Predpisy notifikované v Dohode o technických prekážkach obchodu (TBT WTO) 17. týždeň roku 2023

Číslo/Dátum	Notifikujúca strana	Charakteristika notifikácie	Pripomienková doba
<u>G/TBT/N/EU/968</u> 24/04/2023	European Union	Construction products Draft Commission Delegated Regulation (EU) on the conditions for classification, without testing, of solid wood panelling and cladding with regard to their reaction to fire and amending Decision 2006/213/EC The reaction to fire performance of wood panelling and cladding, and wood ribbon elements, within the classification provided for in Regulation (EU) 2016/364, is well established only when the material is untreated. For this reason, the reaction to fire performance of theseproducts can be deemed, without the need for any further testing, to achieve a certain class of performance, as defined in the European classification system mentioned above but this classification cannot be extended to untreated products. This Delegated Regulation is necessary to prevent misuse of the existing Commission Decision 2006/213/EC.	23/06/2023
G/TBT/N/KOR/1138 24/04/2023	Korea, Republic of	 Medical Devices Proposed partial amendments to the Regulation on medical device approval/report/review, etc.; The proposed amendments to the Regulation on medical device approval/report/review, etc. is as follows: Recognition of real-world evidence when reviewing clinical trial data For clinical trial data, human test data, theses and papers (class of medical device 1 and must be submitted. It is to prepare the basis for recognition of real-world evidence when reviewing clinical trial data depending on the characteristics of medical devices such as rare and urgently needed medical devices. Introducing a custom classification procedure for newly developed medical devices such as digital health devices To support rapid commercialization of newlydeveloped medical devices by establishing a procedure for introducing custom classification procedure for melical devices such as digital health devices Preparation of grounds for multiple purposes description of combination medical devices, a single purpose of use according to the characteristics. In the case of combination medical devices, a single purpose of use is described when applying for permission, but in order to operate a flexible screening and rational system that reflects the characteristics of various combination medical equipment medical equipment. For special medical equipment of which safety and performance are regularly checked through quality control, the certificate of inspection is exempted when distributing used special used products. 	23/06/2023

-Subject of expedited review is expanded to include medical devices subject to production/import suspension reporting and public health crisis response medical devices to promote prompt response and public health in the event of supply/demand occurrences such as production/import suspension

6) Increase test report accreditation body for biosafety data -To expand citizens' choice by increasing the number of laboratory audit institutions designated by the Minister of Food and Drug Safety for biosafety data

7) Minor change improvement

-Revise usage methods and precautions according to reevaluation results, change of appearance of components, etc.

Proposed partial amendments to the Regulation on

<u>G/TBT/N/KOR/1139</u> 24/04/2023 Korea.

Republic of

Medical Devices

23/06/2023

Stability Test Standard for Medical Devices; The proposed amendments to the Regulation on Stability Test Standard for Medical Devices is as follows:1) Measurement period for stability test-For the measurement period, at least one time point, including the last time point, can be set for long-term preservation tests and accelerated aging tests of medical devices using raw materials without physical or chemical changes, such as metals, when the data at the start of the test is replaced.2) Clarification of test items-Test items are divided into biological safety tests, performance tests, and other tests in accordance with the <Regulations on Medical Device Permission, Notification, Review, etc.> and <Regulation on In Vitro Diagnostic Medical Device Permission, Notification, Review, etc.>

<u>G/TBT/N/USA/1985</u>	United
24/04/2023	States of
	America

Side underride guards; Crash protection and restraint 20/06/2023 systems (ICS code(s): 43.040.80); Commercial vehicles (ICS code(s): 43.080)

Side Underride Guards;

Advance notice of proposed rulemaking (ANPRM) -This ANPRM responds to Section 23011(c) of the November 2021 Infrastructure Investment and Jobs Act (IIJA), commonly referred to as the Bipartisan Infrastructure Law (BIL), which directs the Secretary to conduct research on side underride guards to better understand their overall effectiveness, and assess the feasibility, benefits, costs, and other impacts of installing side underride guards on trailers and semitrailers. The BIL further directs the Secretary to report the findings of the research in aFederal Register notice to seek public comment. In addition, this ANPRM also responds to a petition for rulemaking from Ms. Marianne Karth and the Truck Safety Coalition (TSC).

<u>G/TBT/N/AUS/155</u> 25/04/2023 Australia

Infant formula products for sale in Australia and New 07/07/2023 Zealand, including under HS 190110.

