## Predpisy notifikované v Dohode o technických prekážkach obchodu (TBT WTO) 44. týždeň roku 2021

Číslo/Dátum	Notifikujúca strana	Charakteristika notifikácie	Pripomienková doba
G/TBT/N/BRA/1279 01/11/2021	Brazil	ICS codes: 19.080 (Electrical and electronic testing) Inmetro Public Consultation no. 21, 25 October 2021 Inmetro Public Consultation No. 21 provides the proposition of the consolidated Metrological Technical Regulation that establishes the minimum conditions for measurement systems or active and /or reactive electric power meters, electronic, single-phase and polyphasic.	26/12/2021
<u>G/TBT/N/BRA/1280</u> 01/11/2021	Brazil	ICS codes: 29.120.50 (Fuses and other overcurrent protection devices) Inmetro Ordinance No. 444, 26 October 2021 Inmetro Ordinance No. 444 consolidates the technical regulation for stopper and cardboard cartridge type fuses.	
G/TBT/N/BDI/169 01/11/2021	Burundi	ICS codes: 67.120.30 (Fish and fishery products) DEAS 831: 2021, Frozen fish fillets — Specification, Second Edition This Draft East African Standard specifies requirements and methods of sampling and test for frozen fish fillets intended for human consumption.	31/12/2021
G/TBT/N/BDI/170 01/11/2021	Burundi	ICS codes: 67.020 (Processes in the food industry) DEAS 832: 2021, Fish industry — Operational cleanliness and hygiene — Guidelines, Second Edition This Draft East African Standard covers guidelines for operational cleanliness and hygiene in the fish industry.	31/12/2021
<u>G/TBT/N/BDI/171</u> 01/11/2021	Burundi	ICS codes: 67.120.30 (Fish and fishery products) DEAS 827: 2021, Fresh and frozen whole fin fish — Specification, Second Edition This Draft East African Standard specifies requirements and methods of sampling and test for fresh and frozen whole fin fish for human consumption.	31/12/2021
<u>G/TBT/N/BDI/172</u> 01/11/2021	Burundi	ICS codes: 67.120.30 (Fish and fishery products) DEAS 830: 2021, Frozen fish sticks (fish fingers), fish portions and fish fillets — Breaded or in batter — Specification, First Edition 2021 This Draft East African Standard specifies requirements and methods of sampling and test for frozen fish sticks (fish fingers), fish portions and fish fillets — breaded or in batter, intended for human consumption.	31/12/2021

<u>G/TBT/N/BDI/173</u> 01/11/2021	Burundi	ICS codes: 67.120.30 (Fish and fishery products) DEAS 833: 2021,Processing and handling of dried fish and fish products — Code of practice, Second Edition This Draft East African Standard prescribes guidelines for processing and handling of dried fish and fish products intended for human consumption.	31/12/2021
<u>G/TBT/N/BDI/174</u> 01/11/2021	Burundi	Salted fish, fish products  DEAS 834: 2021,Processing and handling of salted fish and fish products — Code of practice, Second Edition  This Draft East African standard prescribes guidelines for processing and handling of salted fish and fish products intended for human consumption.	31/12/2021
<u>G/TBT/N/EU/846</u> 01/11/2021	European Union	Pesticide active substances  Draft Commission Regulation amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for microorganisms  This draft Commission Regulation includes the amendments of the general introduction and the Part B of the Annex to the Commission Regulation (EU) No 283/2013 setting out the data requirements for microorganisms used as active substances in plant protection products.	31/12/2021
<u>G/TBT/N/EU/847</u> 01/11/2021	European Union	Pesticide active substances  Draft Commission Regulation amending Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products and the specific data requirements for plant protection products containing microorganisms  This draft Commission Regulation includes the amendments of the general introduction and the Part B of the Annex to the Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products containing active substances that are micro-organisms.	31/12/2021
<u>G/TBT/N/EU/848</u> 01/11/2021	European Union	Pesticide plant protection products  Draft Commission Regulation amending Regulation (EU) No 546/2011 as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms  This draft Commission Regulation includes the amendments of the Annex to the Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection product.	31/12/2021

G/TBT/N/EU/849 01/11/2021

European Union

Pesticide active substances

31/12/2021

**Draft Commission Regulation amending Annex II** to Regulation (EC) No 1107/2009 as regards specific criteria for the approval of active substances that are micro-organisms

This draft Commission Regulation includes the amendments of the approval criteria of microbial active substances set in Annex II to Regulation (EC) No 1107/2009 which needed to be complemented in order to appropriately reflect the particularities of micro-organisms.

G/TBT/N/JPN/714 01/11/2021

Japan

Labelling for genetically modified (GM) products, 31/12/2021 methods of analysis for nutritional labelling, labelling for soy sauce and edible plant fat and oil

Summary of the draft Amendment of the Food Labelling Standards (regarding labelling for GM products, methods of analysis for nutritional labelling, labelling for soy sauce and edible plant fat and oil.)

The Food Labelling Standards will be partially amended, because soybean with high oleic acid content can now be produced with conventional breeding techniques and are not subject to definition of "specific GM products" anymore.2. The Food Labelling Standards will be partially amended, because soybean with high oleic acid content can now be produced with conventional breeding techniques and are not subject to definition of "specific GM products" anymore.(2) The Food Labelling Standards will be partially amended in accordance with the revision of "Standard Tables of Food Composition in Japan" that adopts some new methods of analysis for nutrients.(3) The Food Labelling Standards for soy sauce and edible plant fat and oil will be partially amended, because the Food Labelling Standards quote Japanese Agricultural Standards (JAS)" provisions and the JAS for soy sauce and edible plant fat and oil were/will be revised corresponding to the international standards.

G/TBT/N/KOR/1002 Korea 01/11/2021

**Pharmaceuticals** 

Notification on Partial Amendment of "Regulation for Herbal medicine Approval, Notification"

The Ministry of Food and Drug Safety, Republic of Korea intends to revise the following matters in 'Regulation for Herbal Medicine Approval, Notification.' 1.Reinforcement of change control including manufacturing procedure for prescription drug 2. New Establishment on Example of indications of precaution for use by specifying package unit for disposable ophthalmic solutions at less than 0.5ml. 3. Abolishment of foreign national drug formulariesbased system to strengthen scientific evidence-based safety and validity review system.

