

Chapter 10

STANDARDS AND CONFORMITY ASSESSMENT SYSTEMS

1. OVERVIEW OF RULES

Standards and conformity assessment systems consist of technical regulations, standards, and procedures for determining whether products conform to those particular technical regulations or standards. These systems, used throughout the world, serve a variety of purposes, such as ensuring public safety and protecting the environment. Restricting trade must not be among their intended purposes.

However, standards and conformity assessment systems can function as *de facto* trade barriers when a country imposes criteria under which it is more difficult for foreign products than for domestic products to meet the relevant standards. Also, governments may implement standards and conformity assessment systems under the guise of the legitimate objectives mentioned above when, in fact, they are designed to limit imports or to subject imports to discriminatory treatment. In such cases, standards and conformity assessment systems can be trade-restrictive.

International disciplines are needed to eliminate the unnecessary trade restrictive effects of standards and conformity assessment systems. Some organizations, such as the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and the Joint FAO/WHO Food Standards Program Codex Alimentarius Commission have been working for years to create a unified system of international standards and conformity assessment systems.

In the GATT context, the Agreement on Technical Barriers to Trade (hereinafter referred to as the “Standards Code”) was concluded in 1979 as part of the Tokyo Round of the GATT negotiations. The Standards Code promoted the harmonization of

standards and conformity assessment systems and established rules on transparency and other aspects of trade related measures. Under the Uruguay Round, the Agreement on Technical Barriers to Trade (hereinafter referred to as the “TBT Agreement”) was created to make obligations under the Standards Code more definitive and to strengthen its provisions.

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”).

Participation in the Standards Code was discretionary. 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

TBT Agreement

The TBT Agreement sets forth certain requirements for technical regulations, standards, and conformity assessment procedures. These terms are defined as follows:

- *Technical regulations* — A document that lays down product characteristics or their related processes and production methods, with which compliance is mandatory;
- *Standards* — A document for products or related processes and production methods, with which compliance is not mandatory;
- *Conformity assessment procedures* — Any procedure used to determine whether relevant requirements in technical regulations or standards are fulfilled and to accredit conformity assessment bodies.

To ensure that such technical regulations, standards and conformity assessment procedures do not act as unnecessary barriers to trade, the TBT Agreement directs Members to ensure that products imported from the territory of any other Member must be accorded both most-favoured-nation treatment and national treatment, and that international standards must be used as a basis for new technical regulations in principle. It also requires Members to take appropriate measures to ensure transparency, such as notifying the WTO when developing or revising technical regulations.

In addition, the TBT Agreement requires two kinds of obligations for Members with respect to their central and local government standardizing bodies and their non-

governmental standardizing bodies. The first is the primary obligation for Members to ensure compliance by their own standardizing bodies with the TBT Agreement. The second is the related obligation for Members to take reasonable measures as may be available to them to ensure compliance by their own standardizing bodies with the TBT Agreement (*see* Figure 10-1).

Figure 10-1
Member Obligations

Level of Government	Compliance (primary obligation)	Reasonable measures to ensure the compliance of local gov. and non- governmental bodies (secondary obligation)
Central government	(1), (2), and <u>(3)</u>	
Local governments on the level directly below the central government (prefectural level)	<u>(1)</u> and <u>(3)</u> (obligation to notify WTO)	(2) (1) and <u>(3)</u> (obligation other than WTO notification)
Other local governments and non-governmental bodies		(1), (2), and <u>(3)</u>

Notes: - (1) = Technical regulations, (2) = Standards, (3) = Conformity assessment procedures
 - An underlined character indicates obligations expanded or strengthened by the TBT Agreement.
 All obligations under (3) were expanded, while (1) was strengthened with respect to local governments positioned one level directly below the central government.

In *EC-Asbestos* (WT/DS135), a Panel and the Appellate Body issued findings on the TBT Agreement's definition of "mandatory regulation". The case considered whether a January 1997 French ban, with a few exceptions, on the import and distribution of products containing asbestos for the purpose of protecting consumers and workers constituted a violation of the TBT and other WTO agreements. France argued that, in relation to the TBT Agreement, the measure was designed to ban asbestos, but not to lay down product characteristics, and therefore fell outside the scope of the TBT Agreement.

