

**Predpisy notifikované v Dohode o technických prekážkach obchodu (TBT WTO)
45. týždeň roku 2021**

Číslo/Dátum	Notifikujúca strana	Charakteristika notifikácie	Pripomienková doba
G/TBT/N/BHR/617 08/11/21	Bahrain, Kingdom of	ICS codes: 67.200 (<i>Edible oils and fats. Oilseeds</i>); EDIBLE OLIVE OIL AND OLIVE POMACE OILS This Draft Gulf Technical Regulation is concerned with olive oil and olive pomace oils.	07/01/22
G/TBT/N/EGY/300 08/11/21	Egypt	ICS codes: 91.100.30 (<i>Concrete and concrete products</i>); Ministerial Decree No. 221 /2021 (2 pages, in Arabic) mandating the Egyptian Standard ES 8473-2 " Silica fume for concrete part:2 Silica Fume For Concrete. Conformity Evaluation G/TBT/N/EGY/300 The Ministerial Decree No. 221 /2021 gives the producers and importers a six-month transitional period to abide by the Egyptian standard ES 8473-2. This part specifies the scheme for the evaluation of conformity of silica fume to EN 13263-1, including certification of conformity by a certification body. This part provides technical rules for production control by the manufacturer, including autocontrol testing of samples, and for the tasks of the certification body. It also provides rules for actions to be followed in the event of non-conformity and the procedure for the certification of conformity. Worth mentioning is that this standard adopts the technical content of EN 13263-2:2005+A1:2009	07/01/22
G/TBT/N/KWT/585 08/11/21	Kuwait, the State of	ICS codes: 67.200 (<i>Edible oils and fats. Oilseeds</i>); EDIBLE OLIVE OIL AND OLIVE POMACE OILS This Draft Gulf Technical Regulation is concerned with olive oil and olive pomace oils.	07/01/22
G/TBT/N/MEX/505 08/11/21	Mexico	<i>Envases, recipientes intermedios para graneles (RIG) y grandes embalajes/envases destinados al transporte de mercancías peligrosas</i> Proyecto de Norma Oficial Mexicana PROY-NOM-007-SCT2-2021, Disposiciones relativas a la construcción, marcado UN y ensayo de embalajes/envases, recipientes intermedios para graneles (RIG) y grandes embalajes/envases destinados al transporte de mercancías peligrosas. G/TBT/N/MEX/505 La presente Norma Oficial Mexicana, tiene como objetivo establecer las características y especificaciones que se deben cumplir para la construcción (fabricación), marcado UN y ensayo de los embalajes/envases, recipientes intermedios para graneles (RIG) y grandes embalajes/envases destinados al transporte de mercancías peligrosas que transitan en las vías generales de comunicación de jurisdicción federal. Esta Norma Oficial Mexicana, dentro de la esfera de	07/01/22

sus responsabilidades, es de aplicación obligatoria para los expedidores, y destinatarios de las mercancías peligrosas, así como de los fabricantes (constructores) y distribuidores responsables de la construcción y reconstrucción de los embalajes/envases, recipientes intermedios para granel y los grandes embalajes/envases, el asegurar que cada uno de éstos sea capaz de pasar los ensayos indicados en esta Norma Oficial Mexicana, y de la persona que ofrece una mercancía peligrosa para ser transportada, el garantizar que el embalaje/envase, recipientes intermedios para graneles y los grandes embalajes/envases, cumplan con la presente Norma Oficial Mexicana.

