CHAPTER 11

STANDARDS AND CONFORMITY ASSESSMENT SYSTEMS

A. OVERVIEW OF RULES

1. BACKGROUND OF RULES

1) STANDARDS AND CONFORMITY ASSESSMENT SYSTEM

Quality related to products "Standards" and assessment of whether products meet the criteria ("Assessment") (hereinafter referred to "Standards and Conformity Assessment System") are domestic measures implemented by each country with various policy objectives such as health protection, consumer protection, environmental protection, quality requirements, information services and so on. Originally, such measures were intended for legitimate policy objectives and were not intended for the purpose of trade restrictions. However, standards and conformity assessment systems may have the effect of trade restrictions when conformity assessment is discriminatory, or when excessive regulations are imposed on imported products even when the same standards are applied to the imported goods and domestic products.

Conventional trade restrictive measures at the border, such as high tariffs or an import licensing system etc. have been reduced gradually by establishing rules through GATT/WTO negotiations. On the other hand, as corrections of trade restrictive measures at the border are made, with the increase in cross-border trade and economic transactions, trade-restrictive aspects of domestic measures like Standards and the Conformity Assessment System have become apparent and is attracting attention as systems for establishing Non-tariff Barriers (NTB)[1] [2].

2) HISTORICAL BACKGROUND

Traditionally, domestic measures including Standards and Conformity Assessment Systems were considered to fall under the authority of each country. In fact, the main objective of the GATT/WTO negotiations at first was the formation of rules for border measures, and GATT was not active in rule-making for domestic regulations. In practice, there are cases where a reasonable difference is observed in product regulations of each country due to differences in climate and geography. Therefore, unification internationally of certain aspects to the Standards and Conformity Assessment Systems is not necessarily fair and rational. On the other hand, where each country

[1] The WTO Annual Report FY2005 (World Trade Report) titled, "Trade, standards and the WTO", sheds light on the tension between trade barriers and legitimate policy objectives. In addition, in the FY2012 world trade report titled, "Trade and public policies: A closer look at non-tariff measures in the 21st century", mainly summarised the TBT Agreement and SPS Agreement along with the recent adjustments to NTB and the trends of international cooperation in the NTB field.

[2] The scope of NTBs is very wide, including domestic taxes, domestic regulatory measures, anti-dumping, countervailing duties, country of origin regulations, quantitative restrictions, subsidies and so on (WTO Annual Report FY2012).

creates arbitrary technical standards and where there is no harmonization mechanism for the regulations, unnecessary obstacles may be created for companies to conduct cross-border trade transactions due to disparity in standards of each country, and economic welfare may decrease as a whole. Moreover, some standards and conformity assessment system are established for the purpose of protecting the domestic industry. Additionally, due to non-transparency in the process of standard-setting by countries, there are cases where changes are made in the established standards which incur high costs for the industries. International rules relating to Standards and Conformity Assessment Systems have been developed based on the coordination of such trade liberalization benefits and domestic regulations that establish standards and conformity assessment systems.

The initial efforts were made with the aim of developing international standards with international non-governmental organizations and for the adoption of those standards by as many countries as possible. Efforts in the formation of Standards and Conformity Assessment Systems were carried out through various international authorities such as ISO: International Organization for Standardization, IEC: International Electro-technical Commission, ITU: International Telecommunication Union, and Joint FAO / WHO: Food Standards Programme Codex Alimentarius Commission.

One of the international rules that was established under the GATT / WTO regime is the "Agreement on Technical Barriers to Trade (GATT Standards Code)" agreed as a result of the Tokyo round in 1979. The GATT Standards Code was joined by interested member countries. To avoid the creation of unnecessary obstacles in trade by Standards and Conformity Assessment Systems established by countries, the GATT Standards Code provided provisions for ensuring prohibition of discriminatory technical regulation for domestic and international products, and ensured transparency of the procedures during establishment of standards and technical regulations and amendments to them. In the agreement, only domestic measures regulating product specifications (specs) such as the quality and performance were covered and domestic measures for process of production such as Processes and Production Methods (hereinafter "PPM") were excluded. Although a limited number of countries joined the GATT Standards Code, there was great significance in reaching an agreement for the first time on a rule to adjust domestic regulations of countries that establish Standards and Conformity Assessment Systems.

Later, in the Uruguay Round which ended in 1995, the GATT Standards Code became a part of the "Agreement on Technical Barriers to Trade" (hereinafter referred to as "TBT") agreed by all member countries. In the TBT Agreement, clarification and strengthening of obligations by member countries and domestic measures for PPM regulations were included. In addition, provisions to promote the international harmonization of Standards and Conformity Assessment Systems, such as the development of technical regulations on the basis of international standards (TBT Agreement Article 2.4) and active participation in international standardization activities (TBT Agreement Article 2.5) etc., were included.

In addition, specific disciplines concerning sanitary and phytosanitary measures were negotiated as a part of the Uruguay Round agricultural negotiations. In the final agreement, however, sanitary and phytosanitary measures were addressed in a separate agreement, the Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter referred to as the "SPS Agreement"). As a result of the Uruguay Round, the TBT Agreement and the SPS Agreement were annexed to the WTO Agreement and subject to the single undertaking requirement. This change has significantly expanded the range of countries covered under agreements in these areas and has strengthened international disciplines.

2. LEGAL FRAMEWORK

1) RELATIONSHIP BETWEEN GATT AND TBT AGREEMENT/SPS AGREEMENT

In order to understand the overall picture of regulations on Standards and Conformity Assessment Systems, first the major provisions related to Standards and Conformity Assessment Systems in the GATT need to be discussed. Members must not treat imported products less favorably in comparison to domestic products (Article III: 4 of the GATT) and there should be no discriminations against any country (Article I: 1 of the GATT) regarding the requirements and regulations affecting the imports from other WTO member countries. Furthermore, measures and laws affecting the sales, distribution, transportation, inspection, processing etc. of products should be published (Article X: 1 of the GATT). In addition, prohibition or restrictions of import/exports is permitted when necessary in order to apply standards related to the classification of products, sales etc. (Article XI: 2(b) of the GATT).

The scope of the TBT Agreement and the GATT overlap to a considerable extent.[3] For example, in Article III: 4 of the GATT related to "requirements and regulations affecting imports", the WTO has imposed an obligation on member countries regarding imported products from other WTO member countries to grant "treatment no less favorable than that accorded to like products" of domestic origin. However, some differences exist in the scope of application and content of regulations between GATT and the TBT Agreement. Measures subject to GATT Article III: 4 laws, regulations and requirements which influence imports -- all measures of the importing country excluding financial payment obligations of tariffs, import taxes, etc. (Articles III:1 and III:2 of GATT). Requirements with which compliance is voluntary are also included in the scope of GATT Article III: 4 (India–Autos (DS146, 175)). In contrast, measures subject to the TBT Agreement are limited to "technical regulations".

According to the Appellate Body precedent in the EC–Asbestos (DS135), "the TBT Agreement imposes obligations on Members that seem to be different from, and additional to, the obligations imposed on Members under the GATT", and it also indicated that GATT and the TBT Agreement are in the relationship of a general law and a special law. However, the Appellate Body in the recent US–Tuna II (DS381) case held that "the obligations under Article 2.1 of the TBT Agreement and Article III: 4 of the GATT are not substantially the same", and criticized the Panel for only making findings under Article 2.1 of the TBT Agreement and failing to do so under GATT Article III:4. In future WTO dispute settlement proceedings, there will be many situations where the GATT and TBT overlap.

2) TBT AGREEMENT

(1) Target products and the three pillars of TBT Agreement

The TBT Agreement, with its three pillars of technical regulations, standards, conformity assessment procedures, provides various mechanisms for the acceleration of international

[3] Products covered by Article III:4 of the GATT are all the products imported by WTO member countries, and the target measures among the laws, regulations and requirements which influence the imports, are all measures of the importing country excluding financial payment obligations of tariffs, import taxes etc., (Articles III:1, III:2 of the GATT). Prohibition of arbitrary requirements is also included in the scope of GATT Article III (India-Autos case (DS146, 175). As described later (in (2) (a)), although the scope of the TBT Agreement is wide, the target disciplines of Article III:4 of the GATT are even wider than the TBT Agreement.

harmonization of regulations and mutual acknowledgement and promotes trade liberalization so that Standards and Conformity Assessment Systems do not create unnecessary obstacles to international trade.

The TBT Agreement covers not only industrial products but also includes all agricultural products (Article 1.3 of the TBT Agreement). However, sanitary and phytosanitary measures in the SPS Agreement and procurement by government agencies for their own production and consumption covered by the Agreement on Government Procurement are exempt from the TBT Agreement. (For details on the Agreement on Government Procurement, refer to Article 1.4 and 1.5 of TBT Agreement and Chapter 14 of Part II).

"Technical regulations" refer to documents that lay down product characteristics or their related PPM, with which compliance is mandatory. "Standards" refers to documents in which compliance is not mandatory. In Japan, typical standards are the Japan Agricultural Standards (JAS) and the Japanese Industrial Standards (JIS). Unlike the GATT Standards Code, the TBT Agreement covers not only domestic measures relating to the quality, performance or the product specifications (specs) but also targets domestic measures related to PPM regulations (Paragraph 1 and 2, Annex 1 of the TBT Agreement). In addition, labelling regulations (origin labelling regulations) and packaging regulations are also included in the scope of technical regulations and standards (TBT Agreement preamble). Consequently, it can be said that pursuant to the TBT Agreement, technical regulations broadly cover product regulations. "Conformity assessment procedures" are a set of procedures to determine whether or not a product is in compliance with the applicable standards. They include product sampling, test/inspection, and procedures for assuring compliance, confirmation, warranty, procedures for registration/authorization etc. (paragraph 3, Annex 1 of the TBT Agreement).

Often contested in WTO dispute settlement procedures, the definitions of technical regulations have been clarified. Three requirements of technical regulations in the EC-Asbestos (DS135) and EC-sardines case (DS231) have been made clear. Namely, (1) the products subject to the regulation are identifiable; (2) the regulation sets the product specification; and (3) compliance with the regulations is mandatory. When determining the necessity of a "TBT notification", the three requirements of technical regulations should be considered (refer to (B) (iv)).

The case that set out the first and second requirements, *"the products subject to regulation are identified and the regulation sets the product specification"*, is EC-Asbestos (DS135). In this case, a major issue was whether or not measures taken by France prohibiting the manufacture, processing, sales and import of asbestos violated Article 2 of the TBT Agreement. The panel judged that the target products were not identified as the measures prohibited all products containing asbestos, and since it did not generally specify particular products, it did not satisfy the above two requirements. However, the Appellate Body overruled this decision, saying that there is no need for the measures to be specific about the target product by the name, etc., and that the measures identifying the target products as "all products (that may contain asbestos as a raw material)" and requiring the specification in a negative form that all products "shall not contain asbestos" was sufficient to satisfy the above two requirements.[4]

In addition, the Appellate Body IN the EU–Seal Products (DS400, 401) case reversed the Panel's decision that the measures prohibiting import/export and regional sale of seals and seal products satisfied the three requirements, and were therefore technical regulation. The Appellate Body

[4] According to the EC-Asbestos case, regulations that target all the products will also be handled as technical regulations. However, at least in practice to date, regulations covering all products are hardly ever discussed, as many of the target regulations of the TBT notifications and TBT Committee are specific to identified products to some extent.

determined that the measures did not regulate the product specifications because the requirements for the exceptions (requirements for allowing import/export and regional sale of seal products) were not aimed at regulating the product specifications but rather sought to prohibit or allow imports depending on the specifications of hunters, hunting methods, and objectives of hunts. Thus, it concluded that the measures were not technical regulations (whether or not the measures regulated PPM and therefore constituted technical regulations could be a separate issue, but the Appellate Body did not made determination, as the Panel did not sufficiently discuss this point).

The cases which set out the third requirement, "compliance with the regulations is made mandatory", are the United States-Tuna II case and the United States-COOL case (DS384, 386). In the United States-Tuna II case (DS381), a ban on the dolphin-safe labelling on landed tuna unless specific fishing methods were used was contested. In this case, distribution/sale of tuna products in the US market was prohibited even without the dolphin-safe labelling. The Panel cited the precedent of "measures to prohibit specific geographical indications" (Article 22 of the TRIPS Agreement) (EC-Geographical Indications (DS290)) and decided that compliance was made mandatory since "labelling is not possible unless tuna is caught using specific fishing methods". (One panelist had the opposing view that it was considered mandatory if the products could be sold in the market without labelling). The Appellate Body rejected the United States' argument that "compliance of labelling is not compulsory because marketing is possible without labelling in the United States", and said that the possibility of sales in the market had no relation with the requirement. On the other hand, the Panel on the United States-COOL case (DS384, 386) determined that the COOL measures were technical regulations. For the related measures (Letter of Secretary of Agriculture facilitating voluntary enforcement of additional regulations), the Panel stated that they needed to consider whether or not it was de facto mandatory, and concluded that the related measures were not technical regulations (the point did not become an issue before the Appellate Body because the United States repealed the Letter and the claims on the said Letter were withdrawn).

