FOURTH TBT QUARTERLY REPORT

2017

Contents

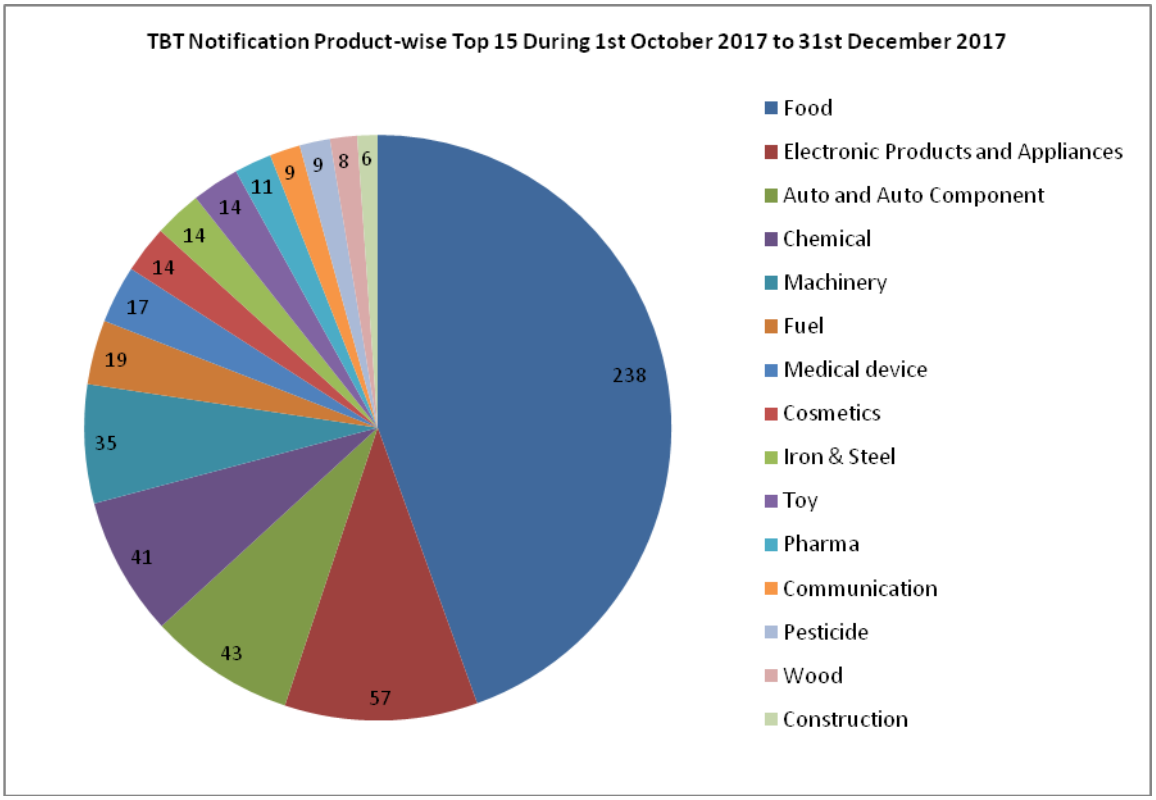
TBT QUARTERLY REPORT (1ST OF OCT '17 TO 31st DEC '17): AT A GLANCE

