

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

Číslo/Dátum	Notifikujúca strana	Charakteristika notifikácie	Pripomienková doba
<a href="#">G/TBT/N/EU/874</a> 28/02/22	European Union	<p><b>ICS codes: 11.120 (Pharmaceutics);</b>  <b>Proposal for a Directive of the European Parliament and of the Council amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland, as well as in Cyprus, Ireland and Malta (COM(2021) 997 final)</b></p> <p>G/TBT/N/EU/874 To ensure legal certainty and predictability the notified draft measure provides for permanent derogations from EU pharmaceutical law to ensure the continued long-term supply of and access to medicines from Great Britain to Northern Ireland (“NI”). In addition, it provides for three-year derogations to address outstanding supply concerns for Cyprus (“CY”), Malta (“MT”) and Ireland (“IE”). Upon fulfilment of certain conditions as applicable, amendments to Directives 2001/20 and 2001/83 would allow imports of medicines without EU manufacturing and import authorisation from parts of the United Kingdom other than Northern Ireland. In addition, amendments to Directive 2001/83 would allow the following: For NI + CY/MT/IE localisation of regulatory functions in parts of the United Kingdom other than Northern Ireland; exports of medicines to parts of the United Kingdom other than Northern Ireland and subsequently into NI/CY/MT/IE without the need to repeat batch testing if already carried out in the EU; quality control testing carried out in parts of the United Kingdom other than Northern Ireland; for CY/MT the placing on the CY/MT market of a medicinal product based on an authorisation by a competent authority in parts of the United Kingdom other than Northern Ireland. For NI the supply to patients in NI of innovative medicines at the same time as any other patients in other parts of the United Kingdom other than Northern Ireland; the marketing authorisation applicant to choose between the mutual recognition/decentralised procedures and the national authorisation procedure in respect of NI.</p>	30/03/22
<a href="#">G/TBT/N/EU/875</a> 28/02/22	European Union	<p><b>ICS codes: 11.120 (Pharmaceutics);</b>  <b>Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom with respect to Northern Ireland as well as in Cyprus, Ireland and Malta (COM(2021) 998 final)</b></p> <p>G/TBT/N/EU/875 The notified draft measure provides for derogations from EU pharmaceutical law to ensure the continued supply of and access to medicines in Northern Ireland, Cyprus, Malta and Ireland. Upon fulfilment of certain conditions as applicable, amendments to Regulation (EU) No 2014/536 would allow imports of medicines without EU manufacturing and import authorisation from parts of the United Kingdom other than Northern Ireland.</p>	30/03/22
<a href="#">G/TBT/N/EU/876</a> 28/02/22	European Union	<p><b>ICS codes: 11.120 (Pharmaceutics);</b></p>	30/03/22