G/TBT/N/OMN/453 08/11/21	Oman	ICS codes: 67.200 (<i>Edible oils and fats. Oilseeds</i>); EDIBLE OLIVE OIL AND OLIVE POMACE OILS This Draft Gulf Technical Regulation is concerned with olive oil and olive pomace oils.	07/01/22
G/TBT/N/QAT/606 08/11/21	Qatar	ICS codes: 67.200 (<i>Edible oils and fats. Oilseeds</i>); EDIBLE OLIVE OIL AND OLIVE POMACE OILS This Draft Gulf Technical Regulation is concerned with olive oil and olive pomace oils.	07/01/22
G/TBT/N/SAU/1224 08/11/21	Saudi Arabia, Kingdom of	ICS codes: 67.200 (<i>Edible oils and fats. Oilseeds</i>); EDIBLE OLIVE OIL AND OLIVE POMACE OILS This Draft Gulf Technical Regulation is concerned with olive oil and olive pomace oils.	07/01/22
G/TBT/N/ARE/522 08/11/21	United Arab Emirates	ICS codes: 67.200 (<i>Edible oils and fats. Oilseeds</i>); EDIBLE OLIVE OIL AND OLIVE POMACE OILS This Draft Gulf Technical Regulation is concerned with olive oil and olive pomace oils.	07/01/22
G/TBT/N/YEM/213 08/11/21	Yemen	ICS codes: 67.200 (<i>Edible oils and fats. Oilseeds</i>); EDIBLE OLIVE OIL AND OLIVE POMACE OILS This Draft Gulf Technical Regulation is concerned with olive oil and olive pomace oils.	07/01/22
G/TBT/N/EGY/301 09/11/21	Egypt	ICS codes: 91.100.10 (<i>Cement. Gypsum. Lime. Mortar</i>), 91.100.40 (<i>Products in fibre-reinforced cement</i>); Ministerial Decree No. 221 /2021 (2 pages, in Arabic) mandating the Egyptian Standard ES 8472-2 "Specification for pozzolanic materials for use with Portland cement - Part 2: High reactivity natural calcined pozzolana" G/TBT/N/EGY/301 The Ministerial Decree No. 221 /2021 gives the producers and importers a six-month transitional period to abide by the Egyptian standard ES 8472-2 which specifies requirements for the production, chemical composition, mechanical and physical properties of high reactivity natural calcined pozzolana for use in combination with	08/01/22

G/TBT/N/EGY/302 09/11/21	Egypt	<p>Portland cement class 42.5 N or greater, conforming with BS EN 197-1:2011, as a component of concrete, mortar or grout. It also specifies requirements for marking, provision of information and conformity criteria for the manufacture's autocontrol system. Worth mentioning is that this standard adopts the technical content of BS 8615-2/2019</p>	08/01/22
G/TBT/N/EGY/303 09/11/21	Egypt	<p><i>ICS codes: 67.140.20 (Coffee and coffee substitutes);</i> The Ministerial Decree No. 219/2021 (1 page, in Arabic) mandating the Egyptian Standard ES 8449 "green coffee beans intended for instant coffee manufacturing" G/TBT/N/EGY/303 The Ministerial Decree No. 219/2021 (1 page, in Arabic) that gives the producers and importers a six-month transitional period to abide by the Egyptian Standard ES 8449 This standard is concerned with the basic requirements and descriptive standards for green coffee beans used in the production of instant coffee and not intended to be used as a final product. It should be noted that this standard cancels and replaces the requirements for instant coffee contained in Egyptian Standard ES No. 517, 1474-1/2005 " Updated 2014" Worth mentioning is that this standard complies with : ISO 3509/2005(confirmed in 2018), ISO 10470/2004(confirmed in 2017)</p>	
G/TBT/N/EGY/304 09/11/21	Egypt	<p><i>ICS codes: 67.140.20 (Coffee and coffee substitutes);</i> The Ministerial Decree No. 219/2021 (1 page, in Arabic) mandating the Egyptian Standard ES 8448 "instant coffee"</p>	

G/TBT/N/EGY/304 The Ministerial Decree No. 219/2021 gives the producers and importers a six-month transitional period to abide by the Egyptian Standard ES 8448 This standard is concerned with the basic requirements and descriptive criteria for the following coffee products: Instant coffee, Decaffeinated instant coffee. It does not apply to both concentrated liquid coffee extract, and coffee-based products (such as cappuccino, etc.). It should be noted that this standard cancels and replaces the requirements for instant coffee contained in Egyptian Standard ES No. 517, 1474-1/2005 "Updated 2014" Worth mentioning is that this standard complies with: ISO 3509/2005(confirmed in 2018), ISO 10470/2004(confirmed in 2017)

[G/TBT/N/EGY/305](#)
09/11/21

Egypt

ICS codes: 97.040.20 (*Cooking ranges, working tables, ovens and similar appliances*); 08/01/22

The Ministerial Decree No. 221 /2021 (2 pages, in Arabic) mandating the Egyptian Standard ES 8434 "Measuring method of the energy consumption of gas fired ovens"

G/TBT/N/EGY/305 The Ministerial Decree No. 221 /2021 gives the producers and importers a six-month transitional period to abide by the Egyptian standard ES 8434 which specifies the method of test for determining the gas energy consumption in gas-fired domestic ovens when they are being used in one or more of the oven cooking modes defined in 3.1. It applies to the gas-fired domestic ovens which are capable of utilizing gases of group H or group E or third family gases, possibly after conversion according to instructions for use. Worth mentioning is that this standard is technically identical with EN 15181:2017+A1:2020