Details Pertaining to TBT Notifications Issued By All WTO Member Countries

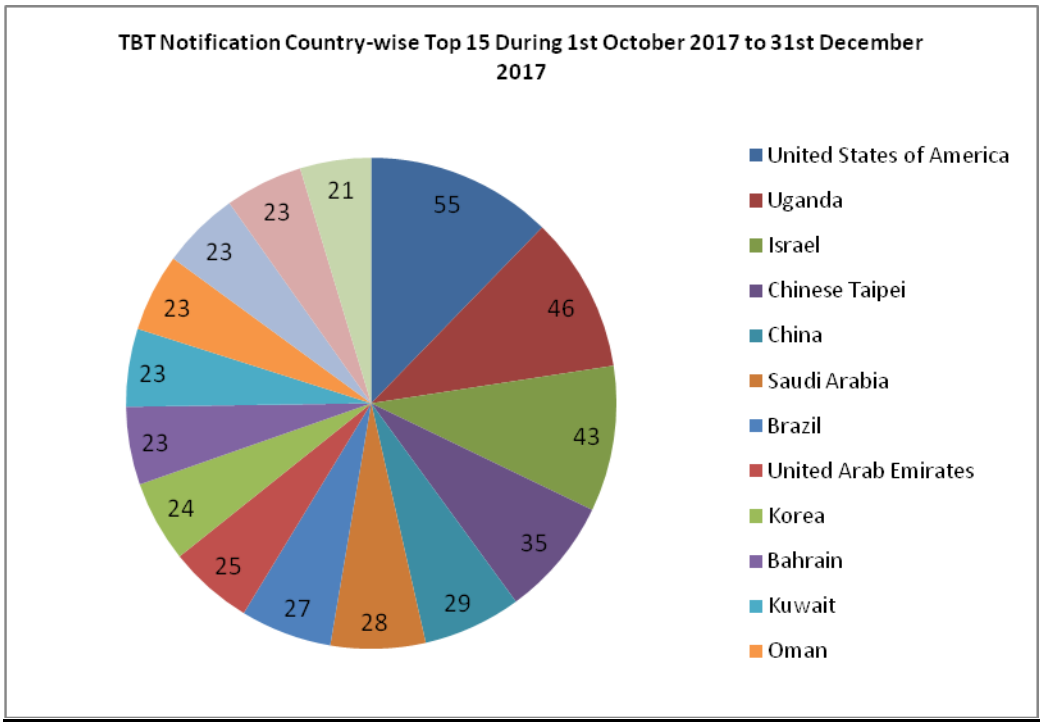
The total number of TBT notifications issued by the various WTO-member countries from 1st of October 2017 to 31st December 2017 was 641. Out of these 641 notifications, India issued 11 TBT notifications. Hence, a total of 630 notifications were studied in the quarter 1st of October 2017 to 31st December 2017 which was relevant to India. Out of 630 notifications, 160 notifications were the addendum of draft regulations notified earlier in the WTO.

Details Pertaining to TBT Notifications Relevant To India

Product-wise Information: Out of the total 630 TBT notifications which were relevant to India, 238 related to food products, 57 related to electronic products and appliances, 43 auto and auto component, 41 chemical, 35 machinery, 19 fuel, 17 related to medical device, 14 related to cosmetics, 14 related to iron & steel, 14 related to toys, 11 related to Pharmaceutical, 9 related to communication, 9 related to pesticide, 8 related to wood, 6 related to construction products and the remaining 95 related to other products.



Country-wise Information: Out of the total 630 TBT notifications relevant to India, United States of America issued 55 notifications, followed by Uganda, Israel, Chinese Taipei, China, Saudi Arabia, Brazil, United Arab Emirates, Korea, Bahrain, Kuwait, Oman, Qatar, Yemen, Mexico with 46, 43, 35, 29, 28, 27, 25, 24, 23, 23, 23, 23, 23 and 21 notifications, respectively. These countries are among the top 15 TBT notification issuing countries. The remaining 182 notifications were from other WTO Member countries.



Details Pertaining to Responses Sent

Notifications-May Impact Indian Industry: (Responses Sent)

Responses have been sent on 25 TBT notifications in the quarter October 2017 to December 2017. In these notifications stakeholders were of the view that, though some of the notifications were in line with International Standards, they may adversely impact Indian exports. Hence, APJ-SLG suggested that the Government of India may seek clarifications from the concerned enquiry point requesting them to provide justification for setting the proposed regulations. These notifications are mentioned below:

Sl. No.	Notification No:	Country	Product	India's Comment
1	G/TBT/N/TUR/104	Turkey	Maximum levels of contaminants in food products.	The Ministry of Food, Agriculture and Livestock has issued this notification proposing amendments to the Turkish Food Codex – Regulation on Food Contaminants. The proposed amendments concerns the maximum levels of nitrate, mycotoxins, metals, dioxins, 3-MCPD, PAH, melamine, and inherent plant toxins in various food products In reply, India stated that: • Section 5- titled as Dioxins and PCBs of the draft contains the maximum limit for dioxins, dioxins and sum of PCBs and total. • In this regard, India stated that the maximum limits for sum of dioxins has been prescribed for fish and fishery products at 3.5 pg/gm wet weight and eel meat at 3.5 pg/g wet weight. In addition, the maximum limits for benzo(a)pyrene on smoked fish and bivalve molluscs in Section 6.1 titled as Benzo(a)pyrene to be stricter than Indian limits. Further, the proposed maximum limits are stringent in

Sl. No.	Notification No:	Country	Product	India's Comment
				nature on comparison with the EU limits. India is of the view that such stringent levels of maximum limits for dioxins and benzo(a)pyrene may pose trade restriction on the trade of aquatic products of India and therefore, the Turkish authorities may take cognizance of India's response before adopting the proposed regulation.
2	G/TBT/N/BRA/737	Brazil	Powdered milk products	The Ministry of Agriculture, Livestock and Food Supply has issued this notification on Draft Ordinance No 93, 9 August 2017. The draft ordinance establishes a public consultation on a Draft MERCOSUR Resolution establishing Technical Regulation on identity and minimum quality requirements for powdered milk. It does not include milk intended for infant formulas and pharmaceutical products to be marketed in the territories of the MERCOSUR and in extrazone imports. In reply, India stated the following: • In Point 2.1 – Definition of Section 2- Description, India finds that the definition of milk powder includes only cow's milk. There are other sources of milk which includes buffaloes, goats, etc and in certain cases, there are mixed milks. In this context, India requested the MAPA authorities to explain the inclusion of only cow's milk as a source for milk powder and to consider the

Sl. No.	Notification No:	Country	Product	India's Comment
				inclusion of other milch animals as a source of milk for the production of milk powder. Further, India requested whether the requirements proposed are also applicable on 'cream powder'. • Further, in Point 4.2.2 – Physico-chemical characteristics, India finds that 'sugar' has been specified as a substance that shall be present in milk powder. In this context, India mentionedthat the term – sugar has the potential to mislead the exporters or manufacturers of milk powder. Hence, India suggested the MAPA authorities to consider replacing 'sugar' with the terms – "Lactose or Milk Sugar". In our view, such changes would provide a better clarity in terms of product characteristics. • India found that the proposed Brazilian levels differ from the compositional parameters set in the international standard – Codex Standard for Milk Powders and Cream Powder (Codex Stan 207-1999). In this context, India sought the attention to the levels prescribed in Codex standard. • In Point 5.1.1, India found that 'Lecithin' has been permitted for use as an emulsifier at the maximum level of 5 g/kg, whereas, the Codex standard has prescribed lecithin at GMP level. As you may be aware that lecithin can be naturally synthesized and generally recognised as safe substance. Hence, India requested the MAPA authorities to consider permitting the usage of lecithin at GMP levels. • In Point 5.1.2, India observed that only six types of food additives are listed to be used in the production of milk powders. In this regard, India mentioned that there may

Sl. No.	Notification No:	Country	Product	India's Comment
				be a technological requirement of 'stabilizers' particularly in the production of milk powder from milk obtained from other milch animals like buffalo.
3	G/TBT/N/JAM/65	Jamaica	milk products	The Bureau of Standards Jamaica has issued standards for liquid low-fat (half-skimmed or partly skimmed) cow's milk and liquid non-fat (skimmed) cow's milk liquid whole cow's milk. In reply, India stated that: India found that the proposed standards intends to establish the minimum requirements for liquid whole milk, liquid low-fat and liquid skimmed milk in terms of product composition, microbiological quality, packaging and labelling. In this regard, India submitted the following concerns. • India found that the proposed standards are applicable only on products of cow's milk. As you may know, there are animals other than cow as a source for milk including buffalo, sheep, goats, and other animals. In this context, India sought clarifications whether the above mentioned products that are produced from milk of animals other than cows would be permitted for