G/TBT/N/KOR/1003 Korea 01/11/2021

Biocidal Active Substances

31/12/2021

"Regulations on the scope and method of preparation of Biocidal Active Substances and **Products Approval application Data"** 

Refinement of component analysis data for identification of biocidal active substances Systematization of scope of human and environmental risk assessment.

G/TBT/N/PRY/127 01/11/2021

Paraguay

Alimentos industrializados

31/12/2021

Proyecto de Resolución del Ministerio de Salud Pública y Bienestar Social: " POR LA CUAL SE APRUEBA EL REGLAMENTO TÉCNICO QUE **REQUISITOS ESTABLECE PARA** ALIMENTOS ENVASADOS DESTINADOS A DIETAS CON RESTRICCIÓN DE LACTOSA"

El Proyecto de Resolución pretende reglamentar los alimentos para dietas con restricciones de lactosa, estableciendo los requisitos que deben cumplir los alimentos envasados con contenido reducido, bajo y sin lactosa, para que puedan ser denominados como tales.

G/TBT/N/RUS/122 01/11/2021

Russian Federation Waste EEE 13.030.30, electrical equipment in general 20/01/2022 29.020, electronic components in general 31.020

Draft amendment No 1, to the technical regulation of the Eurasian Economic Union "On the Restrictions of the Use of Dangerous Substances in Electrotechnical and Radioelectronical Devices" (EAEU TR 037/2016)

Draft amendment № 1, to the technical regulation of the Eurasian Economic Union "On the Restrictions of the Use of Dangerous Substances in Electrotechnical and Radioelectronical Devices" (EAEU TR 037/2016) provides for the clarification of certain provisions of the technical regulation, in terms of updating the scope of the technical regulation, requirements for a list of hazardous substances under control and limiting their content in electrical and electronic products, including requirements for the disposal of electrical and electronic products that have lost consumer properties.

<u>G/TBT/N/RW</u>A/560 01/11/2021

Rwanda

*ICS codes:* 67.120.30 (Fish and fishery products) DEAS 831: 2021, Frozen fish fillets **Specification, Second Edition** 

31/12/2021

31/12/2021

This Draft East African Standard specifies requirements and methods of sampling and test for frozen fish fillets intended for human consumption.

G/TBT/N/RWA/561 Rwanda 01/11/2021

ICS codes: 67.020 (Processes in the food industry) DEAS 832: 2021, Fish industry — Operational cleanliness and hygiene - Guidelines, Second **Edition** 

This Draft East African Standard covers guidelines for operational cleanliness and hygiene in the fish industry.

<u>G/TBT/N/RWA/562</u> 01/11/2021	Rwanda	ICS codes: 67.120.30 (Fish and fishery products) DEAS 827: 2021, Fresh and frozen whole fin fish — Specification, Second Edition This Draft East African Standard specifies requirements and methods of sampling and test for fresh and frozen whole fin fish for human consumption.	31/12/2021
G/TBT/N/RWA/563 01/11/2021	Rwanda	ICS codes: 67.120.30 (Fish and fishery products) DEAS 830: 2021, Frozen fish sticks (fish fingers), fish portions and fish fillets — Breaded or in batter — Specification, First Edition 2021 This Draft East African Standard specifies requirements and methods of sampling and test for frozen fish sticks (fish fingers), fish portions and fish fillets — breaded or in batter, intended for human consumption.	31/12/2021
<u>G/TBT/N/RWA/564</u> 01/11/2021	Rwanda	ICS codes: 67.120.30 (Fish and fishery products) DEAS 833: 2021,Processing and handling of dried fish and fish products — Code of practice, Second Edition This Draft East African Standard prescribes guidelines for processing and handling of dried fish and fish products intended for human consumption.	31/12/2021
<u>G/TBT/N/RWA/565</u> 01/11/2021	Rwanda	Salted fish, fish products  DEAS 834: 2021,Processing and handling of salted fish and fish products — Code of practice, Second Edition  This Draft East African standard prescribes guidelines for processing and handling of salted fish and fish products intended for human consumption.	31/12/2021
<u>G/TBT/N/TZA/657</u> 01/11/2021	Tanzania	ICS codes: 67.120.30 (Fish and fishery products) DEAS 831: 2021, Frozen fish fillets — Specification, Second Edition This Draft East African Standard specifies requirements and methods of sampling and test for frozen fish fillets intended for human consumption.	31/12/2021
<u>G/TBT/N/TZA/658</u> 01/11/2021	Tanzania	ICS codes: 67.020 (Processes in the food industry) DEAS 832: 2021, Fish industry — Operational cleanliness and hygiene — Guidelines, Second Edition This Draft East African Standard covers guidelines for operational cleanliness and hygiene in the fish industry.	31/12/2021
<u>G/TBT/N/TZA/659</u> 01/11/2021	Tanzania	ICS codes: 67.120.30 (Fish and fishery products) DEAS 827: 2021, Fresh and frozen whole fin fish — Specification, Second Edition This Draft East African Standard specifies requirements and methods of sampling and test for fresh and frozen whole fin fish for human consumption.	31/12/2021