[G/TBT/N/EGY/306](#)
09/11/21

Egypt

ICS codes: 71.100.70 (*Cosmetics. Toiletries*); 08/01/22

Ministerial Decree No. 221 /2021(2 pages, in Arabic) mandating the Egyptian Standard ES 3570 "Cosmetics perfumed liquids"

G/TBT/N/EGY/306 The Ministerial Decree No. 221/2021 gives the producers and importers a six-month transitional period to abide by the Egyptian standard ES 3570 which includes perfumed alcoholic solutions and perfume oils, which may be synthetic or natural. This standard cancels and supersedes its last edition in 2005. Worth mentioning is that this standard complies with EC No 1223/2009 Of The European Parliament And Of The Council of 30 November 2009 on cosmetic products.

[G/TBT/N/EGY/307](#)
09/11/21

Egypt

ICS codes: 11.040.70 (*Ophthalmic equipment*); 08/01/22

Ministerial Decree No. 223 /2021 (2 pages, in Arabic) mandating the Egyptian Standard ES 2925-2 for "Ophthalmic optics — Uncut finished spectacle lenses — Part 2: Specifications for power-variation lenses"

G/TBT/N/EGY/307 The Ministerial Decree No. 223 /2021 gives the producers and importers a six-month

transitional period to abide by the Egyptian standard ES 2925-2. This standard specifies requirements and verification methods for the optical and geometrical properties for uncut finished power-variation lenses. Worth mentioning is that this standard is technically identical with ISO 8980-2/2017

G/SPS/N/EU/514	09/11/21 Egypt	<p>ICS codes: 11.040.70 (<i>Ophthalmic equipment</i>);</p> <p>Ministerial Decree No. 223 /2021 (2 pages, in Arabic) mandating the Egyptian Standard ES 2925-1 for "Ophthalmic optics — Uncut finished spectacle lenses — Part 1: Specifications for single-vision and multifocal lenses"</p> <p>G/TBT/N/EGY/308 The Ministerial Decree No. 223 /2021 gives the producers and importers a six-month transitional period to abide by the Egyptian standard ES 2925-1. This standard specifies requirements and verification methods for the optical and geometrical properties for uncut finished single-vision and multifocal spectacle lenses. Worth mentioning is that this standard is technically identical with ISO 8980-1/2017</p>	08/01/22
G/TBT/N/EGY/308 09/11/21	Egypt	<p>ICS codes: 11.040.70 (<i>Ophthalmic equipment</i>);</p> <p>Ministerial Decree No. 223 /2021 (2 pages, in Arabic) mandating the Egyptian Standard ES 2925-1 for "Ophthalmic optics — Uncut finished spectacle lenses — Part 1: Specifications for single-vision and multifocal lenses"</p> <p>G/TBT/N/EGY/308 The Ministerial Decree No. 223 /2021 gives the producers and importers a six-month transitional period to abide by the Egyptian standard ES 2925-1. This standard specifies requirements and verification methods for the optical and geometrical properties for uncut finished single-vision and multifocal spectacle lenses. Worth mentioning is that this standard is technically identical with ISO 8980-1/2017</p>	08/01/22
G/TBT/N/SAU/1225 09/11/21	Saudi Arabia, Kingdom of	<p>8702</p> <p>Technical Regulation of Hydrogen Vehicles</p> <p>G/TBT/N/SAU/1225 This regulation specifies the following: Terms and Definitions, Scope, Objectives, Supplier Obligations, Labelling, Conformity Assessment Procedures, Responsibilities of Regulatory Authorities, Responsibilities of Market Surveillance Authorities, Violations and Penalties, General Provisions, Transitional Provisions, Appendix (lists of standards , HS code, Hydrogen Component List, safety requirements, Conformity Assessment Forms (Type 1a &) and Supplier Declaration of Conformity Form).</p>	08/01/22
G/TBT/N/THA/643 09/11/21	Thailand	<p><i>Minerals</i></p> <p>Notification of the Ministry of Industry has repealed the Notification of the Ministry of Industry Re: Determination of type and nature of minerals prohibited for exportation B.E. 2564 (2021)</p>	