Sl. No.	Notification No:	Country	Product	India's Comment
				importation into Jamaica. However, if the products produced from milk of other milch animals are considered to be non-compliant to these proposed standards merely on the grounds of source of milk, then we would like to mention that these proposed standards may be considered as trade restrictive in nature. • Further, India sought clarifications whether the notifying agency intends to propose specific standards based on source - milch animals in near future. If not, we would like to request the Jamaican authorities to consider the inclusion of other milch animals as a source of milk so that it does not create a barrier on trade of these products. This would have a negative impact on the trade of liquid low-fat and liquid non-fat milk products from India which may be produced from milk of other milch animals.
4	G/TBT/N/JAM/64	Jamaica	recombined milk	The Bureau of Standards Jamaica has issued the standard prescribing the requirements and methods of test for recombined milk. In reply, India stated that: India observed that the Bureau of Standards Jamaica has issued the standard prescribing the requirements and methods of test for recombined milk. In this regard, India had submitted the following concerns. Section -3 concerns 'General Requirements' in which Point 3.3 stated the following: • "The whole milk, low-fat milk or skimmed milk used in the manufacturing of recombined milk, shall be as specified by the Jamaican Standard specifications for

Sl. No.	Notification No:	Country	Product	India's Comment
				liquid whole cow; milk, low-fat milk or skimmed milk." • India stated that only liquid whole milk sourced from cow has been considered as a source for recombined milk. In this context, India would like to request the Jamaican authorities to provide an explanation for listing only liquid whole milk from cow as a source for recombined milk. Further, India sought clarification on whether milk from milch animals other than cow that has been used to produce low-fat milk and skimmed milk can be source for recombined milk. Such details are requested to have clarity on the requirements for India's trade on recombined milk to Jamaica. In addition, India found that the inclusion of only cow's milk poses trade restrictions on the product-recombined milk produced from milk from other milch animals like buffalo. Hence, India requested the Jamaican authorities to consider the inclusion of milk products produced from milk obtained from milch animals other than cow for the production of recombined milk.
5	G/TBT/N/EU/508	EU	Pesticide active substance – Bifenthrin	The European Commission (EC) has proposed Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance bifenthrin. In reply, India stated that: • India read that the use of bifenthrin has been restricted for use and authorised for use only in greenhouses with a permanent structure. Such action has been taken in the context of possibility of bioaccumulation and biomagnification of this substance in the aquatic and terrestrial environment. However, India stated that the proposal laying down the conditions for use of bifenthrin

Sl. No.	Notification No:	Country	Product	India's Comment
				to be restrictive in nature. • India found that the EC has based its decision due to 'insufficient' information on bioaccumulation and biomagnification in the aquatic and terrestrial environment. This decision has resulted from the technical report submitted by the European Food Safety Authority (EFSA). In the report, the EFSA has stated that due to mitigation measures used during the study, the assessment of risk has indicated very low on aquatic organisms. • However, the explanation of the Rapporteur Member State in its assessment on the changes in the monitoring study which led to the conditions of the study. Given this context, we would like to seek your attention to the 'mitigation measures' implemented in the study which has limited the entry of bifenthrin into water bodies. In this regard, India is of the view that the inclusion of 'mitigation measures' as directions on use of this substance would address the concerns of risks due to the use of this substance on non-target organisms. Hence, India had sought whether the EU may consider looking at any additional 'mitigation measures' on the use of this substance rather than proposing restrictions on its use to greenhouses with permanent structure. India suggested the EC to consider directing the registrant of this substance to conduct further monitoring study and submit the required information within a time period.

