



WTO TBT NOTIFICATIONS BULLETIN

A Weekly Publication of the Bureau of Philippine Standards (BPS) of the Department of Trade and Industry (DTI)

BUREAU OF PHILIPPINE STANDARDS

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This publication seeks to provide cohesive information in a weekly basis on the foreign notifications of the WTO members under the TBT agreement on their proposed technical regulations and conformity assessment procedures.

Philippine exporters and relevant stakeholders are invited to review the proposed regulations. Comments that will be received by the BPS will be transmitted to the governments concerned for their consideration.

IN THIS WEEK'S ISSUE

Notifications on agriculture, chemicals, environment/health protection/safety, food, healthcare, mechanical, rubber and plastic industries, services, etc. from Brazil, El Salvador, the European Union, Republic of Korea, The Separate Customs Territory of Taiwan, Penghu, Kinmen and United States of America are listed.

We would like to hear from you. For any questions, suggestions or requests for full text of notified regulations, please contact us at bps@dti.gov.ph

We are glad to be of service to you!

List of WTO TBT NOTIFICATIONS (05 November-11 November 2016)

Product Sector	Country	Date Notified	TBT Notification Symbol	Product Coverage / Title	Final Date for Comments
AGRICULTURE					
PRODUCTS OF THE CHEMICAL INDUSTRY	UNITED STATES OF AMERICA	09/11/2016	G/TBT/N/USA/1220	Chemical substances <i>EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for three chemical substances which were the subject of premanufacture notices (PMNs). The applicable review periods for the PMNs submitted for these chemical substances all ended prior to 22 June 2016, the date on which President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act which amends TSCA). This action would require persons who intend to manufacture (defined by statute to include import) or process any of the chemical substances for an activity that is designated as a significant new use by this proposed rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the intended use within the applicable review period. Manufacture and processing for the significant new use is unable to commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and take such actions as are required with that determination.</i>	28 November 2016

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ENVIRONMENT, HEALTH PROTECTION, SAFETY					
REFRIGERATION PRODUCTS	UNITED STATES OF AMERICA	09/11/2016	G/TBT/N/USA/1215/Add.1	<p>Refrigeration products - Addendum</p> <p><i>The Energy Policy and Conservation Act of 1975, as amended, established the Energy Conservation Program for Consumer Products Other Than Automobiles. Based on provisions in EPCA that enable the Secretary of Energy to classify additional types of consumer products as covered products, the U.S. Department of Energy (DOE) classified miscellaneous refrigeration products as covered consumer products under EPCA. In this direct final rule, DOE is adopting new energy conservation standards for these products that correspond to the recommendations submitted jointly by interested persons that are fairly representative of relevant points of view. DOE has determined that the new energy conservation standards for these products would result in significant conservation of energy, and are technologically feasible and economically justified. A notice of proposed rulemaking that proposes identical energy efficiency standards is published elsewhere in this Federal Register. If DOE receives adverse comment and determines that such comment may provide a reasonable basis for withdrawal, DOE will withdraw the direct final rule and will proceed with the proposed rule. The effective date of this rule is 27 February 2017 unless adverse comment is received by 15 February 2017. If adverse comments are received that DOE determines may provide a reasonable basis for withdrawal of the final rule, a timely withdrawal of this rule will be published in the Federal Register. If no such adverse comments are received, compliance with the new standards established in this direct final rule will be required for miscellaneous refrigeration products as detailed in the SUPPLEMENTARY INFORMATION section of this document. Compliance with these new standards for miscellaneous refrigeration products is required starting on 28 October 2019.</i></p>	—
SULFUR CONTENT IN FUELS	UNITED STATES OF AMERICA	09/11/2016	G/TBT/N/USA/1218/Add.1	<p>Sulfur content in fuels - Addendum</p> <p><i>The Environmental Protection Agency (EPA) is taking direct final action to approve revisions to the District of Columbia state implementation plan (SIP) . The revision pertains to the update of the District of Columbia Municipal Regulations (DCMR) to lower the sulfur content of fuel oil. This action is being taken under the Clean Air Act (CAA) . DATES: This rule is effective on 12 December 2016 without further notice, unless EPA receives adverse written comment by 10 November 2016. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the Federal Register and inform the public that the rule will not take effect.</i></p>	—