<u>G/TBT/N/TZA/660</u> 01/11/2021	Tanzania	ICS codes: 67.120.30 (Fish and fishery products)  DEAS 830: 2021, Frozen fish sticks (fish fingers), fish portions and fish fillets — Breaded or in batter — Specification, First Edition 2021  This Draft East African Standard specifies requirements and methods of sampling and test for frozen fish sticks (fish fingers), fish portions and fish fillets — breaded or in batter, intended for human consumption.	31/12/2021
<u>G/TBT/N/TZA/661</u> 01/11/2021	Tanzania	ICS codes: 67.120.30 (Fish and fishery products) DEAS 833: 2021,Processing and handling of dried fish and fish products — Code of practice, Second Edition This Draft East African Standard prescribes guidelines for processing and handling of dried fish and fish products intended for human consumption.	31/12/2021
G/TBT/N/TZA/662 01/11/2021	Tanzania	Salted fish, fish products  DEAS 834: 2021,Processing and handling of salted fish and fish products — Code of practice, Second Edition  This Draft East African standard prescribes guidelines for processing and handling of salted fish and fish products intended for human consumption.	31/12/2021
<u>G/TBT/N/UGA/1489</u> 01/11/2021	Uganda	ICS codes: 67.120.30 (Fish and fishery products) DEAS 831: 2021, Frozen fish fillets — Specification, Second Edition This Draft East African Standard specifies requirements and methods of sampling and test for frozen fish fillets intended for human consumption.	31/12/2021
<u>G/TBT/N/UGA/1490</u> 01/11/2021	Uganda	ICS codes: 67.020 (Processes in the food industry) DEAS 832: 2021, Fish industry — Operational cleanliness and hygiene — Guidelines, Second Edition This Draft East African Standard covers guidelines for operational cleanliness and hygiene in the fish industry.	31/12/2021
<u>G/TBT/N/UGA/1491</u> 01/11/2021	Uganda	ICS codes: 67.120.30 (Fish and fishery products) DEAS 827: 2021, Fresh and frozen whole fin fish — Specification, Second Edition This Draft East African Standard specifies requirements and methods of sampling and test for fresh and frozen whole fin fish for human consumption.	31/12/2021
<u>G/TBT/N/UGA/1492</u> 01/11/2021	Uganda	ICS codes: 67.120.30 (Fish and fishery products) DEAS 830: 2021, Frozen fish sticks (fish fingers), fish portions and fish fillets — Breaded or in batter — Specification, First Edition 2021 This Draft East African Standard specifies requirements and methods of sampling and test for frozen fish sticks (fish fingers), fish portions and fish fillets — breaded or in batter, intended for human consumption.	31/12/2021

G/TBT/N/UGA/1493 Uganda 01/11/2021

*ICS codes:* 67.120.30 (Fish and fishery products) DEAS 833: 2021, Processing and handling of dried fish and fish products — Code of practice, Second

This Draft East African Standard prescribes guidelines for processing and handling of dried fish and fish products intended for human consumption.

G/TBT/N/UGA/1494 Uganda 01/11/2021

Salted fish, fish products

**Edition** 

31/12/2021

31/12/2021

DEAS 834: 2021, Processing and handling of salted fish and fish products — Code of practice, Second Edition

This Draft East African standard prescribes guidelines for processing and handling of salted fish and fish products intended for human consumption.

G/TBT/N/USA/1792 **USA** 01/11/2021

Phenol, Isopropylated Phosphate (3:1); toxic 27/12/2021 chemicals

Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Phenol, Isopropylated Phosphate (3:1); Further **Compliance Date Extension** 

Proposed rule - The Environmental Protection Agency (EPA) is proposing to amend the regulations applicable to phenol, isopropylated phosphate (3:1) (PIP (3:1)) promulgated under the Toxic Substances Control Act (TSCA). Specifically, EPA is proposing to extend the compliance date applicable to the processing and distribution in commerce of certain PIP (3:1)-containing articles, and the PIP (3:1) used to make those articles until 31 October 2024, along with the associated recordkeeping requirements for manufacturers, processors, and distributors of PIP (3:1)-containing articles. EPA is also announcing its intention to commence a new rulemaking effort on PIP (3:1) and four other persistent, bioaccumulative, and toxic (PBT) chemicals that have been regulated under TSCA section 6(h). EPA is anticipating issuing a proposal to this end in 2023.

G/TBT/N/CAN/654 Canada 02/11/2021

Tomatoes, greenhouse, fresh (HS 070200000201); 31/12/2021 tomatoes, greenhouse, organic (HS 070200000201); cucumbers, greenhouse, fresh (HS 070700300102); cucumbers, greenhouse, organic (HS 070700300112)

Proposed Amendment to the Canadian Grade Compendium: Volume 2 - Fresh Fruit or Vegetables. - Standard for greenhouse cucumbers (3 pages, available in English and French); -Standard for greenhouse mini cucumbers (2 and 3 pages, available in English and French); and -Standard for greenhouse tomatoes (3 pages, available in English and French)

Certain fresh fruit or vegetables (FFV) must be graded in order to be marketed in import or interprovincial trade in Canada. FFV grades and requirements are maintained and enforced by Canadian Food Inspection Agency (CFIA) in an incorporated by reference (IbR) document titled "Canadian Grade Compendium: Volume 2 – Fresh Fruit or Vegetables", incorporated into the Safe Food for Canadians Regulations (SFCR).

CFIA is proposing to modernize and harmonize existing grade requirements related to the quality of FFV and introduce new grade standards to certain commodities. This consultation is being conducted in phases to solicit feedback on proposed changes to the grades and requirements for FFV. Each phase will focus on a different group of commodities. A notification will be sent for each phase of the consultation. This phase focuses on the proposed changes to grades and requirements for greenhouse cucumbers and greenhouse tomatoes, including a new standard for greenhouse mini cucumbers. The Proposed Amendment to the Canadian Grade Compendium: Volume 2 - Fresh Fruit or Vegetables include changes to size requirements, clarifications to terminology for defects and tolerances, and the introduction of new standard for greenhouse mini cucumbers.

<u>G/TBT/N/KOR/1004</u> Korea 02/11/2021

**Pharmaceuticals** 

01/01/2022

#### Regulation on Safety of Pharmaceuticals, etc.

This is to determine the matters entrusted by the law and the details necessary for its implementation including monitoring the implementation of procedures and conditions necessary for Conditional Marketing Authorization (CMA) and establishing Standard Operation Procedure (SOP) for Site Management Organization (SMO) and the Central Institution Review Board (IRB), following the revision of 'Pharmaceutical Affairs Act' (Act No.18307, Promulgation Date, 20 Jul, 2021, Enforcement Date, 21 Jan, 2022), which aims to provide legal basis on CMA which authorizes marketing under the condition that clinical trials result for the medicine user should be submitted and clinical trials consigned and conducted by IRB.