(2) Obligations of the Member

The TBT Agreement imposes various obligations upon WTO member countries. They can be classified into substantive discipline on details of technical regulations, standards, and conformity assessment procedures (hereinafter referred to as "technical regulations etc.") (Below (i) to (iii)) and procedural discipline on the process of establishing or changing technical regulations (below (iv)).

The main obligations of the member countries relating to technical regulations will be explained below. Since for standards and conformity assessment procedures the TBT Agreement includes disciplines parallel to those applying to technical regulations, they will not be dealt with in this document. Refer to Article 5 (conformity assessment procedures by central government agencies) and Annex 3 (code of good practice for the preparation, adoption and application of standards) of the TBT Agreement.

National treatment, Most-Favoured-Nation treatment (TBT Agreement Article 2.1)

Regarding technical regulations for goods imported from other WTO member countries, member countries have the obligation to grant no less favorable treatment for like products of (1) domestic products and (2) products imported from a third country (TBT Agreement Section 2.1). Seeking a level playing field (condition of competition) for domestic products and imported products (and imports from third party countries), this article sets out the national treatment principle (*see* GATT Part II, Chapter 2, Article 1) and the Most-favored-nation principle (GATT Part II, Chapter 1),

which are basic principles of the WTO Agreement.

In past dispute settlement procedures involving Article 2.1 of the TBT Agreement, Panels and the Appellate Body analyzed three issues: (1) whether the target measure was a technical regulation; (2) whether the imported products and domestic products (and imported products from third countries) are like products; and (3) whether imported products are treated less favorably compared to domestic products (and imported products from third countries).

With regard to the above-mentioned concepts of "like products" and "treatment no less favorable", to date Panels and the Appellate Body have made judgments in relation with Article I and Article III of the GATT. Two points should be noted with regard to "treatment no less favorable". The first point is that not only legal discrimination (when the laws and regulations are discriminatory with respect to nationality), but de facto discrimination (where due to differences in regulations for imported goods and domestic goods the conditions of competition faced by imported goods have changed) is also included in "treatment no less favorable". The second point is, unlike the precedent in the EC-Asbestos case (DS135), the United States-Tobacco case (DS406) held that instead of comparing the "overall imported products" and "domestic like products", the comparison of "products of the petitioning country" with the "domestic products of the same type" will suffice; it then found that the United States measures treated products of the petitioning country less favorably. Both of these judgments are attracting attention as they expand the concept of "treatment no less favorable". Hereafter, future cases will be observed carefully as they clarify the scope of the TBT Agreement discipline.

Finally, the balance of the benefits of trade liberalization and the interests of the authority of the technical regulations of the member countries in the interpretation of Article 2.1 of the TBT Agreement is also an important point. In the TBT Agreement, there is no provision on general exceptions corresponding to Article XX of the GATT. In the United States-Tobacco case (DS406), the Appellate Body held that even if changes to the conditions of competition to treat the imported products are less favorably than the domestic products, where there is a "legitimate regulatory distinction" such changes do not amount to discrimination against imports; thus, it does not violate Article 2.1 of the TBT Agreement because such changes do not constitute "treatment less favorable" under that Article. More specifically, the Appellate Body determined whether the design, architecture, structure, operation and application of a technical regulation indicated whether import products are treated in an even-handed manner. The above determination criteria were also used in the reports of the United States–Tuna II case (DS381) and the United States–COOL case (DS384, 386) that were issued after the determination.[5]

Necessity Rule (Article 2.2 of the TBT Agreement)

Article 2.2 of the TBT Agreement provides that WTO countries should not introduce technical regulations that are more trade-restrictive than necessary to achieve the objectives. Unlike the Article 2.1 of the TBT Agreement, this section applies in cases where imported products and domestic products are treated similarly and also in cases where domestic products do not exist. In addition, this Article includes a "necessity test" to determine whether any technical regulation fulfils a legitimate policy objective allowed by the TBT Agreement. Similar to Article 2.1 of the TBT (review of exemptions), it balances the functions of responsibility for the benefits of trade liberalization and the interests of the authority of technical regulations of the member countries.

[5] In the EU-Seal Products case (DS400, 401), the Panel adopted the determination criteria described in the text, but the Appellate Body did not determine that the measures were not technical regulations and thus did not discuss Article 2.1 of the TBT Agreement.

In dispute settlement proceedings to date involving the TBT Agreement, Panels and the Appellate Body analyzed two issues: (1) whether the technical regulations in question fulfill a legitimate objective and (2) whether the technical regulations in question are more trade restrictive than necessary to fulfil that legitimate objective (the United States-Tuna II case (DS381) and the United States-COOL case (DS384, 386)).

According to the TBT Agreement, there are five "legitimate objectives": "the necessity for national security"; "prevention of fraudulent usage"; "protection of human health and safety"; "protection of life and health of animals and plants"; and "environmental safety". However, this is only an illustrative list and technical regulations for other objectives are not excluded. (This is different than Article XX of the GATT, which lists 10 specific justified reasons). According to precedent, determination of the "legitimate objective" was made on the basis of the documents of the technical regulation or its legislative history, as well as other structures and operations etc. of the technical regulations (United States-Tuna II case (DS381)). In addition, it has been decided that a threshold does not exist for the "fulfillment" of the legitimate objective, (United States-COOL case (DS384, 386)).

An assessment of whether the technical regulation is "more trade-restrictive than necessary" involves "holistic weighing and balancing" of the following factors: (1) the degree of contribution of fulfilling the objectives, (2) the degree of trade restrictions, and (3) the risk incurred by non-fulfillment of the objectives. In normal cases, the above three points are addressed by comparing the technical regulation and reasonably available possible alternative measures. Even if any of these factors cannot be accurately quantified and can only be assessed in qualitative terms, the Panel should conduct weighing and balancing rather than ending its analysis with a conclusion that the burden of proof has not been fulfilled. The following three points are specifically considered: (1) whether less restrictive alternative measures exist that can achieve the same policy objectives of the challenged technical regulations; (2) whether such alternative measures fulfill the legitimate objectives of the technical regulations to the same extent; (3) the risk when the legitimate objectives are not fulfilled; and (4) whether the alternative measures can be reasonably implemented (United States-Tuna II (DS381) and United States-COOL (DS384, 386)).

To summarize the above necessity rule, it can be considered that technical regulations that fulfill urgent and important policy objectives do not violate Article 2.2 of the TBT Agreement even if their level of restriction is considerably high. On the other hand, a low level of restriction for less important policy objectives violates the Article 2.2 of the TBT Agreement. In the four precedents to date (United States-Tuna II (DS381), United States-COOL (DS384, 386), EC-Seal Products (DS400, 401), and United States-Tobacco (DS406)) in which a violation of Article 2.2 was alleged, the Appellate Body did not find that the technical regulation violated this Article. However, the Appellate Body in the EC-Seal Products case determined that the measures at issue were not technical regulations and did not make determination on the violation of the TBT Agreement, including this Article. We must await future cases to determine whether the hurdles for violation of this Article are high or low.

Formation of technical regulations with International standards as their basis (Article 2.4 of TBT Agreement)

When relevant international standards exist or establishment is imminent, the WTO member countries bear an obligation to establish such international standards as the basis for their technical regulations. However, if the international standards are neither effective nor applicable to fulfill the legitimate objectives of the technical standards, due to climatic or geographical factors or due to

basic technical problems, then there is no need to use them as the basis (Article 2.4 of the TBT Agreement).

In the United States-Tuna II case (DS381), the Panel and the Appellate Body determined the applicability of the Article using the following three steps: (1) whether a relevant international standard exists or establishment of such a standard was imminent; (2) whether the international standard is used "as a basis" for the challenged technical regulation; and (3) whether there are any reasons for exemption. There is no definition of "international standards" in the TBT Agreement, but the "six principles of international standards" adopted in the second revised triennial TBT Agreement ((d) see (1)) is an interpretative guideline to this Article (the United States-Tuna II case (DS381)). The six principles that international standards should satisfy are: (1) transparency, (2) openness, (3) impartiality and consensus, (4) effectiveness and relevance, (5) coherence, and (6) a development dimension. The TBT Agreement triennial review adopted the text by the consensus of all the WTO member countries.

It should be noted that even when international standards are established after the technical regulations are introduced, Article 2.4 of the TBT Agreement will be applicable according to the EC-Sardines case (DS231).

According to the precedent, the requirement regarding "whether the basis is international standards or not", the technical regulation is not required to be the same as the international standards; however, it should be closely related and should not contradict the international standard (EC-Sardines case (DS231)).

Regarding the burden of proof[6] related to the exemption, as with the precedent regarding Article 3.1 and Article 3.3 of the SPS Agreement (EC-Hormones case (DS26)), first, the claimant is obligated to prove that the relevant international standards are appropriate and effective (EC-Sardines case (DS231)).

Ensuring transparency during the establishment of technical regulations (Article 2.5 to 2.12 and Article 10 of the TBT Agreement)

When WTO member countries establish technical regulations, the TBT Agreement places an obligation to accept comments from other Members and to ensure transparency in establishment procedures.

First, when WTO members make amendments or establish technical regulations, implementing Member countries must notify the WTO Secretariat in advance with a draft of the technical regulations (Article 2.9 of the TBT Agreement). The implementing countries must submit TBT notifications when proposed technical regulations are not consistent with relevant international standards except when the subject product is not traded (Introductory clause, Article 2.9.2 of the TBT Agreement). "Revision and Establishment" not only includes the adoption of technical regulations but also the relaxation of technical regulations; however, they are not included in case of deregulations and TBT notifications are not necessary.

The number of notifications from 1995 to 2014 amounted to 23,401 (including 750 notifications by Japan). The number of notifications made in 2014 was 2,239 (of which 28 were made by Japan), the largest number since 1995 (*see* Figure II-11-1). The number of notifications made in 2015 is not

[6] The concept of burden of proof differs from that of the Japanese code of civil procedure. Under WTO law, the concept is to determine which party shall prove the legal claim (violation or defense) that it makes. Unlike the burden of proof under the Japanese code of civil procedure, it does not require that only a single party exercises the right to prove.

reflected in this report because errors have been found in the annual review accessible at the end of February 2015 (G/TBT/38) and the Secretariat is currently working to correct the relevant data.

A TBT notification format has been established to include the details of the technical regulations, objectives, covered products, enforcement schedule, related laws etc. (It was approved in the first TBT Agreement triennial review decision). Other WTO members can make comments to the country that made the TBT notification regarding the information provided therein, and the implementing country has the obligation to consider these comments (Article 2.9.4 of the TBT Agreement). Additionally, where there are no TBT notifications, Members can request explanations on the validity of the technical regulations from the implementing country (Article 2.5 of the TBT Agreement).

In order to consider and reflect the views and concerns of WTO members, the schedule for the enforcement process of technical regulations etc., is as follows. It is encouraged to provide 60 days for comments on TBT notification (second TBT Agreement triennial review decision). Of the 1,345 TBT notifications made in 2014, the number of notifications with a comment period of at least 60 days was 2,239 (60%) (G/TBT/36). Furthermore, a "sufficient period" must be provided between the end of the comment period and publication of the final measure in order to consider the opinions that have been submitted (fourth TBT Agreement triennial review decision).

In addition, WTO member countries have an obligation to set up an enquiry point to answer a wide range of questions from other WTO members and interested parties about their technical regulations (Articles 10.1 to 10.3 of the TBT agreement). The list of inquiry points in each country has been published on the WTO website.[7] In Japan, the Japan External Trade Organization (JETRO) and the Ministry of Foreign Affairs have been specified as the enquiry points. Furthermore, when requested by other WTO members, the developed WTO member countries have an obligation to provide a summary of the applicable laws under the TBT notification or notification in English, French and Spanish or, if the law is very long, (Article 10.5 of the TBT Agreement).

WTO member countries also have an obligation to ensure that all the technical regulations enforced, can be accessed by stakeholders (Article 2.11 of the TBT Agreement). The Government of Japan releases all enforced technical regulations through the Official Gazette or on its website.

Figure II-11-1 Number of TBT Notifications

	Japan	US	EU	China	India	Brazil	Russia	Total of All Member Countries
No. of Notifications in 2014	28	181	88	49	0	130	13	2,239
Total No. of Notifications since Accession to WTO	750	2,176	1,174	1,131	106	1,210	41	23,401

Source: GATT / WTO documents (G/TBT/36: Twentieth annual review of the implementation and operation of the TBT Agreement)

(3) TBT Committee (Article 13 of the TBT Agreement)

The TBT Committee is the body established by the WTO to deal with matters related to

[7] Refer to G/TBT/ENQ/38/Rev.1 for the list of latest inquiry points of the WTO members.

enforcement of the TBT Agreement and fulfillment of its objectives (TBT Agreement, Article 13). As for the mechanism of the WTO, see 4. "WTO Mechanism", General Remarks of Part II).

The TBT Committee creates guidelines related to the TBT Agreement, mainly on Specific Trade Concerns (STC), which are protectionist measures of member countries in the form of technical regulations (*see* TBT Triennial Review (d)), and, shares experiences of individual countries.

