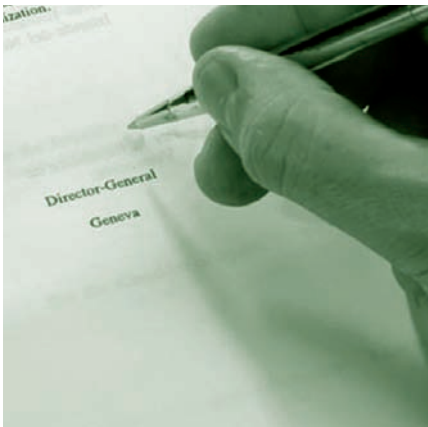
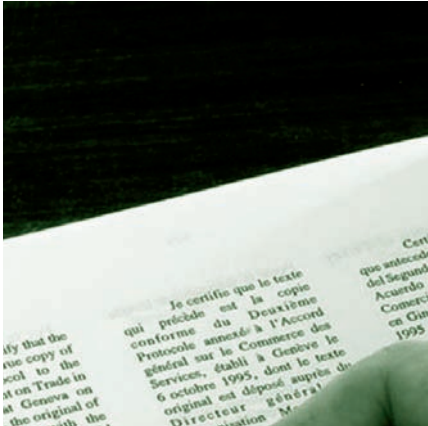




WORLD TRADE
ORGANIZATION

The WTO Agreements Series Sanitary and Phytosanitary Measures



The WTO agreements series

The WTO's agreements are the legal foundation for the international trading system that is used by the bulk of the world's trading nations. This series offers a set of handy reference booklets on selected agreements. Each volume contains the text of one agreement, an explanation designed to help the user understand the text, and in some cases supplementary material. They are intended to be an authoritative aid for understanding the agreements, but because of the legal complexity of the agreements, the introductions cannot be taken as legal interpretations of the agreements.

The agreements were the outcome of the 1986–1994 Uruguay Round of world trade negotiations held under the auspices of what was then the GATT (the General Agreement on Tariffs and Trade). The full set is available in *The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts*. It includes about 60 agreements, annexes, decisions and understandings, but not the commitments individual countries made on tariffs and services. A full package of agreements that includes over 20,000 pages of commitments is available from WTO Publications in a 34-volume set, as well as a CD-ROM, *The Results of the Uruguay Round*.

The volumes in this series

Agreement Establishing the WTO

Agriculture

GATT 1994 and 1947

Sanitary and Phytosanitary Measures

Technical Barriers to Trade

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Introduction

The Agreement on the Application of Sanitary and Phytosanitary Measures (the “SPS Agreement”) entered into force with the establishment of the World Trade Organization on 1 January 1995. It concerns the application of food safety and animal and plant health regulations.

This booklet discusses the text of the SPS Agreement as it appears in the Final Act of the Uruguay Round of Multilateral Trade Negotiations, signed in Marrakesh on 15 April 1994. This Agreement and others contained in the Final Act, along with the General Agreement on Tariffs and Trade as amended (GATT 1994), are part of the treaty which established the World Trade Organization (WTO). The WTO superseded the GATT as the umbrella organization for international trade.

The WTO Secretariat has prepared this booklet to assist public understanding of the SPS Agreement. The first section of the booklet presents the basic structure of WTO agreements; the second looks at the key features of the SPS Agreement; the third addresses a number of frequently-asked questions; and the fourth is the legal text of the agreement. The booklet is not intended to provide a legal interpretation of the agreement.

The basic structure of WTO agreements

The conceptual framework

Broadly speaking, the WTO agreements for the two largest areas of trade — goods and services — share a common three-part outline, even though the detail is sometimes quite different (see Figure 1).

- They start with broad principles: the General Agreement on Tariffs and Trade (GATT) (for goods), and the General Agreement on Trade in Services (GATS). The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) also falls into this category although it has no additional parts.

Figure 1: The basic structure of the WTO agreements

| <i>Umbrella</i> | AGREEMENT ESTABLISHING THE WTO | | |
|----------------------------------|---------------------------------------|--|------------------------------|
| | Goods | Services | Intellectual property |
| <i>Basic principles</i> | GATT | GATS | TRIPS |
| <i>Additional details</i> | Other goods agreements and annexes | Services annexes | |
| <i>Market access commitments</i> | Countries' schedules of commitments | Countries' schedules of commitments (and MFN exemptions) | |
| <i>Dispute settlement</i> | DISPUTE SETTLEMENT | | |
| <i>Transparency</i> | TRADE POLICY REVIEWS | | |

- Then come additional agreements and annexes dealing with the special requirements of specific sectors or issues. These deal with the following:

For goods (under GATT)

Agriculture

Regulations for food safety, animal and plant health protection (SPS)

Textiles and clothing

Product standards (technical barrier to trade)

Investment measures

Anti-dumping measures

Customs valuations methods

Preshipment inspection

Rules of origin

Import licensing

Subsidies and counter-measures

Safeguards

For services (the GATS annexes)

Movement of natural persons

Air transport

Financial services

Shipping

Telecommunications

- Finally, there are the detailed and lengthy schedules (or lists) of commitments made by individual countries allowing specific foreign products or service-providers access to their markets. For GATT, these take the form of binding commitments on tariffs for goods in general, and combinations of tariffs and quotas for some agricultural goods.

For GATS, the commitments state how much access foreign service providers are allowed for specific sectors, and they include lists of types of services where individual countries say they are not applying the “most-favoured-nation” principle of non-discrimination.

Much of the Uruguay Round dealt with the first two parts: general principles and principles for specific sectors. At the same time, market access negotiations were possible for industrial goods. Once the principles had been worked out, negotiations could proceed on the commitments for sectors such as agriculture and services. Negotiations after the Uruguay Round and before the Doha Round began in 2001 focused largely on market access commitments: financial services, basic telecommunications, and maritime transportation (under GATS), and information technology equipment (under GATT).

The agreement in the third area of trade covered by the WTO — on intellectual property — is at the level of basic principles although some details on specific areas (for example on copyright, patents, trademarks, geographical indications) are handled in the agreement. Other details come from conventions and agreements outside the WTO.

The agreements on dispute settlement and trade policy reviews are also essentially at the level of basic principles.

Also important

One other set of agreements not included in the diagram above is also important: the two “plurilateral” agreements not signed by all members: fair trade in civil aircraft and government procurement. (Originally there were four agreements, but those concerning dairy products and bovine meat were terminated at the end of 1997.)

The legal framework

The conceptual structure is reflected in the way the legal texts are organized. The short Marrakesh Agreement Establishing the World Trade Organization sets up the legal and institutional foundations. Attached to it is a much lengthier set of four annexes.

Finally, the Marrakesh texts include a number of decisions and declarations on a wide variety of matters that were adopted at the same time as the WTO Agreement itself.

- Annex 1 contains most of the detailed rules, and is divided into three sections:
 - 1A, containing the revised General Agreement on Tariffs and Trade, the other agreements governing trade in goods, and a protocol which ties in individual countries' specific commitments on goods;
 - 1B, the General Agreement on Trade in Services, texts on specific services sectors, and individual countries' specific commitments and exemptions; and
 - 1C, the Agreement on Trade-Related Aspects of Intellectual Property Rights.

Collectively, the agreements included in Annex 1 are referred to as the Multilateral Trade Agreements, since they comprise the substantive trade policy obligations which all the members of the WTO have accepted.

- Annex 2 sets the rules and procedures for dispute settlement.
- Annex 3 provides for regular reviews of developments and trends in national and international trade policy.
- Annex 4 covers the “plurilateral” agreements which are within the WTO framework but which have limited membership.

The SPS Agreement: An overview

Problem: How do you ensure that your country's consumers are supplied with food that is safe to eat — “safe” at the level you consider appropriate? And at the same time, how can you ensure that unnecessary health and safety regulations are not used as an excuse to protect domestic producers from foreign competition?

The Agreement on the Application of Sanitary and Phytosanitary Measures (“the SPS Agreement”) sets out the basic rules for food safety and animal and plant health requirements.

It allows countries to set their own standards. However, it also specifies that regulations must be based on scientific findings and should be applied only to the extent that they are necessary to protect human, animal or plant life or health; they should not unjustifiably discriminate between countries where similar conditions exist.

WTO member countries are encouraged to use the standards developed by the relevant international bodies whenever they exist. However, members may use measures which result in higher levels of health protection, so long as their measures are based on an appropriate assessment of risks and the approach is consistent, not arbitrary.

The agreement sets out a framework for what countries can do, but is not prescriptive

in how countries use health standards and methods of inspecting products.

Key features

All countries maintain measures to ensure that food is safe for consumers, and to prevent the spread of pests or diseases among animals and plants. These sanitary and phytosanitary measures can take many forms, such as requiring products to come from a disease-free area, inspection of products, specific treatment or processing of products, setting allowable maximum levels of pesticide residues or limiting the permitted use of additives in food. Sanitary (human and animal health) and phytosanitary (plant health) measures apply to domestically-produced food or local animal and plant diseases, as well as to products coming from other countries.

Protection or protectionism?

Sanitary and phytosanitary measures, by their very nature, may result in restrictions on trade. All governments accept the fact that some trade restrictions may be necessary to ensure food safety and animal and plant health protection. However, governments are sometimes pressured to go beyond what is needed for health protection and use sanitary and phytosanitary restrictions to

shield domestic producers from economic competition. A sanitary or phytosanitary restriction which is not actually required for health reasons can be a very effective protectionist device and, because of its technical complexity, it can be a particularly deceptive and difficult barrier to challenge.

The SPS Agreement builds on previous GATT rules to restrict the use of unjustified sanitary and phytosanitary measures for the purpose of trade protection. The basic aim of the SPS Agreement is to maintain the sovereign right of any government to provide the level of health protection it deems appropriate, but to ensure that this sovereign right is not misused for protectionist purposes and do not result in unnecessary barriers to international trade. In other words, it strikes a balance between the right of governments to protect health and their desire to see goods flow smoothly in international trade.

Justification of measures

The SPS Agreement therefore permits governments to maintain appropriate sanitary and phytosanitary protection. At the same time, it reduces the possibility that decisions are arbitrary and encourages consistent decision-making. Sanitary and phytosanitary measures must be applied for no other purpose than to ensure that food is safe and that animals and plants are healthy, or to protect a country's territory from pests. In particular, the agreement clarifies which factors should be taken into account when risks are assessed. Measures to ensure food safety and to protect the health of animals and plants should be based as far as possible on the analysis and assessment of objective scientific data.

International standards

The SPS Agreement encourages governments to apply national SPS measures that are consistent with international standards, guidelines and recommendations. This process is often called "harmonization". The WTO itself does not and will not develop these standards. However, most of the WTO's member governments participate in the development of these standards in other international bodies by leading scientists in the field and governmental experts on health protection. These standards are subject to international scrutiny and review.

International standards are often higher than those actually applied in many countries, including developed countries, but the SPS Agreement explicitly permits governments to choose their own standards. However, if the national requirement results in a greater restriction of trade, a country may be asked by its trading partners to provide scientific justification demonstrating that the relevant international standard would not achieve the level of health protection the country considers appropriate.

Adapting to conditions

Due to differences in climate, existing pests or diseases, or food safety conditions, it is not always appropriate to impose the same sanitary and phytosanitary requirements on food, animal or plant products coming from different countries. Therefore, sanitary and phytosanitary measures sometimes vary, depending on the health situation in the country of origin or destination, of the food, animal or plant product concerned. This is taken into account in the SPS Agreement.

Governments should also recognize pest- and disease-free areas which may not

correspond to political boundaries, and adapt their requirements so that they are appropriate for products from these areas, an approach known as “regionalization”. The agreement, however, prohibits unjustified discrimination in the use of sanitary and phytosanitary measures, whether in favour of domestic producers or among foreign suppliers.

Alternative measures and “equivalence”

An acceptable level of risk can often be achieved in alternative ways. Among the alternatives — and on the assumption that they are technically and economically feasible and provide the same level of food safety or animal and plant health protection — governments should select those that do not restrict trade more than necessary to meet their health objective. Furthermore, if another country can show that the measures it applies provide the same level of health protection, these should be accepted as equivalent. This helps to ensure that protection is maintained while providing the greatest quantity and variety of safe foodstuffs for consumers, the best availability of safe inputs for producers, and healthy economic competition. “Equivalence” is one of the subjects regularly discussed in the SPS Committee.

Risk assessment

Countries’ SPS measures must be based on an appropriate assessment of the actual risks involved. If asked, they must make known what factors they took into consideration, the assessment procedures they used and the level of risk they determined to be acceptable.