G/TBT/N/RUS/123 02/11/2021 Russian Federation Low voltage equipment

30/01/2021

The draft amendments to the technical regulation "On the Safety of Low Voltage Equipment' (CU TR 004/2011) regarding the establishment of forms, schemes, and procedures for conformity assessment on the basis of standard conformity assessment schemes, approved by the Decision No. 44 of the EEC Council of April 18, 2018

The draft amendments include clarifications on the following: amendments to the Article 2 "Definitions" of the CU TR 004/2011; wording of the Article 6 of the CU TR 004/2011 "Ensuring compliance with safety requirements"; wording of the Article 7 of the CU TR 004/2011 "Conformity assessment"; and adding of the articles on conformity assessment (Articles 8 and 9 of the draft amendments of the CU TR 004/2011).

G/TBT/N/RUS/124 02/11/2021

Russian Federation Technical means capable of creating electromagnetic 30/01/2021 interference and (or) the quality of functioning of which depends on the impact of external electromagnetic interference

The draft amendments to the technical regulation "Electromagnetic Compatibility of Technical Means" (CU TR 020/2011) regarding the establishment of forms, schemes, and procedures for conformity assessment on the basis of standard conformity assessment schemes, approved by the Decision No. 44 of the Commission's Council of **April 18, 2018** 

The draft amendments include clarifications on the following: amendments to the Article 2 "Definitions" of the CU TR 020/2011, wording of Article 6 of the CU TR 020/2011 "Ensuring compliance with safety requirements"; wording of Article 7 of the CU TR 020/2011 "Conformity assessment" and adding of the articles on conformity assessment (Articles 8 and 9 in the draft amendments of the CU TR 020/2011).

<u>G/TBT/N/R</u>US/125 02/11/2021

Russian Federation Equipment for explosive environments

30/01/2021

The draft amendments to the technical regulation "On the Safety of Equipment for Explosive Environments" (CU TR 012/2011) regarding the establishment of forms, schemes, and procedures for conformity assessment on the basis of standard conformity assessment schemes, approved by the Decision No. 44 of the EEC Council of April 18,2018

The draft amendments include clarifications on the following: amendments to the Article 2 "Definitions" of the CU TR 012/2011, wording of Article 5 of the CU TR 012/2011 "Ensuring compliance with safety requirements"; wording of Article 6 of the CU TR 012/2011 "Conformity assessment".

**G/TBT/N/USA/1793 USA** 02/11/2021

Commercial harbor craft emissions

#### **Commercial Harbor Craft Regulation**

Proposed rule - Amends rules to provide for more stringent engine emissions performance standards for NOx and particulate matter. Vessel owners and operators would need to meet performance standards between 2023 and 2032 according to a schedule based on vessel category and engine model year. Proposes to amend section 2299.5, title 13, division 3, chapter 5.1 of the California Code of Regulations (CCR) and section 93118.5, title 17, chapter 1, subchapter 7.5,

CCR.

G/TBT/N/USA/1794 **USA** 02/11/2021

Acrylamide in food warnings

#### Proposition 65 Article 6 Acrylamide in Food Warnings

Proposed rule - Adds new section to adopt new safe harbor warning content for exposure to acrylamide from food.

Toluene; safer consumer products

18/11/2021

#### Safer Consumer Products: Priority Products List; Nail Products Containing Toluene

Proposed rule - The Department of Toxic Substances Control (DTSC) proposes to amend section 69511 and add section 69511.6 to Article 11 of the Safer Consumer Products (SCP) regulations. The proposed action will add nail products containing toluene as a Priority Product on the Priority Products List. The listing applies to any nail product, including nail coatings and nail polish thinners, that is placed into commerce in California that contains toluene. For the purposes of this regulation, DTSC defines nail coatings as any clear or colored paint, polish, lacquer, enamel, or gel product marketed or sold for application to fingernails or toenails. This proposed amendment pertains to identification of a Priority Product under the SCP regulations, approved by California's Office of Administrative Law (OAL) and filed with the Secretary of State on 28 August 2013 (effective date: 1 October 2013; OAL Regulatory Action Number: 2013-0718-03).

<u>G/TBT/N/USA/1796</u> USA 02/11/2021

Magni350 and magni650 model engines

# Special Conditions: magniX USA, Inc., magni350 and magni650 Model Engines; Electric Engine Airworthiness Standards

Final special conditions - These special conditions are issued for the magniX USA, Inc., (magniX), magni350 and magni650 model engines, which operate using electrical technology installed on the aircraft for use as an aircraft engine. These engines have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards applicable to aircraft engines. This design feature is an electric motor, controller, and high-voltage systems as the primary source of propulsion for an aircraft. The airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

<u>G/TBT/N/USA/1797</u> USA 02/11/2021

Boeing model 777-9; operation without normal 18/11/2021 electrical power

#### Special Conditions: Boeing Commercial Airplanes Model 777-9 Airplane; Operation Without Normal Electrical Power

Final special conditions; request for comments - These special conditions are issued for the Boeing Commercial Airplanes (Boeing) Model 777-9 series airplane. This airplane will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. This design feature is electrical and electronic systems that perform critical functions, the loss of which could be catastrophic to the airplane. The applicable airworthiness regulations

do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

G/TBT/N/TPKM/471 03/11/2021 Chinese Taipei Copying machines and 30 other commodities

02/01/2022

# Proposal for amendments to the legal requirements for printing or copying machines and 30 other commodities

BSMI proposes to adopt the newest version of the electrical safety specifications, electromagnetic compatibility and related inspection standards, CNS 15598-1: 2020 and CNS15936: 2016 to bring our regulations into line with the international standards to ensure consumers' safety. In addition, CNS 15598-1: 2020 was also revised to meet the ratification requirements of the Minamata Convention on Mercury to address the threat to human health and the environment.

G/TBT/N/TPKM/472 03/11/2021 Chinese Taipei Electric pencil sharpeners

02/01/2022

# Proposal for amendments to the legal requirements for electric pencil sharpeners and 21 other commodities

BSMI proposes to adopt the newest version of the electrical safety specifications, electromagnetic compatibility and related inspection standard, CNS 15598-1:2020 and CNS15936:2016 to bring our regulations in line with the international standards to ensure consumers' safety. In addition, CNS 15598-1: 2020 was also revised to meet the ratification requirements of the Minamata Convention on Mercury to address the threat to human health and the environment. For the video recording or reproducing apparatus, the standard to be adopted contains volume limits requirements to protect consumers from hearing loss. Rechargeable electric pencil sharpener is added in the product scope for legal inspection.