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PROTECTION AGAINST FIRE	UNITED STATES OF AMERICA	09/11/2016	G/TBT/N/USA/1219	Cigarettes <i>Promulgates regulations governing the testing, certification, marking, and enforcement of fire standard compliant cigarettes.</i>	—
FOOD TECHNOLOGY					
FOOD PRODUCTS IN GENERAL	REPUBLIC OF KOREA	11/11/2016	G/TBT/N/KOR/690	Labelling of food <i>The main proposed amendments of the "Labelling Standards for Foods" is as the following:</i> <ul style="list-style-type: none"> · Definition of honey from sugar-fed bees should be labelled with over 12 pt font size on the principal display panel. · Provision of labelling both cautions and contents of flaxseed-used products has been established. · Labelling standard of enzyme contents of enzyme food has been established. · Labelling target of both a name defined in the Food Additives Code and contents of food additives has been changed from chemical synthetics to complex ingredient. · A provision has been established not only to observe the Food Labelling Standards but to observe other regulations of ingredient labelling method. · Labelling of "for adults only" is needed if the food except liquor is labelled as "Non-alcoholic", "alcohol free" or "no alcohol added". And "less than 1% of ethanol is added" should also be labelled if the food is labelled as non-alcoholic. 	60 days from notification
HEALTHCARE TECHNOLOGY					
MEDICAMENTS *INCLUDING MEDICAL PRESCRIPTIONS AND MEDICINAL HERBS	BRAZIL	09/11/2016	G/TBT/N/BRA/327/Add.4	Medicine - Addendum <i>This addendum aims at informing that the Brazilian Health Regulatory Agency (ANVISA) issued the Resolution RDC N° 120, 3 November 2016 (published in the National Gazette in 4 November 2016), amending the Ordinance RDC 73/2016, and approving the rules for drug labelling that have to be registered at ANVISA to be marketed in Brazil. The Draft Resolution n° 46/2009, notified under the document G/TBT/N/BRA/327 - technical regulation that determines the rules for drug labelling that have to be registered at Anvisa for commercialization in Brazil - was published by Anvisa as Resolution RDC n° 71/2009, 22 December 2009. On 16 June 2011, Anvisa published Resolution RDC n° 26/2011, which suspends the requirements for the adaptation period of drug labelling rules established by Resolution RDC N° 71, 22 December 2009. On 8 April 2016 Anvisa published the Ordinance Resolution RDC N° 73, 7 April 2016 in order to reword the Resolution RDC 71/2009 (art. 43), regarding the drugs labelling with post-registration changes. Lastly, on 4 November 2016, Anvisa published the Resolution RDC n° 120, 3 November 2016, which changes the Article 35 of the RDC 73/2016.</i>	—

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MEDICAMENTS *INCLUDING MEDICAL PRESCRIPTIONS AND MEDICINAL HERBS	EUROPEAN UNION	09/11/2016	G/TBT/N/EU/420	<p>Medicinal products for human use</p> <p><i>This draft Implementing Regulation on the detailed arrangements for Good Clinical Practice inspections procedures, including the qualification and training requirements for inspectors, provides for, inter alia:</i></p> <ul style="list-style-type: none"> · requirements as regards the experience, training and qualifications for GCP inspectors; · rules on conflict of interest and impartiality for GCP inspectors; · empowerment of inspectors and applicable confidentiality requirements; · obligation for the Member States to adopt detailed procedural rules, inter alia, for the appointment of experts accompanying inspectors, arranging inspections in third countries; · principle of mutual recognition of inspections findings and obligation of cooperation. 	60 days from notification
PHARMACEUTICS IN GENERAL	EL SALVADOR	10/11/2016	G/TBT/N/SLV/182/Add.1	<p>Pharmaceuticals, medicines - Addendum</p> <p><i>RTS 11.02.01: 15 Pharmaceutical Products. Medicinal products for human use. Bioequivalence and interchangeability.</i></p> <p><i>The Government of El Salvador, reports that extending for six months the validity of RTS 11.02.01: 15 Pharmaceutical Products. Medicinal products for human use. Bioequivalence and interchangeability. Notified the Committee on Technical Barriers to Trade of the World Trade Organization, on an emergency basis under G / TBT / N / SLV / 182 dated September 21, 2015.</i></p> <p><i>This notification is made for reasons of transparency.</i></p>	—
VETERINARY MEDICINE	UNITED STATES OF AMERICA	10/11/2016	G/TBT/N/USA/1202/Add.1	<p>Veterinary biological products- Addendum</p> <p><i>In a final rule published in the Federal Register on 30 August 2016, and effective on 31 October 2016, we amended the Virus- Serum-Toxin Act regulations to make veterinary biologics labeling requirements more consistent with current science and veterinary practice. However, we inadvertently removed a requirement for an indications statement that should appear on final container labels, carton labels, and enclosures. This document corrects that error. Effective 8 November 2016.</i></p>	—