Proposal P1028 Infant Formula –2nd Call For Submissions

Proposal P1028 proposes to amend the Australia New Zealand Food Standards Code (the Code) to ensure that infant formula products are safe and suitable while also taking account of the latest scientific evidence, market developments, changes in the international regulatory context, and revised Australian and New Zealand policy

guidance. The proposed draft variation to the Code will amend infant formula regulation. Relevant aspects include:

•Re-drafting of Standard 2.9.1 and related provisions in Schedule 29 to reflect the differing requirements for subcategories of infant formula products (infant formula, follow-on formula and special medical purpose products for infants (SMPPi);

•Revised nutrient composition values;

•Revised permissions for food additives, contaminants and processing aids

•Addition of a definition for SMPPi, and associated revisions on nutrient composition, restriction of sale and standalone labelling permissions reflective of Standard 2.9.5 -Foods for Special Medial Purpose (FSMP)

•Amendments and new provisions regarding safety-related labelling (including directions for use and storage, warning statements and age-related statements), provision of information (including nutrition information, stage labelling and a prohibition of proxy advertising), and labelling for SMPPi.

•Amendments to clarify the requirements for novel foods when added to infant formula products.

A five year transition period, inclusive of stock-in-trade, is proposed.

FERTILISERS (HS code(s): 31); Fertilizers (ICS code(s): 25/06/2023 Denmark 65.080)Urease inhibitors

> Title i Danish: Udkast til bekendtgørelse om jordbrugsvirksomheders anvendelse af gødningTitle in English: Draft of statutory order on farm enterprises' use of fertilisers;

> The draft will replace the current statutory orderno. 1142 of 10 July 2022 on farm enterprises' usage of fertilisers. With the new draft, a number of rules are changed. The changes are mainly minor clarifications and adjustments. The notification under the WTO TBT agreement relates to section 8, subsection 1 and 2. Section 8 contains requirements for the application of artificial fertilisers containing urea-based nitrogen in order to prevent ammonia emissions. Addition of urease inhibitor to artificial fertilisers is one possible method to fulfill the requirements. With the proposed amendment to the statutory order, the urease inhibitor is required to be CE marked.

European Fruit and vegetables, processed fruit and vegetables, and 25/06/2023 26/04/2023 Union **Bananas Draft Commission Delegated Regulation supplementing** Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards marketing standards for the fruit and vegetables sector, certain processed fruit and vegetable products and the bananas sector, and repealing Commission Regulation (EC) No 1666/1999 and Commission Implementing Regulations (EU) No 543/2011 and (EU) No 1333/2011; The draft delegated act supplements Regulation (EU) No 1308/2013 by merging and amending rules on marketing standards currently contained in Commission Implementing Regulation (EU) No 543/2011, Commission Implementing Regulation (EU) No 1333/2011 and Commission Regulation (EC) No 1666/1999, by aligning these rules to

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		market development and to the Farm to Fork Strategy. It repeals Commission Implementing Regulation (EU) No 543/2011, Commission Implementing Regulation (EU) No 1333/2011 and Commission Regulation (EC) No 1666/1999.This draft delegated act aligns market development with the objectives of the Farm to Fork Strategy, regarding in particular increased information for consumers and reduction of food waste.It modernises and simplifies the rules by merging fruit and vegetables legislation with banana and dried grapes legislation, and deleting obsolete provisions. Some amendments align with recent changes in quality standards adopted by the United Nations Economic Commission for Europe (UNECE).	
<u>G/TBT/N/EU/970</u> 26/04/2023	European Union	 Fruit and vegetables, processed fruit and vegetables, and Bananas Draft Commission Implementing Regulation laying down rules concerning checks on conformity to marketing standards for the fruit and vegetables sector, certain processed fruit and vegetable products and the bananas sector; The implementing act supplements Regulation (EU) No 1308/2013 by merging and amending rules on the control of marketing standards currently contained in Commission Implementing Regulation (EU) No 1333/2011, CommissionImplementing Regulation (EC) No 1666/1999.Control of the quality requirements; Control of the labelling 	25/06/2023
<u>G/TBT/N/EU/971</u> 26/04/2023	European Union	the modifications concern eggs for human consumption 04072100 Draft Commission Delegated Regulation supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards marketing standards for eggs, and repealing Commission Regulation (EC) No 589/2008; The proposal aims at revising common rules for egg marketing standards.	25/06/2023
<u>G/TBT/N/EU/972</u> 26/04/2023	European Union	the modifications concern eggs for human consumption 04072100 Draft Commission Delegated Regulation amending Regulation (EU) No 1308/2013 of the European Parliament and of the Council, as regards marketing standards for eggs; The draft Regulation introduces obligatory marking of eggs at the production site.	25/06/2023
<u>G/TBT/N/EU/973</u> 26/04/2023	European Union	the modifications concern eggs for human consumption 04072100 Draft Commission Implementing Regulation laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards marketing standards for eggs; The proposal aims at revising common rules for egg marketing standards.	25/06/2023
<u>G/TBT/N/EU/974</u> 26/04/2023	European Union	the modifications concern poultrymeat 0207	25/06/2023