<u>G/TBT/N/TPKM/473</u> 03/11/2021 Chinese Taipei Headphones

02/01/2022

#### **Proposal for Legal Requirements for Headphones**

Nowadays, headphones are widely used. The excessive use of smartphones and audio devices with headphones may cause hearing loss of consumers. In order to enhance consumer protection, the BSMI intends to regulate the inspection requirements for headphones. Two alternative conformity assessment procedures, are made available for the choice of applicants, i.e. Registration of Product Certification (RPC) or Type-Approved Batch Inspection (TABI).

G/TBT/N/IDN/136 03/11/2021 Indonesia

ICS codes: 23.120 (Ventilators. Fans. Air- 02/01/2022 conditioners)

Decree of the Minister of Energy and Mineral Resources No.114.K/EK.07/DJE/2021 on The Minimum Energy Performance Standard (SKEM) and Energy Saving Label for Fan Devices Referring to the Regulation of the Minister of Energy and Mineral Resources No 14 of 2021 on Implementation of Performance Standards Minimum Energy (SKEM) for Energy Utilizing Households, the Minister then issues a Decree of the Minister of and Mineral Resources 114.K/EK.07/DJE/2021 on the Minimum Energy Performance Standards (SKEM) and Energy Saving Label for Fan Devices. Domestic manufacturers and importers of fan are required to apply for Minimum Energy Performance Standards (SKEM) through the inclusion of energy-saving labels. The Minimum Energy Performance Standards values for fan are 0.6 (zero point six) for fan with blade diameter less than 12 inches and 1.0 (one point zero) for fan with blade diameter more than 12 inches. Inclusion of the Energy Saving label originating from import products are done in the country of origin. The Energy Saving Label is affixed to or attached with not-easily removed material. The Energy Saving Label on the packaging can be imprinted in a contrasting color. The form and specifications of the Energy Saving Label are as stated in Appendix 1. The certification scheme for testing product is using type 1a in accordance to SNI ISO/IEC 17067:2013 Conformity Assessment - Fundamentals of Product Certification or the changes. Performance testing requirements and procedures are referring to SNI IEC 60789:2013 Performance and construction of electric circulating fans and regulators or the changes. Domestic manufacturers and importers of air conditioning energy must submit a report application of Minimum Energy Performance Standards to Director General of New, Renewable Energy and Energy Conservation periodically every 3 (three months) which include: a. brand; b. type, variant, or model; c. capacity and power; and d. amount, for manufactured and/or imported products. regulation will come into force 12 (twelve) months after stipulation.

<u>G/TBT/N/IDN/137</u> Indonesia 03/11/2021

ICS codes: 97.040 (Kitchen equipment)

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02/01/2022

Decree of the Minister of Energy and Mineral Resources No.115.K/EK.07/DJE/2021 on The Minimum Energy Performance Standard (SKEM) and Energy Saving Label for Rice Cooker Devices Referring to the Regulation of the Minister of Energy and Mineral Resources Number 14 of 2021 concerning Implementation Performance Standards Minimum Energy (SKEM) for Energy Utilizing Households, the Minister then issues a Decree of the Minister of Energy and Mineral Resources 115.K/EK.07/DJE/2021 on The Minimum Energy Performance Standard (SKEM) and Energy Saving for Rice Cooker Devices. Domestic manufacturers and importers of rice cooker devices are required to apply for a minimum energy performance standards (SKEM) through the inclusion of energysaving labels. The minimum energy performance standard is the consumption energy level 250 x V-1/3 watthour/liter. The inclusion of the Energy Saving

Label originating from import products are done in the country of origin. The energy saving label is affixed to the product an packaging using an easy-to-read font size and proportionated and printed or attached with uneasily removed materials. The Energy Saving Label on the packaging can be imprinted in a contrasting color. The form and specifications of the Energy Saving Label are as stated in Appendix 1. The certification scheme for testing product is using type 1a in accordance to SNI ISO/IEC 17067:2013 Conformity assessment - Fundamentals of product certification or the changes Performance testing requirements and procedures are referring to SNI IEC 60335-1 Household and similar electrical appliances-Safety-Part 1: General requirement and SNI IEC 60335-2-15 Household and similar electrical appliances- Safety – Part 2-15 Particular requirements for appliances for heating liquids. Domestic Manufacturers and Importers of rice cooker must submit a report the application of Minimum Energy Performance Standards to Director General of New, Renewable Energy and Energy Conservation periodically every 3 (three months) which includes: a. brand; b. type, variant, or model; c. capacity and power; d. amount for manufactured and/or imported products This regulation will come into force 12 (twelve) months after stipulation.

G/TBT/N/IDN/138 03/01/2021 Indonesia

Food; beverages; drugs and medicine; cosmetics; 02/01/2022 chemical products; biological products; genetically engineered products; consumer goods; slaughtering services; processing services; storage services; packaging services; distribution services; sales services; and serving service

Regulation of Minister of Finance Number 57/PMK.05/2021 regarding Tariff for Public Services provided by Halal Product Assurance Organizing Agency (BPJPH), Ministry of Religious Affairs

This regulation sets the tariff and fee for services provided by BPJPH including: a. halal certification fee for goods and services; b. accreditation fee for halal certification body; c. registration fee for halal auditor; d. training fee for halal auditor and halal supervisor; e. competency certification fee for halal auditor and halal supervisor.

<u>G/TBT/N/UGA/1495</u> Uganda 03/11/2021

Water, Waste water

02/01/2022

### DUS 2411:2021, Standard Test Methods for Chloride Ion in Water, First Edition

This Draft Uganda Standard covers the determination of chloride ion in water, wastewater (Test Method C only), and brines. The following three test methods are included: Test Method A (Mercurimetric Titration), Test Method B (Silver Nitrate Titration) and Test Method C (Ion-Selective Electrode Method).

