

CHAPTER 5

Mandatory and voluntary product standards and sanitary and phytosanitary regulations

Summary of the main rules

Countries often require imported products to conform to the mandatory standards they have adopted for the protection of the health and safety of their people or for the preservation of their environment.

*The Agreement on Technical Barriers to Trade (TBT) provides that such mandatory product standards should not be so applied by countries as to cause **unnecessary obstacles to international trade**. Furthermore, they should be based on scientific information and evidence.*

*The Agreement visualizes that mandatory product standards do not create unnecessary barriers to trade if they are based on **internationally agreed standards**. Where for geographical, climatic and other reasons, it is not possible for member countries to base their mandatory regulations on international regulations, they are obliged to publish these regulations in draft form to give producers in other countries an opportunity to comment on them. The Agree-*

ment also obliges member countries to take such comments into consideration when the standards are finalized, thus ensuring that the characteristics of products produced in, and exported by, other countries are taken into adequate account.

Voluntary standards, with which compliance is not mandatory, may also pose problems in international trade if they differ widely from country to country. The Code of Good Practice for the Preparation, Adoption and Application of Standards, an integral part of the Agreement on TBT, therefore urges countries to use their best endeavours to require national standardizing bodies to use the same principles and rules in preparing and applying voluntary standards as are laid down for mandatory standards.

Countries also require the compliance of imported agricultural products with their national sanitary and phytosanitary regulations. The primary aim of these regulations is to protect human, animal or plant life or health from pests and diseases that may be brought in by imported agricultural products. The rules which the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) lay down are similar to those applicable to mandatory product standards. There are, however, some important differences.

The Agreement on TBT requires mandatory product standards to be applied on a non-discriminatory basis to imported products. The Agreement on SPS permits countries to apply measures on a discriminatory basis, taking into account such factors as the differences in the level of prevalence of specific diseases or pests. The SPS Agreement further permits countries to take measures to restrict imports on a

provisional basis, as a precautionary step, in cases where there is imminent risk of the spread of diseases, but the “scientific evidence is insufficient”. There is no such provision in the TBT Agreement.

1. Role of standards

Product standards play an important role in cutting costs by reducing the variety of inputs and machine tools used in production. This leads to savings in the costs of design, production, handling, storing. Standards are indispensable in international business transactions because they ensure a uniform level of quality in merchandise. Standards also reduce disputes over specifications and the quality of goods and services exported or imported.

Many standards used in business transactions are voluntary. In practice, exporting enterprises may find that some of these have the effect of mandatory standards. This happens when large industries refuse to buy goods that do not conform to the standards they impose.

Governments often lay down health and safety standards for various products. These laws have been passed to protect consumers who have no means of assessing the risks involved in using these goods. Standards are also established to protect the environment and natural resources. In recent years, increasing environmental awareness has led to the promulgation of new health and safety regulations.

When product standards adopted at national level vary from country to country, manufacturers have to adjust their production processes to meet the differing technical specifications of their target markets. This increases tooling costs and prevents companies from taking advantage of economies of scale. This is why efforts are being made in international organizations to harmonize standards on a world-wide basis.

2. Agreement on Technical Barriers to Trade (TBT)

2.1 Product standards

TBT, Annex I

International rules applicable to product standards are contained in the Agreement on Technical Barriers to Trade. The Agreement uses the term “technical regulations” to cover standards with which compliance is mandatory. The term “standard” is used for voluntary standards.

Both terms cover:

- ☐ Product characteristics;
- ☐ Process and production methods (PPM) that have an effect on product characteristics;
- ☐ Terminology and symbols; and
- ☐ Packaging and labelling requirements as they apply to the product.

The rules of the Agreement apply to process and production methods only if these methods have an effect on the quality or other characteristics of the product. Other processes and production methods are not covered by the provisions of the Agreement. (See box 12.)

2.2 Technical regulations

2.2.1 Main conditions

TBT, Preamble

The Agreement recognizes that countries have the right to adopt technical regulations which prescribe mandatory product standards (including packaging and labelling requirements). These regulations are enacted to ensure the quality of exports, to protect human health or safety, animal or plant life

Box 12**DISTINCTION BETWEEN PRODUCT STANDARDS
AND PPM STANDARDS**

Product standards define product characteristics, or the product's quality, design or performance. They need to be distinguished from standards for process and production methods (PPMs, as they are commonly called) which specify norms relating to how goods should be produced. PPM standards apply before and during the production stage, i.e. before the product is placed on the market.

The provisions of the Agreement on TBT apply primarily to product standards. They do not cover PPM standards, except when the production process or method used has an effect on product quality.

