NOVEMBER 2017



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

Contacts	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	
Address:	notified technical regulations and conformity assessment procedures.	
3/F Trade and Industry Bldg.		
Sen. Gil Puyat Ave., Makati	Philippine exporters and relevant stakeholders are invited to review the proposed	
City	regulations. Comments that will be received by the BPS will be transmitted to the	
	governments concerned for their consideration.	
Telephone:		
+632 751 4700	IN THIS WEEK'S ISSUE	
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+632 751 4735	A total of 35 notifications on Chemicals, Construction Materials and Building, Food and Beverages, Health Care Technology, Road Vehicles in General etc.	
1032 731 4733	from Albania, the European Union, Israel, Republic of Korea, the United States	
Email:	of America and other countries are listed.	
bps@dti.gov.ph	of function and other countries are inseed.	
Website:	We would like to hear from you. For any questions, suggestions or requests for	
www.bps.dti.gov.ph	full text of notified regulations, please contact us at <u>bps@dti.gov.ph</u>	
	We are glad to be of service to you!	

List of WTO TBT NOTIFICATIONS (18 - 24 November 2017)

Product Sector	Country	Date	TBT Notification	Product Coverage / Title	Final Date for
		Notified	Symbol		Comments
		-	AGRICULT	URE	
ANIMAL FEEDING STUFFS	UNITED STATES	20/11/2017	<u>G/TBT/N/USA/1320</u>	Animal feed The Food and Drug Administration (FDA, we, the Agency) is amending food additive regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of formic acid and ammonium formate. This action is in response to a food additive petition filed by BASF Corp for Feed Grade Sodium Formate (FAP 2286), which also proposed to amend the animal food additive regulations for formic acid and ammonium formate to limit formic acid and formate salts from all added sources.	13 December 2017

Product Sector	Country	Date	TBT Notification	Product Coverage / Title	Final Date for
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		-	CHEMICA	LS	-
CHEMICALS FOR INDUSTRIAL AND DOMESTIC DISINFECTION PURPOSES	ARGENTINA	24/11/2017	<u>G/TBT/N/ARG/247/Add.1</u>	Disinfectant products - Addendum It is reported that by Resolution No. 2158-E / 2017 of the Ministry of Health the importation, marketing and use of the mala- thion product (CAS No. 121.75.5), in any presentation, as therapeutic agent for the control of human diseases or for the control of vectors of importance for public health.	-
COSMETICS, TOILETRIES	EUROPEAN UNION	22/11/2017	<u>G/TBT/N/EU/527</u>	Cosmetics This draft Commission Regulation aims to restrict the maximum concentration of O-PHENYLPHENOL as a preservative in leave-on cosmetic products from the currently authorised concentration of 0.2% to 0.15%.	60 days from notification
COSMETICS, TOILETRIES	JAMAICA	24/11/2017	<u>G/TBT/N/JAM/71</u>	Cosmetics This standard specifies the general requirements for water used in the preparation of cosmetics. It applies to all cosmetic products in which water is a basic raw material. Specifications for the design and maintenance of the system used in the production of the water are also included. Consideration has been given to the critical levels at which physical, chemical and bacteriological properties can affect the health of the consumer.	13 January 2018
ORGANIC CHEMICALS	SINGAPORE	24/11/2017	<u>G/TBT/N/SGP/37/Add.1</u>	Polychlorinated naphthalenes and trichlorfon - Addendum In July 2017, the National Environment Agency (NEA) of Singapore notified the WTO TBT Committee of its intention to control polychlorinated naphthalenes (PCN) and trichlorfon as Hazardous Substances (HS) under the Environmental Protection and Management Act (EPMA) and EPM (Hazardous Substances) Regulations, and to phase-out the production, import, export and use of PCN by May 2018. Following further consultation with industry, Singapore would like to notify WTO Members of the following 2 changes to the measure: • The measure will be extended to also control short-chain chlorinated paraffins (SCCP) as Hazardous Substances (HS) under the Environmental Protection and Management Act (EPMA) and EPM (Hazardous Substances) Regulations. The production, import, export and use of SCCP and products containing SCCP in Singapore will be phased out. Further details can be found in Annex A.	60 days from the date of notification

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				• The proposed date of adoption and entry into force of the measure for PCN and trichlorfon has both been extended by 1 month. The dates for the proposed adoption and entry into force of the measure for SCCP, PCN and trichlorfon are December 2017 and June 2018 respectively.	
			CONSTRUCTION MATERIA	ALS AND BUILDING	
GAS SUPPLY SYSTEMS	ALBANIA	24/11/2017	<u>G/TBT/N/ALB/84</u>	Gas industry This draft Decision of Council of Ministers defines the regulation of the gas pressure in the service lines for incoming pressures up to 5 bar.	60 days from notification
GAS SUPPLY SYSTEMS	ALBANIA	24/11/2017	<u>G/TBT/N/ALB/85</u>	Gas industry This draft Decision of Council of Ministers defines the regulation of the gas lines with steel pipes for operating pressure up to 16 bar - Construction.	60 days from notification
GAS SUPPLY SYSTEMS	ALBANIA	24/11/2017	<u>G/TBT/N/ALB/86</u>	Gas industry This draft Decision of Council of Ministers defines the regulation of the gas lines with polyethylene pipes for operating pressure up to 10 bar - Construction.	60 days from notification
STRUCTURES OF BUILDINGS	UKRAINE	22/11/2017	<u>G/TBT/N/UKR/117/Add.1</u>	Buildings and structures - Addendum The Government of Ukraine notified the Draft Law "On basic requirements for buildings and structures, as well as conditions of placing on the market of construction products, harmonized with the legislation of the European Union" on 6 January 2017. It has b e e n c h a n g e d on the updated version of the Draft Law "On basic requirements for buildings as well as conditions for placing construction products on the market" and is now available at:http:// w1.c1.rada.gov.ua/pls/zweb2/webproc4_1? pf3511=62622	60 days from the date of notification
		DOMESTIC	CAND COMMERCIAL EQUIPM	ENT, ENTERTAINMENT, SPORTS	
τογς	ECUADOR	24/11/2017	<u>G/TBT/N/ECU/108/Add.3</u>	Juguetes - Addendum The Republic of Ecuador informs that it notified on August 24 Addendum 2 corresponding to the Modification Project 1 of the Ecuadorian Regulation RTE INEN 089 (M1) "Security of the toys. "It is reported that an extension is made to receive comments, even which ends until December 22, 2017.	22 December 2017

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PLAYGROUNDS	ISRAEL	20/11/2017	<u>G/TBT/N/ISR/973</u>	Playground equipment and surfacing First amendment to the Mandatory Standard SI 1498 part 7, dealing with the installation, inspection, maintenance and operation of playground equipment and surfacing. This amendment changes the requirements of paragraph 6.2 dealing with the main annual inspection.	60 days from notification
PLAYGROUNDS	ISRAEL	20/11/2017	<u>G/TBT/N/ISR/975</u>	 Playground equipment Revision of the Mandatory Standard SI 1498 part 8, dealing with the safety requirements for playgrounds. The major differences between the old version and this new revised draft standard are as follow: Removes the accessibility requirement for playground larger than 150 m2, except for playgrounds in kinder-gardens and day-cares; Removes from Table 4 the column dealing with lifted components. 	60 days from notification
		E	ENVIRONMENT, HEALTH PRO	TECTION AND SAFETY	
OCCUPATIONAL SAFETY, INDUSTRIAL HYGIENE	UNITED STATES	20/11/2017	<u>G/TBT/N/USA/497/Add.6</u>	Respirators - Addendum The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces the withdrawal of its 2009 notice of proposed rulemaking (NPRM) . The 2009 NPRM proposed to establish total inward leakage requirements for half- mask, air -purifying particulate respirators approved by NIOSH.	_
	<u> </u>		FOOD AND BEV	/ERAGES	
FOOD PRODUCTS IN GENERAL	INDIA	22/11/2017	<u>G/TBT/N/IND/65</u>	Food products The Draft Food Safety and Standards (Advertisements and Claims) Regulations, 2017 deals with the specification and requirements for advertisements and claims made on food products.	60 days from notification
CEREALS, PULSES AND DERIVED PRODUCTS	ISRAEL	20/11/2017	<u>G/TBT/N/ISR/974</u>	Bread Revision of the partially Mandatory Standard SI 1241, dealing with bread. Both the old standard and this new revised standard will apply from publication in Israel Official Gazette for a period of 1 year. During this time product may be tested according to the old or the new revised standard.	60 days from notification

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COFFEE AND COFFEE SUBSTITUTES	ISRAEL	21/11/2017	<u>G/TBT/N/ISR/977</u>	 Roasted coffee Revision of the Mandatory Standard SI 1103, dealing with roasted coffee. The major differences between the old version and this new revised draft standard are as follow: Amends the test methods according to relevant international standards; Deletes the paragraph dealing with compliance; Requires compliance with Israel regulations relating to food contaminants (heavy metals, pesticide residues and mycotoxins); Deletes Annex A dealing with documentation system. Both the old standard and this new revised standard will apply from publication in Israel Official Gazette for a period of 12 months. During this time products may be tested according to the old or the new revised standard. 	60 days from notification
ANIMAL AND VEG- ETABLE FATS AND OILS	SLOVENIA	24/11/2017	<u>G/TBT/N/SVN/101</u>	Trans fatty acids The proposal of regulation is based on studies showing that significant consumption of trans fats can have negative consequences on the health of children and adults. From analyses of foods made on the Slovenian market, it is evident that just over one third of foods sold in shops, bakeries, delicacies, pastry shops and restaurants, and represent an important part of the diet of Slovenes, contain an increased content of trans fatty acids, up to 9%. The availability of foods with a high content of trans fatty acids is, according to the results of studies in the Slovenian market, increasing. Preliminary estimates of trans fat transfusions in Slovenia indicate that tolerated trans fatty acid tolerance can be repeatedly exceeded in food groups of population groups which, due to certain nutritional patterns or socioeconomic situation, affect foods with a high content of trans fatty acids. In the concern for consumer health, we consider it necessary to adopt a regulation in Slovenia that will limit the maximum permitted levels of trans fatty acids in foodstuffs to an acceptable level.	22 January 2018
FRUITS, VEG- ETABLES	UNITED STATES	20/11/2017	<u>G/TBT/N/USA/1318</u>	Oranges This rule implements a recommendation from the Citrus Administrative Committee (Committee) to relax the minimum size requirements currently prescribed under the marketing Order for oranges, grapefruit, tangerines, and pummelos grown in Florida (Order) . The Committee locally administers the order and is comprised of growers and handlers operating within the production area and one public member.	16 January 2018

Product Sector	Country	Date	TBT Notification	Product Coverage / Title	Final Date for
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				This rule relaxes the minimum size requirements for oranges from 2\8/16\ inches to 2\4/16\ inches in diameter. This rule will maximize shipments by allowing more oranges to be shipped to the fresh market and help reduce the losses sustained by the citrus industry during the September 2017 hurricane in Florida. This rule also contains a formatting change to subpart references to bring the Order language into conformance with Office of Federal Register's guidelines.	
			HEALTH CARE TE	CHNOLOGY	
LABORATORY MEDICINE	BRAZIL	24/11/2017	<u>G/TBT/N/BRA/757</u>	Clinical trials	15 December 2017
				This Draft Resolution defines the procedures and regulatory requirements for the reporting of clinical trials with Products Advanced Research Therapies in Brazil, including the Clinical Development Dossier (DDCTA), to be submitted to Anvisa for consent purposes. This Resolution DOES NOT APPLY to: I - clinical trials with the drugs referred to in Resolution RDC No. 9 of February 2, 2015 and their updates; and II - to post-marketing clinical trials (phase IV) This Resolution is applicable to clinical trials for the purpose of proving safety and efficacy, with Products of Advanced Research Therapies that can be registered and that will have their clinical development in Brazil.	
TRANSFUSION, INFUSION AND INJECTION EQUIPMENT	BRAZIL	24/11/2017	<u>G/TBT/N/BRA/758</u>	Blood This Resolution establishes the minimum requirements for the registration of Hyperimmune Serum in order to guarantee the quality, safety and efficacy of these products. It applies to Hyperimmune Serum submitted for analysis for registration purposes. Due to the biological origin of its Active Principles and the diversity of the technological processes used to obtain these products, all requests for the registration of Hyperimmune Serum will be analyzed according to the requirements established in this Resolution. Only Hyperimmune Serum registered at the Brazilian Health Regulatory Agency - Anvisa, manufactured or imported by establishments authorized by the Federal Government and licensed at a state level, may be marketed and distributed in Brazil. The Hyperimmune Serum manufactured in other countries may only be Authorized (registered) by Anvisa if the product is registered and liberated for use in its country	Not applicable

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				Hyperimmune Serum not registered in their country of manufacture, but registered in another country due to epidemiological necessity, may be registered with Anvisa, after evaluation of the documentation presented, provided that the epidemiological impact of its use in Brazil is proven. Only those Hyperimmune Serum with their validated manufacturing process will be registered and have at least one method of inactivation and / or viral removal validated in their manufacturing process will be registered. For products manufactured in other countries, the latest periodic pharmacovigilance report shall be submitted, if available. Failure to submit any data requested in this Resolution relating to quality, safety and efficacy of the product to be registered shall be technically and scientifically justified.	
STERILIZING EQUIPMENT	ISRAEL	22/11/2017	<u>G/TBT/N/ISR/623/Add.1</u>	Large steam sterilizers - Addendum The revision process of the Mandatory	-
				Standard SI 1338 notified in G/TBT/N/ISR/623 (dated 1 August 2012) has been stopped and a new draft revision should be announced soon.	
STERILIZING EQUIPMENT	ISRAEL	22/11/2017	<u>G/TBT/N/ISR/979</u>	Large steam sterilizers Revision of the Mandatory Standard SI 1148, dealing with large steam sterilizers. This draft standard revision adopts 2 different International Standards with a few changes that appear in the standard's Hebrew section. This new draft standard revision allows to choose between 2 different routes of compliance: • Compliance with the European Standard EN 285: December 2015 with a few changes that appear in the standard's Hebrew section; • Compliance with the American Standard ANSI/AAMI ST8: 2013 with a few changes that appear in the standard's Hebrew section. It is not allowed to combine between the different routes and one should stick to the chosen route in order to achieve compliance with this standard. This new draft revision is significantly different than the old standard.	60 days from notification
MEDICAL EQUIPMENT	REPUBLIC OF KOREA	23/11/2017	<u>G/TBT/N/KOR/739</u>	Medical devices "Regulation on Approval, Notification and Review of the Medical Devices" is to be amend- ed to include the following changes: 1. Clarify definition of single-use medical device 2. Expand the scope of medical devices prohibited from authorization, certificate, and declaration. (to include powdered medical gloves)	60 days from notification

Product Sector	Country	Date	TBT Notification	Product Coverage / Title	Final Date for
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				 Amend the scope of minor changes: delete amendment to the declared product and 2) change to the address of manufacturer (consignee) Expand the scope of medical devices subject to issuance of certificate for confirmation of medical devices. 	
	-	·	MANUFACTURING	ENGINEERING	
MANUFACTURING ENGINEERING	UNITED ARAB EMIRATES	20/11/2017	<u>G/TBT/N/ARE/395</u>	 Product safety UAE Federal Law for product safety and its executive regulation, the provisions of this law shall apply to all products are being traded in the local market, including free zones and the like. The following products are excluded from the provisions of the law: Medicines and veterinary, vaccines, Serums, and the like. Goods to be classified as antiques. Used products that need to be repaired, rehabilitated or modified during the period prior to their placement in the market 	60 days from notification
WELDING CONSUMABLES	ISRAEL	22/11/2017	<u>G/TBT/N/ISR/416/Add.1</u>	Electrodes for welding - Addendum The revision process of the Mandatory Standard SI 1338, notified in G/TBT/N/ISR/416 (dated 11 June 2010) has been stopped and a new draft revision should be announced soon.	_
WELDING CONSUMABLES	ISRAEL	22/11/2017	<u>G/TBT/N/ISR/978</u>	 Electrodes for arc welding Revision of the Mandatory Standard SI 1338, dealing with covered electrodes and low-alloy steel electrodes for arc welding. This draft standard revision adopts 4 different International Standards with a few changes that appear in the standard's Hebrew section. This new draft standard revision allows to choose between 2 different routes of compliance: Compliance with one of 3 different International Standards: ISO 2560 - Third edition: 2009-10-15, ISO 3580 - Third edition: 2010-03-15 or ISO 18275 - Second edition: 2011 -05-01 with a few changes that appear in the standard's Hebrew section; Compliance with the American Welding Association Standard AWS A5.5/A5.5M: 2014 with a few changes that appear in the standard's Hebrew section. It is not allowed to combine between the different routes and one should stick to the chosen route in order to achieve compliance with this standard. This new draft revision is significantly different than the old standard. 	60 days from notification

RODS

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Notified

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Symbol

METALLURGY STEEL BARS AND CHILE 21/11/2017 G/TBT/N/CHL/423 Smooth steel bars 60 days from the notification The purpose of this regulation is to modify of the Supreme Decree N ° 1229, of 1940, of the Ministry of Public Works, thus seeking to prevent possible non-compliances with the requirements established for the reinforcing bars of reinforced concrete, imported and marketed in our country and, additionally, instruct a procedure different from the one currently established, improving the regulation of reinforcement bars for imported reinforced concrete sold in Chile. PETROLEUM AND RELATED TECHNOLOGIES PETROLEUM ALBANIA 24/11/2017 G/TBT/N/ALB/87 Gas industry 60 days from PRODUCTS AND notification NATURAL GAS This draft Decision of Council of Ministers HANDLING defines the cathodic protection against EQUIPMENT corrosion in protective tubes in traffic junction areas, steel pipes of the product under the dynamics procedure. PETROLEUM ALBANIA 24/11/2017 G/TBT/N/ALB/88 Gas industry 60 days from PRODUCTS AND notification This draft Decision of Council of Ministers NATURAL GAS HANDLING defines the documentation of pipeline EQUIPMENT networks of transmission-distribution companies. PRECISION MECHANICS, JEWELLERY JEWELLERY ISRAEL 21/11/2017 G/TBT/N/ISR/976 Children's jewelery 60 days from notification The requirements of the existing standard, SI 6558 part 1, shall be declared mandatory. This standard deals with the safety requirements and health aspects of jewelery intended to be worn by children up to 12 years old. It adopts the requirements and the test methods detailed in the American Standard ASTM F2923 - 14, with a few changes that appears in the standard's Hebrew section. This declaration is in line with the mandatory standardization objective to protect human health and safety. ROAD VEHICLES ENGINEERING ROAD VEHICLES ARGENTINA 24/11/2017 G/TBT/N/ARG/193/Add.5 Automotive vehicles - Addendum IN GENERAL It is reported that by Resolution No. 797-E / 2017 of the Ministry of Environment and Development Sustainable is established that the manufacturers or importers of light automotive vehicles belonging to categories M1 and N1 must declare or present to the Technical Unit Operative of Vehicle Emissions, the Certificates of Approval of Gaseous

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Emissions current or new, respectively, corresponding to the different models

marketed in the country.