G/TBT/N/THA/643 The Ministry of Industry has repealed the Notification of the Ministry of Industry Re: Determination of type and nature of minerals prohibited for exportation B.E. 2564 (2021) This Notification aims to determine type and nature of minerals prohibited for exportation (1) Gold ore (2) Ore containing gold (3) Gold alloy (4) Coal

[G/TBT/N/UKR/208](#)
09/11/21

Ukraine

Medicines and medical products

08/01/22

Draft Resolution of the Cabinet of Ministers of Ukraine "Some aspects of stock management of medicines and medical products and implementation of labelling control (identification) signs of medicines"

G/TBT/N/UKR/208 The draft Resolution is designed to establish organizational principles for successful implementation of labelling control (identification) signs and monitoring the circulation of medicines stocks. The draft Resolution is aimed at regulating implementation of the electronic inventory management system for medicines and medical e-Stock products. Adoption of the draft Resolution will reduce the risks of getting into circulation of falsified medicines, introducing a verification model medicines according to the European model.

[G/TBT/N/USA/1800](#)
09/11/21

United States of America

Mercury-added products

ICS codes: 13.020 (*Environmental protection*), 71.100 (*Products of the chemical industry*);

Response to Vacatur of Certain Provisions of the Mercury Inventory Reporting Rule

G/TBT/N/USA/1800 Final rule - The Environmental Protection Agency (EPA) is revising regulations associated with persons who must report data to the Agency's mercury inventory established under the Toxic Substances Control Act (TSCA). Those reporting requirements were set forth in a final rule entitled "Reporting Requirements for TSCA Mercury Inventory: Mercury" (hereafter "mercury inventory reporting rule"). These revisions implement an order issued by the United States Court of Appeals for the Second Circuit (Second Circuit), on 5 June 2020

[G/TBT/N/USA/1801](#)
09/11/21

United States of America

Transport of liquefied natural gas by rail

23/12/21

ICS codes: 03.220.30 (*Transport by rail*), 13.020 (*Environmental protection*), 75.060 (*Natural gas*);

Hazardous Materials: Suspension of HMR Amendments Authorizing Transportation of Liquefied Natural Gas by Rail

G/TBT/N/USA/1801 Notice of proposed rulemaking - PHMSA, in coordination with the Federal Railroad Administration (FRA), proposes to amend the Hazardous Materials Regulations to suspend authorization of liquefied natural gas (LNG) transportation in rail tank cars pursuant to a final rule published in July 2020, pending the earlier of either completion of a separate rulemaking under RIN 2137-AF54 evaluating potential modifications

to requirements governing rail tank car transportation of LNG, or 30 June 2024.

[G/TBT/N/USA/1801](#)
09/11/21

United States of America

Transport of liquefied natural gas by rail
ICS codes: 03.220.30 (Transport by rail), 13.020 (Environmental protection), 75.060 (Natural gas); Hazardous Materials: Suspension of HMR Amendments Authorizing Transportation of Liquefied Natural Gas by Rail

23/12/21

G/TBT/N/USA/1801 Notice of proposed rulemaking - PHMSA, in coordination with the Federal Railroad Administration (FRA), proposes to amend the Hazardous Materials Regulations to suspend authorization of liquefied natural gas (LNG) transportation in rail tank cars pursuant to a final rule published in July 2020, pending the earlier of either completion of a separate rulemaking under RIN 2137-AF54 evaluating potential modifications to requirements governing rail tank car transportation of LNG, or 30 June 2024.

[G/TBT/N/EGY/309](#)
10/11/21

Egypt

ICS codes: 91.100.30 (Concrete and concrete products);

09/01/22

Ministerial Decree No. 221 /2021 (2 pages, in Arabic) mandating the Egyptian Standard ES 8473-1 " Silica fume for concrete part:1 Definitions, requirements and conformity criteria"

G/TBT/N/EGY/309 The Ministerial Decree No. 221 /2021 gives the producers and importers a six-month transitional period to abide by the Egyptian standard ES 8473-1 which applies to the silica fume which is a by-product of the smelting process used to produce silicon metal and ferro-silicon alloys. This part of gives requirements for chemical and physical properties for silica fume to be used as a type II addition in concrete conforming to EN 206-1, or in mortars, grouts and other mixes. This part also states conformity criteria and related rules. This standard does not give rules for the use of silica fume in concrete. Some rules are given in EN 206-1. NOTE 1 Supplementary rules related to the use of silica fume in concrete may be given in non conflicting national standards for concrete. NOTE 2 EN 206-1 (5.2.5.1 in the 2000 edition) provides conditions for national acceptance of silica fumes coming from calcium silicon alloys production or other silica fumes, not conforming completely to EN 13263, as type II additions for use in concrete. Worth mentioning is that this standard adopts the technical content of EN 13263-1:2005+A1:2009

[G/TBT/N/JPN/717](#)
10/11/21

Japan

Substances with probable effects on the central nervous system

Emergency measure

Designation of Shitei Yakubutsu (designated substances), based on the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the Act). (1960, Law No.145)

G/TBT/N/JPN/717 Proposal for the additional designation of 4 substances as Shitei Yakubutsu, and their proper uses under the Act.