		Draft Commission DelegatedRegulation supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards marketing standards for poultrymeat, and repealing Commission Regulation (EC) No 543/2008; The delegated regulation aims at revising common rules for poultrymeat marketing standards.	
<u>G/TBT/N/EU/975</u> 26/04/2023	European Union	the modifications concern poultrymeat 0207 Draft Commission Implementing Regulation laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards marketing standards for poultrymeat; The (Implementing) Regulation aims at revising common rules for poultrymeat marketing standards.	25/06/2023
<u>G/TBT/N/EU/976</u> 26/04/2023	European Union	the modifications concern honey, fruit juices and certain similar products intended for human consumption, fruit jams, jellies and marmalades intended for human consumption, certain partly or wholly dehydrated preserved milk for human consumption Proposal for a Directive of the European Parliament and of the Council amending Council Directives 2001/110/EC relating to honey, 2001/112/EC relating to fruit juices and certain similar products intended for human consumption, 2001/113/EC relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for humanconsumption, and 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption (COM(2023)201 final); The proposal proposes to revise common rules for honey origin labelling, revise the nutrition claims regarding sugar content that can be made on fruit juices and certain similar products, create a new category for fruit juices whose naturally occurring sugars have been partially removed, revise the minimum quantity of fruit to be used in the manufacture of jam, jelly, extra jam or extra jelly, and authorise a treatment to produce lactose-free milk products.	25/07/2023
<u>G/TBT/N/KEN/1422</u> 26/04/2023	Kenya	Parts and accessories for tractors, motor vehicles for the transport of ten or more persons, motor cars and other motor vehicles principally designed for the transport of persons, motor vehicles for the transport of goods and special purpose motor vehicles of heading 8701 to 8705, n.e.s. (HS code(s): 8708); Indicating and control devices (ICS code(s): 43.040.30) DKS 2295-1:2023 Maximum Road speed limiters for motor vehicles Part 1: Performance and installation requirements; This Part 1 of this Kenya Standard specifies requirements for the performance and installation of devices designed to limit the maximum road speed of motor vehicles by control of engine power. This standard also specifies performance requirements of speed recording and reporting devices. This may be a separate unit to be installed on the vehicle as an add-on or on-board system built in the vehicle. This standard does not cover methods of test and procedure for type approval which are covered under KS 2295-2. The two	24/06/2023

		parts of this standard cannot therefore be read in isolation.	
<u>G/TBT/N/KEN/1423</u> 26/04/2023	Kenya	Mineral or chemical fertiliserscontaining the two fertilising elements nitrogen and potassium or one principal fertilising substance only, incl. mixtures of animal or vegetable fertilisers with chemical or mineral fertilisers (excl. those in tablets or similar forms, or in packages with a gross weight of $\langle = 10 \text{ kg} \rangle$ (HS code(s): 310590); Fertilizers (ICS code(s): 65.080) KS 2290: 2023 Organic Fertilizer-Specification; This Kenya standard specifies requirements for organic fertilizers.	25/06/2023
<u>G/TBT/N/KEN/1424</u> 26/04/2023	Kenya	 Municipal waste (HS code(s): 382510); Wastes (ICS code(s): 13.030) The Sustainable Waste Management Act (No. 31 of 2022) (Extended Producer Responsibility) Regulations, 2022; (1) The purpose of these Regulations shall be to: (a) extend the responsibility of a producer over a product and its packaging during the entire life cycle of the product or its packaging; (b) provide an overarching framework for establishment and operation of mandatory extended producer responsibility schemes; (c) optimize the life cycle approach to management of products and associated wastes; (d) enhance resource mobilization for management of products and sustainable waste management; (e) operationalization of polluter pays principle; and (f) promote collaborative approach in management of products and associated wastes; 2. These Regulations shall apply to: (a) a producer; (b) an individual extended producer responsibility organisation. 3. (i)These Regulations shall apply to the products set out in the First Schedule.(ii) The products covered under these Regulations shall be those that negatively impact the environment and health due to: (a) the challenge they pose on: (i) reuse; (ii) recyclability; and (iii) recoverability. (b) the high management cost of the products at postconsumer stagebecause of the: (i) quantities involved; (ii) hazardous nature; (iii) risks involved. 	25/06/2023
<u>G/TBT/N/PAN/127</u> 26/04/2023	Panama	Sección I -ANIMALES VIVOS Y PRODUCTOS DEL REINO ANIMALCapítulo 1 Animales vivos todo el Capítulo 1 excepto:a) los peces, los crustáceos, moluscos y demás invertebrados acuáticos, de las partidas 03.01, 03.06,03.07 o 03.08; b) los cultivos de microorganismos y demás productos de la partida 30.02; c) los animales de la partida 95.08Capítulo 7 HORTALIZAS, PLANTAS, RAICES Y TUBERCULOS ALIMENTICIOS desde partida 7.01 hasta 7.14.Capítulo 8 FRUTAS Y FRUTOS COMESTIBLES desde la partida 8-01 hasta la 8.14Capítulo 10 CEREALES (todo el capítulo)Capítulo 11 Cereales (productos de la molinería como malta, almidón y fécula, inulina, gluten de trigo) Resolución Ministerial "Que establece los requisitos generales y sanitarios que deben cumplir los alimentos	25/06/2023