G/TBT/N/UGA/1496 03/01/2021 Uganda

Electrical Insulating Liquids

02/01/2022

#### FDUS 2347:2021, Standard Guide for Sampling, Test Methods, and Specifications for Electrical Insulating Liquids, First Edition

This Final Draft Uganda Standard describes methods of testing and specifications for electrical insulating liquids intended for use in electrical cables, transformers, liquid circuit breakers, and other electrical apparatus where the liquids are used as insulating, or heat transfer media, or both. The purpose of this guide is to outline the applicability of the available test methods. Where more than one is available for measuring a given property, their relative advantages are described, along with an indication of laboratory convenience, precision, (95 % confidence limits), and applicability to specific types of electrical insulating oils. This guide is classified into the following categories: Sampling Practices, Physical Tests, Electrical Tests, Chemical Tests, and Specifications.

G/TBT/N/IDN/135 03/11/2021 Ukraine

Energy utilizing household

02/01/2022

#### Regulation of the Minister of Energy and Mineral Resources No 14 of 2021 on The Implementation of Minimum Energy Performance Standard (SKEM) for Energy Utilizing Household

Minimum Energy Performance Standard (SKEM) is a specification that contains a number of minimum energy performance requirements under certain conditions which is meant to effectively limit the number pf maximum energy consumption allowed for energy use product. Both domestic producers and importers are required to apply for SKEM on energy utilizing household products which will traded in Indonesia's market. The implementation of SKEM is proved by inclusion of SKEM label or Energy Saving label. The Energy Saving Label is a label that states energy utilization equipment products have met the requirements of certain energy saving. To carry out the inclusion of the SKEM mark or the inclusion of Energy Saving Label, domestic producers and importers are required to have Energy Saving Certificate issued by an Accredited or Appointed Product Certification Body through Energy Saving Certification. Energy Saving Certificate is valid for 4 (four) years and can be extended. Domestic producers and importers are required to submit reports every 3 (three) months regarding: a. brand; b. type, variant, or model; c. capacity / power / volume / diameter; and d. amount, of the production or imported Energy Utilization Products When this Ministerial Regulation comes into force: a. self-ballasted lamp test results from the laboratory tests that have been set before this regulation comes into force, is declared to remain valid for one-time application for Energy Saving Certificate; b. Domestic manufacturer and importer of self-ballasted lamps which already has the determination of the test results before this Regulation comes into force, must submit application for issuance of Energy Saving Certificate according to the

provisions in this Regulation no later than 12 (twelve) months since this Regulation comes into force; c. Certificate of Energy Saving for Air Conditioning Appliances issued or stipulated before this Ministerial Regulation comes into force, is declared to remain valid until the term of the Energy Saving Certificate expires; d. Product Certification Body that has been appointed before this Regulation comes into force, is declared to remain valid until the appointment time expires.

G/TBT/N/UKR/207 03/11/2021 Ukraine

Medical devices, in vitro diagnostic medical devices, 02/01/2022 active implantable medical devices

#### Draft Law of Ukraine "On Medical Devices"

The draft Law aims at: elimination of ambiguous interpretation of the norms regarding classification of medical devices; reduction of the circulation of counterfeit medical devices; elimination of double proof of safety of medical devices (deregulation); regulation of advertising of medical devices; creation of legal grounds for the development of legal acts concerning clinical investigations and performance evaluation; determination of the legal grounds for taking market surveillance measures for all medical devices, regardless of the method of placing on the market; simplification of the conformity assessment procedure through the use of remote audits.

G/TBT/N/BDI/175 04/11/2021 Burundi

Medical cotton swabs

03/01/2022

DEAS 1070:2021, Medical cotton swabs – Specification, First Edition

This Draft East African Standard specifies requirements, sampling and test methods for medical cotton swabs. This standard does not apply to flocked swabs for clinical use.

G/TBT/N/BDI/176 04/11/2021 Burundi

Cotton ear buds

03/01/2022

DEAS 1069:2021, Cotton ear bud — Specification, First Edition

This Draft East African Standard specifies requirements, sampling and test methods for cotton ear buds.

G/TBT/N/JPN/715 04/11/2021 Japan

ICS codes: 11.120 (Pharmaceutics)

01/12/2021

Partial amendment to the Minimum Requirements for Biological Products

Amendment of the provisions for Mycoplasma test in the "Inactivated Polio Vaccine".

<u>G/TBT/N/KEN/1150</u> Kenya 04/11/2021 ICS codes: 11.160 (First aid)

30/12/2021

DKS 2949:2021 Specification for aquatic spine boards for recovering casualties in controlled aquatic conditions

This draft Kenya Standard specifies the construction and performance of aquatic spine boards for use in the rescue, from water, of casualties with suspected spinal injuries. It is applicable only to aquatic spine boards for use in controlled aquatic conditions. Pharmaceuticals, quasi-drug

03/01/2022

#### Notification on Partial Amendment of 'Regulation for Pharmaceutical Approval, Notification and Reviews'

The Ministry of Food and Drug Safety, Republic of Korea intends to revise the following matters in Regulation for Pharmaceutical Approval, Notification and Reviews. 1.Reinforcement of change control including manufacturing procedure for prescription drug 2. Abolishment of mandatory regulation on submission of manufacturing and Free Sales Certificate for imported new drug. 3. New Establishment on Example of indications of precaution for use by specifying package unit for disposable ophthalmic solutions at less than 0.5ml 4. Abolishment of foreign national drug formulariesbased system to strengthen scientific evidence-based safety and validity review system.