G/TBT/N/CHN/1628 10/11/21	China	<i>Flush valve for water closets or urinals</i> ICS codes: 91.060 (<i>Elements of buildings</i>); National Standard of the P.R.C., Minimum Allowable Values of Water Efficiency and Water Efficiency Grades for Flush Valve for Water Closets G/TBT/N/CHN/1628 This document specifies the limit values and grades, technical requirements and test methods of the water efficiency of flush valves for water closets or urinals. This document is applicable to flush valves for water closets or urinals installed on cold water supply pipelines in building facilities under the condition that the static pressure of the water supply is not greater than 0.6 MPa.	09/01/22
G/TBT/N/CHN/1629 10/11/21	China	<i>AC Contactors</i> ICS codes: 27.010 (<i>Energy and heat transfer engineering in general</i>); National Standard of the P.R.C., Minimum Allowable Values Of Energy Efficiency And Energy Efficiency Grades For AC Contactors G/TBT/N/CHN/1629 This document specifies the energy efficiency grade, energy efficiency limit value, energy efficiency evaluation value, test methods of AC contactor. This document is applicable to three pole Electromechanical, direct acting and integral contactors of AC-3 with rated frequency of 50Hz, rated working voltage of main circuit of 1000V and below, rated working current of 6A ~ 630A and rated control power supply voltage of AC 400V and below. This document does not apply to external power saving devices, household and similar contactors and semiconductor contactors (solid state contactors). Note: the "direct acting" mentioned in this document refers to the products in which both the contact system and the electromagnetic system are direct acting.	09/01/22
G/TBT/N/CHN/1630 10/11/21	China	<i>Fluorescent Lamps</i> ICS codes: 27.010 (<i>Energy and heat transfer engineering in general</i>); National Standards of the P.R.C., Minimum Allowable Values of Energy Efficiency and Energy Efficiency Grades for Fluorescent Lamps for General Lighting Service G/TBT/N/CHN/1630 This document specifies the energy efficiency grades, minimum allowable values of energy efficiency and test methods for self-ballasted fluorescent lamps, double-capped fluorescent lamps, single-capped fluorescent lamps, self-ballasted electrodeless fluorescent lamps and single-capped electrodeless fluorescent lamps used for general lighting in homes and similar situations. This document is applicable to the self-ballasted fluorescent lamps, with rated voltage of AC 220V, rated frequency of 50Hz, rated power of 3W ~ 60W,	09/01/22

Edison base or bayonet base, and integrated control parts that enable lamps to start and light stably. This document is not applicable to the self-ballasted fluorescent lamps with outer envelope. This document is applicable to the preheat cathode lamps working in AC circuits with starter and on high-frequency line, as well as the preheat cathode lamps only working on high-frequency line. This document is applicable to the single-capped fluorescent lamps with preheating cathode equipped with internal starter or external starter. This document is applicable to the self-ballasted electrodeless fluorescent lamps with rated voltage of AC 220V, rated frequency of 50Hz, rated power of 10W ~ 60W, Edison base or bayonet base, and integrated control parts that enable lamps to start and light stably. This document is applicable to the internalcoupling or externalcoupling single-capped electrodeless fluorescent lamps with rated power of 30W ~ 400W.