(4) The TBT Agreement Triennial Review (Article 15.4 of the TBT Agreement)

In accordance with Article 15.4 of the TBT Agreement, the TBT Committee reviews the implementation and management of the TBT Agreement every three years. The TBT Agreement Triennial Review has been conducted every three years since 1997. In December 2015, the 7th TBT Triennial Review Decision was adopted by consensus by the all WTO member countries.

In subsequent TBT Agreement Triennial Reviews, procedures for TBT notifications and the implementation procedures by the TBT Committee have been debated and the rules for implementation have been gradually defined. Notably, six principles for international standards adopted in the second TBT Agreement Triennial Review are considered to be a reference to Article 2.4 of the TBT Agreement regarding the procedures for dispute resolutions and hold significant influence (see (b) (iii)).

In the seventh TBT Agreement Triennial Review, countries including Japan sent written proposals (a total 12 countries), and extensive discussions were carried out in informal meetings of the TBT Committee held between June and November 2015. The topics discussed were: (1) good regulatory practices, (2) regulatory cooperation between members, (3) conformity assessment procedures, (4) standards, (5) transparency, (6) technical assistance, (7) special and differential treatment, and (8) operations of the committee. The four main points raised were as follows.

The first point is Good Regulatory Practice (GRP). GRP is a concept that includes various efforts for lowering trade barriers caused by standards and conformity assessment systems. (However, this term is not used in the TBT Agreement). As was recommended in the sixth review, the Committee agreed in the seventh review to continue to exchange information on mechanisms of GRP adopted by Members that facilitate the implementation of the TBT Agreement, and discuss issues including the extent to which Regulatory Impact Assessments (RIAs) could facilitate the implementation of the TBT Agreement, considering the constraints facing developing countries in carrying out RIAs.

The second point is regulatory cooperation between Members. So far, the exchange of information regarding initiatives of Members had taken place in the context of a thematic session. Switzerland and China suggested that Members exchange their experiences, with a focus on topical issues such as food labelling regulations and energy efficiency standards. Based on such discussion, with a view to enhancing the exchange of information regarding regulatory cooperation between Members, the Committee agreed to deepen and broaden its information exchange and discussion on new and emerging issues, based on topics identified by Members.

The third point is conformity assessment procedures. Members provided information on criteria and methods for choosing a means to conduct conformity assessment procedures, as well as the importance of quality infrastructure (e.g. testing, certification, accreditation and metrology) for facilitating trade and the examples of use of such quality infrastructure. As the first step toward promoting conformity assessment procedures, Japan proposed that Members accept foreign test results on condition that a certain level of reliability is ensured (while presenting the test results obtained through schemes such as IECEE CB for electric appliances and OECD GLP for chemicals as such reliable test results). Based on such discussion, the Committee agreed to continue to exchange information on initiatives of Members to enhance regulators' reliance on international

and/or regional systems for conformity assessment, and discuss approaches regarding the use of quality infrastructure for facilitating trade and factors that are necessary to promote the acceptance of tests and other conformity assessment results in other Members.

The fourth point is standards. As an approach to enhance transparency in standard-setting, Japan proposed that standardizing bodies publish their work programs on specific websites and notify the ISO/IEC Information Centre of the specific website address. Meanwhile, Australia and the United States reported that many standardizing bodies accepted the Code of Good Practice. Based on such discussion, the Committee agreed to recommend Japan's proposal regarding the approach to ensure transparency in standard-setting, and continue to exchange information on measures taken by Members to ensure the acceptance of the Code of Good Practice by local government and non-governmental standardizing bodies.

3) SPS AGREEMENT

The SPS Agreement seeks to prevent the application of sanitary and phytosanitary (SPS) measures as disguised trade restrictions and to harmonize national SPS measures based on international standards. The main points are as follows:

1. Members shall ensure that any SPS "measure is applied only to the extent necessary to protect human, animal, or plant life or health," based on scientific principles (Article 2.2).
2. Members shall ensure that SPS "measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail. . . .Sanitary and phytosanitary measures shall not be applied in a manner that would constitute a disguised restriction on international trade" (Article 2.3).
3. "Members shall base their sanitary or phytosanitary measures on international standards, guidelines, or recommendations, where they exist, except as otherwise provided for in the Agreement" (Article 3.1).
4. "Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is scientific justification" to do so (Article 3.3).
5. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment taking into account risk assessment techniques developed by the relevant international organizations. (Article 5.1).
6. Members shall conduct risk assessment taking into account available scientific evidence (Article 5.2).
7. Members shall avoid arbitrary or unjustifiable distinctions in the level of sanitary or phytosanitary protection that result in discrimination or disguised restrictions on international trade (Article 5.5).
8. Members shall ensure that such measures are not more trade-restrictive than required to achieve the appropriate level of sanitary or phytosanitary protection (principle of proportionality, Article 5.6).
9. "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members" (Precautionary principle, Article 5.7).

10. "Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures to ensure transparency." (Articles 7).

3. *Practical tips for taking advantage of the TBT Agreement*

1) Status of Utilization and Background of the TBT Agreement

As mentioned in this document, from the strategic point of view of individual industries, the TBT Agreement is an international rule that can affect product regulations of other countries; however, Japanese industries that use the TBT Agreement are limited (e.g. steel, chemical, cosmetics, information technology device, and industrial machine industries).[8] One of the reasons for this could be that the existence of the TBT Agreement or application procedures is not well-known in the industry.

Prior research and literature related to the TBT Agreement is mainly focused on the dispute settlement procedures or on previous cases and analysis from a logical point of view. Benefits can be realized only when the procedures for application of the TBT Agreement are explained or discussions of the TBT Committee are introduced from a more practical point of view, and the TBT Agreement is vigorously applied.[9]

This section aims to explain how the Japanese industry should act when faced with trade-restrictive measures of a foreign government, and explains how to apply the TBT Agreement in detail and how a collaborated effort with the government will make the TBT Agreement even more effective. The discussion in this section will be restricted to the TBT Agreement and the approach of the TBT Committee in response to the trade-restrictive measures, and does not intend to deny the industry seeking other means and channels. Rather, it is desirable to respond effectively by combining the demands and requests to the other country with requests and negotiations in bilateral talks in collaboration with the government.

2) Viewpoint for Finding Out Problems

When faced with trade-restrictive measures of a foreign government, first there is a need to examine whether or not the measure falls within the scope of the TBT Agreement. In such situations, besides examining the definition of technical regulations, the following aspects of the technical regulation should also be examined.

- Are Japanese products (one's own products) subjected to discrimination in comparison to domestic products or products of third countries without any reasonable explanation? (*See* Article 2.1 of the TBT Agreement. For details, *see* (2) (2) (b) (i))
- Are the regulations more excessive than necessary to attain legitimate policy objectives of the country imposing the measures? (*See* Article 2.1 of the TBT Agreement. For details, see (2) (2)(b) (ii))

[8] The industries that utilized the TBT Committee in November 2014 are listed.

[9] Japanese literature which introduced a detailed status of the discussions of the TBT Committee is p.47 - 51 of the September 2012 issue of Law Times "Multilateral review of trade concerns" by Takuya Izumi.

<Example Case> With the objective of improving automobile safety,

(1) technical standards for automotive parts are specified; (2) quarterly factory inspection by the local government is mandatory; and (3) disclosure of production know-how and business information that is irrelevant to safety is made obligatory. Regarding (1), it is necessary to examine the details of the technical standards to ensure they are rational. Regarding (2) the frequency of factory inspection is too high, and should be reduced to once in three years for instance. Regarding (3), the regulations on disclosure of business information are unnecessary to achieve the policy objectives.

- Is there a rational explanation for the regulations in comparison to the policy objectives? (*See* Article 2.1 of the TBT Agreement. For details, see (2) (2)(b) (i) and (ii))

  <Example Case> In order to prevent sales of imported beef as domestic beef, a dual system (a system which prevents sales of domestic beef in retail outlets where imported beef is sold) was introduced. However, a similar system was not applied to closely-related categories of pork and marine products. (Reference: Republic of Korea-Measures Affecting Imports of Fresh, Chilled and Frozen Beef (DS 161, 169)). By pointing out the inconsistency of the regulation, there is a possibility to effectively persuade that rational amendments should be made to the regulation.

- Are independent measures introduced instead of adopting relevant international standards without rational reasons? (*See* Article 2.1 of the TBT Agreement. For details, see (2) (2)(b) (i) and (ii)) <Example Case> When there is an international standard that specifies plating method A for material X, and the domestic law obligates the use of an independent plating method B without rational reasons.

- Are there any defects in the procedures, such as no TBT notifications are made where required, the 60-day comment period is not given without a valid reason, and the measure is enforced as soon as the comment period is over? (*See* Articles 2.9, 2.12 and 10 of the TBT Agreement. For details, see (2) (2) (b) (iv)).

3) SPECIFIC APPLICATION OF THE TBT AGREEMENT

(1) Information collection (Examining the TBT notification)

When conformity of a measure to the TBT Agreement is questionable, first, it is necessary to examine the details of the measure. While most WTO member countries publish details of measures on their websites, it is better to also check for any TBT notifications.

As mentioned in (2)(b)(2)(iv), WTO member countries are obligated to submit a prior TBT notification when establishing technical regulations and conformity assessment procedures. Since the WTO publishes all TBT notifications on its website, industries can check for TBT notifications. A TBT notification contains the details of the proposed technical regulations, the objectives, target products, enforcement date, and related laws etc. By examining the TBT notification, the effects possibly affecting a company by the proposed technical regulation can be verified.

There have been cases where several countries have not submitted a TBT notification or have not provided a 60-day comment period without a valid reason (see Part I). Management of the notification process should be improved and fulfillment of the recommended guidelines in the TBT Agreement and the subsequent the TBT Agreement Triennial Review Decision is necessary.

(2) Commenting on the TBT notification and Utilizing the TBT enquiry point)

Next, how to express views and concerns to the enforcing country when there is a need. The

response will be mainly through comments on the TBT notification if it is within the TBT notification period. Many member countries generally gather opinions from stakeholders through public comments; however, it is advisable to check how to comment on the TBT notification.

As mentioned in this document in (2)(b)(2)(iv), member countries have the obligation to consider comments made with respect to TBT notifications. Not only the government of Japan, but the industry (industry organizations or individual companies) can also comment on TBT notifications. Also, enquiry and requests for information are possible via enquiry points even for cases without TBT notifications).[10]

In order for the country implementing the measure to consider and reflect on the comments, it is generally advised to comment on the TBT notification at an early stage. (Footnote 9). The list of enquiry points for each country is published on the WTO website. In Japan, the Ministry of Foreign Affairs and Japan External Trade Organization (JETRO) are appointed as enquiry points. In addition, it is desirable to make claims based specifically on provisions of the TBT Agreement or international rules rather than merely expressing concerns.

(3) Utilizing the TBT Committee

The advantage of challenging protectionist measures via the TBT Committee

When the enforcing country does not revise the measure even though views and concerns have been expressed, the concerns should be expressed and requests should be filed directly through the government at bilateral consultations held during the period of TBT Committee meetings, and consideration should be given to raising such measure as a "Specific Trade Concern (STC)" in the TBT Committee. Cases of harmonization and revision of such measures as a result of directly approaching the enforcing country have been noticed. Regarding the STC of the TBT Committee, countries expressing concerns should register the STC 14 days prior to the TBT Committee through the WTO Secretariat, and the list of STCs registered 10 days before will be distributed to the WTO member countries (The TBT Agreement Triennial Review Decision); it is possible to collaborate with other countries that share the same concerns. Detailed minutes of the proceedings of the TBT Committee decision are published on the WTO website. The TBT Committee is generally held three times every year (March, June and November) in Geneva; hence it is possible to check the status of the revision of the measures of the other countries.

Member countries are aggressively using specific trade measures as a tool to rectify protectionist measures taken through technical regulations. Particularly after the financial crisis of 2008, there was a sharp rise in the number of STCs (Figure II-11-2) due to increasing protectionist measures taken by developing nations. In 2012, there were 94 STC cases, breaking the previous highest level.

The number of concerns expressed by countries via STC by the end of 2015 can be categorized as follows: (1) request for clarification and additional information (328); (2) accusation of unnecessary trade barriers (289); (3) lack of transparency (264); (4) rationality of the policy objectives (209); (5) conformity to international standards (189); (6) discrimination against imported products (142); and (7) securing adequate comment period (114). It may be useful to re-examine the measures in question from these viewpoints.