		que sean, contengan o deriven de Organismos Genéticamente Modificados, cuya producción sea nacional, de exportación o de importación, para consumo humano dentro del mercado nacional, incluido su etiquetado".; Establecer los requisitos generales para la producción nacional, exportación e importación de alimentos para consumo humano, que sean, contengan o deriven de Organismos Genéticamente Modificados (OGM), incluido su etiquetado o etiqueta complementaria, dentro del mercado nacional, con la finalidad de garantizar el derecho a la información de los consumidores y la debida protección a la salud humana.	
<u>G/TBT/N/VNM/256</u> 26/04/2023	Viet Nam	New assembled, manufactured and imported automobiles; ROAD VEHICLES ENGINEERING (ICS 43) Draft Amendment 01:2023 of QCVN 109:2021/BGTVT to the National Technical Regulation on the fifth level of gaseous pollutants emissions for new assembled, manufactured and imported automobiles; This Draft Amendment of National Technical Regulation regulates the emission limits, exhausting test(s) and method(s), administration requirements and implementation of the fifth level of gaseous pollutants emissions inquality control of technical safety and environmental protection for new assembled, manufactured and imported motor vehicles.This Draft Amendment of National Technical Regulation applies to automobiles manufacturing and assembling establishments, enterprises that manufacture or import automobile components and organizations and agencies involved in the management, inspection and testing of automobiles and automotive parts.	25/06/2023
<u>G/TBT/N/RWA/860</u> 27/04/2023	Rwanda	<i>Filtering or purifying machinery and apparatus for liquids</i> :(<i>HS code(s): 84212</i>); <i>Ceramic products (ICS code(s):</i> <i>81.060.20</i>) DRS 561: 2023, Ceramic water filters —Specification; This Draft Rwanda standard specifies requirements, sampling and test methods for ceramic water filter used to filter water for human consumption.	27/05/2023
<u>G/TBT/N/TTO/135</u> 27/04/2023	Trinidad and Tobago	 Products of the chemical industry in general (ICS code(s): 71.100.01); Chemicals for industrial anddomestic disinfection purposes (ICS code(s): 71.100.35); Surface active agents (ICS code(s): 71.100.40) General purpose cleaning, bleaching and disinfecting products -Compulsory requirements; This standard establishes chemical and labelling requirements for general purpose cleaning, bleaching and disinfecting products (including dilutable products) for use in Trinidad and Tobago. This standard applies to the following products: a) general purpose cleaners, including but not limited to multipurpose and multi-surface cleaners; EXAMPLE Products for cleaning floors, kitchens, countertops, sinks and hard surfaces such as stovetops, cooktops, and microwaves etc. 	26/06/2023

b) disinfectants including disinfectants containing quaternary ammonium compounds (QACs) in liquid, powder, cream, tablet and gel forms;

c) hand dishwashing detergents in liquid, cream, paste and gel forms;

d) automatic dishwasherdetergents;

e) bleaching agents including calcium hypochlorite in solution, granular, tablet, foam, cream, powder formats and bleaching gel pens;

f) engine degreasers;

g) automotive cleaners in liquid, cream, gel formats for multipurpose applications;

h) spot or stain removers;

i) aerosols that function as general purpose cleaners; and

j) sanitizers not designed for human application.