The Panel chose to deal separately with the ban and the exceptions to the ban. The Panel found that the exceptions, but not the ban itself, comprised a technical regulation under the TBT Agreement. The Appellate Body overturned this decision, determining that the ban and the exceptions to the ban should be examined as an "integrated whole" and, accordingly, found that the measure comprised a technical

regulation under the TBT Agreement. However, given that the Panel found the ban to be outside the scope of the TBT Agreement, the Panel made no findings on the substantive claims under the Agreement. In addition to the fact that the TBT Agreement had never been previously interpreted by a panel, the Appellate Body decided that it had no adequate basis to examine claims regarding TBT consistency and declined to do so.

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:

- 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).
- 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).
- “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).
- “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).
- 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).
- Members shall conduct risk assessment taking into account available scientific evidence (Article 5.2).
- 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).
- 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).
- “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).

- “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. NOTIFICATION TO THE WTO

The WTO disciplines on standards and conformity assessment systems emphasize the improvement of transparency by requiring notification of measures. The TBT Agreement and the SPS Agreement both include an obligation to notify other Members through the WTO Secretariat and to allow reasonable time for other Members to make comments when a relevant international standard does not exist and if new standards or conformity assessment systems may have a significant effect on the trade of other Members. The Committee on TBT and the Committee on SPS, established under the TBT Agreement and the SPS Agreement, recommend that this period of time be 60 days. (If possible, Members are encouraged to extend the comment period to ninety days.)

As supplementary information, we outline below the number of notifications made under the Standards Code and the TBT Agreement. Between 1980 and 2005 there were a total of 11,333 notifications, of which 939 were from Japan (*see* Figure 10-2). In 2004, 352 out of the total of 638 notifications (53 percent) provided comment periods in excess of the 60 days recommended, but in 2005, there was a slight improvement to 517 out of 771 (67 percent; *see* Figure 10-3).

Article 2.12 of the TBT Agreement and Article 2 of Annex B of the SPS Agreement provide that Members shall allow a reasonable interval between the publication of regulations and their entry into force. This allows time for producers in exporting Member countries, particularly in developing countries, to adapt their products and methods of production to the requirements of the importing Member. During the Fourth WTO Ministerial Meeting, held in November 2001, the phrase “reasonable interval” was declared to mean a period normally of not less than 6 months, except when this would hinder fulfilling the intended legitimate objectives.

Figure 10-2
Number of Notifications

Country	Under Standards Code		Under TBT Agreement			Total
	Year of participation	1980-1994	1995-2004	2005	Sub-Total	
Australia	1992	54	135	8	143	197
Canada	1980	396	249	38	287	683
EU	1980	226	259	22	281	507
Japan	1980	548	365	26	391	939
United States	1980	500	293	72	365	865
Total (including others)		4,464	6,098	771	6,869	11,333

(Source: GATT/WTO Documents)

Figure 10-3
Length of Comment Period

Country	2004				2005			
	Less than 45 days	45-59 days	60 days or more	Not specified or lapsed	Less than 45 days	45-59 days	60 days or more	Not specified or lapsed
Australia	4	2	4	0	1	5	2	0
Canada	3	5	23	1	1	6	29	2
EU	9	3	15	3	5	0	17	0
Japan	6	2	14	0	2	7	17	0
United States	6	17	14	1	13	27	32	0
Total (incl. Others)	87	68	352	150	79	112	517	72

(Source: WTO Documents)

4. RECENT DEVELOPMENTS

(1) TBT Triennial Review

Article 15.4 of the TBT Agreement requires the TBT Committee to review the implementation and operation of the Agreement every three years (the “triennial review”). The first triennial review was conducted in 1997, the second in 2000, the third in 2003 and the fourth in 2006.

The discussion at the fourth triennial review focused on the implementation and operation of the Agreement, including good regulatory practice (GRP), conformity assessment procedures, transparency, technical assistance and special and different treatment. The review covered most of the important topics surrounding the TBT Agreement except international standards, which was emphatically discussed at the second triennial review (WTO document number G/TBT/13).

The results of the fourth triennial review, as applicable, are detailed in the following sections.