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MEDICAL EQUIPMENT	UNITED STATES OF AMERICA	09/11/2016	G/TBT/N/USA/1216/Add.1	<p>Ozone-depleting substances - Addendum</p> <p>The Food and Drug Administration (FDA, the Agency, or we) is amending its regulation on uses of ozone-depleting substances (ODSs), including chlorofluorocarbons (CFCs), to remove the designation for certain products as "essential uses" under the Clean Air Act. Essential-use products are exempt from the ban by FDA on the use of CFCs and other ODS propellants in FDA-regulated products and from the ban by the Environmental Protection Agency (EPA) on the use of ODSs in pressurized dispensers. The products that will no longer constitute an essential use are: Sterile aerosol talc administered intrapleurally by thoracoscopy for human use and metered-dose atropine sulphate aerosol human drugs administered by oral inhalation. FDA is taking this action because alternative products that do not use ODSs are now available and because these products are no longer being marketed in versions that contain ODSs. This direct final rule is effective 23 February 2017. Submit either electronic or written comments on the direct final rule by 27 December 2016. If FDA receives no significant adverse comments within the specified comment period, the Agency will publish a document confirming the effective date of the final rule in the Federal Register within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the Agency will publish a document in the Federal Register withdrawing this direct final rule before its effective date.</p>	—

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MECHANICAL					
AIR CONDITIONERS	UNITED STATES OF AMERICA	09/11/2016	G/TBT/N/USA/552/Rev.1/Add.1	<p>Air conditioners, heat pumps - Addendum</p> <p><i>The U.S. Department of Energy (DOE) has completed a provisional analysis to translate the residential central air conditioner and heat pump energy conservation standard levels recommended by the CAC/HP ECS Working Group--expressed in terms of the test procedure at the time of the Working Group negotiations--into levels consistent with the DOE test procedure proposed in the August 2016 test procedure SNOPT. At this time, DOE is not proposing any energy conservation standard for residential central air conditioners and heat pumps. However, it is publishing these analysis results and the underlining assumptions and calculations that might ultimately support a proposed standard. DOE encourages stakeholders to provide any additional data or information that may improve the analysis.</i></p> <p><i>Any comments submitted must identify the NODA for central air conditioners and heat pumps, and provide docket number EERE-2014-BT-STD-0048 and/or regulatory information number (RIN) number 1904-AD37.</i></p>	14 November 2016.
SERVICES					
PRODUCT AND COMPANY CERTIFICATION. CONFORMITY ASSESSMENT	BRAZIL	11/11/2016	G/TBT/N/BRA/697	<p>All products, services and processes that are subject to a conformity assessment procedure</p> <p><i>Draft regulation to improve for Object Registration by which Inmetro, authorizes, the use of the Conformity Identification Seal and the commercialization of the object, subject to the existence of attestation of Conformity by the use of a third party certification scheme , in order to provide a level of confidence to customers</i></p> <p><i>It revokes Inmetro Ordinance N° 491, 13 December 2010, within 6 months of the date of publication of this Ordinance.</i></p> <p><i>The regulations, in force without the Object Register informed, shall be Reviewed.</i></p>	Not applicable