EXAMPLE: Tyre, engine, dashboard, console, carpet, upholstery, oven, window, floor, bathroom, fabric and kitchen cleaners etc.

TTCS 21: 20XX also applies to the concentrated versions of the products mentioned above and cleaning wipes and disinfecting wipes (or pads) related to the aforementioned products.

This standard does not apply to the following products:

1) automotive hard paste waxes with no cleaning or disinfecting properties;

2) automotive rubbing or polishing compound with no cleaning or disinfecting properties;

3) floor polishes and waxes with no cleaning or disinfecting properties;

4) alcohol-based and non-alcohol based handrubs or hand sanitizers;

5) fabric softeners with no cleaning or disinfecting properties;

6) liquid sodium hypochlorite solutions which are covered under the national standard TTCS 1, Sodium hypochlorite solution (Liquid chlorine bleach) – Compulsoryrequirements;

7) laundry detergents (pods, bars, liquids and powders) which are covered under the national standard TTCS 7, Laundry detergents –Compulsory requirements 8) cosmetics:

9) cleaning products primarily intended for use on human beings and animals;

10) pesticides which are covered under the national standard TTS 76: Part 8, Requirements for labelling-Part 8: Labelling of retail packages of pesticides;

11) products covered under any other national standards; and 12) products covered under national primary or secondary legislation issued by other Government Ministries and agencies.

<u>G/TBT/N/BRA/1482</u> Brazil 28/04/2023

FOOD TECHNOLOGY (ICS code(s): 67) Draft resolution 1158, 24 April 2023;

31/07/2023

This Draft Resolution contains provisions on proof of safety and authorization for the use of novel foods and novel ingredients. This regulation will be also notified to the SPS Committee.

<u>G/TBT/N/IND/254</u> 28/04/2023	India	Resin treated compressed wood laminates (compregs) -For electrical purposes, For chemical purposes and For general purposes Resin treated compressed wood laminates (Quality	27/06/2023
		 Control) Order, 2023; Resin treated compressed wood laminates (Quality Control) Order, 2023 Resin treated compressed wood laminates, also known as compregs, are laminates made from thin wood veneers and thermosetting phenol or cresol formaldehyde resins. They combine within themselves enhanced mechanical properties with the stabilizing and moisture-proof qualities of thermosetting resins; besides, they have good machining. properties, and resistance to corrosive agents and termite attack. Compregs are manufactured in different shapes, such as, sheets, rods and moulded shapes. Resin treated compressed wood laminates is made up of Timber, Synthetic Resins, Solvents, Varnishes and Unless otherwise specified the thickness of resin treated compressed wood laminate boards shall be 3 mm,4 mm, 5mm,6 mm, 8 mm, 12mm, 16mm, 20 mmm, 25 mm,32 mm,40 mm, 50 mm, 60 mm and 70 mm. 	
<u>G/TBT/N/NZL/122</u> 28/04/2023	New Zealand	The standard will set production and processing rules for food, beverage, plant, and animal products labelled as organic. Ministry for Primary Industries National Organic standard; The proposed national organic standard establishes requirements for the production and processing of food, beverages, plant and animal products labelled as organic products. This operationalises aspects of the Organic Products and Production Act 2023.	27/06/2023
<u>G/TBT/N/GBR/61</u> 28/04/2023	United Kingdom	Cosmetics products are as defined by Article 2(1)(a) of Regulation (EC) No 1223/2009. HS code: HS 33 http://tariffdata.wto.org/ReportersAndProducts.aspxfor cosmeticsCS codes: ICS 71.100.70 https://www.iso.org/ics/71.100.70/x/for cosmetics The Cosmetic Products (Restriction of Chemical Substances) Regulations 2023 These measures will amend the Cosmetics Regulation 1223/2009 as applicable in GB ("the Cosmetics Regulations") as they apply in [England, Wales and Scotland]. They will amend permitted levels of certain chemicals in the Cosmetics Regulations.We will be amending the Cosmetics Regulations to permit the use of methyl-N-Methylanthranilate for use up to 0.1% for leave-on and 0.2% for rinse-off cosmetic products, and the use of HAA299 and HAA299 (nano) up to a level of 10%, excluding use in spray and/or aerosol products.	27/06/2023