(2) Good Regulatory Practice (GRP)

At the fourth triennial review, it was recognized that the discussion on GRP will contribute to the effective implementation of a TBT agreement that aims to remove unnecessary obstacles to international trade in the preparation, adoption and application of technical regulations, standards and conformity assessment procedures.

Regarding domestic regulatory policy in particular, it was noted that appropriate approaches other than regulation and the consideration of whether existing regulations should be maintained are important if regulatory authorities are to achieve their policy objectives and that regulatory impact assessments (RIAs) can be effective as a means to that end. Further, it was pointed out that it is important to reduce regulation in the form of compulsory standards, to standardize the performance of regulation, and to make full use of international standards and guidelines. Acceptance of other members’ standards as being on a par (Article 2.7 of the TBT Agreement) and cooperation between competent authorities and with other interested parties were also recognized as elements in GRP. In order to share these GRP experiences, it was agreed that a GRP workshop would be held in March 2007 to coincide with a meeting of the TBT Committee.

(3) Conformity Assessment Procedures

Conformity assessment procedures were also discussed at the third triennial review, and an exchange of information was carried out for the period of three years on the basis of the work programme as a priority agenda. Specifically, a “special meeting on conformity assessment” was held in July 2004 to coincide with the TBT Committee,

and the Workshop on Supplier's Declaration of Conformity and a workshop on different approaches to conformity assessment, including the acceptance of conformity assessment results, were held in March 2005 and in March 2006, respectively. At the 2005 workshop in particular, the recognition that the Supplier's Declaration of Conformity as one of the approaches to conformity assessment matters to be considered (risk levels and administrative costs), the need for technical assistance to developing members in building up the credibility for the utilization of Supplier's Declaration of Conformity, and the necessity of building infrastructure for conformity assessment to help enhance market confidence were confirmed. Based on these results, further discussions were held at the fourth triennial review.

The fourth triennial review reconfirmed the importance of the TBT Agreement rules (Article 5 to Article 9) on conformity assessment procedures, and also reaffirmed the importance of utilizing relevant international standards, guidelines or recommendations and accepting the results of conformity assessment procedures obtained at other member states. In particular, there was agreement that the unilateral approval of conformity assessment results in other countries, including the designation by governments, is an effective approach to facilitate the acceptance of conformity assessment results. It was also continuously encouraged to accept the participation of foreign conformity assessment bodies in domestic conformity assessment procedures. Furthermore, the review meeting agreed on an exchange of views on the necessity of conformity assessment procedures as well as on matters for consideration in deciding types of such procedures, and on the continuation of discussions on such matters as the benefits of and points of caution in suppliers' declaration of conformity (such as establishing test screenings) and the orientation of the accreditation as a means of ascertaining the technical capabilities of conformity assessment bodies.

(4) Mutual Recognition

Arrangements for mutual recognition between governments are called "Mutual Recognition Agreements (MRAs)." As the conclusion of an MRA allows conformity assessment procedures that were previously required to take place in an importing country to take place in an exporting country, it is expected to contribute to simplifying procedures and reducing the cost associated with conformity assessment, thereby further smoothing international trade. Article 6.3 of the TBT Agreement encourages WTO member states to enter into negotiations for the conclusion of mutual recognition agreements.

Japan has so far concluded (a) conventional-type (designated entrustment-type) MRAs; and (b) and external designation-type MRAs.

Conventional-type (designated entrustment-type) MRAs include the "Agreement on Mutual Recognition between Japan and the European Community" (hereafter referred to the "Japan-Europe MRA") and the "Agreement between Japan and the Republic of Singapore for a New Age Economic Partnership (JSEPA)", (of which Chapter 6 (hereafter referred to as "Japan-Singapore MRA") is dedicated to mutual recognition. Under conventional-type (designated entrustment-type) MRAs, even when

technical standards and conformity assessment procedures assigned to products differ between countries for the purpose of ensuring safety, if a third-party organization (conformity assessment body) designated by the government of an exporting country carries out the assessment of conformity on the basis of technical standards and conformity assessment procedures of the government of the importing country, the government of the importing country accepts the assessment results as good as a conformity assessment conducted in the importing country.