Sl. No.	Notification No:	Country	Product	India's Comment
6	G/TBT/N/JAM/63	Jamaica	Milk Products	The Bureau of Standards Jamaica has issued standards forliquid low-fat (half-skimmed or partly skimmed) cow's milk and liquid non-fat (skimmed) cow's milk. In reply, India stated that: • Point 2.2 – "whole cow milk. Pasteurized, or raw unpasteurized milk, shall contain not less than 3.25% of milk fat, 8.25% of solid-not- fat and 11.5% of total milk solids. The prescribed percentages shall be obtained only by the addition or removal of cream or milk, or by the addition of pasteurized, or raw unpasteurized milk from which the fat has been wholly or partially removed, and to the exclusion of dried milk solids, butter oil, butterfat, non-milk solids and non-milk fat." • In this point, India mentioned that milk solids can also be obtained from cow's milk and can be added into whole cow milk for the purpose of meeting the required total solids level of the milk. Therefore, the milk solids including dried milk solids, butter oil, butter fat that are exclusively derived from the cow milk shall be allowed to be added in the definition of whole cow's milk. Hence, India suggested the following sentence for the Jamaican authorities consideration: *The prescribed percentages shall be obtained only by the addition or removal of cream or milk, or by the addition of pasteurized, or raw unpasteurized milk from which the fat has been wholly or partially removed, and to the exclusion of non-milk solids and non -milk fat'.* • Point 2.5 – "butterfat or milk fat. The fat of milk with a specific gravity of not less than 0.905 at a temperature of l5.5°C and a tocopherol content of not more than 50g."In this point, India found that the definition of

Sl. No.	Notification No:	Country	Product	India's Comment
				butterfat or milk fat mentions both the requirements of specific gravity and tocopherol. However, it does not contain other essential parameters like fat, moisture, etc. India requested the Jamaican authorities to include such parameters in the definition for the purpose of product characterization. • Further, in Point 2.14 – "sterilized milk", India observed that there is no mention of sterilization temperature. As sterilization temperature is crucial, India requested the Jamaican authorities to indicate an appropriate 'sterilization temperature'. • In Section 3 – General requirements, Table 3 – Average mineral/vitamins values for fortified low-fat and skimmed milk, India found that the value of Vitamin D is listed as 0.30 µg. However, in Section 4- Optional ingredients, Point 4.1.1 states that "Vitamin D, if added, shall be of food quality grade and shall be present in such quantity that each litre of the food contains not less than 5 µg (200 IU) and not more than 10 µg (400 IU)." On comparison, India observes differences in value of Vitamin D. Hence, India requested the Jamaican authorities to specify a uniform value for Vitamin D.
7	G/TBT/N/JAM/67	Jamaica	Physical and chemical test methods for hydraulic cements	These Jamaican standards describe the procedures for the chemical analysis, and physical test methods for hydraulic cement. In reply, India stated that: • Hydraulic cement is regulated as per standards prescribed by the Bureau of Indian Standards (BIS). It has issued standards related to physical and chemical test of cement for determination of soundness, consistency of standard, initial and final setting times,
8	G/TBT/N/JAM/68	Jamaica	Physical and chemical test methods for hydraulic cements	

Sl. No.	Notification No:	Country	Product	India's Comment
				strength, heat of hydration, density, drying shrinkage, air content, water retentivity, false set, etc. Hence, India requested the Jamaican authorities provide equivalence to standards prescribed by BIS and allow exports from India. In this regard, India sought for bilateral discussions with the Jamaican authorities
9	G/TBT/N/UGA/746,	Uganda	Textile Products	Ugandan have issued standards, specifications and basic requirements for warp-knitted fabrics, blazer fabrics, polyester and wool fabrics, polyester and viscose fabrics, polyester and cotton fabrics, shirting and blouse fabrics, fabrics containing textured yarns. In reply, India stated that: • The Section-6.1- Packing of DUS 1700-1: 2017 states that "Unless otherwise required, each piece shall be rolled, full-width and face inward, on an acceptable tube. Only pieces of the same type, width, design (when relevant), colour(s) and finish shall be packed together in a bulk container. In this context, India stated that allowing only pieces of same types of fabrics, particularly in case of bulk container may be trade restrictive. Hence, India requested the Ugandan authorities to provide the rationale for allowing only same types of fabrics in a bulk container. • The drafts also stated that, products that conform to Ugandan standards may be marked with Uganda National Bureau of Standards (UNBS) Certification Mark. This mark can be used only by those licensed under the certification mark scheme operated by UNBS and in conjunction with the relevant Uganda Standards. The presence of this mark on a product or in relation to a product is an assurance that the goods comply with the
10	G/TBT/N/UGA/747,	Uganda	Textile Products	
11	G/TBT/N/UGA/748,	Uganda	Textile Products	
12	G/TBT/N/UGA/749,	Uganda	Textile Products	
13	G/TBT/N/UGA/750,	Uganda	Textile Products	
14	G/TBT/N/UGA/751,	Uganda	Textile Products	
15	G/TBT/N/UGA/752,	Uganda	Textile Products	
16	G/TBT/N/UGA/753	Uganda	Textile Products	