Assume that country A prohibits imports of pharmaceuticals from country B. Its grounds are that country B has failed to meet its requirements for proper manufacturing practices and plant cleanliness, thereby affecting product quality. In this case the PPM standard is covered by the TBT Agreement and country A can justify its action if it can establish that its production and processing requirements have an impact on product quality.

Now assume that country A prohibits imports of steel on the grounds that pollution standards at the steel plant in country B are much lower than those enforced by country A. In this case, no environmental damage is done to the importing country; country A's process standard would therefore not be covered by the Agreement and its prohibition on imports would not be justifiable.

or the environment, among other objectives. The Agreement requires member countries to ensure that their technical regulations meet certain conditions:

TBT, Article 2.1

- ☐ They should be applied on an MFN basis to imports from all sources;

TBT, Article 2.1

- ☐ They should not extend to imported products treatment that is less favourable than that extended to domestically produced products (national treatment principle);

TBT, Article 2.2

- ☐ They should not be formulated and applied in a manner as to cause an “unnecessary obstacle to trade”; and
- ☐ They should be based on scientific information and evidence.

TBT, Article 2.2

The Agreement also specifies criteria which regulatory authorities have to bear in mind in formulating technical regulations, in order to ensure that they do not create unnecessary obstacles to trade.

2.2.2 Requirement to base technical regulations on international standards

TBT, Article 2.4

One way of ensuring that technical regulations do not create barriers to trade is to base them on international standards. The Agreement therefore imposes an obligation on countries to use international standards as a basis for their technical regulations. An exception is made when the regulatory authorities believe that the international standards would be ineffective or inappropriate in view of climatic, geographical, or technological factors. Further, in order to harmonize technical regulations on an international basis, the Agreement calls on WTO member countries to participate actively in the work of International Organization for Standardization (ISO) and other international standardization organizations.

2.2.3 Opportunity to comment on draft standards

TBT, Article 2.9

The Agreement also prescribes certain procedural rules to be followed when countries are adopting mandatory technical regulations that are not based on existing international standards. Member countries are required to publish a notice and to notify the WTO secretariat when they adopt technical regulations not based on existing international

standards. In addition, they must provide sufficient notice in advance of the adoption of the regulation. These provisions are intended to provide interested exporting countries with an opportunity to comment on the draft standards with a view to ensuring that, when the final regulations are adopted, the characteristics of products produced in their countries are taken into account. The Agreement imposes an obligation on countries proposing the adoption of a technical regulation to take the comments of the exporters into account when finalizing the regulation.

2.2.4 Rules governing certification of conformity with standards

For some of the products to which mandatory standards apply, the regulatory authorities may require that imports can be sold only if the manufacturer or exporter is able to obtain a certificate of *positive assurance* from a recognized institution or laboratory in the importing country that the product is in conformity with the standard. In order to ensure that foreign suppliers are not put in a disadvantageous situation when obtaining certificates of positive assurance of conformity, the Agreement stipulates that:

- ☐ Conformity assessment procedures should not accord to foreign suppliers treatment which is less favourable than that accorded to domestic suppliers;
- ☐ Any fees charged to foreign suppliers should be equitable in relation to those chargeable for products of domestic origin; and
- ☐ The selection of samples for testing should not be made as to cause inconvenience to foreign suppliers.

2.2.5 *Mutual recognition of certificates of conformity assurance*

TBT, Article 6

For products for which regulatory authorities require assurance of conformity to standards, the Agreement encourages countries to accept the results of the inspections and tests carried out by competent certifying bodies in the exporting countries if they are satisfied that product standards and the procedures for assessment of conformity are *equivalent* to their own. However, it emphasizes that entering into arrangements for the mutual recognition of conformity assessment certificates will be possible only if the importing country has confidence in the technical competence of the conformity assessment body of the exporting country.

2.2.6 *Obligations of local government bodies*

TBT, Article 7

In a number of countries, technical regulations imposing mandatory standards as well as systems for assessing conformity with such standards are formulated and applied not only by central government bodies but also by local and non-governmental bodies. The Agreement imposes a binding obligation on member countries to require their central government bodies to abide by its discipline in formulating and applying mandatory standards. However, as the central governments which are signatories to the Agreement are not allowed by the constitutions of some countries to assume binding obligations on behalf of local bodies, it calls on these governments to “take such reasonable measures as may be available to them” to ensure that these local bodies abide by the Agreement’s discipline.

2.3 *Voluntary standards*

As noted earlier, many of the standards used by industries and exporters are voluntary standards.

TBT, Article 4; TBT, Annex 3

These are often formulated by national standardizing bodies in the various member countries. Voluntary standards can create problems in international trade if they vary widely from country to country. The Agreement has therefore developed a *Code of Good Practice* with which national standardizing bodies are expected to abide in preparing, adopting and applying standards. The code requires national standardizing bodies to follow principles and rules that are similar to those specified for mandatory standards. Thus the code urges them:

- ❑ To use international standards as a basis for its national standards;
- ❑ To participate fully, within the limits of their resources, in the preparation of international standards for products for which it proposes to adopt national standards.