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PRODUCT AND COMPANY CERTIFICATION. CONFORMITY ASSESSMENT	BRAZIL	11/11/2016	G/TBT/N/BRA/698	Parts & accessories for adp. machines & units <i>Conformity assessment procedures that must be regarding the Evaluation Program for the Computer Accessories and Peripherals Asset Compliance.</i>	25 November 2016
OTHERS					
PRESSURE VESSELS	THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU	07/11/2016	G/TBT/N/TPKM/254	Gas cylinders and the fuel the[...]torches and refillable lighters <i>Gas cylinders and the fuel thereof for portable gas stoves, blowtorches and refillable lighters are subject to mandatory inspection under the certification system of the Bureau of Standards, Metrology and Inspection (BSMI) . The BSMI intends to adopt the revised version of CNS 14530 "Gas cylinders for portable gas cooker" (announced on 8 April 2014) as the testing and inspection standard. The conformity assessment procedure for the gas cylinders and the fuel thereof for portable gas stoves, blowtorches and refillable lighters remains unchanged, i.e. Type Approved Batch Inspection (TABI) Scheme.</i>	60 days from notification
TYRES	UNITED STATES OF AMERICA	10/11/2016	G/TBT/N/USA/803/Add.1	Tires and rims - Addendum <i>This document amends Federal Motor Vehicle Safety Standard (FMVSS) No. 110 to make it clear that special trailer (ST) tires are permitted to be installed on new trailers with a gross vehicle weight rating (GVWR) of 4,536 kg (10,000 lbs.) or less. It also excludes these trailers from a requirement that a tire must be retained on its rim when subjected to a sudden loss of tire pressure and brought to a controlled stop from 97 km/h (60 mph) . The agency proposed these changes and, after a review of the comments received, has determined that these two revisions are appropriate and will not result in any degradation of motor vehicle safety. This final rule is effective on 9 November 2016.</i>	27 December 2016

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VEHICLE • ROAD VEHICLE SYSTEMS	UNITED STATES OF AMERICA	10/11/2016	G/TBT/N/USA/1188/Add.2	Speed limiting devices - Addendum <i>NHTSA and FMCSA have received requests to extend the comment period for their proposal that would require vehicles with a gross vehicle weight rating of more than 11,793.4 kilograms (26,000 pounds) to be equipped with a speed limiting device and that such device be maintained for the service life of the vehicle. In the proposal, NHTSA and FMCSA established a deadline for the submission of written comments of 7 November 2016. The Agencies have also received a letter opposing any extension of the comment period. To ensure that all interested parties have a sufficient amount of time to fully develop their comments, the Agencies are extending the deadline for the submission of written comments on the proposal, including comments on the Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis and Draft Environmental Assessment accompanying the proposal, by 30 days.</i>	7 December 2016
NAVIGATION AND CONTROL EQUIPMENT	EUROPEAN UNION	11/11/2016	G/TBT/N/EU/421	Marine equipment <i>The draft Implementing Regulation replaces the technical annex of Directive 96/98/EC on marine equipment, which has been repealed by Directive 2014/90/EU and adapts it to changes in the relevant international instruments.</i>	60 days from notification
CONDITIONS • TEST CONDITIONS AND PROCEDURES IN GENERAL	UNITED STATES OF AMERICA	11/11/2016	G/TBT/N/USA/1221	Manufactured housing <i>The U.S. Department of Energy (DOE) is publishing a proposed rule to establish test procedures for manufactured housing (MH) . This test procedure would support standards DOE is directed to establish by the Energy Independence and Security Act of 2007. DOE proposes to establish test procedures applicable to manufactured homes for determining compliance with the following metrics that were included in a 17 June 2016, notice of proposed rulemaking: The R-value of insulation; the U-factor of windows, skylights, and doors; the solar heat gain coefficient of fenestration; U-factor alternatives to R-value requirements; the air leakage rate of air distribution systems; and mechanical ventilation fan efficacy. DOE will accept comments regarding this proposed rule.</i>	9 December 2016