<u>G/TBT/N/KOR/1006</u> Korea 04/11/2021

Pharmaceuticals

03/01/2022

# Enforcement Rule of Act on Encouragement of Development and Emergency Distribution of Medical Countermeasures for Public Health Emergency

1) Establishment of Committee for Safety Management and Circulation of Medical Countermeasures (MCs) for Public Health Emergency (PHE) (Article 3 of the Draft) Tenure of the commissioner (2 year) of the committee and the ground such as mental and physical disability to dismiss the committee, which was delegated from the decree. has been prepared Expulsion/avoidance/evasion of committee commissioner (Article 4 of the draft) If it is not available for a commissioner to fairly deliberate and vote, it is possible to expel, avoid and evade the commissioner 3) Operation of committee (Article 5 of the draft) Detailed guidance concerning operation such as role of the chair, convocation of the committee, reproposal, decision criteria and consultation has been established 4) Composition of subcommittee (Article 6 of the draft) For more professional deliberation, subcommittee for safety management and circulation have been established 5) Designation of preliminary MCs for PHE (Article 9 of the draft) Designation of preliminary MCs for PHE form, application method, issuance of designation and designation notification method, etc. have been specified 6) Procedure and method of priority review, rolling review (Article 10 and 11 of the draft) Review on preliminary MCs for PHE shall be conducted within 40 days and document submission and authorization form for rolling review has been specified 7) Application for conditional marketing authorization (Article 13 of the draft) For application for conditional marketing authorization of preliminary MCs for PHE, data to be submitted for each medical product shall be clearly defined 8) Procedure and method of Emergency Use Authorization (EUA) (Article 14 of the draft) Required procedure, date to be

submitted by manufacturer and processing procedure for EUA shall be specified 9) Procedure and method of safety use (Article 15 of the draft) Procedure on Type and reporting of safety use and report analysis of medical products obtained conditional marketing authorization shall be prepared 10) Reporting adverse event (Article 16 of the draft) Procedure on reporting on adverse event for medical products granted conditional marketing authorization to Korea Institute of Drug Safety & Risk Management (KIDS) and National Institute of Medical Device Safety Information (NIDS) shall be prepared 11) Establishment of traceability and tracking system (Article 17 of the draft) Item and timeline required for traceability and tracking system shall be specified 12) Designation process and method of MCs for PHE (Article 19 of the draft) Designation process, method, issuance of designation form and publication on the website of MCs for PHE shall be specified. 13) Scopemethod and process for investigation (Article 20 of the draft) Investigation scope of medical products, notice for investigation target and qualification for investigator 14) Establishment of standards of administrative disposition (Article 21 of the draft) Standards of administrative disposition for violation of this Act shall be established.

<u>G/TBT/N/KOR/1007</u> Korea 04/11/2021

Quasi-drugs

03/01/2022

### Proposed amendments to the "Regulation on Labels of Quasi-drugs"

The "Regulation on Labels of Quasi-drugs" is being amended by the Ministry of Food and Drug Safety (MFDS) as follows: The labelling of external disinfectants must include a warning statement "For external use only" and a graphic symbol (refer to the attachment).

<u>G/TBT/N/MWI/52</u> Malawi 04/11/2021

ICS codes: 71.060.50 (Salts)

03/01/2022

This draft Malawi standard applies to salt used as an ingredient of food, both for direct sale to the consumer and for food manufacture. It applies also to salt used as a carrier of food additives and/or nutrients. It does not apply to salt from origins other than those mentioned in this draft Malawi standard, notably the salt which is a by-product of chemical industries.

DMS 188:2021, Edible salt — Specification

<u>G/TBT/N/MWI/53</u> Malawi 04/11/2021

ICS codes: 67.220.10 (Spices and condiments)
DMS 745: 2021, Mayonnaise – Specification

03/01/2022

This draft Malawi standard specifies the requirements, sampling and methods of test, for mayonnaise intended for human consumption.

<u>G/TBT/N/MWI/54</u> Malawi 04/11/2021 ICS codes: 67.120.10 (Meat and meat products)
DMS 769:2021, Meat burgers – Specification

03/01/2022

This draft Malawi standard prescribes the requirements and method of sampling for meat burgers made from comminuted meat (beef, lamb and mutton, poultry, pork).

ICS codes: 67.220.20 (Food additives) G/TBT/N/MWI/55 Malawi 03/01/2022 04/11/2021 DMS 1645:2021, Mango chutney - Specification This draft Malawi standard specifies requirements and methods of test and sampling for mango chutney offered for direct consumption, including for catering purposes or repacking if required. G/TBT/N/MEX/504 Mexico Transporte de ciertas clases de mercancías peligrosas 03/01/2022 04/11/2021 Proyecto de Norma Oficial Mexicana PROY-NOM-011-SCT2/2021, Condiciones para transporte mercancías peligrosas de embaladas/envasadas en cantidades limitadas La presente Norma Oficial Mexicana tiene como objetivo establecer las especificaciones a que deberá sujetarse el transporte de ciertas clases de mercancías embaladas/envasadas en cantidades peligrosas Es de aplicación obligatoria para los limitadas. expedidores, transportistas y destinatarios de las mercancías peligrosas especificadas. ICS codes: 11.040.70 (Ophthalmic equipment) G/TBT/N/PER/138 Peru 03/01/2022 04/11/2021 Proyecto de Norma Metrológica Peruana PNMP 02X:202X "INSTRUMENTOS OFTÁLMICOS -**IMPRESIÓN** TONÓMETROS  $\mathbf{DE}$ APLANAMIENTO – Parte 1: Requisitos técnicos y metrológicos; Parte 2: Procedimientos de pruebas; y Parte 3: Formato de informe de pruebas" - 1ra Edición Este Proyecto de Norma Metrológica Peruana especifica los requisitos para la conformidad del diseño y la construcción de tonómetros de impresión y aplanamiento que se utilizan para la determinación de la presión intraocular (PIO) en aplicaciones clínicas. Al referirse a tonómetros de aplanamiento, son aquellos que miden la fuerza necesaria para aplanar la córnea sobre un diámetro determinado usando el lado de contacto plano de un cuerpo de presión, este Proyecto de Norma Metrológica Peruana incluye el método desarrollado por Hans Goldmann. G/TBT/N/RWA/566 Rwanda Medical cotton swabs 03/01/2022 04/11/2021 DEAS 1070:2021, Medical cotton swabs —

swabs for clinical use.

G/TBT/N/RWA/567 Rwanda
04/11/2021 Cotton ear buds
05/01/2022

DEAS 1069:2021, Cotton ear bud — Specification,

**Specification, First Edition** 

DEAS 1069:2021, Cotton ear bud — Specification, First Edition

This Droft Fast African Standard specifies

This Draft East African Standard specifies requirements, sampling and test methods for medical cotton swabs. This standard does not apply to flocked

This Draft East African Standard specifies requirements, sampling and test methods for cotton ear buds.