Sl. No.	Notification No:	Country	Product	India's Comment
				requirements of that standard under a system of supervision, control and testing in accordance with the certification mark scheme of the Uganda National Bureau of Standards. UNBS marked products are continually checked by UNBS for conformity to that standard. In this context, India sought clarification that whether the Ugandan authorities will accredit any third party certification agencies in exporting countries like India, which will inspect and provide certification mark on behalf of UNBS. India is of view that such provision will certainly facilitate exports from India and reduce cost of exports into Uganda. India sought clarifications from the Ugandan authorities on the following: a) Whether exports confirming to relevant ISO norms will be treated equivalent to US ISO norms. b) Whether products have to be accompanied with a certificate showing their compliance with relevant ISO norms? c) Whether products already confirmed to ISO standards still have to be bear an UNBS mark? d) Whether products confirmed to ISO standard will get easy access for import into Uganda without an UNBS mark?

Sl. No.	Notification No:	Country	Product	India's Comment
17	G/TBT/N/JAM/66	Jamaica	Toys	Jamaica has proposed a standard, which applies to the safety aspects of toys and playthings intended specifically for children. No toy or plaything, when in normal use or when subjected to reasonably foreseeable damage or abuse, shall, because of its design or manufacture, present a risk of personal injury or illness In reply, India stated that: • Toys and playthings for children are regulated as per standards prescribed by the Bureau of Indian Standards (BIS). It has issued standards related to safety aspects related to mechanical and physical properties of toys along with flammability, migration limits and phthalates content in toys. Hence, India requested the Jamaican authorities provide equivalence to standards prescribed by BIS and allow exports from India. In this regard, India also sought for bilateral discussion with the Jamaican authorities.
18	G/TBT/N/UGA/754	Uganda	Glycerol for cosmetic use	This draft Uganda standard specifies general and specific requirements, sampling, packaging and labeling details and test methods for glycerine for cosmetic use. In reply, India stated that: As per this notification, this draft standard has referred the following Bureau of Indian Standard (BIS) standards: DUS 1832:2017 1. IS 1796 (1986): Glycerine – Specification 2. IS 12590 (1988): Glycerine for Cosmetic Industry In this regard, India stated that the above mentioned Indian standards are in line with standards issued by International Organization for Standardization (ISO). Hence, India sought a clarification from the UNBS authorities whether Uganda

Sl. No.	Notification No:	Country	Product	India's Comment
				will provide equivalence to Indian standards and allow products confirming to relevant BIS standards into Uganda.
19	G/TBT/N/CHN/1215	China	Medical devices	The CFDA has notified "Related Policies about Encouraging the Innovation of Drugs and Medical Devices and Accelerating the Review and Approval for the Launching of New Drugs and Medical Devices". In reply, India stated that: • As per this notification, priority review and approval for medicinal drugs and medical equipments would be given on the basis of China's national science and technology projects. In this context, India was of the view that setting priority for approval or review on the basis of the linkage of medical drugs or devices to the nation's science and technology policy may foster an inherent bias against new drugs or devices emerging from other countries. However, India sought clarification on whether CFDA would consider providing priority to the new drugs or devices from other countries if there is a linkage to China's national projects.