G/TBT/N/CHN/1631 10/11/21	China	<p><i>Compressed Air Foam Extinguishing Agent</i> ICS codes: 13.220.10 (<i>Fire-fighting</i>); National Standard of the P.R.C., Compressed Air Foam Extinguishing Agent G/TBT/N/CHN/1631 This document specifies terms and definitions, classification, requirements, test methods, inspection rules, marking, packaging, transportation and storage of compressed air foam extinguishing agents. This document is applicable to compressed air foam extinguishing agents.</p>	09/01/22
G/TBT/N/CHN/1632 10/11/21	China	<p><i>Luminaires and electrical supply track systems for luminaires</i> ICS codes: 29.140.40 (<i>Luminaires</i>); National Standard of the P.R.C., Luminaires and Electrical Supply Track Systems for Luminaires —Safety Requirements G/TBT/N/CHN/1632 This document specifies safety requirements for, marking, mechanical construction, electrical construction and photobiology of luminaires incorporating electric light sources for operation from supply voltages up to 1000 V, and electrical supply track systems for luminaires. This document is applicable to luminaires incorporating electric light sources for operation from supply voltages up to 1 000 V, and electrical supply track systems for luminaires.</p>	09/01/22
G/TBT/N/CHN/1633 10/11/21	China	<p><i>Household and similar electrical appliances</i> ICS codes: 13.120 (<i>Domestic safety</i>); National Standard of the P.R.C., Household and Similar Electrical Appliances General Requirements –Product Safety G/TBT/N/CHN/1633 This document specifies the terms, definitions, requirements and verification methods for general safety of household and similar electrical appliances. This document is applicable to installation, use, maintenance, repair and other aspects of the life cycle of household and similar</p>	09/01/22

electrical appliances. This document is also applicable to the electrical parts of sporting goods and electric toys.

G/TBT/N/CHN/1634 10/11/21	China	<p><i>Biological safety cabinets</i></p> <p>ICS codes: 11.100 (<i>Laboratory medicine</i>);</p> <p>National Standard of the P.R.C., Biological Safety Cabinets</p> <p>G/TBT/N/CHN/1634 This document specifies the terms and definitions, classification, material, structure and performance, test methods, signs, labelling, inspection rules, random documents, packaging, transportation and storage requirements for biological safety cabinets. This document is applicable to biological safety cabinets.</p>	09/01/22
G/TBT/N/CHN/1635 10/11/21	China	<p><i>Disposable sanitary products</i></p> <p>ICS codes: 11.080 (<i>Sterilization and disinfection</i>);</p> <p>National Standard of the P.R.C., Hygienic Requirements for Disposable Sanitary Products</p> <p>G/TBT/N/CHN/1635 This document specifies the hygienic requirements for the raw materials, production process and products, as well as test methods, packaging, transportation, storage and labelling requirements of disposable sanitary products. This document is applicable to all disposable sanitary products sold and used within the territory of the People's Republic of China. This document does not apply to sanitary wipes used on surfaces of objects.</p>	09/01/22
G/TBT/N/EU/850 11/11/21	European Union	<p><i>Software, applications of information technology (for both: included when embedded in hardware); AI as a component of products subjects to product safety legislation (any code)</i></p> <p>ICS codes: 35.080 (<i>Software</i>), 35.240 (<i>Applications of information technology</i>);</p> <p>Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence act) and amending certain union legislative acts (COM(2021) 206 final)</p> <p>G/TBT/N/EU/850 The draft Regulation defines an ‘artificial intelligence system’ (AI system) as meaning software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with. The draft Regulation introduces provisions that will regulate the development, marketing and placing on the European Union market of AI systems. These rules are limited to the minimum necessary requirements to protect the safety and fundamental rights of persons considering the risks and challenges posed by AI systems, without unduly constraining or hindering technological development or otherwise disproportionately increasing the cost of placing AI solutions on the market. The draft rules differ</p>	09/02/22

according to the degree of risk AI systems are considered to present. AI systems considered a clear threat to the safety, livelihoods and rights of people will be banned in the European Union. This includes AI systems or applications that manipulate human behaviour to circumvent certain users' free will (e.g. toys using voice assistance encouraging dangerous behaviour of minors) and systems that allow 'social scoring' by governments. The prohibitions cover practices that have a significant potential to manipulate persons through subliminal techniques beyond their consciousness or exploit vulnerabilities of specific vulnerable groups such as children or persons with disabilities in order to materially distort their behaviour in a manner that is likely to cause them or another person psychological or physical harm. In addition, the 'real time' use of remote biometric identification systems in publicly accessible spaces for law enforcement purposes is prohibited in principle. Narrow exceptions are strictly defined and regulated (such as where strictly necessary to search for a missing child, to prevent a specific and imminent terrorist threat or to detect, locate, identify or prosecute a perpetrator or suspect of a serious criminal offence). When permitted, such use is subject to authorisation by a judicial or other independent body and to appropriate limits in time, geographic reach and the data bases searched. High-risk AI systems will be subject to strict obligations before they can be placed on the European Union market. AI systems identified as high-risk include AI technology listed in the Annexes of the proposal and used in the following broad areas: Real time and ex post remote biometric identification systems; Critical infrastructures (e.g. transport), that could put the life and health of people at risk; Educational or vocational training, that may determine the access to education and professional course of someone's life (e.g. scoring of exams); Safety components of regulated products subject to third party conformity assessment under EU sectoral product safety legislation (e.g. AI application in robot-assisted surgery); Employment, workers management and access to self-employment (e.g. CV-sorting software for recruitment procedures); Essential private and public services (e.g. credit scoring denying people the opportunity to obtain a loan); Law enforcement that may interfere with people's fundamental rights (e.g. evaluation of the reliability of evidence); Migration, asylum and border control management (e.g. verification of authenticity of travel documents); Administration of justice and democratic processes (e.g. applying the law to a concrete set of facts). Requirements for high-risk AI systems concern: Adequate risk assessment and mitigation systems; High quality of the datasets feeding the system to minimise risks and discriminatory outcomes; Logging of activity to ensure traceability of results; Detailed documentation providing all information necessary