G/TBT/N/TZA/663 04/11/2021 Tanzania

Medical cotton swabs

03/01/2022

### DEAS 1070:2021, Medical cotton swabs Specification, First Edition

This Draft East African Standard specifies requirements, sampling and test methods for medical cotton swabs. This standard does not apply to flocked swabs for clinical use.

G/TBT/N/TZA/664 04/11/2021 Tanzania Cotton ear buds

03/01/2022

### DEAS 1069:2021, Cotton ear bud — Specification, First Edition

This Draft East African Standard specifies requirements, sampling and test methods for cotton ear buds.

<u>G/TBT/N/THA/641</u> Thailand 04/11/2021

ICS codes: 77.140.50 (Flat steel products and semi-products)

#### Draft Ministerial Regulation on Hot-Rolled High Strength Flat Steel with Improved Formability for Automobile Uses (TIS 1884 - 25XX(20XX))

The draft ministerial regulation mandates hot-rolled high strength flat steel with improved formability for automobile uses to conform with the standard for Hot-Rolled High Strength Flat Steel with Improved Formability for Automobile Uses (TIS 1884 -25XX(20XX)). The Thai Industrial Standards Institute (TISI) is in the process of withdrawing the standard for Hot-Rolled High Strength Steel Coil Strip Plate and Sheet with Improved Formability for Automobile Structural Uses (TIS 1884 - 2542(1999)) and the standard for Hot-Rolled High Strength Flat Steel with Improved Formability for Automobile Uses (TIS 1884 - 25XX(20XX)) will be replaced. This standard covers hot-rolled high strength flat steel with improved formability for automobile uses, both unalloyed and alloy steels, used for automobile uses, electrical equipment, construction materials, etc. The scope excludes: - Other hot-rolled flat steel which is regulated as a mandatory standard such as Hot Rolled Flat Steel for General Structure (TIS 1479 2558(2015))- Other hot-rolled flat steel which is processed in sequential rerolling, but excluding the one followed by skin pass or temper rolling or roll formingThis standard specifies types, grades, materials, chemical composition, mechanical properties, mass and tolerances on dimensions and shape, appearance, marking and labelling, sampling and criteria for conformity, and testing.

<u>G/TBT/N/THA/642</u> Thailand 04/11/2021

ICS codes: 77.140.50 (Flat steel products and semi-products)

# Draft Ministerial Regulation on Hot-Dip Zinc-Coated Hot Rolled Flat Steel (TIS 3243 - 25XX(20XX))

The draft ministerial regulation mandates hot-dip zinc-coated hot rolled flat steel to conform with the standard for Hot-Dip Zinc-Coated Hot Rolled Flat Steel (TIS 3243 - 25XX(20XX)). This standard covers hot-dip zinc-coated hot rolled flat steel, both sheet and coil, which is used for construction materials, electrical appliances, etc. It is made by hot rolled flat

steel which is processed further by hot-dip zinc coating or/and oil coating chemical treatment. The scope excludes: - Hot-dip galvannealed flat steel -Other hot-dip zinc-coated hot rolled flat steel which is regulated as a voluntary standard such as hot-dip galvanized and galvannealed flat steel for automobile uses (TIS 2985 - 2562(2019)) - Other hot-dip zinccoated hot rolled flat steel with other elements which is regulated as a voluntary standard such as hot-dip zinc-5% to 13% aluminium-2% to 4% magnesium alloyed-coated flat steel (TIS 2981 - 2562(2019)) This standard specifies types, grades, chemical composition, mechanical properties, zinc coating, oil coating, chemical treatment, mass and tolerances on dimensions and shape, appearance, marking and labelling, sampling and criteria for conformity, etc.

<u>G/TBT/N/UGA/1497</u> 04/11/2021

Uganda

Medical cotton swabs

03/01/2022

### DEAS 1070:2021, Medical cotton swabs — Specification, First Edition

This Draft East African Standard specifies requirements, sampling and test methods for medical cotton swabs. This standard does not apply to flocked swabs for clinical use.

<u>G/TBT/N/UGA/1498</u> 04/11/2021

Uganda

USA

Cotton ear buds

03/01/2022

### DEAS 1069:2021, Cotton ear bud — Specification, First Edition

This Draft East African Standard specifies requirements, sampling and test methods for cotton ear buds.

<u>G/TBT/N/USA/1798</u> 04/11/2021 Product-safety testing and certification services

#### Modification to the List of Appropriate NRTL Program Test Standards and the Scope of Recognition of Several NRTLs

Notice - In this notice, OSHA announces the final decision to: (1) Add seven new test standards to the Nationally Recognized Testing Laboratories (NRTL) Program's list of appropriate test standards; (2) delete or replace several test standards from the NRTL Program's list of appropriate test standards; and (3) update the scope of recognition of several NRTLs.

G/TBT/N/JPN/716 05/11/2021 Japan

Fertilizer (HS: 3101, 3105)

04/01/2022

### Establishment of new standards for Normal Fertilizers

MAFF will amend administerial rules for official specification of normal fertilizer as follows; 1. The government of Japan establishes new standards for "Fused Silicate Fertilizer". 2. The government of Japan establishes new standards of Raw-materials Specification.

<u>G/TBT/N/USA/1799</u> USA 05/11/2021

Cooking products, test procedures

03/01/2022

### **Energy Conservation Program: Test Procedures** for Cooking Products

Notice of proposed rulemaking and announcement of public meeting - The U.S. Department of Energy ("DOE") proposes to establish a test procedure for a

category of cooking products, i.e., conventional cooking tops, under a proposed new appendix. The proposed test procedure would adopt the latest version of the relevant industry standard with modifications to adapt the test method to gas cooking tops, offer an optional method for burden reduction, normalize the energy use of each test cycle, include measurement of standby mode and off mode energy use, update certain test conditions, and provide certain clarifying language. This NOPR also proposes to retitle the existing cooking products test procedure for microwave ovens only. DOE is seeking comment from interested parties on the proposal.