Because of the above-described mechanism, the government of an exporting country needs to designate and oversee a conformity assessment body within an exporting country on the basis of relevant laws and regulations of the government of an importing country.

Under external designation-type MRAs, the government of an importing country directly designates a conformity assessment body in an exporting country on the basis of its domestic laws and regulations, and the results of conformity assessments conducted by a conformity assessment body in an exporting country on the basis of technical standards and conformity assessment procedures of an importing country are mutually accepted.

Japan has so far concluded an external designation-type MRA with the Philippines, and is considering the conclusion of external designation-type MRAs with other countries going forward.

Against the background described above, after confirming that there still exist difficulties regarding governmental mutual recognition agreements arising from the different levels of development among member states, costs, opacity and the nature of not having most-favoured-nation status, the fourth triennial review by the TBT Committee reconfirmed that the utilization of international standards, guidelines, and recommendations and further harmonization of conformity assessment procedures will help facilitate the agreement of mutual recognition agreements. Furthermore, it was noted that if governments mutually introduce external designation systems for the same area of products, it would lead to mutual recognition agreements with a high degree of cost-benefit performance.

The outcome of the discussions reflects views expressed in Japan's proposal paper concerning the report of the fourth triennial review.

Note: Japan's proposal paper (March 2006) (G/TBT/W/263)

The paper proposed: (i) promotion of the utilization of international standards and guidelines for conformity assessment; (ii) encouragement of the adoption of external designation schemes for the acceptance of results of conformity assessments carried out by conformity assessment bodies of other countries; (iii) promotion of the understanding that mutual adoption by member states of external designation schemes for the same product areas is one form of mutual recognition agreements; and (iv) promotion of the participation of developing countries in international standardization

activities.

The fourth triennial review meeting also agreed that the existence of voluntary mutual recognition arrangements between domestic conformity assessment bodies and foreign conformity assessment bodies may help promote the acceptance of the results of conformity assessment conducted in other countries, and further agreed on an exchange of information on the status of the administration of existing governmental mutual recognition agreements and the cost-benefit performance of governmental mutual recognition agreements as well as on voluntary mutual recognition arrangements between conformity assessment bodies and their utilization by regulatory authorities.

(5) Transparency

When member states develop standards and conformity assessment systems in their country, the TBT Agreement, for the purpose of ensuring the transparency in the process of developing domestic regulations, requires that such states notify other member states through the WTO Secretariat of an outline of draft plans and other matters and set forth a period during which they will accept comments from other members. At the fourth triennial review meeting, it was noted that there are no unified methods for making prior announcements of intention in accordance with Article 2.9.1 and Article 5.6.1 of the TBT Agreement, and it was agreed to consider such announcement methods going forward. Also, in order to promote the access to draft proposals for compulsory standards or conformity assessment procedures notified to the TBT Committee, member states were encouraged to provide information on access methods in the notification forms. Furthermore, the review meeting reconfirmed that the comment period on the notification to the TBT Committee should be “at least 60 days, and possibly 90 days” and the period between the announcement and enforcement of compulsory standards should be “at least six months,” and also encouraged member states to “set up a sufficient period” between the end of the comment period and the announcement of compulsory standards and conformity assessment procedures.

(6) Technical Assistance

With regard to shared recognition among member states, the implementation of appropriate technical assistance stipulated under Article 11 of the TBT Agreement requires support that adequately meets the needs of developing member states. At the third triennial review it was agreed to consider the creation of an information coordination mechanism to be based on voluntary notification by aid donors and aid recipients about current and future technical assistance activities. In the wake of this accord, an agreement was worked out in November 2005 on the format concerning needs and responses for specific technical assistance, and trial operation of the voluntary notification system is already under way using the agreed format. At the fourth triennial review meeting, member states were encouraged to utilize the newly created notification system. The operation of the notification system is to be reviewed at the end of 2007.

(7) Special and Different treatment

At the fourth triennial review meeting, member countries were encouraged to notify the TBT Committee of special and different treatment accorded to developing member states in their planning of compulsory standards and conformity assessment procedures, including information about how they considered such special and different treatment, and developing nations were encouraged to make an assessment of the usefulness and benefits of such special and different treatment.