on the system and its purpose for authorities to assess its compliance; Clear and adequate information to the user; Appropriate human oversight measures to minimise risk; High level of robustness, security and accuracy. Public and private providers of such high-risk AI systems will have to follow conformity assessment procedures to demonstrate compliance with the abovementioned requirements before those systems can be placed on the Union market or used in the Union. To facilitate this, the draft Regulation includes provisions relating to the future harmonisation and drawing up of harmonised technical standards to be adopted by the European standardisation organisations (CEN/CENELEC and ETSI) based on a mandate from the European Commission. Predictable, proportionate and clear obligations are also placed on providers and users of high-risk AI systems to ensure safety and respect of existing legislation protecting fundamental rights throughout the whole AI systems' lifecycle. AI systems with specific transparency obligations: When using AI systems such as chatbots, people should be aware that they are interacting with a machine so they can take an informed decision to continue or step back. People should also be informed in case they are exposed to emotion recognition and biometric categorisation systems as well as deepfakes. Minimal risk: Subject to compliance with existing legislation, the proposal allows the free use of all other AI applications that are not prohibited, qualified as 'high-risk' or requiring specific transparency obligations. The vast majority of AI systems fall into this category. The draft Regulation does not intervene here, as these AI systems represent only minimal or no risk for peoples' rights or safety, but providers of non-high-risk AI systems can voluntarily adhere to voluntary codes of conduct to demonstrate trustworthiness of their applications. In terms of governance, the Commission proposes that national competent market surveillance authorities supervise the new rules, while the creation of a European Artificial Intelligence Board will facilitate their implementation, as well as drive the development of standards for AI. Additionally, specific measures are proposed to support small-scale providers and users as well as regulatory sandboxes to facilitate responsible innovation.

[G/TBT/N/ECU/510](#)
12/11/21

Ecuador

La presente normativa técnica sanitaria tiene como objeto establecer el procedimiento y requisitos para la autorización de comercialización bajo la modalidad de pack de medicamentos en general, productos biológicos, productos naturales procesados de uso medicinal y productos homeopáticos; así como el procedimiento y requisitos para la autorización de agotamiento de existencias de envases, etiquetas, prospectos y del producto terminado de medicamentos en general, productos biológicos, productos naturales

11/01/22

procesados de uso medicinal y productos homeopáticos. La aplicación de la presente normativa técnica sanitaria es obligatoria para los titulares del registro sanitario de medicamentos en general, productos biológicos y productos naturales procesados de uso medicinal y para los titulares de la notificación sanitaria de productos homeopáticos, que deseen comercializar sus productos bajo la modalidad de pack o requieran realizar el agotamiento de existencias de sus envases, etiquetas, prospectos o de su producto terminado.

Proyecto de Normativa Técnica Sanitaria Sustitutiva para autorizar la comercialización bajo la modalidad de Pack y el agotamiento de existencias de envases, etiquetas, prospectos y del producto terminado de Medicamentos en general, productos Biológicos, productos Naturales Procesados de Uso Medicinal y de Productos Homeopáticos

G/TBT/N/EUC/510 La presente normativa técnica sanitaria tiene como objeto establecer el procedimiento y requisitos para la autorización de comercialización bajo la modalidad de pack de medicamentos en general, productos biológicos, productos naturales procesados de uso medicinal y productos homeopáticos; así como el procedimiento y requisitos para la autorización de agotamiento de existencias de envases, etiquetas, prospectos y del producto terminado de medicamentos en general, productos biológicos, productos naturales procesados de uso medicinal y productos homeopáticos. La aplicación de la presente normativa técnica sanitaria es obligatoria para los titulares del registro sanitario de medicamentos en general, productos biológicos y productos naturales procesados de uso medicinal y para los titulares de la notificación sanitaria de productos homeopáticos, que deseen comercializar sus productos bajo la modalidad de pack o requieran realizar el agotamiento de existencias de sus envases, etiquetas, prospectos o de su producto terminado.