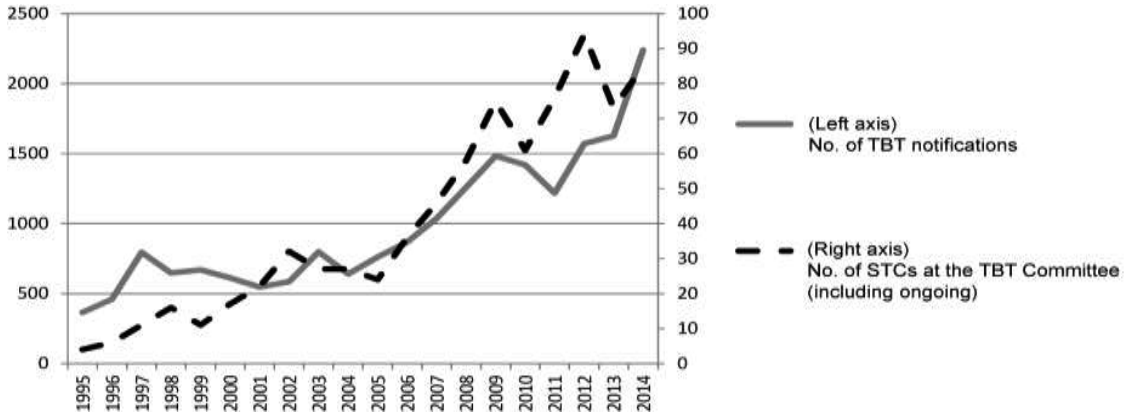
Following are the advantages of having protectionist measures revised through the TBT Committee: 1. by carrying out rule-based discussions between the trade authorities at multiple

[10] The list of inquiry points in each country have been published on the WTO website. In Japan, the Ministry of Foreign Affairs and Japan External Trade Organization (JETRO) are specified as the inquiry points.

venues, a revision of the measure by the enforcing country is possible without making it a political problem; 2. it becomes easy for the country to correct the measure because at the TBT Committee the domestic regulations can be discussed starting at the development stage (TBT notifications should be made no later than six months prior to the introduction of regulations, and the measures pertaining to the notifications will be the subject of discussions); and 3. There is a tendency to voluntarily improve irrational regulations, because the trade authorities become accountable as the regulator in the enforcing country.

Figure II-11-2 Status of TBT notifications and STCs in the TBT Committee

Source: GATT/WTO documents (G/TBT/36: Twentieth annual review of the implementation and operation of the TBT Agreement; as mentioned in (2)2)(b)(iv), data for 2015 is not reflected in this figure.)



Specific examples

Below, the United States - transportation regulations for lithium ion batteries will be introduced as an example of correcting a measure accused of inconsistency with the agreement by utilizing the TBT Agreement and the TBT Committee, combined with other means and channels of the government and industry (see Chapter 3, Part I of "2012 Report on Compliance by Major Trading Partners with Trade Agreements").

In January 2010, The United States Department of Transportation announced a proposal for safe transportation of lithium ion batteries. This measure was devised to prevent abnormal ignition accidents during air transport, which occurred frequently in the United States at that time. The legitimate policy objective of the measure was to ensure safe transportation by an aircraft.

In February 2012, a TBT notification related to this measure was submitted to the WTO.

Japan, the EU, China and the Republic of Korea strongly opposed the new rules. The reason was that if the measure was enforced, it would significantly increase the cost of transportation, causing disadvantages to industry and consumers. Also, this measure was alleged to be not in conformity with existing international standards (Article 2.4 of the TBT Agreement), and also that the measure was more trade-restrictive than necessary to achieve the policy objective (Article 2.2 of the TBT Agreement).

Through government channels, between 2010 and 2012 concerns were repeatedly expressed at bilateral talks and in TBT Committee meetings, in collaboration with other interested countries. They demanded conformity with international standards as well as eliminating the unnecessarily trade-restrictive effect of the regulation, which was not necessary to meet the policy objective. Also,

using private channels, the battery industry and the transportation industry submitted public comments and collaborated with United States domestic organizations to pressure the United States government.

As a result, in February 2013, the United States Congress decided to introduce a policy based on new rules that conform to the international standards, and the new rules were published in the Official Gazette in January 2015. A majority of problems are expected to be eliminated with implementation of the new rules. In this case, the policy objective of the United States and the benefits of trade liberalization for Japan have collided; however, by utilizing the TBT Committee, a positive result for the Japanese industry was secured and the interests of both countries were reconciled.

(4) Utilizing WTO dispute settlement procedures

When concerns are still not resolved with the above procedures, requesting a WTO dispute settlement proceeding is one of the options (see Chapter 17). The main body that utilizes the dispute settlement procedures is the government. However, important factors for companies are the provision of information, and requests from individual companies and industries for the government to recognize questionable measures taken by other countries, to consider adverse effects to domestic industries, and the necessity to utilize dispute settlement procedures. In general, private participation is beneficial in addressing problem measures of other countries. Particularly when there is a possibility to apply for dispute resolution proceedings in the future, it is extremely important to share information and collaborate with the government from an early stage.

The main TBT dispute cases to date are shown in Figure II-11-3; however, there are no cases involving Japan. Disputes concerning the interpretation of the TBT Agreement in WTO dispute settlement proceedings were rare until recently. However, in 2012, there were three reports issued by the Appellate Body clarifying specific details of the TBT Agreement. Furthermore, currently four disputes have been referred to the WTO dispute settlement procedures. As the numbers of cases build up, the TBT Agreement will be further clarified and elaborated, and easier understanding of its provisions by industries is expected. In addition, by the application of the dispute settlement procedures, not only can the individual problem measures be improved, but the prevention of implementing further trade-restrictive measures and copying of the problem measures by other countries can also be expected. There is a deep-rooted apprehension in the industry that application of the dispute settlement procedures tends to deteriorate bilateral relations. However, nearly 20 years have passed since the establishment of the WTO and China and Russia's accession, and it can be generally said that dispute settlement procedures have followed a rule-based practice worldwide.

When contemplating whether to initiate WTO dispute settlement procedures, the following points should be considered: The first is the time taken to solve the case. If it is solved at an initial stage of discussions, the WTO dispute settlement procedures will end in two to three months. However, if the case extends to the decision of the Appellate Body, it may take two to three years. The second point is the cost of lawyers, etc. (However, in WTO dispute settlement proceedings, there are no fees incurred for the WTO Secretariat or the Panel). It is desirable to conduct a legal analysis at an early stage for dealing with trade-restrictive measures; however, when applying the WTO dispute settlement procedures, hiring professional legal services is indispensable. It is necessary to examine if such investment justifies the benefits from resolving the problem measures. The third point is that, basically, the effects of recommendations given by the WTO dispute settlement procedures are only prospective (achieved in the future), and the problem measures will only be improved from that point of time onwards. Retrospective relief can only be realized

separately through domestic litigation in the other country.

Figure II-11-3 List of major TBT dispute cases

Case Number	Case Name	Stage	Agreement Interpretation (Upper: Panel, Lower: Appellate body)				
			Technical Standards Conformity	Article 2.1, TBT Agreement	Article 2.2, TBT Agreement	Article 2.4, TBT Agreement	Article 5, TBT Agreement
DS135	EC-Asbestos case Complainant: Canada (Appellate Body Report circulated: April 2001)	P	Judgment (denied)	No judgment	No judgment	No judgment	-
		AB	Judgment (accepted)	No judgment	No judgment	No judgment	-
DS231	EC-Sardines case Complainant: Peru (Appellate Body Report circulated: September 2002)	P	Judgment (accepted)	-	-	Violation	-
		AB	Judgment (accepted)	-	-	Violation	-
DS381	US—Tuna II case Complainant: Mexico (Appellate Body Report circulated: March 2012)	P	Judgment (accepted)	Non-violation	Violation	No violation	-
		AB	Judgment (accepted)	Violation	No violation	No violation	-
	Compliance proceedings of the same case Complainant: Mexico (Panel established:: January 2014)	P	Judgment (accepted)	Violation	-	-	-
	Appellate Compliance proceedings of the same case (Appellate Body Report circulated: November 2015)	AB	Judgment (accepted)	Violation	-	-	
DS384 DS386	US-COOL case Complainants: Canada, Mexico (Appellate Body Report circulated: July 2012)	P	Judgment (accepted)	Violation	Violation	-	-
		AB	No dispute	Violation	No violation	-	-
	Compliance proceedings of the same case Complainants: Canada, Mexico (Panel established: September 2013	P	Judgment (accepted)	Violation	No violation	-	-
	Appellate compliance proceedings of the same case (Appellate Body Report circulated: May 2015)	AB	Judgment (accepted)	Violation	No determination (Panel's judgment was nullified)	-	-
DS 400 DS401	EC-Seal Products case Complainants: Canada, Norway (Appellate Body Report circulated: May 2014)	P	Judgment (accepted)	Violation	No violation	-	• Violation of the 1st sentence of Article 5.1.2 • No violation of the 2nd sentence of Article 5.1.2 • No violation of Article 5.2.1

Case Number	Case Name	Stage	Agreement Interpretation (Upper: Panel, Lower: Appellate body)				
			Technical Standards Conformity	Article 2.1, TBT Agreement	Article 2.2, TBT Agreement	Article 2.4, TBT Agreement	Article 5, TBT Agreement
		AB	Judgment (denied)	No determination (Panel's judgment was nullified)	No determination (Panel's judgment was nullified)	-	-
DS406	US-Clove cigarettes case Complainant: Indonesia Appellate Body Report circulated: April 2012	P	Judgment (accepted)	Violation	No violation	-	-
		AB	Judgment (accepted)	Violation	-	-	-
DS434 DS435 DS441 DS458 DS467	Australia—Tobacco Plain Packaging case Complainants: Ukraine, Honduras, Indonesia, Dominica, Cuba (Panel established: September 2012, September 2013, March 2014, April 2014, April 2014)	P	Panel pending	Panel pending	Panel pending	-	-

(Stage: examination stage, P: Panel, AB: Appellate Body)

Source: GATT/WTO documents

4) SUMMARY

As mentioned before, the TBT Agreement is a significant tool with huge possibilities to affect the product regulations set by foreign governments. Combining the wide-ranging definition of technical regulations, and the effective use of the TBT Agreement, trade-restrictive measures employed by other countries in several industries can be prevented in advance or can be contained to a minimum level. In the future, it can be hoped that industry will use the TBT Agreement as one of their corporate strategies, collaborating with the government effectively for its active utilization.

4. ECONOMIC ASPECTS AND SIGNIFICANCE

When significant differences exist between the standards and conformity assessment systems of different countries, the smooth development of free trade is likely to be impeded because exporters must deal with separate measures for each country, causing manufacturing and sales costs to increase. Furthermore, when such measures discriminate between domestic and foreign products, or limit the quantity of imports, international trade is unreasonably distorted. To enhance free trade, it is essential to promote the international harmonization of standards and conformity assessment systems, to provide more transparency in the drafting and administration processes of domestic standards regulations and to ensure that equal treatment is accorded to domestic and foreign products.

SPS measures are applied to prevent the entry of diseases and pests from abroad, taking into account their prevalence in the exporting and importing country, as well as other relevant factors that are based on scientific and technical grounds. Although differences in the SPS systems adopted by different countries exist, they should not be used to disguise restrictions on international trade.

B. MAJOR CASES

(1) EC – Measures Concerning Meat and Meat Products (Hormones) (SPS Agreement – DS26)

In December 1985, the EU, responding to consumer concerns, decreed that as of January 1988, all imports of meat from animals raised using hormones would be banned (a decision not to use hormones within the EU territories was made in March 1988). The United States requested consultations under Article XXIII of the GATT, arguing that the measures lacked scientific evidence and were inconsistent with Article 7.2 of the Tokyo Round Standards Code. In January 1989, the EU began enforcing a total ban on imports of meat raised with growth hormones. The United States, in response, imposed retaliatory measures that same month under Section 301: 100-percent tariffs on EU imports of beef, tomato-based products, coffee, alcoholic beverages, and pet food, totaling approximately $90 million.

The matter remained unresolved. As a result, in June 1995, the United States charged that the EU measures lacked a scientific basis and were in violation of both the GATT and the SPS Agreement. The Unites States stated it would refer the matter to WTO dispute settlement if it was not resolved by the end of 1995.

In response, the EU convened a "Scientific Conference on the Use of Growth Promoters in Meat Production" for scientists and consumer groups. The Conference's report, published in January 1996, concluded that the data on the use of natural and artificial hormones and related compounds showed no evidence of human health risk. Notwithstanding, the EU agriculture ministers decided to continue the import ban.

In January 1996, the United States requested consultations under GATT Article XXII, alleging that the EU measures were inconsistent with Articles III and XI of the GATT, and Articles 2, 3, and 5 of the SPS Agreement. In May 1996, a panel was established. In July 1996, Canada also requested consultations under GATT Article XXII; a panel was established in October 1996.

In August 1997, the Panel report was issued. The Panel found that the EU measures were neither based on international standards nor on any risk assessment and that the arbitrary or unjustifiable distinctions in the level of protection resulted in discrimination or a disguised restriction on international trade. The Panel therefore found the EU measures in violation of Articles 3.1, 5.1 and 5.5 of the SPS Agreement.

In September 1997, the EU appealed the Panel finding to the Appellate Body. In January 1998, the Appellate Body issued its report, finding that the EU measures were not discriminatory, did not constitute a disguised restriction on international trade and, therefore, were not inconsistent with Article 5.5 of the SPS Agreement. However, the Appellate Body upheld the Panel's findings that the EU measures were not based on sufficient risk assessment and therefore violated Article 5.1 of the SPS Agreement. Lastly, the Appellate Body reversed the Panel's interpretation regarding the burden of proof by finding that the burden of proof to establish a WTO infraction resides with the complaining country (in this case, the United States) in cases where a country introduces or maintains sanitary or phytosanitary measures and the question is whether the measures result in a higher level of protection than would be achieved by relevant international standards.

In February 1998, the Appellate Body report was adopted, directing the EU to bring its measures into WTO compliance by May 1999.

The WTO Dispute Settlement Body (DSB) recommended the EU to take appropriate measures in

conformity with the Appellate Body report. The EU, however, failed to withdraw the import ban by the deadline. The United States and Canada, after going through arbitration under paragraph 6, Article 22 of the DSU, obtained DSB approval for the countermeasures (suspension of the application) and raised the tariff rates in July and in August 1999, respectively.

The EU again filed a complaint in accordance with the WTO dispute settlement procedures, claiming that the countermeasures were in violation of GATT Article II, etc. because the Unites States and Canada continued the countermeasures even after the EU corrected the measures (DS320: US-Continued Suspension of Obligations in the EC-Hormones Dispute). The Panel report and the Appellate Body report were circulated in March and October 2008, respectively. The Appellate Body determined that the parties involved were required to first initiate a compliance proceeding, in order to confirm whether the EU had removed the measures found to be inconsistent with the SPS agreement based on the decisions of DS26. Subsequently, a settlement was reached in September 2009.

(2) EC – Labelling Regulations on Sardines (TBT Agreement – DS231)

In June 1989, the EU adopted Council Regulation No. 2136/89, which permits the word "sardine" on canned sardines manufactured only from European sardines (*Sardina pilchardus*). This regulation does not permit non-European sardines to be labelled "sardines" even when qualified by a geographical reference, for example, "X sardines".

The international standard for sardine-type products adopted by the Codex Alimentarius Commission of FAO/WHO in 1978 ("Codex standard") defines canned sardines as those manufactured from fresh or frozen fish on a list of 21 fish species, including the European sardine and the Peruvian sardine (*Sardinops sagax*). However, under that standard, only the European sardine can be labelled simply as "sardines". The other 20 species, including the Peruvian sardine, can be labelled as "sardines" only if the name "sardine" is qualified by a country, geographic area or species reference, for example, "X sardines".

In March 2001, Peru requested consultations with the EU pursuant to GATT Article XXII, arguing that the EU Regulation violates Article 2.4 and other provisions of the TBT Agreement, which require that technical regulations be based on relevant international standards. A panel was established in July of that year.

The main issues in this case were: (i) whether the EU Regulation constitutes a "technical regulation" as defined in the TBT Agreement; (ii) whether the Codex standard is a "relevant international standard" as defined in Article 2.4 of the TBT Agreement; and (iii) whether this is a case in which using such relevant international standards would be an ineffective or inappropriate means for fulfilling the legitimate objectives (Article 2.4).

The Panel issued a report in May 2002, finding that: (i) the EU Regulation constitutes a "technical regulation" under the TBT Agreement; (ii) the Codex standard is a "relevant international standard" as defined in Article 2.4 because both the EU and the Codex standards refer to the same product (preserved sardines) and the EU Regulation sets forth labelling requirements that correspond to the Codex standard although the Codex standard was not used "as a basis for" the EU Regulation; and (iii) the complaining party only bears the burden of establishing a *prima facie* case by demonstrating that a relevant international standard exists and has not been used as a basis for the technical regulation in question, while the defending party bears the burden of demonstrating that the relevant international standards would be "an ineffective or inappropriate means for the fulfilment of the legitimate objectives." The Panel found that the EU failed to demonstrate that the Codex standard was an ineffective or inappropriate means for the fulfilment of the legitimate objectives (and conversely, Peru demonstrated that the Codex standard was an

effective and appropriate means for such objectives). Therefore, the Panel concluded that the EU Regulation violates Article 2.4 of the TBT Agreement.

The EU appealed the Panel's decision to the Appellate Body in June 2002. The Appellate Body circulated the report in September of that year and found that, as the complaining party, Peru bears the burden of demonstrating that the Codex standard is an effective and appropriate means to fulfill these legitimate objectives. But on all other points, it upheld the Panel's findings and confirmed that the EU Regulation is in violation of Article 2.4 of the TBT Agreement. The Report was adopted in October 2002 and the DSB recommended that the EU bring the Regulation into conformity with its obligations under the TBT Agreement. Subsequently, a settlement was reached in July 2003.

(3) United States - Measures Concerning the Importation, Marketing and Sales of Tuna and Tuna Products (TBT Agreement - DS381)

The United States has enforced a ban on use of the dolphin-safe labeling on tuna products produced from landed tuna based on specific fishing methods (hereinafter referred to as "the labeling regulations"). In Mexico, tuna which habitually swim along with the dolphins were caught conventionally with purse seine nets. However, due to the labeling regulations, the United States will not display dolphin-safe labels on tuna products produced from tuna caught by this method. The United States claims that the objective of the labeling regulation is to inform consumers about whether or not the tuna was landed without harming dolphins.

Mexico requested that the DSB establish a panel on March 9, 2009, alleging that the labeling regulations created unfair barriers for Mexican tuna exports to the United States and was inconsistent with the multilateral treaty, the "Agreement on the International Dolphin Conservation Program" (hereinafter referred to as "AIDCP"), and so violate-ds Articles I and III of GATT as well as Article 2 of the TBT Agreement.

The main issues in this matter were: (1) whether the labeling regulations were technical regulations under the TBT Agreement, (2) whether there was a violation of the national treatment obligation (TBT Agreement, Article 2.1), (3) whether the labeling regulations were more trade-restrictive than necessary for the fulfillment of legitimate objectives (TBT Agreement, Article 2.2), and (4) whether there is a need to base the labeling regulations on the AIDCP which is a related international standard (Article 2.4 of the TBT Agreement).

The Panel issued its report on September 15, 2011. Regarding the above-mentioned four claims, the Panel findings were as follows: (1) the labeling regulations are technical regulations within the meaning of the TBT Agreement; (2) the labeling regulations are neutral to nationality and hence do not violate Article 2.1 of the TBT Agreement; (3)although the policy objectives of the labeling regulations are legitimate, the United States violates Article 2.2 of the TBT Agreement and should adopt less trade-restrictive measures of AIDCP as alternatives to achieve the same policy objectives; (4) while acknowledging the AIDCP as an international standard, the AIDCP alone cannot inform American consumers adequately about the tuna fishing methods; thus, the panel concluded that there is no need to adopt AIDCP as a basis for the labeling regulations. However, the Panel exercised "judicial economy" and did not give an opinion on the GATT claims.

In response, Mexico and the United States filed an appeal to the Appellate Body on October 31, 2011. The Appellate Body distributed its report on May 16, 2012.

Concerning (1), the Appellate Body rejected the United States' claim, stating that "conformity to the labeling regulations is not mandatory and it is possible to market in the United States even without the labeling". The Appellate Body held that the possibility to market has no relation to the judgment on this case, and that compliance to the labeling regulation is mandatory since labeling is

restricted to specific fishing methods. Concerning (2), the labeling regulations violate the Article 2.1 of the TBT Agreement because the products of the United States and Mexico are not treated equally and the competitive conditions are changed disadvantageously to the Mexican products. Concerning (3), the Appellate Body judged the conformity to the Article by using two steps: whether the technical regulations in question fulfill the legitimate objectives or whether they are more trade-restrictive than necessary to fulfill the legitimate objectives. With regard to the "legitimate objectives", they ruled that by comparing the contents, legislation process, structure and implementation of the technical regulations, AIDCP cannot become an alternative measure to the labeling regulations to equally fulfill the policy objectives of the United States, and so Article 2.2 of the TBT Agreement was not violated. Concerning (4), conformity to this Article was judged by analyzing three steps -- whether any relevant international standards exist or will be enacted in the near future; whether the technical regulations are based on international standards; and whether there are any applicable exemptions. In the second TBT Agreement Triennial Review conducted in 2000, the interpretation of "the six principles for international standards" was adopted by uniform consensus of all WTO member countries. It was concluded that the AIDCP does not meet the requirements of an international standard because such standards must be open to all WTO member countries. The DSB adopted the above-mentioned Appellate Body Panel reports in July 2012. In September of the same year, the parties agreed to set the reasonable period for compliance at 13 months (until July 2013).

However, Canada and Mexico requested the establishment of a compliance panel in November 2013, claiming that compliance by the United States was insufficient. On April 14, 2015, the compliance panel circulated its report. The panel conducted analysis, focusing on the three elements of the amended measure of the United States: (A) the eligibility requirement: Mexican tuna products made from tuna caught by setting on dolphins are ineligible to receive the US dolphin-safe label; (B) certification requirement: for tuna caught in the Eastern Tropical Pacific Ocean (ETP) by a large purse seine vessel (the majority of the Mexican tuna fleet) to receive the dolphin-safe label, it must be certified by the captain and an independent on-board observer who has a certain qualification that (i) no dolphins were killed or seriously injured and that (ii) the fishing method of setting on dolphins was not used; and (C) tracking requirement: tuna to be contained in tuna products labelled dolphin-safe must be accompanied by a statement certifying that it was segregated from non-dolphin-safe tuna from the time it was caught through processing, and tuna caught in the ETP by a large purse seine vessel must be accompanied by an additional statement. Regarding (A) the eligibility requirement, the panel found that the measure to treat tuna product made from tuna caught by setting on dolphins as being ineligible for the dolphin-safe label in itself is not inconsistent with Article 2.1 of the TBT Agreement, in light of the risk of such fishing method. However, it found that the other two requirements impose a discriminatory burden and therefore are inconsistent with that Article, on the grounds that regarding (B) the certification requirement: while an independent observer's certification is required in addition to the captain's certification for tuna caught in the ETP, only the captain's certification is required for tuna caught in other fisheries; and regarding (C) the tracking requirement, different verification and tracking methods are required depending on where tuna was caught, and a greater burden is imposed on tuna caught in the ETP. Conformity with Article 2.2 and Article 2.4 was not included in the issues discussed by the panel.

Dissatisfied with the conclusions by the panel, the United States filed an appeal with the Appellate Body in June 2015.

On November 20, 2015, the Appellate Body circulated its report. It reversed the panel's decision, holding that the panel erred in analyzing the three elements of the amended tuna measure separately

because these elements are related to one another. Based on dispute settlement precedent, the Appellate Body conducted a two-step analysis concerning less unfavorable treatment of imported products in the meaning under Article 2.1 of the TBT Agreement, from the viewpoints of whether (A) the US amended measure has a detrimental impact on Mexican tuna products and (B) such detrimental impact stems exclusively from a legitimate regulatory distinction. Regarding (A), the Appellate Body found that the amended tuna measure modifies the conditions of competition to the detriment of Mexican tuna products in the US market by excluding most Mexican tuna products from access to the dolphin-safe label, while treating tuna products from the United States and other countries as being eligible for access to the label on certain conditions (the amended measure is identical with the original measure on this point). Regarding (B), the Appellate Body considered that it is necessary to assess whether the regulatory distinction by the amended measure is "calibrated" to the risks to be prevented by the measure in order to assess whether the amended measure lacks "even-handedness". Although the Appellate Body was unable to conduct a full analysis of "calibration" in the absence of a proper assessment by the panel of the respective risks posed to dolphins inside and outside the ETP large purse-seine fishery, it found that the determination provisions (an observer certification is required for non-ETP purse seine fishing if the competent authorities determine that certain conditions are met) do not require an observer certification for both ETP large purse seine fishing and other fishing methods in all circumstances of comparably high risks. As a result, the tracking and verification requirements impose a greater burden on ETP large purse seine fishing than other fishing methods. Thus, it cannot be said that the amended measure is designed so that it is "calibrated" to the risks to dolphins arising from different fishing methods. Such detrimental impact of the amended measure cannot be said to stem exclusively from a legitimate regulatory distinction. Based on these grounds, the Appellate Body found that the amended measure is inconsistent with Article 2.1 of the TBT Agreement. The Appellate Body also found that the amended measure is inconsistent with Articles I: 1 and III: 4 of the GATT 1994, and concluded that the measure is not justified under Article XX of the GATT 1994.

(4) United States - Labeling Measures on Imported livestock (TBT Agreement - DS384, 386)

Regarding meat, the United States has outlined the following five categories and introduced a labeling system with distinguishable labels for each category.

(1) Category A: Produced in the United States

Meat derived from animals that are born, bred and slaughtered exclusively in the United States.

(2) Category B: Produced in multiple countries

Meat derived from animals that are born and bred in multiple other countries but slaughtered exclusively in the United States.

(3) Category C: Imported for immediate slaughter

Meat derived from animals that are imported into the United States for immediate slaughter.

(4) Category D: Produced in a foreign country

Meat that is derived from animals that are not born, bred or slaughtered in the United States.

(5) Category E: Ground meat

The labels for each of the categories are as follows. For products derived from 100% Category A meat, label A meaning "-produced in the United States" can be affixed. For Category B & C meat,

all countries of birth, breeding or slaughter must be displayed. However, the country of origin can be displayed in any order for Category B. Furthermore, products derived from meat in these categories along with Category A meat are not permitted to use only the label "produced in the United States" (label A) and must affix a label (label B or C) indicating all the producing countries. However, the country of origin can be displayed in any order if the mixing process is completed in one production day. Regarding Category D meat, a label with country names (label D) in accordance with the rules of origin will be affixed. Regarding Category E meat, the list of all producing countries is necessary.

In response to the United States claim that the objective of these Country of Origin Labeling (COOL) measures was to communicate the country of origin to consumers, Canada and Mexico argued that the real intention lay in domestic industry protection, alleged violations to Article 2.1 and 2.2 of the TBT Agreement and requested that the DSB establish a Panel.

The Panel decided that, according to the COOL decision, information on the countries involved in each stage of the entire process of the supply chain (birth, breeding, slaughter and processing) must be maintained. In order to maintain such information on the country of origin, the necessity to manage livestock separately according to their countries of origin will arise, and due to increased cost of imported livestock compared to livestock produced in the United States by such separation, the Panel judged that this will become an incentive for the traders to use livestock produced in the United States rather than to use imported livestock. The Panel therefore concluded that the COOL measures discriminated against imported livestock and hence violated Article 2.1 of the TBT Agreement.

The panel acknowledged that the COOL measures are based on a legitimate objective of providing consumers with the country of origin information. However, -the Panel held that the contents of the label for labels B and C do not convey correct information about the country of origin to the consumer and hence the COOL measures do not fulfill above objective and so violate TBT Agreement, Article 2.2.

The Appellate Body supported the Panel's decision that the unfavorable effects on the imported products was not caused by a legitimate regulatory distinction but was due to discrimination against the imported products, and so the COOL measures violated TBT Agreement, Article 2.1. (The Panel came to its decision after examining the judgment criteria set out in the Appellate Body's decision in the United States-Tobacco case and the United States-Tuna II case discussed in other paragraphs). However, with regard to the decision on the violation of Article 2.2 of the TBT Agreement, the Appellate Body followed the criteria it set out in the United States-Tuna II case regarding the COOL measures and alternative measures claimed by Canada and Mexico, and so it modified the Panel's interpretations to consider the following: (1) the degree of contribution to the fulfillment of the objectives; (2) the degree to which it limits the trade; and (3) the seriousness of the risk and results of not achieving the objectives. The Appellate Body found no thresholds regarding the fulfillment of legitimate objectives. Regarding the measures, the Appellate Body stated that the Panel did not make rulings on enough facts to determine the degree of contribution to fulfill the objectives. It overruled the Panel's decision on this point, and held that it could not determine whether the COOL measures violated Article 2.2 of the TBT Agreement.

The United States responded to the above decision and corrected the COOL measure, but Canada and Mexico requested the DSB to establish a compliance panel in August 2013, claiming that compliance by the United States was insufficient. The compliance panel determined that the revised COOL measures more adversely affected the competitive opportunities for imported products than the original measures because the revised COOL measures required more detailed labeling of the country of origin than the original COOL measures and imposed a heavier burden on separate

management and recordkeeping of livestock, thus creating a stronger incentive to choose domestic products over imported products. The compliance panel then determined that the measures that discriminated between livestock produced in the United States and imported livestock were in violation of Article 2.1 of the TBT Agreement because the increased burden of recordkeeping, the continued risk of incorrect labeling, and the continuation of exceptions such as the use at restaurants and in processed foods, etc. caused adverse effects not related to a legitimate regulatory distinction. With respect to Article 2.2 of the TBT Agreement, the compliance panel compared the revised COOL measures and four alternative measures claimed by the complainants, and determined that (1) the revised COOL measures only contributed partially to the regulatory objectives, (2) the degree of trade restrictions was higher than before the revision, (3) the degree of risk incurred by non-fulfillment of the regulatory objectives in consideration of the interests of consumers, etc. could not be confirmed by the evidence submitted, and (4) hat either the alternative measures claimed by the complainants did not contribute to the regulatory objectives to the same degree as the revised COOL measures or the content of the alternative measures was not properly identified by the complainants. The compliance panel then concluded that the complainants failed to sufficiently demonstrate that the revised COOL measures were more trade-restrictive than necessary, and therefore did not determine whether there was a violation of Article 2.2. In November 2014, the United States filed an appeal with the Appellate Body.

In May 2015, the Appellate Body circulated its report. It found no errors in the panel's findings concerning consistency with Article 2.1 of the TBT Agreement, and upheld the panel's conclusion that the amended COOL measure is inconsistent with that Article.

Regarding Article 2.2 of the TBT Agreement, the Appellate Body held that an assessment of whether a technical regulation is "more trade restrictive than necessary" involves the "holistic weighing and balancing" of all relevant factors, namely, (i) the degree of contribution of the regulation to a legitimate objective, (2) its trade-restrictiveness, and (3) the risk incurred by non-fulfillment of the objective. In light of the nature of the objective pursued by a technical regulation, the level of protection sought, as well as the nature, quantity, and quality of evidence, and the characteristics of the regulation as revealed by its design and structure, it will not always be possible to quantify a particular factor. For example, even if the degree of contribution can only be assessed with low accuracy (that is, a factor cannot be accurately quantified and can only be assessed in qualitative terms), the panel must not end its analysis with a conclusion that the burden of proof has not been fulfilled, but rather it must conduct weighing and balancing. Thus, the Appellate Body found that the panel erred in concluding that it was unable to ascertain the gravity of the consequences of non-fulfilment of the amended COOL measure's objective and therefore that it was unable to ascertain whether the proposed alternative measures would make an "equivalent" degree of contribution to the amended measure's objective. Based on such grounds, the Appellate Body reversed the panel's decision that the complainant did not make a prima facie case that the amended COOL measure is more trade restrictive than necessary. On the other hand, the Appellate Body concluded that there were not sufficient findings of facts to complete the analysis of whether the amended COOL measure is consistent with Article 2.2 of the TBT Agreement.

With regard to the panel's finding that the amended COOL measure is inconsistent with Article III: 4 of the GATT 1994, the Appellate Body dismissed the United States' argument that in the context of permitting imposition of a certain amount of costs necessary for country of origin labeling the Panel erred in not taking into consideration Article IX of the GATT 1994 in interpreting Article III: 4 of the GATT 1994. It upheld the panel's decision.

(5) United States - Measures Affecting the Production and Sales of Clove Cigarettes (TBT Agreement-DS406)

The United States implemented measures banning production and sales of clove-flavored cigarettes (hereinafter referred to as "the prohibition measures"). According to a congressional Committee the objective of the prohibition measures is to protect public health and to reduce cigarette smoking in people aged less than 18 years. The reason for prohibition is to remove from the market flavored cigarettes, which cause new smokers to adjust easily to smoking, and for the purpose of preventing young people from acquiring regular smoking habits. However, menthol cigarettes were explicitly exempted from the prohibition measures.

In response, Indonesia requested the establishment of a panel on June 9, 2010, alleging that the measures of the United States which prohibit flavored cigarettes except for menthol, treat clove cigarettes imported from Indonesia less favorably and so are inconsistent with the national treatment obligation in Article 2.1 of the TBT Agreement (alternatively Article III: 4 of the GATT).

In accordance with dispute resolution procedure in previous cases, conformity to Article 2.1 of the TBT Agreement was disputed based on: (1) whether the measures in question are technical regulations; (2) whether the imported product and the domestic product are "like products"; and (3) whether the imported products are being treated less favorably as compared to the domestic products. However, in this case the applicability of (2) like product and (3) treatment no less favorable were mainly contended.

Regarding "likeness" in the above-mentioned (2), the Panel found that the prohibition measures were technical regulations. While stating that the judgment on "likeness" in decisions on Article III: 4 of the GATT and the conventional standards based on the competitive relationship of products do not apply automatically to "likeness" pursuant to Article 2.1 of the TBT Agreement, and among the above conventional standards as a result of giving special consideration to the "physical characteristics" of the product and "consumer tastes and habits", the Panel found that the two cigarettes were "like products". Regarding (2) above the Panel said that based on the preamble of the TBT Agreement and that the prohibition measures affect technical regulations, and because the standards based on competitive relationship adopted in likeness judgments of panels in GATT Article III:4 cases do not automatically apply to the likeness judgment of Article 2.1 of the TBT Agreement. Therefore, the Panel focused on the legitimate objective of the prohibition measures and conducted an evaluation placing special emphasis on the physical characteristics included in the above-mentioned conventional standards and consumer tastes and habits, and it concluded that the two cigarettes were "like products". Regarding (3) above, "treatment no less favorable", the Panel not only acknowledged that the treatment for clove cigarettes imported from Indonesia can be compared with domestically-produced menthol cigarettes, but also held that the these products are treated differently affecting the conditions of competition for the imported product and hence the prohibition measures are inconsistent with Article 2.1 of the TBT Agreement.

The United States raised objections to the Panel judgment and appealed to the Appellate Body on January 5, 2012 (additionally, it appealed regarding the Panel decision regarding violation of Articles 2.9.2 and 2.12 of the TBT Agreement).

The Appellate Body thoroughly examined the preamble of the TBT Agreement and held that it extends the GATT rules (Recital 2) and that both agreements should be interpreted as being consistent with each other. Also, along with the aim to remove trade barriers for advancement of trade liberalization (Recital 5), it recognizes the right of member countries to establish technical regulations for legitimate objectives (Recital 6); and the Appellate Body stated that each provision should be interpreted consistently with these benefits. In addition, regarding (2) above, "likeness",

in light of the above-mentioned objectives described in the preamble of the TBT Agreement, the Appellate Body stated that "likeness" of the products in question should be based on the quality and degree of the competitive relationship as with Article III: 4 of the GATT, and disagreed with the Panel's judgment because the Panel considered the legitimate objective of the technical regulation to determine "likeness". Additionally, as appealed by the United States, the Appellate Body conducted an analysis of the Panel findings about the end uses of clove cigarettes and menthol cigarettes and consumer tastes and habits in relation to these products; the Appellate Body supported the Panel's judgment that clove cigarettes and menthol cigarettes are like-products within the context of Article 2.1 of the TBT Agreement, though it did so for different reasons. With regard to (3) above, "treatment no less favorable", in light of the relationship between Recital 6 in the preamble of the TBT Agreement and Article III:4 of the GATT, the Appellate Body held that if the technical regulations in question do not legally discriminate against imported products, it does not necessarily constitute "treatment no less favorable" just because there is an adverse effect on the competitive opportunities for imported products against similar ("like") domestic products. The analysis should be conducted on whether or not the cause is exclusively based on a distinction in the legitimate regulatory objective, rather than reflecting discrimination against the imported products based on the adverse effect to it. To determine whether or not the technical regulations are discriminating against the imported products, the design of the technical regulations, particularly its even-handedness must be examined. In addition, the Appellate Body held that conformity to the national treatment obligation under Article 2.1 of the TBT Agreement should be determined by comparison of the products imported from the claimant with domestic products of same type. In addition, based on the evidence from statistical data, the prohibition measures which prohibited imports of clove cigarettes from Indonesia and permit-teds domestically-produced menthol cigarettes, the Appellate Body concluded that the design of the system prohibition measures resulted in adverse impact on the competitive opportunities for clove cigarettes. The stated objective of the prohibition measures was to reduce the number of young smokers by banning flavored cigarettes which are typically easier to smoke than regular cigarettes. However, since this characteristic is common to both menthol cigarettes and clove cigarettes, the Appellate Body concluded that the cause of the adverse impact on the competitive opportunities for clove cigarette was not due to distinction based on differences related to legitimate regulatory objectives of the regulations. From the foregoing, although the prohibition measures do not explicitly set out discriminatory treatment of imported products as compared to domestically-produced products of the same type, it functions as the form of discrimination. In other words, the Appellate Body judged that by excluding menthol cigarettes from the prohibition measures against flavored cigarettes, clove cigarettes imported from Indonesia are treated less favorably than domestically-produced products of the same type. The decision also ruled that prohibition measures were inconsistent with Article 2.12 of the TBT Agreement.

The DSB adopted the Appellate Body report in April 2012, and a settlement between parties was reached in October 2014.

(6) EC – Measures Prohibiting the Importation and Marketing of Seal Products (TBT Agreement – DS400, 401)

The EU introduced a measure to prohibit import/export and sales of all pinnipeds (seals, sea lions, and walruses; hereinafter simply referred to as "seals") and seal products in the region (hereinafter referred to as the "measure"). The measure exempted (1) traditional hunting conducted for a living by indigenous people such as Inuit (Inuit exception), (2) hunting for the purpose of sustainable management of marine resources (management hunting exception), and (3) import of products by tourists, etc. for personal use (tourist exception). In addition, implementation regulations of the

measure, which provided procedures required for distributing seals and seal products in the EU market based on the measure, (hereinafter referred to as the "implementation regulations") were published in August 2010.

Canada and Norway requested the establishment of a panel on February 14, 2011 and March 14, 2011, respectively, claiming that the measure violated the WTO Agreements.