Sl. No.	Notification No:	Country	Product	India's Comment
				• In this regard, India was of the view that, in majority of the countries, priority to review or approval may be considered on the basis of prevalence of diseases or any other specified criteria including situations concerning public health. Hence, India requested the Chinese authorities to provide details of various criteria used by the authorities for priority review and approval of medicinal drugs and medical equipments in China. • The CFDA proposed to establish registration or submission of the details of raw materials of the medicinal drugs along with the packaging materials. In this regard, India sought clarifications whether it is applicable for existing drugs, drugs of new registrations for market authorization or both.
20	G/TBT/N/CHN/1216	China	Drugs and medical devices.	The CFDA has notified "Related Policies about Encouraging the Innovation of Drugs and Medical Devices and Reforming the Management of Clinical Trial". In reply India stated that: • The proposed policies are intended to foster and strengthen the establishment of clinical trial institutions in the country. India appreciated that the foreign enterprises or institutions may be allowed to conduct phase-I clinical trials in China. • India cited that such policies include provisions related to employee/personnel like job promotion, title, wages and related incentive mechanisms and other aspects of remuneration. In this regard, India sought clarifications whether such employee related matters would be applicable for institutions located in other countries. Such detail is requested as we find that the CFDA would undertake on-site inspections for granting an approval

Sl. No.	Notification No:	Country	Product	India's Comment
				for institutions conducting clinical trials. Further, India mentioned that such employee related matters with respect to income is beyond the parameters of WTO – TBT Agreement. Hence, • India also sought the rationale for including such parameters in the promotion of clinical trials. • India found that the policies intend to support clinical trials institutions if there is a relation to the national science and technology projects. In this regard, India sought clarifications whether such support would be extended to the multi-center drug trials with simultaneous foreign operations. • India found that clinical trial data from other countries may be accepted only if it meets the requirements laid out by laws and regulations of China followed by an on-site inspection. Given the international multi-center drug trials, on-site inspections may become a burden on such clinical trials and institutions involved. Hence, India sought whether CFDA would consider mutual recognition between countries on registry of clinical trial institutions. • In addition, India found that the applicant for a new drug or medical devices must provide clinical trial data without racial differences. In this regard, India asked the Chinese authorities whether each trial data must include ethnic profile of China. If so, whether the Chinese authorities intend providing details on the requirement of ethnicity based clinical trial data. India also mentioned that such ethnic data may hinder the registration of new drugs or devices in China whose data is generated at the multi-center drug trial situated across countries which may not necessarily include

Sl. No.	Notification No:	Country	Product	India's Comment
				China. Further, India was of the view that such requirement of clinical trial data without racial differences may be feasible for drugs that targets specific disease of a particular ethnic origin. However, this requirement may become a barrier for registration of drugs or devices that intends to address a disease with global presence. Hence, India requested the Chinese authorities to provide clarity on the requirement of clinical trial data without racial differences.
21	G/TBT/N/CHN/1217	China	medical drugs and devices	CFDA issued this notification on "Related Policies about Encouraging the Innovation of Drugs and Medical Devices and Implementing the Whole Life Cycle Management of Drugs and Medical Devices". In reply, India stated that: • The notified document stated that, in case of any adverse reaction found in medical devices, it must be reported by the license holder of the device to the regulatory authorities. However, if the license holder does not file any report on such incidents but it is reported by medical institutions or patients, the license holder would be held liable for concealing such adverse reports. • In this regard, India mentioned that, in many times, reporting by license holder concerning a medical device depends on reports from medical institutions or patients. Until the license holder receives a complaint or report from medical institutions or patients, the license holder may not be in a position to make the report with the regulatory authorities. In such situations, India requested the Chinese authorities to clarify whether the license holder would be held responsible for failing to

Sl. No.	Notification No:	Country	Product	India's Comment
				report any such adverse events. Further, India also sought clarification whether the Chinese authorities would establish a timeframe for reporting such adverse events.
22	G/TBT/N/EU/521	EU	Hazardous substances	The European Commission (EC) has issued this draft regulation concerning classification, labelling and packaging of substances and mixtures. This proposal intends to update the categorisation of chemical substances in relation to advancements made in scientific and technical arena of chemicals. EC has introduced revision to the harmonised classification and labelling of 34 substances. In reply India stated that: India sought the response on two chemical substances – isoproturon and propiconazole. • In case of isoproturon, India found that the substance is additionally classified as 'specific target organ toxicity – repeated exposure (STOT RE 2)' and in propiconazole, the substance is also • classified as 'Reproductive toxicity (Repr 1B)'. In practice, India has observed the EU to base its decision on scientific risk assessments. India observed that there has been no mention of results of scientific risk assessment for the two above mentioned substances indicating their toxicity vis-à- vis exposure assessment. In this regard, India was of the view that any addition of