[G/TBT/N/EU/851](#)
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European
Union

Internal combustion engines to be installed in non-road mobile machinery.

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**ICS codes: 27.020 (Internal combustion engines);
Draft Commission Delegated Regulation amending Delegated Regulation (EU) 2017/655 as regards adaptation of the provisions on monitoring of gaseous pollutant emissions from in-service internal combustion engines installed in non-road mobile machinery to include engines with power of less than 56 kW and more than 560 kW**

G/TBT/N/EU/851 The purpose of this draft Delegated Regulation is to adopt in-service monitoring requirements for internal combustion engines installed in non-road mobile machinery for engines other than sub-categories NRE-v-5 and

			NRE-v-6, meaning with a power of less than 56 kW and more than 560 kW.	
G/TBT/N/IND/216 12/11/21	India	<i>Food products</i>	Draft Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Amendment Regulations, 2021. G/TBT/N/IND/216 These regulations propose changes in the procedure for grant of prior approval for non-specified food and food ingredients including change in application form for seeking approval for such foods.	11/01/22
G/TBT/N/IND/217 12/11/21	India	<i>Pre-packaged foods</i>	Draft Food Safety and Standards (Prohibition and Restrictions on Sales) Amendment Regulations, 2021. (3 pages, in Hindi and English) G/TBT/N/IND/217 These regulations prescribe to substitute the words 'Multi source edible vegetable oil' with 'Multi-source edible oil' in the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011.	11/01/22
G/TBT/N/ISR/1222 12/11/21	Israel	<i>Prepackaged food products</i>	ICS codes: 67.230 (Prepackaged and prepared foods); SI 1059 - Tolerances for weight and volume of prepackaged food products G/TBT/N/ISR/1222 The existing Mandatory Standard, SI 1059, dealing with prepackaged food products, shall be declared voluntary. This declaration aims to remove unnecessary obstacles to trade and lower trade barriers.	11/01/22
G/TBT/N/KOR/1008 12/11/21	Korea, Republic of	<i>Foods</i>	Proposed Revision of the "Enforcement Rule of the Act on Labeling and Advertising of Foods" G/TBT/N/KOR/1008 The proposed amendment is to - In connection with "Act on Labeling and Advertising of Foods(Act NO.18445, 17. Aug, 2021., Partial Amendment)" to replace the "sell-by date" in food labeling with "use-by date" - Milks as defined in subparagraph 2 of Article 4 of the "Livestock Products Sanitary Control Act", which requires improvement in cold storage standards, can be applied from 1 January 2023.	11/01/22
G/TBT/N/KOR/1009 12/11/21	Korea, Republic of	<i>Foods</i>	Proposed Revision of the "Enforcement Decree of the Act on Labeling and Advertising of Foods" G/TBT/N/KOR/1009 The proposed amendment is to - In connection with "Act on Labeling and Advertising of Foods (Act NO.18445, 17. Aug, 2021., Partial Amendment)" to replace the "sell-by date" in food labeling with "use-by date"	11/01/22
G/TBT/N/THA/644 12/11/21	Thailand	<i>Electrical appliances for skin or hair care (ICS 13.120)</i>	ICS codes: 13.120 (Domestic safety);	11/01/22

Draft Ministerial Regulation on Household and similar electrical appliances – Safety – Part 2-23: Particular requirements for appliances for skin or hair care (TIS 60335 Part 2(23)-2564)

G/TBT/N/THA/644 The draft ministerial regulation mandates electrical appliances for skin or hair care to conform with the standard for Household and similar electrical appliances – Safety – Part 2-23: Particular requirements for appliances for skin or hair care (TIS 60335 Part 2(23)-2564). This standard is identical to IEC 60335-2-23 Edition 6.1: 2019 Household and similar electrical appliances - Safety - Part 2-23: Particular requirements for appliances for skin or hair care.