Issues in dispute in this case were (1) whether or not the measure violated Article 2.1 of the TBT Agreement, (2) whether or not the measure violated Article 2.2 of the TBT Agreement, (3) whether or not the implementation regulations violated Article 5.1.2 of the TBT Agreement, which provides conformity assessment procedures shall not be more trade-restrictive than necessary, and (4) whether or not the implementation regulations violated Article 5.2.1 of the TBT Agreement, which provides that conformity assessment procedures shall be undertaken in a no less favorable order for products originating in the territories of other Members than for like domestic products. (3) and (4) are the first cases where issues concerning conformity assessment procedures are being determined in a WTO dispute settlement proceeding.

The Panel released its report on November 25, 2013. With regard to (1), the Panel determined that seals from Greenland and the EU are like products of Canadian seals. The Panel then determined that the measure caused a detrimental impact on competitive conditions for Canadian seals on the grounds that while the Inuit exception and management hunting exception are only minimally applicable to Canadian seals, they are broadly applicable to seals from Greenland and the EU. The Panel concluded that the measure was not based on legitimate policy objectives because this distinction could not reasonably be explained by the policy objectives of the EU, i.e. animal welfare, and thus violated Article 2.1 of the TBT Agreement. With regard to (2), the Panel determined that the measure contributed to the policy objectives of the EU to a certain extent. The Panel then determined that the measure did not violate Article 2.2 of the TBT Agreement on grounds that the alternative measure presented by Canada and Norway (setting animal welfare requirements, certifying conformity to animal welfare requirements, and presenting conformity certification) were not proven to achieve the same degree of achievement of the policy objectives as the measure. With regard to (3), the Panel determined that the implementation regulations violated the first sentence of the Article 5.1.2 of the TBT Agreement because they were published only three days before its entry into force (published on August 17, 2010) and that short period created unnecessary obstacles to international trade. On the other hand, the Panel determined that the implementation regulations did not violate the second sentence of Article 5.1.2 (which provides that conformity assessment procedures shall not be more strict or be applied more strictly than is necessary) because the alternative measures were not proven, the same reason given regarding (2). With regard to (4), the Panel determined that it could not conclude that the implementation regulations violated Article 5.2.1 of the TBT Agreement because the Panel was not provided with a sufficient basis.

The parties appealed to the Appellate Body in January 2014, and the Appellate Body report was published in May 2014. It determined that the requirements for the exceptions of the measures (requirements for allowing import/export and regional distribution of seal products) related to the specifications of hunters, hunting methods, and objectives of hunts and not to "product characteristics" under paragraph 1, Annex 1 of the TBT Agreement. For this reason, the Appellate Body rejected the Panel's ruling that the measures were "technical regulations", and did not made legal determination on the claims that assumed the measures were "technical regulations" under the TBT Agreement (Articles 2.1, 2.2, 5.1.2, and 5.2.1). (This included the issue of whether or not the measures regulated PPM under paragraph, Annex 1 of the TBT Agreement and therefore constituted technical regulations.

COLUMN: DEVELOPMENTS IN MULTI-LAYERED RULE-MAKINGS ON PRODUCT REGULATIONS

1. INTRODUCTION

1) The clarification of the objectives of the rules and details in the TBT Agreement

Traditionally in Japan, the TBT Agreement was considered as a rule to approve standards related to the quality of the product and conformity assessment. However, the concept of technical regulations in the TBT Agreement not only includes the commonly assumed "standards" but also includes the packaging and labeling regulations and all domestic regulations related to the product. This came to light in the recent judgment in a TBT Agreement-related case where the sale of luxury goods was banned and labeling regulations were violated.

In addition, the fact that TBT Agreement allows restrictive rules to a certain degree in the content of technical regulations should be observed. Specifically, the product regulations of the member countries are required to eliminate domestic and international discrimination, reduce trade restrictions to a minimum and to establish a foundation for the formation of international standards; therefore they are important from these aspects. Regarding these rules, the formation and development of specific judgment standards in recent dispute settlement precedents means that there is progress in the elaboration of the disciplines related to practical product regulations.

The accumulation of precedents related to the TBT Agreement and the revitalization of discussions in relation to the product regulations by the countries in the TBT Committee suggests that other countries are expanding the room for questioning the validity and necessity of applying the WTO to product regulations that were once within the scope of domestic regulations.

2) Objective of the column

As certain rules on border measures have been developed through the past GATT/WTO negotiations, across-the-border business activities are expanding and diversifying, resulting in a situation where problems relating to domestic regulations ("behind-the-border issues") have become a matter of concern to the governments and enterprises of each country. In other words, in addition to the tariffs and import regulations of other countries, the significance of domestic regulations aiming at environment and safety acting as barriers to trade and economic transactions is increasing for enterprises seeking to expand their operations globally.

However, regarding such domestic regulations, harmonization of international regulations is not always fair and rational when the disparity owing to geographical differences of each country and the right to establish domestic regulations according to the legitimate policy objectives of the governments are reflected. Considering these characteristics of domestic regulations, clarification and elaboration of general rules related to product regulations and conformity assessment systems in the TBT Agreement is important from the viewpoint of promoting free and fair international trade and economic transactions. From a strategic view of the government and enterprises of each country, there is a need for establishing self-serving product regulations against other countries and to eliminate unfavorable product regulations of other countries. In fact, from this point of view, governments and enterprises encourage rule-making on product regulations at various levels and also try to affect the product regulations of other countries by participating in the process. The column introduces examples of how the government and enterprises have influenced product regulations of other countries in various forms and as a whole, and attempts to make clear the international trend of developments in multi-layered rule-makings on product regulations. (This

column will deal with the Japanese initiatives relating to the international standardization to the extent required to meet the objective of this column as mentioned above. It does not intend to examine the past policies of Japan, or the current views of the Japanese government or strategy for future policies.)

2. International standardization Initiatives by the EU, the United States, and Japan

First, as an example of traditional initiatives by the governments, the active promotion by the United States and EU to harmonize regulations of various countries worldwide based on international regulations through private standardization agencies, will be explained. In addition, Japanese initiatives with regard to international standardization will be introduced.

1) International standardization of the EU[11]

From early on, in order to create a single market by unifying the existing regional markets, the EU has taken initiatives to harmonize the regulations of member states; in other words, the EU has many years of experience in the establishment of European standards. Therefore, the EU acknowledges the importance of the harmonization of regulations, and actively promotes international standardization as a policy with the objective of improving competitive capabilities of European enterprises.[12]

One feature of this policy is that the EU promotes the establishment of standards devised by international standardization agencies in which the EU has strong influence and as a result, aims to realize the harmonization of regulations that is beneficial to the European industry. Typical agencies are the International Standards Organization (ISO), the International Electrotechnical Commission (IEC), and the International Telecommunication Union (ITU).[13] In the European context, the corresponding agencies to these three agencies are the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI). Agreements are concluded between ISO, IEC and ITU respectively for document exchange and technological cooperation and simultaneous establishment of standardization work. The magnitude of influence of the European countries can be understood from the fact that as an example in the ISO, the EU member states serve as secretary countries of internal agencies like the technical committee and the sub-committees, and as the chiefs of working groups. In this way, the EU through the undertakings of secretary countries and chiefs by the member countries actively participates in the activities of these agencies to promote international standardization. In addition, for example, in the NAMA negotiations of the WTO Doha Rounds, the EU took the position of proposing regulations established by these three agencies as international standards in the field of electrical and electronic safety, and attempted to increase the influence of these agencies through the WTO Agreement.

---

[11] The "Regulatory power and standardization strategy by the EU" by Yoichiro Usui and the "Regulatory power of the EU" by Ken Endo /Kazuto Suzuki were referred to regarding this section.

[12] In 1999, the Ministerial Council adopted the "resolution on the role of the standardization in Europe" and adopted the policy to strengthen the competitiveness of the European industry through standardization. Recently, the European Commission adopted "an integrated industrial policy for the globalization era" in 2010 and "a strategic vision for European standards" in 2011, clarifying its policy to utilize international standardization to increase the competitiveness of the European industry in the global economy.

[13] However, among these three organizations, ITU is a specialized organization of the United Nations, while ISO and IEC are non-profit private organizations.

2) International standardization of the United States[14]

a) The U.S. standardization system

The United States has traditionally emphasized standardization led by industries and the government did not actively promote standardization as a policy. Based on this fact, in the U.S. standardization system, there are more than 800 private standards organizations by industry, and the feature of this system is that various domestic and international government agencies as well as the private sector, consumer organizations and research organizations participate in these organizations, which is a remarkable contrast to the majority of countries where standards are mainly established by standards organizations which are closely related to the government or a minority of government agencies. The American National Standards Institute (ANSI) was established to regulate the domestic standards in order to select the standards that were best for the United States. ANSI, which is a private non-profit organization, does not establish standards, but provides guidelines for the development of standards to domestic standards organizations and approves the standards created by these organizations based on these guidelines. The standards developed by these approved organizations are specified as American National Standards (ANS).

The two main points to focus on concerning the above-mentioned United States standardization system are as follows.

Firstly, in addition to the fact that numerous domestic and international bodies participate as mentioned above, after the war, the United States market was overwhelming in scale and the standards set by the U.S. standards organizations had a great influence worldwide. For example, the U.S. standards were adopted by international standards organizations such as the ISO, and also by other countries as national standards, practically functioning as international standards.

The leading examples are ASTM International (publicly known as United States Society of Testing and Materials (ASTM)), the American Society of Mechanical Engineers (ASME) and the Institute of Electrical and Electronics Engineers (IEEE).

Secondly, ANSI emphasizes the formation of standards by the consensus of the representatives of all the interested parties of such standard (e.g., manufacturers, users, government and consumers), and therefore items such as openness, balance, consensus and adequacy are required by the ANSI Essential Requirements and must be met for the approval of a standards organization.

b) The United States International standardization strategy

As mentioned above, the United States government was not active in the area of international standardization; however, due to influencing factors such as increasing dependency of the United States economy on foreign trade, establishment of the TBT Agreement in 1995, and a strong policy of standardization by Europe, the United States is currently seeking to actively utilize international standardization.

In the United States standardization strategy, it was explicitly stated that the strength of the United States standardization system lies in standardization by conventional industry-led consensus, and such procedure shall be maintained. Acknowledging that the United States standardization system is based on the six principles of international standards[15] adopted by the TBT Agreement

---

[14] Chapter 10 of "Introduction to Standardization" (Trial Edition) by the Industrial Science and Technology Policy and Environment Bureau was referred to regarding this section. "Introduction to Standardization" (Trial Edition) can be obtained from the following website: http://www.jisc.go.jp/policy/hyoujunka_text/index.html.

[15] The six principles to be followed by an international standard according to the TBT Agreement -- (1) transparency; (2) openness; (3) fairness; (4) efficiency and market relevance; (5) consistency; and (6) consideration towards developing countries -- were adopted in the 2nd TBT agreement triennial review held in 2000.

and the TBT Committee for the advancement of the international standards (transparency, openness, fairness, efficiency and market compliance, consensus, performance base, consistency, appropriate procedures and technological support to developing countries), the United States has positioned itself to accelerate the consistent interpretation and application of these principles with a global-level strategy. In addition, the strategy expresses that the development and formation of the standardization system is still in progress, and outreach activities will be conducted to disseminate the huge benefits reaped by the business world, consumers and the entire society to the countries providing important commercial and market opportunities.[16]

This basic policy aims to clearly position the standards developed by the United States standards organizations that practically function as international standards organization as international standards for the TBT Agreement, and to further expand the influence of those standards by utilizing the power of the TBT Agreement by emphasizing that standardization by the consensus method complies with the six principles for international standards. Not limited to the above, the strategy includes the effort of having developing countries accept the United States standards. Judging from the above, the basic strategy of international standardization of the United States can be valued for encouraging international standardization by expanding the influence of the United States standards organizations formed on the basis of the already existing domestic standards system.

3) International standardization of Japan[17]

Traditionally, in Japan, the creation of superior products has been the major objective for companies and industries. As for the standards forming the framework, there is a tendency to expect that as a result of product development, standards used will naturally conform to international standards. In other words, the de facto standards obtained by companies or industries have been the center of the international standardization for Japan. On the other hand, as a main member of the ITU, Japan has been actively contributing to initiatives relating to de jure standards through international standardization organizations. However, in the ISO and IEC, Japan's efforts were weak. Some suggest that the government lacks the perspective of positioning the international standardization as a part of industrial and technology policies.

As a result of not being involved in the development of ISO 9000 series due to strong confidence in quality control of the Japanese industry, a situation emerged where the Japanese industry was forced to re-evaluate quality control after the ISO series was established as international standards in 1987. Through this experience, Japan realized the importance of participating in the development of international standards of ISO and IEC. Moreover, after the conclusion of the TBT Agreement in 1995, Japan completely switched its policy to actively participate in international standardization.

Important examples of such initiatives are "The way of future standardization policy of Japan"

---

[16] The above-mentioned contents are described in United States Standards Strategy (the revised national standards strategy of 2000) established by ANSI in coordination with the government, industries, standards organizations, consumer groups and academic societies in 2005. Furthermore, the strategy indicated other policy items such as reinforcement of partnership between the government and private sectors, enhancement of standardization in the environment, health and safety fields, promotion of active consumer participation in the development of standards, unification of procedures to utilize voluntary standards specified in the regulations, prevention and elimination of trade barriers by foreign regulations, continuation of efforts to accelerate and improve the efficiency of standardization, ensuring consistency of standards developed by different organizations, and the policy to enhance the standardization education.