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				The certification refers to the values of CO2 emissions and fuel consumption, according to the procedure specified by IRAM-AITA 10274, regulation ECE R.101 or Directive European 715/2007 and later, as appropriate in each case.	
COMMERCIAL VEHICLES	KAZAKHSTAN	21/11/2017	<u>G/TBT/N/KAZ/19</u>	Wheeled vehicles	20 January 2018
				Clarification of the procedures related to introduction of changes into the construction of a wheeled vehicle in operation.	
ROAD VEHICLE SYSTEMS	REPUBLIC OF KOREA	21/11/2017	<u>G/TBT/N/KOR/738</u>	Motor vehicles The following amendments will be made:	60 days from notification
				Expansion of installation target on LDWS and AEBS (Article 14-2 and Article 15-3): Expanding installation target to all passenger vehicles with 11 or more people and all commercial vehicles above 3.5 ton in gross vehicle weight (GVW) on Lane Departure Warning System (LDWS) and Advanced Emergency Braking System (AEBS), which are the advanced safety devices for motor vehicles. Harmonization of the Korean Safety and Performance Regulations with UN Regulations (Article 38, Article 38-3, Article 39-2, Article 40-3, Article 47~49, Article 53-2, Article 53-3, Article 75-80, Article 82, Table 5-17~5-23, Table 5-32~5-36, Table 6-3~6-18, Table 6-21~6- 28, Table 6-30~6-32, Table 16): Improving safety standards on the vehicle lighting and light signalling system (UN Regulation No. 4, 6, 7, 19, 23, 37, 38, 48, 53, 73, 77, 87, 91, 98, 99, 112, 119, 123, and 128) and the seat belt (UN Regulation No. 16). Expansion of installation target on the backward safety device for pedestrians (Article 53-2): Expanding installation target from heavy-duty commercial vehicles etc. to all vehicles on the backward safety device for pedestrians in order to avoid pedestrian accidents. Introduction of the regulation on AVAS for quiet road transport vehicles (Article 1 Paragraph 64, Article 53-3, Table 6-33): Introducing a new regulation on Acoustic Vehicle Alerting System (AVAS) for quiet road transport vehicles such as electric vehicles, hybrid electric vehicles, and fuel cell electric vehicles in order to avoid pedestrian	
CYCLES	REPUBLIC OF KOREA	24/11/2017	<u>G/TBT/N/KOR/740</u>	accidents. Bicycle	60 days from notification
	NUNLA			A draft revision for safety assurance criteria for electronic bicycle notice has been revised as follows. - Safety requirements (Maximum speed, Weight) for electronic bicycle are revised.	notification

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				- For consumer products subject to the safety assurance, manufacturers or importers are required to confirm safety by reporting to safety certification agency with attachment of test and inspection certificates from testing agency designated by models of the products before product release or clearance through the customs to identify whether they conform to the safety criteria.	
ROAD VEHICLES IN GENERAL	UNITED STATES	20/11/2017	<u>G/TBT/N/USA/1319</u>	Vehicle emissions The Environmental Protection Agency (EPA) is proposing to repeal the emission standards and other requirements for heavy-duty glider vehicles, glider engines, and glider kits based on a proposed interpretation of the Clean Air Act (CAA) under which glider vehicles would be found not to constitute "new motor vehicles" within the meaning of CAA section 216(3), glider engines would be found not to constitute "new motor vehicle engines" within the meaning of CAA section 216(3), and glider kits would not be treated as "incomplete" new motor vehicles. Under this proposed interpretation, EPA would lack authority to regulate glider vehicles, glider engines, and glider kits under CAA section 202(a)(1).	05 January 2018