Furthermore, in order to acquaint foreign producers with the work on standardization that is being undertaken by national bodies in different countries, it requires these bodies to publish their work programme “at least once every six months”, giving information on the standards that they are preparing and the standards they have adopted in the preceding period. At the time of publication, the national bodies are also required to notify the ISO/IEC¹¹ Information Centre of the name of the publication and how and where it can be obtained.

The code also requires standardizing bodies to allow a period of at least 60 days for the submission of comments by interested parties in outside countries. The comments are usually forwarded

11 ISO/International Electrotechnical Commission.

through their national standardizing bodies. The code calls on the standardizing body formulating the standard to take these comments into account when finalizing the standard.

3. Sanitary and phytosanitary measures (SPS)

A number of imported agricultural products — particularly plants, fresh fruits and vegetables, meat, meat products and other food products — may be required to satisfy sanitary and phytosanitary regulations as well as product standards. In addition, many countries restrict the export of these products if they do not meet the quality requirements specified by regulations. Box 13 illustrates how these regulations can affect international trade.

The Agreement on the Application of Sanitary and Phytosanitary Measures, which was negotiated in the Uruguay Round, specifies the principles

Box 13

WHY KNOWLEDGE OF HEALTH AND SANITARY REGULATIONS IS IMPORTANT IN PLANNING FOR EXPORT: AN EXAMPLE FOR FRESH FRUITS AND VEGETABLES

A number of major importers of fresh fruits and vegetables have strict regulations on plant protection. These countries require fresh commodities from countries with specific pests, especially the fruit fly of the *Tephritidae* family, to be treated to prevent the establishment of the pests in their territories. In the past, ethylene dibromide (EDB) was widely used for the fumigation of such produce prior to importation. The prohibition of EDB by the United States, Japan, and other countries jeopardized trade in fresh fruits and vegetables originating from tropical and semi-tropical countries. Alternative treatments to EDB fumigation such as vapour and dry heat treatment, hot water dips, refrigeration at near 0°C for a specific duration, and treatment with other chemicals such as methyl bromide, phosphine and cyanide, are now used with varying degrees of success.

SPS, Annex A

and rules which member countries must use in regulating imported products. The Agreement defines sanitary and phytosanitary measures as measures taken to protect human, animal or plant life or health:

- ❑ “From risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- ❑ ...from risks arising from additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs;
- ❑ ...from diseases carried by animals, plants or products thereof”.

Like the Agreement on TBT, the SPS Agreement requires countries:

SPS, Preamble

- ❑ To base their SPS regulations on international standards, guidelines or recommendations;

SPS, Preamble

- ❑ To play a full part in the activities of international organizations, particularly the Codex Alimentarius Commission, International Office Epizootics and International Plant Protection Convention, in order to promote the harmonization of SPS regulations on an international basis;

SPS, Annex B:5

- ❑ To provide an opportunity to interested parties in other countries to comment on draft standards when they are not based on international standards or the international standards are not considered appropriate; and

SPS, Article 4

- ❑ To accept the SPS measures of exporting countries as equivalent if they achieve the same level of SPS protection.

The SPS Agreement, however, differs from the TBT Agreement in three important respects:

- First, the TBT Agreement requires that product standards should be applied on an MFN basis. The SPS Agreement permits standards to be applied on a discriminatory basis provided that they “do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail”. The rationale for this rule is that, owing to differences in climate, the incidence of pests or diseases, and food safety conditions, it is not always appropriate to impose the same sanitary and phytosanitary standards on animal and plant products originating from different countries.
- Second, the SPS Agreement provides greater flexibility for countries to deviate from international standards than is permitted under the TBT Agreement. As noted earlier, the TBT Agreement allows a country to deviate from international standards if this is necessitated by “fundamental climatic or geographical factors or fundamental technological problems”. Its provisions thus make it clear that the adoption of a standard which is different (either lower or higher) will have to be justified on scientific or technical grounds.

