</b> This Resolution contains provisions on validation and permeability assays with Caco-2 cells.</p>	
<a href="#">G/TBT/N/BRA/1446</a> 14/09/2022	Brazil	<p><i>FOOD TECHNOLOGY (ICS code(s): 67)</i></p> <p><b>Draft resolution number 1114, 06 September 2022;</b> This Draft Resolution contains provisions on a proposed Normative Instruction that "Establishes the form of regularization of the different categories of food and packaging, and the respective documentation that must be presented" This regulation will be also notified to the SPS Committee.</p>	13/12/2022
<a href="#">G/TBT/N/BRA/1447</a> 14/09/2022	Brazil	<p><i>FOOD TECHNOLOGY (ICS code(s): 67)</i></p> <p><b>Draft resolution number 1113, 06 September 2022;</b> This Draft Resolution contains provisions on the regularization of food and packaging under the competence of the National Health Surveillance System (SNVS) intended for supply in the national territory. This regulation will be also notified to the SPS Committee</p>	13/12/2022
<a href="#">G/TBT/N/BRA/1448</a> 14/09/2022	Brazil	<p><i>Medical equipment (ICS code(s): 11.040)</i></p> <p><b>Draft resolution number 1112, 6 September 2022;</b> This Draft Resolution contains provisions on the essential safety and performance requirements applicable to medical devices and in vitro diagnostic (IVD) medical devices. The proposed Resolution will take as reference the document prepared by the International Medical Device Regulators Forum -IMDRF/GRRP WG/N47:2018 Essential Principles</p>	14/11/2022

of Safety and Performance of Medical Devices and IVD Medical Devices.

<a href="#">G/TBT/N/CHN/1699</a> 14/09/2022	China	<p><i>Cosmetics (HS code(s): 33); (ICS code(s): 71.100.70)</i></p> <p><b>Provisions for the Supervision of Cosmetics Online Distribution (Draft);</b></p> <p>The document is to standardize the online cosmetics distribution and the service behavior on e-commerce platform of cosmetics to ensure the safety of consumers' health.</p>	13/11/2022
<a href="#">G/TBT/N/USA/1917</a> 14/09/2022	United States of America	<p><i>Heavy-duty engine and vehicle fuel efficiency; Spark-ignition reciprocating or rotary internal combustion piston engines. (HS code(s): 8407); Compression-ignition internal combustion piston engines (diesel or semi-diesel engines). (HS code(s): 8408); Tractors (other than tractors of heading 87.09). (HS code(s): 8701); Motor vehicles for the transport of ten or more persons, including the driver.(HS code(s): 8702); Motor cars and other motor vehicles principally designed for the transport of persons (other than those of heading 87.02), including station wagons and racing cars. (HS code(s): 8703); Motor vehicles for the transport of goods. (HS code(s): 8704); Special purpose motor vehicles, other than those principally designed for the transport of persons or goods (for example, breakdown lorries (wreckers), crane lorries (mobile cranes), fire fighting vehicles, concrete mixer lorries (concrete-mixers), road sweeper lorries (road sweepers), spraying lorries (spraying vehicles), mobile workshops, mobile radiological units). (HS code(s): 8705); Quality (ICS code(s): 03.120); Air quality (ICS code(s): 13.040); Test conditions and procedures in general (ICS code(s): 19.020); Road vehicles in general (ICS code(s): 43.020); Internal combustion engines for road vehicles (ICS code(s): 43.060); Commercial vehicles (ICS code(s): 43.080); Passenger cars. Caravans and light trailers (ICS code(s): 43.100)</i></p> <p><b>Improvements for Heavy-Duty Engine and Vehicle Fuel Efficiency Test Procedures, and Other Technical Amendments;</b></p> <p>Proposed rule -The National Highway Traffic Safety Administration (NHTSA) is proposing minor technical amendments to the test procedures for heavy-duty engines and vehicles to improve accuracy and reduce testing burden. These amendments affect the certification procedures for fuel efficiency standards and related requirements. These proposed amendments increase compliance flexibility, harmonize with other requirements, add clarity, correct errors, and streamline the regulations. Given the nature of the proposed changes, NHTSA does not expect either significant environmental impacts or significant economic impacts for any sector.</p>	14/11/2022
<a href="#">G/TBT/N/EU/924</a> 15/09/2022	European Union	<p><i>Cosmetic products</i></p> <p><b>Draft Commission Regulation (EU) amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards labelling of fragrance allergens in cosmetic products.;</b></p> <p>The draft measure proposes that additional fragrance allergens are individually labelled on the package of a</p>	14/11/2022

		cosmetic product, if their concentration exceeds 0,001 % in leave-on products and 0,01 % in rinse-off products. It further introduces some updates and simplifications in the names of those substances. It is all done through amendments of Annex III to Regulation (EC) No 1223/2009.	
<a href="#">G/TBT/N/PRY/135</a> 15/09/2022	Paraguay	<i>Agua, incluidas el agua mineral y la gaseada, con adición de azúcar u otro edulcorante o aromatizada, y demás bebidas no alcohólicas, excepto los jugos de frutas u otros frutos o de hortalizas de la partida 20.09. (Código(s) del SA: 2202)</i> <b>Proyecto de Reglamento Técnico que establece los requisitos para las aguas envasadas de consumo humano y para las aguas envasadas bajas en sodio.;</b> El proyecto de Reglamento Técnico notificado tiene por objeto establecer los requisitos para las aguas envasadas de consumo humano y para las aguas envasadas bajas en sodio.	16/11/2022
<a href="#">G/TBT/N/VNM/238</a> 15/09/2022	Vietnam	<i>Articles, products, commodities and equipment containing Persistent Organic Pollutants (POPs)</i> <b>Draft National Technical Regulation on thresholds for Persistent Organic Pollutants (POPs) in articles, products, commodities and equipment;</b> This draft National Technical Regulation prescribes the allowed maximum limit (threshold) of POPs in articles, products, commodities and equipment, and specific parts of articles, products, commodities and equipment containing POPs. This draft National Technical Regulation applies to agencies, organizations, and individuals engaged in importing, manufacturing, trading, using and conformity assessment activities related to the contents mentioned above in the territory of the Socialist Republic of Vietnam.	14/11/2022
<a href="#">G/TBT/N/ARE/549</a> 16/09/2022	United Arab Emirates	<i>Aircraft and space vehicles in general (ICS code(s): 49.020)</i> <b>UAE control scheme for Products and Systems of Unmanned Aircraft and Aircraft;</b> This control scheme applies to the products of unmanned aircraft systems that are used/trading in the country, including the free zones. Scheme applies to products and manufactured parts, Excluded from the scope of the scheme: 1-Drone products classified for military and security purposes 2-Unmanned Air Balloon Products	15/11/2022
<a href="#">G/TBT/N/ARE/550</a> 16/09/2022	United Arab Emirates	<i>Road vehicle systems (ICS code(s): 43.040)</i> <b>UAE Technical Regulation "Requirements for Automated Driving Vehicles";</b> This UAE Technical regulation concerned with the fully automated vehicles designed and constructed for the carriage of passengers and/or carriage of goods or dual mode vehicles. it might operate in a predefined area or on a predefined route, that may include fixed start and end points. It is an automobile OEMs responsibility to determine its system's automation level in conformity with automated levels define below: a. Highly automated (L4) means the vehicle can itself perform all driving tasks and monitor the driving environment necessarily that is to perform the Dynamic Driving Task (DDT) in the Operational Design Domain (ODD). Such ADS does not require a fallback-ready	15/11/2022



user. b. Fully automated (L5) means that all aspects of the driving task and monitoring of the driving environment and the dynamic driving task are to be undertaken by the vehicle system. The vehicle can operate on all roads at all times.

[G/TBT/N/USA/1918](#)  
16/09/2022

United  
States of  
America

*Chemical substances; Environmental protection (ICS code(s): 13.020); Production in the chemical industry (ICS code(s): 71.020); Products of the chemical industry (ICS code(s): 71.100)*

17/10/2022

**Modification of Significant New Uses of Certain Chemical Substances (21-1.M);**

Proposed rule -EPA is proposing to amend the significant new use rules (SNURs) for certain chemical substances identified herein, which were the subject of one or more premanufacture notices (PMNs) and in some cases significant new use notices (SNUNs). This action would amend the SNURs to allow certain new uses reported in the SNUNs or PMNs without additional notification requirements and modify the significant new use notification requirements based on the actions and determinations for the SNUN or PMN submissions or based on the examination of new test data or other information. EPA is proposing these amendments based on our review of new and existing data for the chemical substances.