(8) Labelling

Using labelling as a tool to provide consumers with information is increasing among many Members. A large number of specific labelling systems of Members have been brought before the TBT Committee. Since the second triennial review, discussions over labelling have focused on whether it could create unnecessary obstacles to trade. At the second triennial review, the EC proposed a work program on multifaceted guidelines for labelling. This, however, was strongly opposed by developing countries, which worried that the guidelines could legitimise labelling as disguised trade restrictions. Consequently, no agreement was reached. The TBT Committee continues to discuss the issue and proposals were submitted to the TBT Committee by Canada, Japan, the EC and other members in March and June 2002¹. This led to recognizing the need to determine the relevant facts and, in October of that year, the Secretariat prepared a paper summarizing the labelling issues that had so far been brought before the meeting. Also, a “learning event” was held in October 2003 to develop greater understanding on labelling (because of strong opposition from mainly developing countries to create a forum for reviewing the pros and cons of individual labelling systems, the forum was named a learning event rather than a workshop and let countries learn the case studies of other countries).

Discussions during the third triennial review disclosed conflicts among the EU, Switzerland and other countries, which argued for further clarification of rules and creating a work plan. The United States, developing countries and others strongly opposed this approach. As a result, the third triennial review, as did the second, concluded that a need for discussion continued to exist.

Environmental labelling was also on the agenda of the WTO “Committee on Trade and Environment” (CTE). Environmental labelling involves affixing a label indicating that a product is environment-friendly in order to communicate the environmental benefits of the product to consumers and to expand the market for conservation-oriented goods. Such systems have been adopted by Japan and many other developed countries.

¹ The Japanese Paper was submitted in June 2002. Japan conducted a factual analysis based on interviews with industry members and submitted a paper to the TBT Committee recommending international standardization in conjunction with existing international standardizing bodies, arguing for the need for acceptance of Annex 3 of the TBT Agreement (Code of Good Practice for the Preparation,

Developed and developing countries differ in their views of environmental labelling. The developed countries argue that such labelling is useful for conservation purposes and has very little detrimental impact on trade; the developing countries have concerns that trade could indeed be impaired. All countries agree, however, that it is important to maintain transparency in such systems and that the issues need to be fully discussed in the future. (However, differences exist over which WTO committee should be responsible for the discussions. Some demand that the CTE take up the responsibility, while others claim that the TBT Committee is the proper authority.)

If environmental labelling is covered by the TBT Agreement, then transparency will be ensured through the application of the provisions of the Agreement. Members, however, differ on the question of whether mandatory labelling based on processes and production methods that are unrelated to product characteristics would be covered by the TBT Agreement. For example, the “Life Cycle Assessment” (LCA) has become an increasingly common standard for environmental labelling. This approach considers the positive and negative effects on the environment at all stages of a product’s life cycle, from design to disposal. In addition to the environmental characteristics of the product itself (energy savings and other attributes), the LCA also considers processes and production methods that are not directly related to the characteristics of the product. For example, waste fluids generated by the production process or the use of CFCs would be considered.

Some have argued that mandatory labelling based on processes and production methods not directly related to product characteristics could violate a basic GATT principle: that like products be treated equally. This is an issue that will require careful discussion in the future.

At the fourth triennial review, a proposal for itemized discussion on labelling was made, but it was not adopted on the grounds that the issue had already been fully discussed at the second and third triennial review meetings.

5. 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.

Adoption and Application of Standards) and promoting the use of performance-based standards.

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.

6. MAJOR CASES

EU – 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 complainant 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 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.

EU – 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, totalling 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 United 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 EU, however, failed to withdraw the import ban by the deadline, prompting the United States and Canada on May 14, 1999, to seek approval from the WTO for temporary suspension of concessions on imports from the EU equivalent to \$220 million and \$70 million, respectively.

On July 12, 1999, a WTO arbitrator found that economic damage to the United States and Canada as a result of the EU measures totalled \$117 million and \$11.3 million, respectively. The DSB approved a suspension of concessions based on these findings. In accordance with WTO procedures, the United States increased tariff rates effective 29 July 1999. Canada did likewise, effective 1 August 1999.