SPS, Article 2:3

SPS, Article 3:3

The SPS Agreement, on the other hand, states that a country may introduce or maintain an SPS measure resulting in a higher level of SPS protection than that achieved by an international standard if there is scientific justification or when the country determines that a higher level of protection would be appropri-

- ate. In the latter case, the Agreement offers certain guidelines. It states that the appropriate level of protection should be based on an assessment of risk appropriate to the circumstances, available scientific evidence, relevant process and production methods, and the prevalence of specific diseases or pests.
- SPS, Article 5.2
- SPS, Article 5.3 ☐ Third, in assessing the risk to animal or plant life or health, economic factors such as the establishment or spread of pests or disease; the costs of control or eradication in the importing member country; and the relative cost-effectiveness of alternative approaches to limiting risks should be taken into consideration.
- SPS, Article 5.4 ☐ Fourth, in determining the appropriate level of SPS protection, the objective of minimizing negative trade effects should be borne in mind.
- SPS, Article 5.7 ☐ Fifth, the SPS Agreement permits countries to adopt SPS measures on a provisional basis, as a precautionary step, in cases where there is imminent risk of the spread of diseases, but the “scientific evidence” is insufficient.

4. Business implications

The number of technical regulations laying down mandatory standards is steadily increasing in most countries. The trend is the response of governmental regulatory authorities to growing public demand that products marketed should meet minimum quality and safety standards, and not have any adverse impact on the health of the consuming public and on the environment. The same considerations often impel regulatory authorities to set and apply stricter health and sanitary regulations. Box 14 pre-

sents an illustrative list of products for which countries adopt mandatory safety or health standards. Box 15 lists agricultural products to which health and sanitary regulations are applicable in most countries.

One of the main problems enterprises face in developing export trade is the lack of adequate information about the standards and health and sanitary regulations applicable to their products in target mar-

Box 14

ILLUSTRATIVE LIST OF IMPORT PRODUCTS SUBJECT TO MANDATORY STANDARDS

Machinery and equipment

- Boilers
- Electrically driven construction and assembly tools
- Metal and wood-working equipment
- Medical equipment
- Food processing equipment

Consumer articles

- Pharmaceuticals
- Cosmetics
- Synthetic detergents
- Household electric appliances
- Video and TV sets
- Cinematographic and photographic equipment
- Automobiles
- Toys
- Certain food products

Raw materials and agricultural inputs

- Fertilizers
- Insecticides
- Hazardous chemicals

Box 15**LIST OF AGRICULTURAL PRODUCTS GENERALLY SUBJECT
TO HEALTH AND SANITARY REGULATIONS**

Fresh fruits and vegetables
Fruit juices and other food preparations
Meat and meat products
Dairy products
Processed food products

TBT, Article 10:3
SPS, Annex B:3

kets. To help enterprises obtain such information, the two Agreements require each member country to establish *enquiry points* from which information can be obtained by interested business enterprises on:

- ☐ Technical regulations and voluntary standards adopted or proposed to be adopted;
- ☐ Conformity assessment procedures, adopted or proposed to be adopted;
- ☐ Sanitary and phytosanitary regulations adopted or proposed to be adopted;
- ☐ Control and inspection procedures, production and quarantine treatment, pesticide tolerance treatment and food additive approval procedures;
- ☐ Risk assessment procedures.

Appendices I and II list the enquiry points that have been established by different member countries under the provisions of TBT and SPS Agreements.

As has been noted, the two Agreements aim at protecting the interests of foreign suppliers. They do this by requiring that standards — both mandatory and voluntary — as well as health and sanitary standards should not be formulated and applied in such a way as to cause *unreasonable barriers to trade*. It is therefore in the interest of exporting enterprises to examine whether the product standards, health or sanitary regulations or the testing and inspection requirements of their export markets conform with the criteria and rules laid down by the Agreements whenever they encounter difficulties in complying with them. If such examination shows non-conformity, they should bring the matter to the notice of the appropriate authorities in their national governments. This will enable their governments to raise the matter either bilaterally with the government of the importing country or in WTO forums with a view to securing modifications in the offending standards or regulations.

In effect, the ability of governments to derive full advantage from these Agreements will depend on how far the practical problems encountered by enterprises in their foreign markets are brought to their notice. Enterprises in turn can do this only if they have full knowledge and understanding of the provisions and rules of the Agreements.

The Agreements further visualize that, in certain areas, their implementation will be possible only if appropriate arrangements are established for consultations and cooperation between national standardizing bodies and authorities responsible for overseeing the operation of the Agreements on the one hand and exporting industries and/or their associations on the other hand. Thus, the Agreements require that in order to ensure that the adoption of standards

does not create an unnecessary obstacle to trade, countries should participate actively in the work of international organizations developing international standards for the product for which they propose to adopt standards or regulations. This participation, however, calls for cooperation among national standardizing bodies, producing enterprises, and government departments. In most cases, responsibility for the research and the preparation of technical studies required for international discussions devolves on producing enterprises.

The Agreements further require that where the standards on which technical or health and sanitary regulations are based do not conform to international standards, the draft regulations should be published and an opportunity provided to member countries to comment on it. The basic purpose of this rule is to ensure that regulations adopted take into adequate account the production and other standards prevailing in other countries. The main responsibility for providing such comments falls on the producing and exporting industries.