Transparency

The SPS Agreement makes sanitary and phytosanitary measures more transparent. Governments are required to notify each other, through the WTO Secretariat, of any new or changed sanitary and phytosanitary requirements which affect trade. Each WTO member must also set up offices (called “Enquiry Points”) to respond to requests for more information on new or existing SPS measures, including how they justify their requirements and how they apply their food safety and animal and plant health regulations. By systematically communicating information and exchanging experiences, WTO member governments can improve their national standards. The increased transparency also protects consumers and trading partners alike from protectionism hidden in unnecessary technical requirements. This information is now readily available in a comprehensive online database, the SPS Information Management System (<http://spsims.wto.org>).

SPS Committee

A special committee has been established within the WTO as a forum for member governments to exchange information on all aspects of the SPS Agreement’s implementation. The SPS Committee reviews how countries are complying with the agreement, discusses issues that may impact on trade and maintains close co-operation with technical organizations in the field. If a legal dispute arises on a sanitary or phytosanitary measure, the normal WTO dispute settlement procedures are used, and advice from appropriate scientific experts can be sought.

Frequently-asked questions

What are sanitary and phytosanitary measures? Does the SPS Agreement cover a country's measures to protect the environment, its consumer interests and animal welfare?

"Sanitary" refers to human and animal health, including food safety, and "phytosanitary" means plant health. For the purposes of the SPS Agreement, sanitary and phytosanitary measures are defined as any measures applied:

- to protect human or animal life from risks arising from additives, contaminants, toxins or disease-causing organisms in their food or beverages;
- to protect human life from plant- or animal-carried diseases (known as "zoonoses");
- to protect animal or plant life from pests, diseases, or disease-causing organisms;
- to prevent or limit other damage to a country from the entry, establishment or spread of pests.

Sanitary and phytosanitary measures include measures taken to protect the health of fish, forests and wildlife, as well as farmed animals and plants.

Some measures for environmental protection may fall within the scope of the SPS Agreement (as defined above), such as to avoid contaminating drinking water, to

prevent farm soils or fish stocks from being contaminated by heavy metals, or to protect biodiversity. Measures purely to protect consumer interests or animal welfare are not covered by the SPS Agreement. These concerns, however, may be addressed by other WTO agreements (i.e., the TBT Agreement – see below – or Article XX of GATT).

Weren't governments allowed to protect food safety and animal and plant health before the SPS Agreement?

Yes, since 1948, national food safety, animal and plant health measures which affect trade were subject to GATT rules. One of GATT's most important principles is non-discrimination. GATT's first article ("most-favoured nation") says products imported from different WTO member countries must be treated equally. The third article says laws and other requirements must not be tougher on imports than on domestically-produced products. These rules apply, for instance, to pesticide residue and food additive limits, as well as to restrictions for animal or plant health purposes. Article XI does not permit governments to impose import bans or limits on the quantities of imports permitted.

The GATT rules also contain an exception (Article XX:b) which permits countries

to take measures “necessary to protect human, animal or plant life or health” as long as these do not unjustifiably discriminate between countries where the same conditions prevail, or are not a disguised restriction to trade. In other words, where necessary, for the purposes of protecting human, animal or plant health, governments could impose more stringent requirements on imports than they required of domestic goods, and could ban imports that presented a serious health risk.

In the Tokyo Round of multilateral trade negotiations (1974-79), an Agreement on Technical Barriers to Trade was negotiated (the 1979 TBT Agreement or “Standards Code”). Only some countries signed it. Although the primary purpose of this agreement was not the regulation of sanitary and phytosanitary measures, it covered all technical requirements including those resulting from food safety and animal and plant health measures, pesticide residue limits, inspection requirements and labelling.

Governments that signed the 1979 TBT Agreement agreed to use relevant international standards (such as those for food safety developed by the Codex Alimentarius Commission), except when they considered that these standards would not adequately protect health. They also agreed to notify other governments, through the GATT Secretariat, of any technical regulations which were not based on international standards. The 1979 TBT Agreement included provisions for settling trade disputes arising from the use of food safety and other technical restrictions.

Postscript: The original GATT was revised as part of the 1986-94 Uruguay Round. The revision is officially “GATT 1994”. It incorporates the original “GATT 1947”, much of which remains untouched. The revised GATT is the WTO’s umbrella treaty for trade in

goods. Its rules apply when not superseded by a more specific WTO agreement. For food safety and animal and plant health measures the rules of the SPS Agreement prevail over those of the updated GATT.

The Uruguay Round also updated the TBT Agreement. The older 1979 version took effect on 1 January 1980. At the end of 1994, before it was superseded by the new version, its signatories were the European Union (12 countries at the time, plus 8 countries which subsequently became members) and 26 others. The Uruguay Round made two broad changes: the WTO TBT Agreement revised the original version, and has been signed by all WTO members as part of the “single undertaking”, which also includes the SPS Agreement and the majority of WTO treaties.

Why have an SPS Agreement?

Because sanitary and phytosanitary measures can so effectively restrict trade, WTO member governments want to have clear rules on how they can be used. When they negotiated the Uruguay Round, they wanted to reduce trade barriers, including through the Agriculture Agreement. This increased fears that sanitary and phytosanitary measures might be used for protectionist purposes.

The SPS Agreement is designed to close this potential loophole. It sets out clearer, more detailed rights and obligations for food safety and animal and plant health measures which affect trade. Countries are permitted to impose only those requirements needed to protect health which are based on scientific principles.

A government can challenge another country’s food safety or animal and plant health requirements on the grounds that they are not justified by scientific evidence. When asked, a country must make its procedures and decisions available to others. Governments have to be consistent in their decisions on

what safe food is and in their responses to animal and plant health concerns.

How do you know if a measure is SPS or TBT? Does it make any difference?

The scope of the two agreements is different (see Figure 2). The SPS Agreement covers all measures whose purpose is to protect:

- human or animal health from food-borne risks;
- human health from animal- or plant-carried diseases;
- animals and plants from pests or diseases;
- the territory of a country from damage caused by pests;

whether or not these are technical requirements.

The TBT (Technical Barriers to Trade) Agreement covers all technical regulations, voluntary standards and the procedures to ensure that these are met, except when these are sanitary or phytosanitary measures as defined by the SPS Agreement.

The type of measure determines whether it is covered by the TBT Agreement. The purpose of the measure is relevant in determining whether it is subject to the SPS Agreement.

TBT measures can cover any product, from car safety and energy-saving devices, to the shape of food cartons. To give some examples pertaining to human health, TBT measures could include pharmaceutical restrictions, or the labelling of cigarettes.

Most measures to control human disease come under the TBT Agreement, unless they concern diseases which are carried by plants or animals (such as rabies or BSE). For food,

most labelling requirements, information on nutrition and quality and packaging regulations are generally not considered to be sanitary or phytosanitary measures and hence are normally subject to the TBT Agreement.