[17] Chapter 6 of the "Introduction to Standardization" (Trial Edition) by the Industrial Science and Technology Policy and Environment Bureau was referred to regarding this section.

and "Standardization strategy" published by the Japan Industrial Standards Commission (JISC) in November 1997 and August 2001, respectively, emphasizing the importance of standardization, and the "International standardization public and private sectors strategic meeting" held by the Ministry of Economy, Trade and Industry in November 2011, strategically encouraging the standardization on par with the American and European countries before 2015. "The Aim of National standardization strategy" includes: (1) doubling the number of proposals for international standardization and (2) equaling the United States and Europe with respect to the number of people acting as secretariat of the ISO and IEC. In addition, in December, 2006, the Cabinet Secretariat intellectual strategic headquarters specified the following five items in the "International standards comprehensive strategy": (1) change the awareness of industries towards strengthening of standardization activity; (2) strengthen the international standardization activities in the nation as a whole; (3) develop human resource in international standards; (4) strengthen relations with other Asian countries; and (5) contribute to fair rule-making for international standards.

Japan's approach to international standardization is basically oriented in the same way as the international standardization of the EU, focusing on the reinforcement of participation in the development of international standards by international standards organizations such as the ISO and IEC. On the other hand, because the above-mentioned international standards organizations establishes standards through voting by the participating countries, Japan acknowledges the fact that it is necessary to deepen the relations with as many countries as possible in order to reflect its opinions; and the uniqueness of Japan's approach is the efforts for joint development and proposals of international standards and the promotion of standardization technological cooperation by conducting local seminars, sending exports and inviting scholars, especially with the Asia-pacific region with which Japan has a strong economic relationship.

3. ECONOMIC PARTNERSHIP AGREEMENTS

Next, how the product regulations of other countries are influenced through the economic partnership agreements will be examined. As an example, the FTA between the EU, the United States, and Republic of Korea including recent interesting regulations related to the TBT will be discussed.

Looking into the details, it can be seen that economic partnership agreements are a part of the international standardization strategy because contents of the rules pursued through an economic partnership agreement between the two countries reflect the strategic approach for international standardization by both countries. In addition, Japan's EPAs so far have provided affirmation of rights and obligations as well as mutual authentication based on the TBT Agreement (the system of approving the result of evaluation of conformity to standards of contracting country with Japan (conformity assessment)), but the contents do not directly influence the standards of the other contracting country.

1) The EU- Korea FTA

a) The general rules relating to the TBT

With regard to the TBT in general, the EU- Korea FTA stipulates the strengthening of cooperation with the objective to further understand the systems of both countries and improved market access, further strengthening measures of transparency and verification of obligations under the TBT Agreement related to technical regulations (when conducting a public consultation upon the development of technical regulations, interested persons such as partner companies are granted opportunities equal to its own people), exchange of information related to standards and conformity assessment procedure, along with the establishment of a TBT coordinator for monitoring the

implementation of the agreement. In addition, the FTA contains Annexes for electrical equipment, automobile and auto parts, medicine, medical equipment, and chemical products providing special provisions.

b) Annex related to electrical equipment

The Annex applies to technical regulations, standards and conformity assessment procedures introduced and maintained by concerned countries related to safety and electromagnetic compatibility of electrical equipment. The point to be focused on in this Annex is that, ISO, IEC and ITU have been designated as the international standards organizations, and if any international standards established by these organizations exist, then the related parts will be the basis for developing technical regulations and conformity assessment procedures. Along with that, the Annex stipulates that discussions should be held with the objective to establish a common approach and for the domestic standards organizations to participate in the development of the international standards by these organizations.

Other than that, when technical regulations and conformity assessment procedures by the concerned countries exist, an arrangement is made so that "self-declaration of conformity" by the supplier is deemed sufficient. Despite the fact that the approval of self-declaration of conformity by suppliers is mandatory for all the products immediately after the enforcement of the agreement, the EU restricted Republic of Korea to apply self-declaration of conformity only to certain products, and the EU has the authority to request the declaration to be based on evaluation reports issued by certain agencies.[18] Also, for three years from the enforcement of the agreement, mutual recognition is permitted instead of self-declaration of conformity. The point to be noted is that the EU has taken a restrictive and phased approach against Republic of Korea.

c) Annex related to automobile and automotive parts

In the Annex, both countries approved the World Forum for Harmonization of Vehicle Regulations, commonly known as WP29 as the international standardization organization (it falls under the framework of United Nations Economic Commission for Europe (UNECE)) and agreed to actively participate in the development of the WP29 regulations and to cooperate in the adoption of new WP29 regulations without delay.

Moreover, by utilizing the 1958 Agreement and 1998 Agreement (hereinafter, collectively referred to as "UNECE standards") provided by WP29, both the countries have placed provisions aiming for harmonization of their standards. Specifically, with regard to technical regulations related to automobile and automotive parts, provisions for recognition were provided to the effect that, if either UNECE standards or standards of one of the contracting countries are met, the technical regulations of the other country will be considered fulfilled, and also provisions for harmonization were provided to oblige harmonization with UNECE standards within five years of the enforcement of the agreement. In addition, when a trade problem occurs related to a technical regulation that is not covered by the recognition provisions or is covered by the harmonization provisions but is not yet harmonized, the country imposing the regulations shall respond to negotiation requests of the other country and set out the basis of such regulation with detailed explanations of related scientific or technical information.

The contracting countries should not introduce new regulations that deviate from the UNECE standards, but when such regulations deviating from the UNECE standards are maintained or

[18] However, with regard to products subject to mutual recognition, Republic of Korea must evaluate the risks arising out of the adoption of self-declaration of conformity every three years and must examine whether to implement the self-declaration of conformity or not.

introduced by a contracting country, the legitimate reason for the imposition of such a regulation will be examined every three years and the results along with scientific and technical grounds must be published and notified to the other country.

d) Reflections of International standardization strategy

The above is the major focus of the EU- Korea FTA that reflects the adoption of a strategy to promote the international standardization of standards set by the organizations on which the EU has strong influence. In the FTAs, ISO, IEC, ITU and WP29 were approved as international standards organizations and placed provisions aiming for active participation by both countries for development and formation of standards and regulations. The EU engaged Republic of Korea in its international standardization strategy and it is evident that the EU is trying to harmonize the standards and regulations of Republic of Korea with the international standards of these organizations. The strategy is directly manifested in the provisions of automobile and automotive parts that establishes recognition and harmonization of the UNECE standards.

2) The US - Korea FTA

a) General rules related to the TBT

The TBT chapter of the US- Korea FTA reconfirms the rights and obligations of the TBT Agreement, and strengthening areas such as standards, technical regulations and conformity assessment procedures and improving transparency (national treatment obligations related to participation in the developmental process of standards, technical regulations and conformity assessment procedures). In addition, provisions for monitoring the implementation of the agreement and establishment of the TBT Committee for accelerating the cooperation are included. The TBT chapter's provision regarding deciding the existence of international standards in the TBT Agreement based on the six principles for international standards is worthy of attention. The emphasis on the six principles for international standards should be regarded as a reflection of the international standardization strategy of the United States.

b) Rules related to automotive regulations

In the US- Korea FTA, in addition to the above general rules, the cabinet ministers of both countries exchanged correspondence establishing special rules related to the automotive sector. The main contents of the rules either substitutes or exempts Republic of Korean standards as follows.

Firstly, when the fleet average emission standard of non-methane organic gas emission specified according to the number of vehicles and year model sold in Republic of Korea is met, Korea's Ultra Low Emission Vehicle Standards (K-ULEV) are considered to be fulfilled and Republic of Korea's standard will be substituted. Particularly, in the standards stipulated as substitutes for the Republic of Korea standards, the standard values specified in the regulations of California, United States were applied; as a result, Republic of Korea approved the United States standards.

In addition, Republic of Korea introduced new regulations pertaining to motor vehicle fuel economy and greenhouse gas emissions in October 2010 but, Korea agreed to consider conformity to the reference standards of the above-mentioned regulations; for motor vehicles produced by a manufacturer who sold not more than 4500 units in 2009, either the average fuel economy or the average CO2 emissions meet a relaxed standard value of 19% of the reference standard value specified in the regulations.

Furthermore, if a US manufacturer sold no more than 25,000 motor vehicles in the Korean market in a certain calendar year and if such manufacturer's vehicle satisfies the U.S. Federal Motor-Vehicle Safety Standards (the "FMVSS"), it would be regarded as complying with Korean

Motor-Vehicle Safety Standards (the "KMVSS"). As a result, Republic of Korea had to approve the United States standards; however, regarding a part of commercial vehicles like buses and trucks, the Republic of Korean safety standards are applicable. In addition, if Republic of Korea introduces newly revised regulations related to automobile safety standards, they will not be applied to imported vehicles for at least two years after issuance.

As a result, the exemption and substitution of Republic of Korean standards imply that Republic of Korea has adopted the United States standards. This is consistent with the United States international standardization strategy which aims for other countries to adopt the standards set by standards organizations of its own country with large global impact, and can be regarded to have direct influence on the domestic standards and regulations of Republic of Korea. However, consistency with the agreement needs to be examined, as Republic of Korea only exempts vehicles fulfilling the United States standards from domestic standards.

4. Approach to Product Regulations by the Private Sector

There are enterprises in the private sector that actively and successfully participate in rule-makings in relation to product regulations of other countries. Recently, with regard to environmental issues, market environment preparations by developing countries, and changing consumer awareness in developing countries, the number of TBT notifications has been increasing, and it is certain that number of domestic product regulations subject to TBT notifications has been increasing. In addition, the act of pushing forward the regulatory harmonization at the governmental level in order to lower the trade barrier effects due to product regulations of a country in force means that cases of regulations established by one country or region spreading to other countries or regions are on the rise. Under these circumstances, specifically for enterprises operating on a global scale, it is very important that the international standards or product regulations of developing countries should be favorable to their business activities and should not become a hindrance. For that reason, in the private sector, a situation exists where enterprises not only seek support from their governments, but also involve themselves actively in the development of international standards and product regulations of other countries and increase efforts to reflect their interests by various means.

For governments, the main aspect is that foreign enterprises also revitalize the domestic economy and create jobs. Therefore, it is necessary to ensure opportunities for foreign enterprises to express opinions as provided by the TBT Agreement and economic partnership agreements. Also, foreign enterprises are treated as stakeholders of the domestic product regulations, and some governments are even keen to listen to those opinions. It may be said that the improvement of transparency in the development process of such product regulations means that opportunities to participate in the rule-making process have increased for the private sector.

As a specific example, the approach of a Japanese company in the development process of the WEEE Directives of the EU can be cited. In the development process of the WEEE Directives of the EU for environmental protection purposes, at the first reading of the European cabinet meeting the proposal imposed an excessive cost burden because enterprises in Europe were obligated to reuse and recycle a wide range of electric and electronic products. So the Japanese company explained this to each member of the European Parliament and distributed materials to convince the members that imposing recycling responsibilities on the equipment makers is unrealistic and absurd considering the fact that a majority of consumables are not manufactured by electric and electronic equipment makers. As a result, the claims of the Japanese company were accepted and revision of the bill was agreed upon at the second reading.

Another example is the approach of a Japanese company related to the tax treatment of lactic

acid bacteria beverage. The Japanese company started business selling the lactic acid bacteria beverage featuring health benefits; however, in many countries, a diary product must contain 50% to 70% milk constituent; the company's lactic acid bacteria beverage only contained 40% of milk constituent, and hence it was classified under soft drinks and subjected to unfavorably high taxation without regard for its health benefits. So, the Japanese company described the health benefits at the Codex Committee which develops and enforces international food standards, which finally resulted in the implementation of the company's request, thereby successfully avoiding being subjected to unfavorable taxation world-wide.

The increase in such successful cases indicate that the involvement of the private sector in the development process of international standards and product regulations of other countries has become an effective means to maintain and strengthen the international competitive power of an enterprise. Furthermore, this kind of multi-layered approach surrounding the rule formations for product regulations is becoming an important factor that cannot be ignored.

5. SUMMARY

As mentioned above, amidst the expansion and diversification of enterprises' activities beyond their national borders, it can be observed that governments and industries are trying to influence the rule-making for product regulations in many ways. Granted that product regulations cannot always be integrated internationally with fairness and rationality, the general goal of clarification and elaboration relating to the product regulations and the conformity assessment procedures basing on the TBT Agreement is considered as an important basis for rule-making for product regulations. With that in mind, every government is oriented towards expanding self-benefiting product regulations to other countries by utilizing various means including economic partnership agreements, and the private sector aims to maintain and strengthen its international competitive power by participating in the development process of international standards and product regulations of other countries. To understand the rule-making for the product regulations, which is the leading example of issues relating to domestic regulations, it is necessary to take into consideration such a multi-layered approach.