		<p><b>Commission Delegated Regulation of 17.12.2021 amending Delegated Regulation (EU) 2016/161 as regards the derogation from the obligation of wholesalers to decommission the unique identifier of medicinal products exported to the United Kingdom</b></p> <p>G/TBT/N/EU/876 The Commission Delegated Regulation amending Regulation (EU) 2016/161 extends for a further three-year period the existing derogation from the obligation of wholesalers to decommission the unique identifier of medicinal products exported to the United Kingdom.</p>	
<p><a href="#">G/TBT/N/ISR/1242</a> 28/02/22</p>	Israel	<p><i>Finger paints</i></p> <p><b>ICS codes: 97.200.50 (Toys);</b></p> <p><b>SI 562 Part 7 - Safety of toys: Finger paints - Requirements and test methods</b></p> <p>G/TBT/N/ISR/1242 Revision of the Mandatory Standard SI 562 part 7, dealing with finger paints. This draft standard revision adopts the European Standard EN-71-7: 2014 and A3: April 2020, with a few changes that appear in the standard's Hebrew section as follows: Changes the standard's normative references (Section 2); Adds translation of the definition of finger paints (Section 3); Adds new marking requirement to the primary packaging (Section 5.2.1.2) Both the old standard and this new revised standard will apply from entry into force of this revision for a period of 6 months. During this time, products may be tested according to the old or the new revised standard.</p>	29/04/22
<p><a href="#">G/TBT/N/ISR/1243</a> 28/02/22</p>	Israel	<p><i>Antenna receiving systems</i></p> <p><b>ICS codes: 33.120.40 (Aerials), 91.120.01 (Protection of and in buildings in general);</b></p> <p><b>SI 799 - Common antenna receiving systems, individual antenna receiving systems and amateur radio vertical antenna mast</b></p> <p>G/TBT/N/ISR/1243 The existing Mandatory Standard, SI 799, dealing with antenna receiving systems, shall be declared voluntary. The standard deals with the installation process of antenna systems and their performance testing after the installation. These procedures are made by professional who anyhow uses the standard's requirements as guidelines. The declaration aims to remove unnecessary obstacles to trade and lower trade barriers.</p>	29/04/22
<p><a href="#">G/TBT/N/ISR/1244</a> 28/02/22</p>	Israel	<p><i>Liquid carbon dioxide</i></p> <p><b>SI 388 - Liquid carbon dioxide</b></p> <p>G/TBT/N/ISR/1244 The existing Mandatory Standard, SI 388, dealing with liquid carbon dioxide, shall be declared voluntary. This declaration aims to remove unnecessary obstacles to trade and lower trade barriers. This original standard applies to the filling of pressure vessels, LPG cylinders and fire extinguishers, all covered by other mandatory standards that refer to this standard for the requirements of liquid carbon dioxide. Therefore the requirements of this standard are compulsory by reference and do not require to be mandatory.</p>	29/04/22
<p><a href="#">G/TBT/N/KOR/1061</a> 28/02/22</p>	Korea, Republic of	<p><i>Cosmetics</i></p> <p><b>Proposed amendments to the “Regulation on Safety Standards etc. of Cosmetics”</b></p> <p>G/TBT/N/KOR/1061 The proposed amendments to the “Regulation on Safety Standards etc. of Cosmetics” include: 1) Addition of prohibited ingredients for cosmetics and stringent</p>	29/04/22

restrictions on usesA. Addition of Persistent pollutants, some components of perfluorinated compounds, and 1,2,4-trihydroxybenzene to Prohibited ingredientsB. Prohibition on the use of benzalkonium chloride, a preservative, in spray-type products 2) Newly established exceptions for ingredients prohibited for use in cosmeticsA. management standards for CBD and THC that can be unintentionally included in parts excluded from cannabisB. permissible limits for radioactive materials that may exist in natureC. permissible limits for Fluorescent Brightener 367 among fluorescent brighteners, which are prohibited for use in cosmetics 3) Addition of ingredients that can be used as a hair dye and their maximum concentration limit 4) Clarification and modification of terms in the regulation

<a href="#">G/TBT/N/USA/1840</a> 28/02/22	United States of America	<p><i>Commercial warm air furnaces</i> <b>ICS codes:</b> 03.120 (<i>Quality</i>), 13.020 (<i>Environmental protection</i>), 19.020 (<i>Test conditions and procedures in general</i>), 25.180 (<i>Industrial furnaces</i>);</p> <p><b>Energy Conservation Program: Test Procedure for Commercial Warm Air Furnaces</b></p> <p>G/TBT/N/USA/1840 Notice of proposed rulemaking and announcement of public meeting - The U.S. Department of Energy ("DOE") proposes to amend the test procedures for commercial warm air furnaces ("CWAFs") to incorporate the latest versions of the industry standards that are currently incorporated by reference. DOE also proposes to establish a new metric, Thermal Efficiency Two ("TE2"), and corresponding test procedure. Use of the newly proposed test procedure would become mandatory at such time as compliance with amended energy conservation standards based on TE2 is required, should DOE adopt such standards. DOE also proposes additional specifications for CWAFs with multiple vent hoods or small-diameter vent hoods. DOE is seeking comment from interested parties on the proposal.</p>	26/04/22
<a href="#">G/TBT/N/TPKM/485</a> 01/03/22	Chinese Taipei	<p>2523.29. <i>Other portland cements</i> 2523.90 <i>Other hydraulic cements</i></p> <p><b>Proposal for Amendments to the Legal Inspection Requirements for Cement</b></p> <p>G/TBT/N/TPKM/485 With a view to enhancing the quality of cements, the Bureau of Standards, Metrology and Inspection (BSMI) is proposing to update the inspection standard CNS 61 for Portland Cement to its current version, published in 2021. The changes mainly involve maximum limits of added ingredients, maximum value of loss on ignition and insoluble residues in chemical substances, test of physical properties in fitness, specific surface, packaging and labeling. The conformity assessment procedures remains the same, i.e. Monitoring Inspection (MI) or Monitoring Inspection of Products from Premises with Registered Management System (MS-Based Monitoring Inspection). The obligatory inspection applicants will be allowed to print the Commodity Inspection Mark by themselves, instead of purchasing labels from the BSMI.</p>	30/04/22
<a href="#">G/TBT/N/ISR/1245</a> 01/03/22	Israel	<p><i>Audio/video, information and communication technology equipment</i> <b>ICS codes:</b> 33.160.01 (<i>Audio, video and audiovisual systems in general</i>), 35.020 (<i>Information technology (IT) in general</i>);</p>	30/04/22

**SI 62368 part 1 - Audio/video, information and communication technology equipment: Crosslinked polyethylene (PE-X): Pipes**

G/TBT/N/ISR/1245 Revision of the Mandatory Standard SI 62368 part 1 and the voluntary standard SI 60950 part 22, dealing with audio/video, information and communication technology equipment, to be replaced with SI 62368 part 1. This draft standard revision adopts the International Standard IEC 62368-1 - Edition 3.0: 2018-10, with a few changes that appear in the standard's Hebrew section. The major differences between the old version and this new revised draft standard are as follow: Adds new requirements for optical radiation (Table 39 and sub-sections 10.4.1 and 10.4.3); Adds requirements for insulating liquids (Sub-sections 3.3.5.4, 4.4.4, 5.4.12, 6.4.9 and F.4); Adds requirements for work cells (Sub-sections 3.3.6.16 and 8.5.4.2); Adds requirements for WPT - Wireless Power Transmitters (Sub-sections 3.3.3.12 and 9.6); adds requirements for FIW - Fully Insulated Winding wire (Sub-sections 3.3.18 and G.5.3.4); Adds alternative method for determination of top, bottom and side openings for fire enclosures (Sub-section 6.4.8.3 and Annex S dealing with the testing of fire enclosures); Adds alternative requirements for sound pressure (Sub-sections 3.3.19, Table 39 and 10.6.2. and Annex E). All special safety requirements for outdoor equipment combined into this revision will remain voluntary. Both the old standard and this new revised standard will apply from the entry into force of this revision until 6 January 2023 (unless not published till then). During this time products may be tested according to the old or the new revised standard.

[G/TBT/N/AUS/138](#)  
02/03/22

Australia

*Products regulated by the Therapeutic Goods Administration (TGA) as 'biologicals' including human tissue-based products (e.g., skin, bone, ocular, cardiovascular donor tissue); cell-based products (e.g., genetically modified cells); immunotherapy products containing genetically engineered human cells (e.g., CAR-T cells); products that comprise or contain live animal cells, tissues or organs (e.g., pancreatic islet cells isolated from pigs); autologous human cell and tissue (HCT) products (e.g., human stem cell transplants); and faecal microbiota transplant (FMT) products.*

01/05/22

**Priority Review pathway for biologicals: feasibility, potential eligibility criteria and determination process**

G/TBT/N/AUS/138 Australia's Therapeutic Goods Administration (TGA) is seeking feedback on a proposed priority pathway for assessment of certain novel and life-saving biologicals. The proposed 'Priority Review' pathway will align with the pathway already in place for medicines and offer a faster formal assessment pathway for biologicals in certain circumstances. This will allow consumers with life-threatening diseases or seriously debilitating conditions to access these treatments in less time if the assessment results in a decision by the TGA to include the biological in the Australian Register of Therapeutic Goods (ARTG). Australia does not currently have a formal mechanism to expedite the assessment and inclusion of biologicals in the ARTG. Depending on the feedback received, the TGA could propose to the Australian Government that a priority pathway be implemented for the pre-market assessment and registration of novel biologicals that address unmet clinical needs for Australian consumers. This would require changes to the Therapeutic Goods Regulations 1990. The TGA is

conducting a public consultation on the proposed pathway between February 2022 and March 2022 to seek feedback on: whether stakeholders support introduction of such a pathway eligibility criteria for the Priority Review pathway for biologicals the Process for determining whether a biological application meets the eligibility criteria for Priority Review (the ‘Determination Process’).

<a href="#">G/TBT/N/ISR/1246</a> 02/03/22	Israel	<p><i>Plastics piping systems</i>  <b>ICS codes:</b> 23.040.20 (<i>Plastics pipes</i>), 91.140.60 (<i>Water supply systems</i>);  <b>SI 5433 Part 2 - Plastics piping systems for hot and cold water installations inside buildings - Crosslinked polyethylene (PE-X): Pipes</b>  G/TBT/N/ISR/1246 Third amendment to the Mandatory Standard SI 5433 part 2. This proposed amendment adopts ISO 15875-2:2003/Amd.2: November 2020.</p>	01/05/22
<a href="#">G/TBT/N/ISR/1247</a> 02/03/22	Israel	<p><i>Plastics piping systems</i>  <b>ICS codes:</b> 23.040.20 (<i>Plastics pipes</i>), 91.140.60 (<i>Water supply systems</i>);  <b>SI 5433 Part 3 - Plastics piping systems for hot and cold water installations inside buildings - Crosslinked polyethylene (PE-X): Fittings</b>  G/TBT/N/ISR/1247 Third amendment to the Mandatory Standard SI 5433 part 3. This proposed amendment adopts ISO 15875-3:2003/Amd.1:2020-12.</p>	01/05/22
<a href="#">G/TBT/N/ISR/1248</a> 02/03/22	Israel	<p><i>Plastics piping systems</i>  <b>ICS codes:</b> 23.040.20 (<i>Plastics pipes</i>), 91.140.60 (<i>Water supply systems</i>);  <b>SI 5433 Part 5 - Plastics piping systems for hot and cold water installations inside buildings - Crosslinked polyethylene (PE-X): Fitness for purpose of the systems</b>  G/TBT/N/ISR/1248 First amendment to the Mandatory Standard SI 5433 part 5. This proposed amendment adopts ISO 15875-5:2003/Amd.1:2020-12.</p>	01/05/22
<a href="#">G/TBT/N/ISR/1249</a> 02/03/22	Israel	<p><i>Iron chloride used for purifying drinking water</i>  <b>ICS codes:</b> 71.100.80 (<i>Chemicals for purification of water</i>);  <b>SI 5438 part 11 - Chemicals used for treatment of water intended for drinking: Iron (III) chloride</b>  G/TBT/N/ISR/1249 Revision of the Mandatory Standard SI 5438 part 11 deals with iron chloride used for purifying drinking water. This draft standard revision adopts both the European Standard EN 888: November 2004 and the American Standard ANSI/AWWA B 407-18, allowing for compliance with either, subject to the changes included in the standard's Hebrew section. The changes introduced in the updated American compliance route are the main difference between the old version and this proposed standard.</p>	01/05/22
<a href="#">G/TBT/N/JPN/728</a> 02/03/22	Japan	<p><b>(1) Partial amendment to the Minimum Requirements for Biological Products (2) Partial amendment to the Public Notice on National Release Testing</b>  G/TBT/N/JPN/728 (1) The Minimum Requirements for Biological Products will be partially amended to add the standard for a vaccine product to be newly approved. (2) The fee, criterion and test sample quantity for National Release</p>	01/04/22

Testing will be partially amended to provide for the above-mentioned vaccine product.

<a href="#">G/TBT/N/USA/1841</a> 02/03/22	United States of America	<i>Variable refrigerant flow (VRF) multi-split air conditioners and VRF multi-split system heat pumps</i> <b>ICS codes:</b> 13.020 (Environmental protection), 23.120 <b>Energy Conservation Program: Energy Conservation Standards for Variable Refrigerant Flow Multi-Split Air Conditioners and Heat Pumps</b> G/TBT/N/USA/1841 Notice of proposed rulemaking and request for comment - In this document, the U.S. Department of Energy ("DOE" or the "Department") is proposing amended energy conservation standards for variable refrigerant flow (VRF) multi-split air conditioners and VRF multi-split system heat pumps (collectively referred to as "VRF multi-split systems") that rely on a new cooling efficiency metric and are equivalent to those levels specified in the industry standard. DOE has preliminarily determined that it lacks the clear and convincing evidence required by the statute to adopt standards more stringent than the levels specified in the industry standard. This document also announces a public meeting webinar to receive comment on these proposed standards and associated analyses and results. DOE will hold a public meeting via webinar on Wednesday, 23 March 2022, from 1:00 p.m. to 4:00 p.m. Eastern Time. See section VII, "Public Participation," for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.	02/05/22
<a href="#">G/TBT/N/DNK/127</a> 03/03/22	Denmark	<b>Draft Order on weapons and ammunition which can be used for hunting etc.</b> G/TBT/N/DNK/127 Regulatory act which impose restrictions on hunters in Denmark. It bans use and bringing bullets for hunting ammunition to rifles which contains a concentration of lead that is equal or greater than 1 % w/w (percentage weight) for hunting and derogation shooting. The ban includes only centrefire hunting ammunition and is expected to enter into force on 31 March 2024 after a transition phase. The act itself is expected to enter into force on 1 July 2022.	02/05/22
<a href="#">G/TBT/N/FRA/223</a> 03/03/22	France	<i>Emballages</i> <b>Décret relatif à la proportion minimale d’emballages réemployés à mettre sur le marché annuellement</b> G/TBT/N/FRA/223 Le décret définit pour les années 2023 à 2027 la proportion minimale d’emballages réemployés à mettre sur le marché annuellement en France afin d’atteindre les objectifs de réemploi fixés par l’article L. 541-1 du code de l’environnement soit 5 % en 2023 et 10 % en 2027. Il précise les producteurs concernés et prévoit la possibilité pour ces producteurs de se regrouper au sein d’une structure collective ou de s’appuyer sur leur éco-organisme pour remplir leur obligation d’emballages réemployés. La possibilité pour les producteurs de s’appuyer sur l’éco-organisme auprès duquel ils sont déjà adhérent pour leur obligation de responsabilité élargie (REP) en leur versant une éco-contribution facilitera grandement la mise en œuvre de cette nouvelle obligation. En contrepartie, le décret précise que les éco-organismes agréés pour les emballages sont chargés de développer le réemploi des emballages pour le compte des producteurs. Ce décret entre en vigueur le 1er janvier 2023.	02/05/22

**Draft Notification of the Committee on Labels, entitled Determination of Adjuvant Products and Soil Conditioner Products as Label-Controlled Products**

G/TBT/N/THA/656 For the reason that adjuvant products and soil conditioner products are not included in the Fertilizer Act nor the Hazardous Substances Act, as well as in order to protect consumer rights, the Committee on Label, by virtue of the Consumer Protection Act B.E. 2522 and as amended by the Consumer Protection Act (No.2), B.E. 2551(2008), deems it necessary to designate plant enhancers and soil conditioner products as label-controlled products. Therefore, the use of statements, figure, artificial mark, or image, as appropriate, on the product label claiming to have properties or have active ingredients to improve soil quality or promote plant growth, such as surfactants, additives, plant enhancers, chitosan, seaweed extracts and amino acids for plants, soil conditioners, and soil enhancing substance, shall be in accordance to the elements in this draft, which is summarized as follows: 1. Prescribing definition of additives products and soil conditioner products. 2. Determination of additives products and soil conditioner products as label-controlled products. 3. The Label of label-controlled products shall be specified the statement, figure artificial mark or image as appropriate depending on the case. But such statement must be true, do not cause misunderstanding in products. This regulation does not apply for products manufactured for export and for sale in Thailand. 4. The detail of label-controlled products must be specified as follow clause 4 of this draft Notification such as name of category, name of trade mark, chemical name, date of manufacture, date of expiration, warning etc. 5. In the case the label can not be display as specified in Clause 3 and 4 of this draft Notification, it shall be displayed either the statement, figure, artificial mark or image in any part of the products or container or packaging or be insert or included with the products or container or packaging of the product or in the documents or manuals to use accompanying with product. 6. This notification shall enter into force after 120 days following the date of its publication in the Government Gazette onwards.