On the other hand, regulations which address the microbiological contamination of food, or set allowable levels of pesticide or veterinary drug residues, or identify permitted food additives, fall under the SPS Agreement. Some packaging and labelling requirements, if directly related to the safety of the food, are also subject to the SPS Agreement.

The two agreements share some common elements. These include basic obligations not to discriminate. They both require governments to notify proposed measures in advance. Both require governments to set up information offices (“Enquiry Points”). Nonetheless, many of the substantive rules are different. For example, both agreements encourage governments to use international standards. However, under the SPS Agreement, if a government wants to set its own standards for food safety or to protect animal and plant health, it has to base this on a scientific assessment of the potential health risks. In contrast, under the TBT Agreement, governments can use other justifications, such as fundamental technological reasons or geographical factors, to set their own standards.

In addition, sanitary and phytosanitary measures can only be used when necessary to protect human, animal or plant health, on the basis of scientific information. However, governments can use TBT regulations when necessary to meet a number of objectives, such as national security or to prevent deceptive practices. The obligations that governments have accepted are different under the two agreements, and therefore it is important to know whether a measure is a sanitary or phytosanitary measure, or comes under the TBT Agreement.

Figure 2: SPS or TBT?

Which agreement does a measure come under?

Is it food, drink or feed, and is its objective to protect one of those from these risks?

human life

- additives, contaminants, toxins or disease-causing organisms in food or drink
- plant- or animal-carried disease

animal life

- additives, contaminants, toxins or disease-causing organisms in feed or drink
- diseases
- disease-causing or disease-carrying organisms

plant life

- pests
- diseases
- disease-causing or disease-carrying organisms

a country

- pests entering, establishing or spreading

YES

NO

Is it a technical regulation, standard or procedure for assessing whether a product conforms with a standard?

NO

OTHER

YES

SPS

TBT

Examples

| | | |
|-----------------------|---|------------|
| Fertilizer | Regulation on permitted fertilizer residue in food and animal feed | SPS |
| | Specifications to ensure fertilizer works effectively | TBT |
| | Specifications to protect farmers from possible harm from handling fertilizer | TBT |
| Food labelling | Regulation on permitted food safety: health warnings, use, dosage | SPS |
| | Regulation on size, construction/structure, safe handling | TBT |

| Examples | | |
|--|---|------------|
| Fruit | Regulation on treatment of imported fruit to prevent pests spreading | SPS |
| | Regulation on quality, grading and labelling of imported fruit | TBT |
| Bottled water: specifications for the bottles | Materials that can be used because safe for human health | SPS |
| | Requirements: no residues of disinfectant, so water not contaminated | SPS |
| | Permitted sizes to ensure standard volumes | TBT |
| | Permitted shapes to allow stacking and displaying | TBT |
| Cigarette packets | Government health warning: "Smoking can seriously damage your health": the label's objective is health but it is not about food, so it is not SPS | TBT |

To summarize

| SPS measures typically deal with: | TBT measures typically deal with: |
|---|--|
| <ul style="list-style-type: none"> ▪ additives in food or drink | <ul style="list-style-type: none"> ▪ labelling of food, drink and drugs |
| <ul style="list-style-type: none"> ▪ contaminants in food or drink | <ul style="list-style-type: none"> ▪ grading and quality requirements for food |
| <ul style="list-style-type: none"> ▪ poisonous substances in food or drink | <ul style="list-style-type: none"> ▪ packaging requirements for food |
| <ul style="list-style-type: none"> ▪ residues of veterinary drugs or pesticides in food or drink | <ul style="list-style-type: none"> ▪ packaging and labelling for dangerous chemicals and toxic substances |
| <ul style="list-style-type: none"> ▪ certification: food safety, animal or plant health | <ul style="list-style-type: none"> ▪ regulations for electrical appliances |
| <ul style="list-style-type: none"> ▪ processing methods with implications for food safety | <ul style="list-style-type: none"> ▪ regulations for cordless phones, radio equipment, etc. |
| <ul style="list-style-type: none"> ▪ labelling requirements directly related to food safety | <ul style="list-style-type: none"> ▪ textiles and garments labelling |
| <ul style="list-style-type: none"> ▪ plant/animal quarantine | <ul style="list-style-type: none"> ▪ testing vehicles and accessories |
| <ul style="list-style-type: none"> ▪ declaring areas free from pests or disease | <ul style="list-style-type: none"> ▪ regulations for ships and ship equipment |
| <ul style="list-style-type: none"> ▪ preventing disease or pests spreading to a country | <ul style="list-style-type: none"> ▪ safety regulations for toys |
| <ul style="list-style-type: none"> ▪ other sanitary requirements for imports (e.g. imported pallets used to transport animals) | <ul style="list-style-type: none"> ▪ etc... |
| <ul style="list-style-type: none"> ▪ etc... | |

How do governments and the public know who is doing what?

The transparency provisions of the SPS Agreement are designed to ensure that the public and trading partners know about measures taken to protect human, animal and plant health. The agreement requires governments to promptly publish all sanitary and phytosanitary regulations. When other governments ask, they have to explain the reasons for any particular food safety or animal or plant health requirement.

All WTO member governments must maintain an Enquiry Point, an office designated to receive and respond to any requests for information regarding that country's sanitary and phytosanitary measures. Such requests may be for copies of new or existing regulations, information on relevant agreements between two countries, or information about risk assessment decisions. Contact details for Enquiry Points can be consulted electronically through the SPS Information Management System (SPS IMS – <http://spsims.wto.org>).

Whenever a government is proposing a new regulation (or modifying an existing one) which differs from an international standard and may affect international trade, it must notify the WTO Secretariat, which then circulates the notification to other WTO member governments. The notifications are also available to the public on the WTO web site's Documents Online (<http://docsonline.wto.org>, search document symbol "G/SPS/N/"), or through the SPS Information Management System (<http://spsims.wto.org>). Alternatively, notifications can be requested from the Enquiry Point of the country which is proposing the measure.

Governments have to submit the notification before a proposed new regulation is implemented, so that trading partners

have an opportunity to comment. The SPS Committee has developed recommendations on how the comments must be handled. (See document G/SPS/7/Rev.3 for more information.)

Sometimes, governments have to act fast to deal with an emerging SPS situation by promptly adopting a new SPS measure. Urgent measures should be temporary, until sufficient information is available to assess whether they should be permanent. When acting in emergencies, governments must notify other members, through the WTO Secretariat, immediately after the adoption of the new SPS measure. When they determine whether a permanent measure is needed, they must also consider any comments submitted by other WTO member governments.

Does the SPS Agreement restrict a government's ability to establish food safety and plant and animal health laws? Are food safety or animal and plant health levels determined by the WTO or some other international institution?

The SPS Agreement explicitly recognizes the right of governments to take measures to protect human, animal and plant health, as long as these are based on science, are necessary for the protection of health, and do not unjustifiably discriminate among foreign sources of supply. Likewise, governments determine the food safety levels and animal and plant health protection in their countries. Neither the WTO nor any other international body does this.

The SPS Agreement does, however, encourage governments to "harmonize" or base their national measures on the international standards, guidelines

and recommendations developed in other international organizations. These organizations are:

- for food safety, the joint FAO/WHO Codex Alimentarius Commission (Codex);
- for animal health, the World Organisation for Animal Health (previously known as the Office International des Epizooties - OIE);
- and for plant health, the International Plant Protection Convention (IPPC), based in FAO.

Most WTO member governments have long participated in the work of these organizations to set limits for pesticides, contaminants or additives in food and to reduce the effects of pests and diseases on animal and plant health. The work of these technical organizations is scrutinized and reviewed internationally.

One problem is that international standards are often so stringent that many countries have difficulties implementing them. But being encouraged to use international standards does not mean that countries have to accept them as a floor or ceiling for national standards. National standards do not violate the SPS Agreement simply by differing from international norms. Governments can set requirements that are stricter than the international standards. However, if governments do set their own standards, they may be required to justify their higher standards if the difference gives rise to a trade dispute. Their justification must be based on an analysis of scientific evidence and the risks involved.

What does harmonization with international food safety standards mean? Does this result in weaker health protection, i.e., downward harmonization?

Harmonization with international food safety standards means basing national requirements on the standards developed by the FAO/WHO's Codex Alimentarius Commission. (Codex also develops standards for food quality, nutrition and labelling. These come under the TBT Agreement, not SPS.) Codex standards are not a "lowest common denominator". They are based on the input of leading scientists in the field and national experts on food safety. These are the same government experts who are responsible for the development of national food safety standards. For example, the recommendations for pesticide residues and food additives are developed for Codex by international groups of scientists who use conservative, safety-oriented assumptions and who operate without political interference.

In many cases, the standards developed by Codex are higher than those of individual countries, including developed countries. Governments may nonetheless choose to use higher standards than the international ones, if the international standards do not meet their health protection needs.

Can governments take adequate precautions in setting food safety and animal and plant health requirements? What about in emergencies or when there is not enough scientific evidence to judge risks? Can unsafe products be banned?

The SPS Agreements allows three different types of precautions:

- First, safety margins are used routinely to ensure governments take adequate precautions to protect health; this comes from risk assessment and determination of acceptable levels of risk.
- Second, as each country determines its own level of acceptable risk, it can respond to national concerns about necessary health precautions.
- Third, the SPS Agreement clearly allows a government to take temporary measures as a precaution when it considers that the scientific evidence is not sufficient to decide whether a product or process is safe. This also allows governments to act immediately in emergency situations.

There are many examples of governments banning the production, sale and import of products because of scientific evidence that the products pose an unacceptable risk to human, animal or plant health. The SPS Agreement does not affect a government's ability to ban products under these conditions.

Can food safety and animal and plant health requirements be set by local or regional governments? Can there be differences in requirements within a country?

The SPS Agreement accepts that food safety and animal and plant health regulations do not necessarily have to be set by the highest governmental authority. Differences within a country are allowed. However, if these differences affect international trade, they have to meet the same requirements as if they were set by the national government. The national government remains responsible for implementing the SPS Agreement, and should ensure that state or provincial governments also observe it. Governments should use the services of non-governmental institutions only if these comply with the SPS Agreement.

Does the SPS Agreement require countries to give priority to trade over food safety, or animal and plant health?

No, the SPS Agreement allows countries to give food safety, animal and plant health priority over trade, provided they can demonstrate that their food safety and health requirements are based on science. Each country has the right to assess the risks and determine what it considers to be an appropriate level of food safety and animal and plant health.

Once a country has decided on its acceptable level of risk, there are often a number of alternative measures which may be used to achieve this protection (such as treatment, quarantine or increased inspection). The SPS Agreement says that when a government chooses among the alternatives, it must use

measures which do not restrict trade any more than is necessary to achieve its objectives to protect health, assuming the measures are technically and economically feasible. For example, if a country faces a risk because of an exotic pest entering with its imports, it could ban the imports or it could require the exporters to fumigate the shipment. Either method could reduce the risk to the level that the government considers acceptable, but fumigation restricts trade less than an outright ban.

Can national food safety and animal and plant health legislation be challenged by other countries? Can private entities bring trade disputes to the WTO? How are disputes settled in the WTO?

Since the General Agreement on Tariffs and Trade (GATT) entered into force in 1948, it has been possible for governments to challenge other countries' food safety and plant and animal health laws as artificial barriers to trade. The 1979 TBT Agreement also had procedures for challenging another signatory's technical regulations, including food safety standards and animal and plant health requirements. The SPS Agreement makes more explicit not only the basis for food safety and animal and plant health requirements that affect trade but also the basis for challenges to those requirements. While a nation's ability to establish legislation is not restricted, a specific food safety or animal or plant health requirement can be challenged by another country on the grounds that there is not sufficient scientific evidence to support the need for the trade restriction. The SPS Agreement provides greater certainty for regulators and traders alike, enabling them to avoid potential conflicts.

As the WTO is an intergovernmental organization, only governments, not private entities or non-governmental organizations, can submit trade disputes to the WTO's dispute settlement procedures. Non-governmental entities can, of course, make trade problems known to their government and encourage the government to seek redress, if appropriate, through the WTO.

By accepting the WTO Agreement, governments have agreed to be bound by the rules in all of the multilateral trade agreements attached to it, including the SPS Agreement. In the case of a trade dispute, the WTO's dispute settlement procedures encourage the governments involved to "settle out of court" through consultations. If the governments cannot resolve their dispute, they can choose to follow any of several means of dispute settlement, including the "good offices", conciliation, mediation and arbitration. Alternatively, a government can formally ask for an impartial dispute settlement panel of experts to hear all sides of the dispute and to make recommendations.

In a dispute on SPS measures, the panel can seek scientific advice, and even set up a technical experts group. If the panel concludes that a country is violating its obligations under any WTO agreement, it will normally recommend that the country bring its measure into conformity with its obligations. This could, for example, involve procedural changes in the way a measure is applied, modification or elimination of the measure altogether, or simply elimination of discriminatory elements.

The panel submits its recommendations for consideration by the WTO Dispute Settlement Body (DSB), which consists of WTO member countries. Countries in the dispute can appeal the panel's findings. The final ruling is adopted by the DSB, unless

the DSB decides by consensus to reject it. If the measure is found to be wrong, the defending country has to implement the panel's recommendations and to report on how it has complied.

Have there been any formal disputes involving the SPS Agreement? What have they been about?

Although only one panel was asked to consider sanitary or phytosanitary trade disputes during the 47 years of the former GATT dispute settlement procedures, in the first 15 years since the establishment of the WTO, almost 40 complaints were formally lodged with reference to the SPS Agreement. This is not surprising as the agreement clarifies the basis for challenging sanitary or phytosanitary measures which restrict trade without scientific justification. The range of issues involved include inspection and quarantine procedures, animal diseases, plant pests, the use of veterinary drugs on animals, and genetically modified organisms. Dispute settlement panels have been requested to examine 14 of the complaints; the other disputes have been or are likely to be settled through consultation.

More information on all of the SPS-related disputes is available on the WTO dispute settlement gateway (www.wto.org/disputes).

Who was responsible for developing the SPS Agreement? Did developing countries participate in the negotiation of the SPS Agreement?

The decision to negotiate an SPS Agreement was made in 1986 when the Uruguay Round was launched. The SPS negotiations were

open to all of the 124 governments which participated. Many governments were represented by their food safety or animal and plant health protection officials. The negotiators also drew on the expertise of technical international organizations such as FAO, Codex and OIE.

Developing countries participated in all aspects of the Uruguay Round negotiations to an unprecedented extent, including on sanitary and phytosanitary measures. Both before and during the Uruguay Round negotiations, the GATT Secretariat assisted developing countries to establish effective negotiating positions.

Has there been public participation in the WTO's SPS work or in negotiating the SPS Agreement? Are private sector interests or consumer interests excluded?

The WTO is an intergovernmental organization. Private entities and non-governmental organizations do not directly participate in its work, but they have influence through their contact with their own governments. In addition, the WTO Secretariat maintains regular contact with many non-governmental organizations.

GATT, like the WTO, was an intergovernmental organization. Therefore, only governments participated in the GATT Uruguay Round talks that led to the SPS Agreement. However, the public debate was unprecedented, as many governments consulted with their public and private sectors and with non-governmental organizations on various aspects of the negotiations, including the SPS Agreement. Some governments established formal channels for public consultation and debate, while others did so less formally. The

GATT Secretariat also had considerable contact with international non-governmental organizations as well as with the public and private sectors of many countries involved in the negotiations. The final Uruguay Round results were subject to national ratification and implementation processes in most GATT member countries.

What is the SPS Committee and who sits on it?

The SPS Agreement established a Committee on Sanitary and Phytosanitary Measures (the “SPS Committee”) to provide a forum for governments to discuss food safety and animal and plant health measures which affect trade, and to ensure the implementation of the SPS Agreement. The SPS Committee, like other WTO committees, is open to all WTO member countries. Observer governments in the higher level WTO bodies (such as the Goods Council) are also eligible to be observers in the SPS Committee. Representatives of several international intergovernmental organizations are also observers, including Codex, OIE, IPPC, WHO, the United Nations Conference on Trade and Development (UNCTAD) and the International Organization for Standardization (ISO). Some regional governmental bodies working on SPS issues are also observers. Governments may send whichever delegates they believe appropriate to participate in the meetings of the SPS Committee, and many send their food safety authorities or veterinary or plant health officials.

The SPS Committee usually holds three regular meetings each year. It also regularly holds informal meetings, and special meetings or workshops to address particular issues.

What does the SPS Committee do? What are the issues it considers?

Governments inform each other about their regular and emergency SPS measures through the Secretariat. They use procedures and standardized formats that have been reviewed periodically (document G/SPS/7/Rev.3). The huge number of notifications, submitted by virtually all WTO members, provides an opportunity for their trading partners to comment on planned regulations before they are adopted, and for producers to adapt to the new requirements.

The committee also considers information provided by governments regarding their national regulatory procedures, their use of risk assessment in the development of sanitary and phytosanitary measures and the status of diseases in their territories. For example, many countries have provided information on bovine spongiform encephalopathy (BSE or “mad cow” disease), avian influenza (“bird flu”), foot-and-mouth disease and fruit fly and on what they have done to control these.

WTO members can also raise specific trade concerns regarding SPS measures imposed by other members in the SPS Committee. Almost 300 specific trade concerns, covering the full range of SPS issues, were raised in the committee’s first 15 years. This is an opportunity for countries to ask their trading partners to explain or justify requirements that make it difficult for them to export. The specific trade concerns raised in the SPS Committee can be consulted through the SPS IMS (<http://spsims.wto.org>).

The SPS Committee monitors countries’ use of international standards, under a provisional procedure required by Articles 3.5 and 12.4 of the SPS Agreement

(G/SPS/11/Rev.1). The committee also agreed on guidelines to ensure consistency in risk management decisions, in order to reduce possible arbitrariness in the actions taken by governments. (Article 5.5, G/SPS/15). In addition, the committee has developed a number of guidelines to assist governments in the implementation of Article 4 on “equivalence” (G/SPS/19/ Rev.2), and Article 6 on recognition of areas free of pests or diseases (G/SPS/48).

In 1998, 2005 and 2010, the committee reviewed the operation of the SPS Agreement (G/SPS/12, G/SPS/36, G/SPS/53), a four-yearly task.

The committee can consider any issue raised by members. One issue that has been discussed a lot is private standards, SPS-related requirements established by private associations or individual companies. In 2005, St Vincent and the Grenadines raised a concern regarding private (GLOBALGAP) standards for bananas sold in Europe. A number of other developing countries subsequently raised concerns about standards of private retailers or associations that establish food safety requirements for products, particularly in some developed country markets. Although there is no agreement among members about the extent to which such private standards are subject to WTO provisions, the committee is trying to identify practical actions that can be taken to reduce any negative effects such private requirements may have on the trade of developing countries.

Who benefits from the SPS Agreement? Does it benefit developing countries?

Consumers in all countries benefit. The SPS Agreement helps ensure the safety of

their food, and in many cases enhances it. It does so by encouraging the systematic use of scientific information, thus reducing the scope for arbitrary and unjustified decisions. More information has become available to consumers as a result of greater transparency in governmental procedures and on the reasons behind their food safety, animal and plant health. The elimination of unnecessary trade barriers allows consumers to benefit from a greater choice of safe foods and from healthy international competition among producers.

Developing countries benefit from the SPS Agreement because it provides an international framework for sanitary and phytosanitary arrangements among countries, irrespective of their political and economic strength or technological capacity. Without the agreement, developing countries could be at a disadvantage when challenging unjustified trade restrictions. Furthermore, under the agreement, governments must accept imported products that meet their safety requirements, whether these products are the result of simpler, less sophisticated methods or the most modern technology. Increased technical assistance to help developing countries in the area of food safety and animal and plant health, whether bilateral or through international organizations, is also an element of the agreement.

Exporters of agricultural products in all countries benefit from the elimination of unjustified barriers to their products. The agreement reduces uncertainty about the conditions for selling to a specific market. Efforts to produce safe food for an export market should not be thwarted by regulations imposed for protectionist purposes under the guise of health measures. In addition, ministers from WTO member countries have decided that the interval between the

publication of a new SPS measure and the date of its entry into force must be not less than six months – except in an emergency – so as to allow sufficient time for exporters to comply with the importing market's new SPS requirements (WT/MIN(01)/17).

Importers of food and other agricultural products also benefit from the greater certainty of border measures. The agreement clarifies the basis for restricting trade through sanitary and phytosanitary measures. This makes the basis for challenging unjustified requirements clearer. It also benefits the many processors and commercial users of imported food or of animal or plant products.

What difficulties do developing countries face in implementing the SPS Agreement? Are there special provisions for developing countries?

Although a number of developing countries have excellent food safety and veterinary and plant health services, others do not. For the latter, the agreement's requirements can sometimes present a challenge to improve the health situation of their people, livestock and crops. Because of this difficulty, the agreement allowed developing countries to delay meeting all requirements, other than those dealing with transparency (notification and the establishment of Enquiry Points), until 1997, and until 2000 for the least-developed countries. Countries which need time to implement certain programmes, for example to improve their veterinary services or to implement specific obligations of the agreement, can ask the SPS Committee to grant them further delays. Developing countries can also request special treatment or technical assistance to meet importing countries' requirements (G/SPS/33/Rev.1). Many developing countries have already

adopted international standards (including those of Codex, OIE and IPPC) as the basis for their own requirements, thus avoiding the need to devote their scarce resources to duplicate work already done by international experts. The agreement encourages them to participate as actively as possible in these organizations, contributing to new international standards which address their needs.

Developing countries benefit from the six-month period that WTO members have agreed between a measure being adopted and coming into force (subject to certain conditions, see WT/MIN(01)/17).

Do developing countries receive any help in implementing the SPS Agreement? Who provides assistance? How is this done?

The SPS Agreement calls for assistance for developing countries to enable them to strengthen their food safety and animal and plant health protection systems. Many international organizations, including the FAO, WHO, OIE and the World Bank, operate programmes for developing countries in these areas. Many countries also provide direct support, recognizing that the best way to ensure the safety of the products they are importing can be to ensure that they are produced safely, following good agricultural or manufacturing practices.

The WTO Secretariat also provides training to ensure that officials in developing countries fully understand their obligations under the agreement, but also how to make use of the agreement to increase their exports and improve health in their countries. Training is provided nationally, upon request from governments, or regionally. Regional training is provided in cooperation with Codex, OIE

and IPPC, to ensure that governments are fully aware of the role these organizations can play in assisting countries to meet SPS requirements and enjoy the benefits of the agreement. The WTO Secretariat also offers e-Training courses on the agreement, and an intensive three-week advanced training course for officials from developing countries.

A procedural step-by-step manual for SPS national Notification Authorities and Enquiry Points is available at www.wto.org/sps. Furthermore, a “mentoring” system of assistance relating to the transparency provisions of the SPS Agreement has been established to assist WTO developing country members (G/SPS/W/217). This deals particularly with the operation of the SPS National Notification Authority and the National Enquiry Point.

In 2001, the heads of the FAO, OIE, WHO, WTO and the World Bank agreed to work together to improve technical assistance in SPS. This led to the creation of the Standards and Trade Development Facility (STDF), which serves to raise awareness of the importance of compliance with international SPS standards and coordinates the provision of SPS-related technical assistance. The STDF also works on project development, the mobilization of funds, exchange of experiences and the dissemination of good practice in relation to the provision and receipt of SPS-related assistance. Limited grant financing is also available to developing countries seeking to gain and maintain market access by complying with international SPS standards. More information, including eligibility criteria and application forms, is available on the STDF website (www.standardsfacility.org).

Agreement on the Application of Sanitary and Phytosanitary Measures (the legal text)

Members,

Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

Desiring to improve the human health, animal health and phytosanitary situation in all Members;

Noting that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols;

Desiring the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade;

Recognizing the important contribution that international standards, guidelines and recommendations can make in this regard;

Desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health;

Recognizing that developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard;

Desiring therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)¹;

Hereby agree as follows:

Article 1

General Provisions

1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.
2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.
3. The annexes are an integral part of this Agreement.
4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.

Article 2

Basic Rights and Obligations

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.
2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.
3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

1. In this Agreement, reference to Article XX(b) includes also the chapeau of that Article.

4. Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

Article 3

Harmonization

1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.
2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.
3. 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 a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.² Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.
4. Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.

2. For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

5. The Committee on Sanitary and Phytosanitary Measures provided for in paragraphs 1 and 4 of Article 12 (referred to in this Agreement as the “Committee”) shall develop a procedure to monitor the process of international harmonization and coordinate efforts in this regard with the relevant international organizations.

Article 4

Equivalence

1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member’s appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.
2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

Article 5

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.
2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.
3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.
5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.
6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.³
7. 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. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.
8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

3. For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

Article 6

Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence

1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area — whether all of a country, part of a country, or all or parts of several countries — from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, inter alia, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.
2. Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.
3. Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

Article 7

Transparency

1. Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

Article 8

Control, Inspection and Approval Procedures

1. Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and

otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

Article 9

Technical Assistance

1. Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, inter alia, in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.
2. Where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.

Article 10

Special and Differential Treatment

1. In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.
2. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.
3. With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs.
4. Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations.

Article 11

Consultations and Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement, except as otherwise specifically provided herein.
2. In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.
3. Nothing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement.

Article 12

Administration

1. A Committee on Sanitary and Phytosanitary Measures is hereby established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives, in particular with respect to harmonization. The Committee shall reach its decisions by consensus.
2. The Committee shall encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary or phytosanitary issues. The Committee shall encourage the use of international standards, guidelines or recommendations by all Members and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination and integration between international and national systems and approaches for approving the use of food additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs.
3. The Committee shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention, with the objective of securing the best available scientific and technical advice for the administration of this Agreement and in order to ensure that unnecessary duplication of effort is avoided.
4. The Committee shall develop a procedure to monitor the process of international

harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefor, and, in particular, whether it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B.

5. In order to avoid unnecessary duplication, the Committee may decide, as appropriate, to use the information generated by the procedures, particularly for notification, which are in operation in the relevant international organizations.
6. The Committee may, on the basis of an initiative from one of the Members, through appropriate channels invite the relevant international organizations or their subsidiary bodies to examine specific matters with respect to a particular standard, guideline or recommendation, including the basis of explanations for non-use given according to paragraph 4.
7. The Committee shall review the operation and implementation of this Agreement three years after the date of entry into force of the WTO Agreement, and thereafter as the need arises. Where appropriate, the Committee may submit to the Council for Trade in Goods proposals to amend the text of this Agreement having regard, inter alia, to the experience gained in its implementation.

Article 13

Implementation

1. Members are fully responsible under this Agreement for the observance of all obligations set forth herein. Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of this Agreement by other than central government bodies. Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regional bodies in which relevant entities within their territories are members, comply with the relevant provisions of this Agreement. In addition, Members shall not take

measures which have the effect of, directly or indirectly, requiring or encouraging such regional or non-governmental entities, or local governmental bodies, to act in a manner inconsistent with the provisions of this Agreement. Members shall ensure that they rely on the services of nongovernmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement.

Article 14

Final Provisions

1. The least-developed country Members may delay application of the provisions of this Agreement for a period of five years following the date of entry into force of the WTO Agreement with respect to their sanitary or phytosanitary measures affecting importation or imported products. Other developing country Members may delay application of the provisions of this Agreement, other than paragraph 8 of Article 5 and Article 7, for two years following the date of entry into force of the WTO Agreement with respect to their existing sanitary or phytosanitary measures affecting importation or imported products, where such application is prevented by a lack of technical expertise, technical infrastructure or resources.

Annex A

Definitions⁴

1. Sanitary or phytosanitary measure – Any measure applied:

- a. to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- b. to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- c. to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
- d. to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

2. Harmonization – The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.

3. International standards, guidelines and recommendations

- a. for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;

4. For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

- b. for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
- c. for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
- d. for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

4. Risk assessment — The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

5. Appropriate level of sanitary or phytosanitary protection – The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

NOTE: Many Members otherwise refer to this concept as the “acceptable level of risk”.

6. Pest- or disease-free area – An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease does not occur.

NOTE: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area – whether within part of a country or in a geographic region which includes parts of or all of several countries -in which a specific pest or disease is known to occur but is subject to regional control measures such as the establishment of protection, surveillance and buffer zones which will confine or eradicate the pest or disease in question.

7. Area of low pest or disease prevalence – An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease occurs at low levels and which is subject to effective surveillance, control or eradication measures.

Annex B

Transparency of sanitary and phytosanitary regulations

Publication of regulations

1. Members shall ensure that all sanitary and phytosanitary regulations⁵ which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.

2. Except in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

Enquiry points

3. Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:

- a. any sanitary or phytosanitary regulations adopted or proposed within its territory;
- b. any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;
- c. risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;
- d. the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this Agreement, and the texts of such agreements and arrangements.

5. Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

4. Members shall ensure that where copies of documents are requested by interested Members, they are supplied at the same price (if any), apart from the cost of delivery, as to the nationals⁶ of the Member concerned.

Notification procedures

5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:

- a. publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;
- b. notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;
- c. provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;
- d. without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.

6. However, where urgent problems of health protection arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 5 of this Annex as it finds necessary, provided that the Member:

- a. immediately notifies other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);
- b. provides, upon request, copies of the regulation to other Members;
- c. allows other Members to make comments in writing, discusses these comments upon request, and takes the comments and the results of the discussions into account.

6. When "nationals" are referred to in this Agreement, the term shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

7. Notifications to the Secretariat shall be in English, French or Spanish.

8. Developed country Members shall, if requested by other Members, provide copies of the documents or, in case of voluminous documents, summaries of the documents covered by a specific notification in English, French or Spanish.

9. The Secretariat shall promptly circulate copies of the notification to all Members and interested international organizations and draw the attention of developing country Members to any notifications relating to products of particular interest to them.

10. Members shall designate a single central government authority as responsible for the implementation, on the national level, of the provisions concerning notification procedures according to paragraphs 5, 6, 7 and 8 of this Annex.

General reservations

11. Nothing in this Agreement shall be construed as requiring:

- a. the provision of particulars or copies of drafts or the publication of texts other than in the language of the Member except as stated in paragraph 8 of this Annex; or
- b. Members to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.

Annex C

Control, inspection and approval procedures⁷

1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
 - a. such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;
 - b. the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;
 - c. information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs;
 - d. the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favourable than for domestic products and in such a manner that legitimate commercial interests are protected;
 - e. any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary;

7. Control, inspection and approval procedures include, inter alia, procedures for sampling, testing and certification.

- f. any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service;
- g. the same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents;
- h. whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned; and
- i. a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified.

Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.

2. Where a sanitary or phytosanitary measure specifies control at the level of production, the Member in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.

3. Nothing in this Agreement shall prevent Members from carrying out reasonable inspection within their own territories.

Abbreviations

Codex The FAO/WHO Joint Codex Alimentarius Commission

FAO The Food and Agriculture Organization of the United Nations

GATT The General Agreement on Tariffs and Trade, established in 1947. The abbreviation is used both with reference to the legal text and to the institution

GATT 1994 The General Agreement on Tariffs and Trade, as revised in 1994, which is part of the WTO Agreements. GATT 1994 includes the original General Agreement, which is known as GATT 1947.

IPPC The Secretariat of the International Plant Protection Convention, based in FAO

OIE The World Organisation for Animal Health (previously known as the Office International des Epizooties)

SPS Sanitary and phytosanitary measures, as defined by the WTO Agreement on the Application of Sanitary and Phytosanitary Measures

TBT Technical barriers to trade, as covered by the WTO Agreement on Technical Barriers to Trade. References to the previous GATT Agreement by the same name are indicated as the "1979" TBT Agreement

WHO The World Health Organization


WTO The World Trade Organization, established as the successor to the GATT on 1 January 1995

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