Sl. No.	Notification No:	Country	Product	India's Comment
				classification of harmfulness for any substances must be based on scientific risk assessment of technical data establishing such harm beyond reasonable doubt. Hence, India requested the EU authorities to provide an explanation for proposing additional hazard classification for these substances. • Further, it was observed that there is no detail on assessment of socio-economic impact of such additional hazard classification for these substances. India was of the view that such assessment is crucial as it has a linkage to other EU regulations. In turn, it may pose challenges to the trade on other products from India to the European Union market. • India sought a "Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation – Evaluation Report" 3. This report points out the regulatory incoherence between CLP legislation with others like Cosmetic product regulation, plant protection product regulation, and biocides regulation. Further, the report also mentioned the need to consider other factors beyond scientific criteria in evaluating and classifying a substance so that it facilitates innovation and economic feasibility. Thus, India stressed on the need to consider factors like trade, technological feasibility and other factors in classifying the substances – propiconazole and isoproturon. Hence, India requested the EU authorities to consider the proposed amendments concerning these substances.

Sl. No.	Notification No:	Country	Product	India's Comment
23	G/TBT/N/BRA/757	Brazil	Advanced research therapy (pharmaceuticals)	The Brazilian Health Regulatory Agency (ANVISA) has proposed this resolution in order to establish procedures and regulatory requirements concerning clinical trials of Products of Advanced Research Therapies in Brazil. The proposed resolution is to ensure the safety and efficacy of the products of Advanced Research Therapies. In reply, India stated that: The proposed resolution is applicable on products falling under HS Code – 98041000. HS Code has been reserved for special uses by the contracting parties Hence, India requested the Brazilian authorities to provide a description of this HS Code. Such information is requested to understand the scope of this proposed resolution. In addition, in Chapter – VII on "Import", the resolution states that the listed documents on products that may be used in clinical trials must be submitted to ANVISA prior to its arrival at the Brazilian territory. However, India found no details on the time that may be required by ANVISA to conduct inspection and provide results accordingly. Since, these products are critical in nature, India was of the view that providing a timeline may be beneficial to the parties involved or conducting a clinical trial. Hence, India requested the ANVISA authorities to fix a timeline for inspection and clearance of import products.

Sl. No.	Notification No:	Country	Product	India's Comment
24	G/TBT/N/DOM/224	Dominican Republic	Food products	The Ministry of Public Health authorities of Dominican Republic issued "Food Health Regulations". In reply, India stated that: • The regulation mandates the requirement of a 'certification of free sale' indicating the permit of free sale in the country of origin for health registration of imported food products which is duly signed by the Dominican Consular or apostille in the country of origin. In this context, India mentioned that the food products are certified for its quality and safety depending upon the requirements for domestic consumption or importing country. • In some cases, the food products may not be permitted for marketing or distribution in the country of origin. However, it may be allowed for manufacturing only for exportation of such food products. Hence, India was of the view that the food business operators may face difficulties to comply with the requirement of submission of a 'certification of free sale' in the originating country. • Further, the requirement of legalisation from Dominican Consular or apostille for submission of this certificate to the competent authorities of Dominican Republic seems to be cumbersome for adherence for any food business operators. As a result, such requirements may pose restrictions to trade of food products. However, India stated that a 'certificate of free sale' is mandated to ensure the safety and quality of food products entering Dominican territory. In this regard, India suggested the Dominican authorities to consider the
25	G/TBT/N/DOM/224/Add.1	Dominican Republic	Food products	

Sl. No.	Notification No:	Country	Product	India's Comment
				requirement of a certificate from the competent authorities of the originating country indicating the quality and safety of the food products in accordance to the requirements of Dominican Republic. Thus, the imported food products may be exempted from the requirement of certificate of free sale in the origin country.

Note: