

**T H E W T O
A G R E E M E N T S
S E R I E S**

4

**SANITARY &
PHYTOSANITARY
MEASURES**

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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.

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 the over-20,000 pages of commitments is available from WTO Publications in a 34-volume set, and also a CD-ROM, *The Results of the Uruguay Round*.

This series of smaller volumes includes introductions explaining the accompanying legal texts. They are intended to be an authoritative aid for understanding the agreements, but because of the legal complexity and the fact that a number of issues have not been tested — for example in the WTO's dispute settlement procedures — the introductions cannot be taken as legal interpretations of the agreements.

Another WTO publication, *Guide to the Uruguay Round Agreements* (shortly to be published jointly by the WTO and Kluwer Law International), is a comprehensive explanation of all the agreements. A simpler guide to the agreements is in *Trading into the Future*, a booklet and electronic guide introducing all aspects of the WTO's work that can also be found on the WTO website: <http://www.wto.org>.

The volumes in this series

(the sequence follows their order of appearance in the WTO Agreement):

- | | |
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| 1. Agreement Establishing the WTO | 11. Rules of Origin |
| 2. GATT 1994 and 1947 | 12. Import Licensing Procedures |
| 3. Agriculture | 13. Subsidies and Countervailing Measures |
| 4. Sanitary and Phytosanitary Measures | 14. Safeguards |
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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 the FAO
OIE	The Office International des Epizooties, also known as the World Animal Health Organization
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 of the United Nations
WTO	The World Trade Organization, established as the successor to the GATT on 1 January 1995

PREFACE
THE AGREEMENT ON
SANITARY AND PHYTOSANITARY MEASURES

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 key features of the agreement; the second addresses a number of frequently asked questions; and the third is the legal text of the agreement. The booklet is not intended to provide legal interpretation of the agreement.

May 1998

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.

In a nutshell					
The basic structure of the WTO agreements					
	Goods	Services	Intellectual property	Disputes	Trade policy reviews
<i>Basic principles</i>	GATT	GATS	TRIPS	Dispute settlement	TPRM
<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)			

- ◆ 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 at present it has no additional parts.)
- ◆ Then come **additional agreements and annexes** dealing with the special requirements of specific sectors or issues. These deal with the following specific sectors or issues:

For goods (under GATT)

Agriculture	Customs valuation
Health regulations for farm and food products (SPS)	methods
Textiles and clothing	Preshipment inspection
Product standards (TBT)	Rules of origin
Investment measures	Import licensing
Anti-dumping measures	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 have 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: civil aircraft, government procurement. (Originally there were four: the agreements on 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. A 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.

- ◆ **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 of 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 four “**plurilateral**” agreements which are within the WTO framework but which have limited membership.

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.

4 THE WORLD TRADE ORGANIZATION AGREEMENTS

INTRODUCTION

The Sanitary and Phytosanitary Measures Agreement

Problem: How do you ensure that your country's consumers are being supplied with food that is safe to eat — "safe" by the standards you consider appropriate? And at the same time, how can you ensure that strict health and safety regulations are not being used as an excuse for protecting domestic producers?

*The **Agreement on the Application of Sanitary and Phytosanitary Measures** sets out the basic rules for food safety and animal and plant health standards.*

It allows countries to set their own standards. But it also says regulations must be based on science. They should be applied only to the extent necessary to protect human, animal or plant life or health. And they should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.

Member countries are encouraged to use international standards, guidelines and recommendations where they exist. However, members may use measures which result in higher standards if there is scientific justification. They can also set higher standards based on appropriate assessment of risks so long as the approach is consistent, not arbitrary.

The agreement still allows countries to use different standards and different 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 of allowable maximum levels of pesticide residues or permitted use of only certain 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 to use sanitary and phytosanitary restrictions to shield domestic producers from economic competition. Such pressure is likely to increase as other trade barriers are reduced as a result of the Uruguay Round agreements. 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, a particularly deceptive and difficult barrier to challenge.

The Agreement on Sanitary and Phytosanitary Measures (SPS) 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 these sovereign rights are not misused for protectionist purposes and do not result in unnecessary barriers to international trade.

Justification of measures

The SPS Agreement, while permitting governments to maintain appropriate sanitary and phytosanitary protection, reduces possible *arbitrariness* of decisions and encourages consistent decision-making. It requires that sanitary and phytosanitary measures be applied for no other purpose than that of ensuring food

safety and animal and plant health. In particular, the agreement clarifies which factors should be taken into account in the assessment of the risk involved. 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 and accurate scientific data.

International standards

The SPS Agreement encourages governments to establish national SPS measures consistent with international standards, guidelines and recommendations. This process is often referred to as “*harmonization*”. The WTO itself does not and will not develop such standards. However, most of the WTO’s member governments (132 at the date of drafting) participate in the development of these standards in other international bodies. The standards are developed by leading scientists in the field and governmental experts on health protection and are subject to international scrutiny and review.

International standards are often higher than the national requirements of many countries, including developed countries, but the SPS Agreement explicitly permits governments to choose not to use the international standards. However, if the national requirement results in a greater restriction of trade, a country may be asked to provide scientific justification, demonstrating that the relevant international standard would not result in the level of health protection the country considered 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 country of origin of the food, animal or plant product concerned. This is taken into account in the SPS Agreement. Governments should also recognize disease-free areas which may not correspond to political boundaries, and appropriately adapt their requirements to products from these areas. The agreement, however, checks *unjustified discrimination* in the use of sanitary and phytosanitary measures, whether in favour of domestic producers or among foreign suppliers.

Alternative measures

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 — governments should select those which are *not more trade restrictive than required* 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 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.

Risk Assessment

The SPS Agreement increases the *transparency* of sanitary and phytosanitary measures. Countries must establish SPS measures on the basis of an appropriate assessment of the actual risks involved, and, if requested, make known what factors they took into consideration, the assessment procedures they used and the level of risk they determined to be acceptable. Although many governments already use risk assessment in their management of food safety and animal and plant health, the SPS Agreement encourages the wider use of systematic risk assessment among all WTO member governments and for all relevant products.

Transparency

Governments are required to notify other countries of any new or changed sanitary and phytosanitary requirements which affect trade, and to set up offices (called “Enquiry Points”) to respond to requests for more information on new or existing measures. They also must open to scrutiny how they apply their food safety and animal and plant health regulations. The systematic communication of information and exchange of experiences among the WTO’s member governments provides a better basis for national standards. Such increased transparency also protects the interests of consumers, as well as of trading partners, from hidden protectionism through unnecessary technical requirements.

A special Committee has been established within the WTO as a forum for the exchange of information among member governments on all aspects related to

the implementation of the SPS Agreement. The SPS Committee reviews compliance with the agreement, discusses matters with potential trade impacts, and maintains close co-operation with the appropriate technical organizations. In a trade dispute regarding a sanitary or phytosanitary measure, the normal WTO dispute settlement procedures are used, and advice from appropriate scientific experts can be sought.

QUESTIONS AND ANSWERS

What are sanitary and phytosanitary measures? Does the SPS Agreement cover countries' measures to protect the environment? Consumer interests? Animal welfare?

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;
- ◆ to protect human life from plant- or animal-carried diseases;
- ◆ 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.

These include sanitary and phytosanitary measures taken to protect the health of fish and wild fauna, as well as of forests and wild flora.

Measures for environmental protection (other than as defined above), to protect consumer interests, or for the welfare of animals are not covered by the SPS Agreement. These concerns, however, are addressed by other WTO agreements (i.e., the TBT Agreement or Article XX of GATT 1994).

Weren't a nation's food safety and animal and plant health regulations previously covered by GATT rules?

Yes, since 1948 national food safety, animal and plant health measures which affect trade were subject to GATT rules. Article I of the GATT,¹ the most-

¹ The original GATT Agreement was revised as part of the Uruguay Round and the

favoured nation clause, required non-discriminatory treatment of imported products from different foreign suppliers, and Article III required that such products be treated no less favourably than domestically produced goods with respect to any laws or requirements affecting their sale. These rules applied, for instance, to pesticide residue and food additive limits, as well as to restrictions for animal or plant health purposes.

The GATT rules also contained an exception (Article XX:b) which permitted countries to take measures “necessary to protect human, animal or plant life or health,” as long as these did not unjustifiably discriminate between countries where the same conditions prevailed, nor were a disguised restriction to trade. In other words, where necessary, for purposes of protecting human, animal or plant health, governments could impose more stringent requirements on imported products than they required of domestic goods.

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”).² Although this agreement was not developed primarily for the purpose of regulating sanitary and phytosanitary measures, it covered technical requirements resulting from food safety and animal and plant health measures, including pesticide residue limits, inspection

revised text, GATT 1994, constitutes an integral part of the WTO. Its rules continue to apply where not superseded by a more specific WTO Agreement. For food safety and plant or animal health measures as defined by the SPS Agreement, the rules of this latter prevail over those of the GATT 1994.

² The 1979 TBT Agreement took effect on 1 January 1980. At the end of 1994, before it was superseded by the WTO TBT Agreement (which is applicable to all WTO Members), the following were parties to the Agreement: Argentina (did not ratify), Australia, Austria, Brazil, Canada, Chile, the Czech Republic, the Slovak Federal Republic, Egypt, the European Community and its twelve member states (Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, United Kingdom), Finland, Hong Kong, Hungary, India, Indonesia, Israel, Japan, the Republic of Korea, Malaysia, Mexico, Morocco, New Zealand, Norway, Pakistan, Philippines, Romania, Rwanda, Singapore, Slovenia, Sweden, Switzerland, Thailand, Tunisia, the United States and Yugoslavia.

requirements and labelling. Governments which were members of the 1979 TBT Agreement agreed to use relevant international standards (such as those for food safety developed by the Codex) 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.

What is new in the SPS Agreement?

Because sanitary and phytosanitary measures can so effectively restrict trade, GATT member governments were concerned about the need for clear rules regarding their use. The Uruguay Round objective to reduce other possible barriers to trade increased fears that sanitary and phytosanitary measures might be used for protectionist purposes.

The SPS Agreement was intended to close this potential loophole. It sets 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. The procedures and decisions used by a country in assessing the risk to food safety or animal or plant health must be made available to other countries upon request. Governments have to be consistent in their decisions on what is safe food, and in 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. 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;

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. It is thus the type of measure which determines whether it is covered by the TBT Agreement, but the purpose of the measure which is relevant in determining whether a measure is subject to the SPS Agreement.

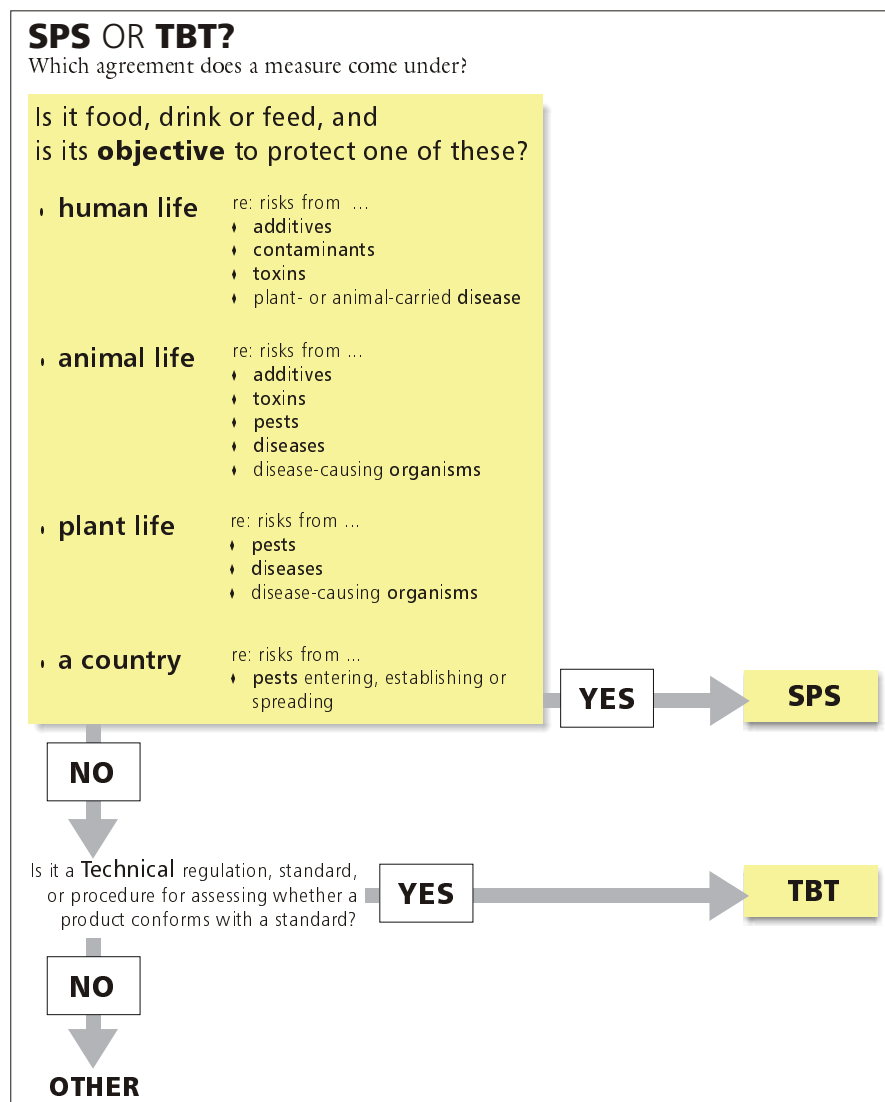
TBT measures could cover any subject, from car safety to energy-saving devices, to the shape of food cartons. To give some examples pertaining to human health, TBT measures could include pharmaceutical restrictions, or the labelling of cigarettes. Most measures related to human disease control are under the TBT Agreement, unless they concern diseases which are carried by plants or animals (such as rabies). In terms of food, most labelling requirements, nutrition claims and concerns, 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, by definition, regulations which address 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.

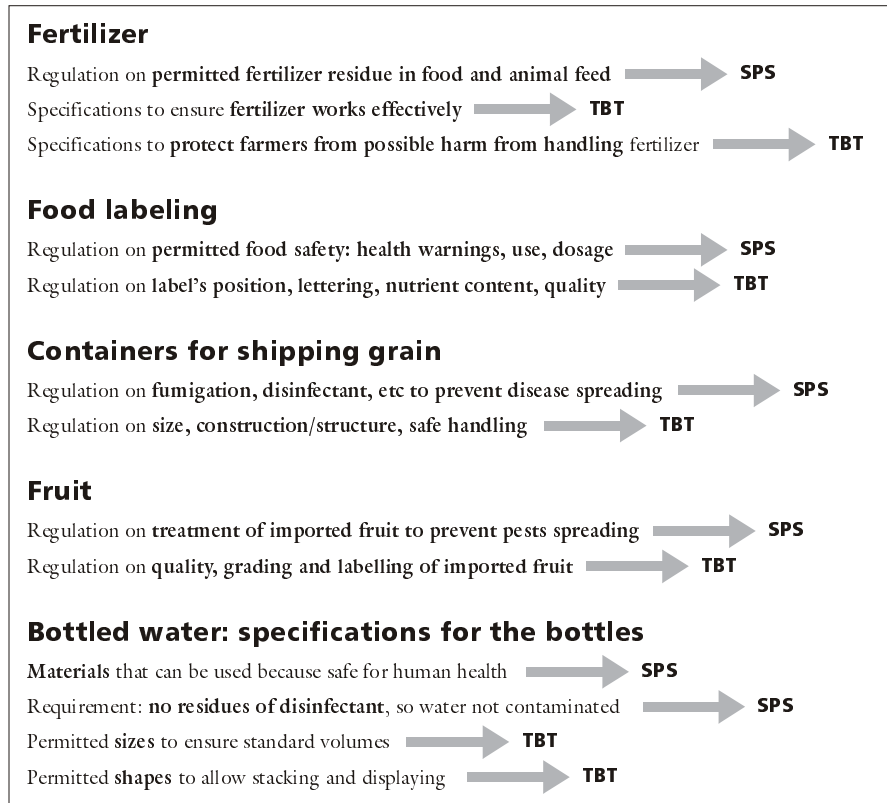
The two agreements have some common elements, including basic obligations for non-discrimination and similar requirements for the advance notification of proposed measures and the creation of information offices (“Enquiry Points”). However, many of the substantive rules are different. For example, both agreements encourage the use of international standards. However, under the SPS Agreement the only justification for not using such standards for food safety and animal/plant health protection are scientific arguments resulting from an assessment of the potential health risks. In contrast, under the TBT Agreement governments may decide that international standards are not appropriate for other reasons, including fundamental technological problems or geographical factors.

Also, sanitary and phytosanitary measures may be imposed only to the extent necessary to protect human, animal or plant health, on the basis of scientific information. Governments may, however, introduce TBT regulations when

necessary to meet a number of objectives, such as national security or the prevention of deceptive practices. Because the obligations that governments have accepted are different under the two agreements, it is important to know whether a measure is a sanitary or phytosanitary measure, or a measure subject to the TBT Agreement.



For example



What about this?

**GOVERNMENT HEALTH WARNING:
SMOKING CAN SERIOUSLY
DAMAGE YOUR HEALTH**

The warning.

Objective: human health

→ TBT

The label's appearance.

Typography, colour, size, position, etc

→ TBT

Why is it TBT and not SPS?

Because although the label's objective is health — it's not about food

Summary

SPS measures typically deal with:

- ◆ additives in food or drink
- ◆ contaminants in food or drink
- ◆ poisonous substances in food or drink
- ◆ residues of veterinary drugs or pesticides in food or drink
- ◆ certification: food safety, animal or plant health
- ◆ processing methods with implications for food safety
- ◆ labelling requirements directly related to food safety
- ◆ plant/animal quarantine
- ◆ declaring areas free from pests or disease
- ◆ preventing disease or pests spreading to a country
- ◆ other sanitary requirements for imports (e.g. imported pallets used to transport animals)
- ◆ etc ...

TBT measures typically deal with:

- ◆ labelling of food, drink and drugs
- ◆ quality requirements for fresh food
- ◆ packaging requirements for fresh food
- ◆ packaging and labelling for dangerous chemicals and toxic substances
- ◆ regulations for electrical appliances
- ◆ regulations for cordless phones, radio equipment etc.
- ◆ textiles and garments labelling
- ◆ testing vehicles and accessories
- ◆ regulations for ships and ship equipment
- ◆ safety regulations for toys
- ◆ etc ...

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

The transparency provisions of the SPS Agreement are designed to ensure that measures taken to protect human, animal and plant health are made known to the interested public and to trading partners. The agreement requires

governments to promptly publish all sanitary and phytosanitary regulations, and, upon request from another government, to provide an explanation of 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. The addresses of the Enquiry Points can be consulted electronically at the WTO's home page (<http://www.wto.org>, "Documents on Line", search document symbol "SPS/ENQ/").

Whenever a government is proposing a new regulation (or modifying an existing one) which differs from an international standard and may affect trade, they must notify the WTO Secretariat, who then circulates the notification to other WTO member governments (over 2,600 such notifications were circulated during the first seven years of implementation of the SPS Agreement). The notifications are also available to the interested public and can be consulted on the WTO web site (search document symbol "G/SPS/N/"). Alternatively, notifications can be requested from the Enquiry Point of the country which is proposing the measure.

Governments are required to submit the notification in advance of the implementation of a proposed new regulation, so as to provide trading partners an opportunity to comment. The SPS Committee has developed recommendations on how the comments must be dealt with.

In cases of emergency, governments may act without delay, but must immediately notify other members, through the WTO Secretariat, and also still 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? Will food safety or animal and plant health levels be 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 will continue to determine the food safety levels and animal and plant health protection in their countries. Neither the WTO nor any other international body will do this.

The SPS Agreement does, however, encourage governments to “harmonize” or base their national measures on the international standards, guidelines and recommendations developed by WTO member governments in other international organizations. These organizations include, for food safety, the joint FAO/WHO Codex Alimentarius Commission; for animal health, the Office International des Epizooties; and for plant health, the FAO International Plant Protection Convention. WTO member governments have long participated in the work of these organizations — including work on risk assessment and the scientific determination of the effects on human health of pesticides, contaminants or additives in food; or the effects of pests and diseases on animal and plant health. The work of these technical organizations is subject to international scrutiny and review.

One problem is that international standards are often so stringent that many countries have difficulties implementing them nationally. But the encouragement to use international standards does not mean that these constitute a floor on national standards, nor a ceiling. National standards do not violate the SPS Agreement simply because they differ from international norms. In fact, the SPS Agreement explicitly permits governments to impose more stringent requirements than the international standards. However, governments which do not base their national requirements on international standards may be required to justify their higher standard if this difference gives rise to a trade dispute. Such justification must be based on an analysis of scientific evidence and the risks involved.

What does harmonization with international food safety standards mean? Will this result in a lowering of health protection, i.e., downward harmonization?

Harmonization with international food safety standards means basing national requirements on the standards developed by the FAO/WHO Joint Codex Alimentarius Commission.³ Codex standards are not “lowest common denominator” standards. 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 countries such as the United States. As noted in the reply to the previous question, 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 when there may not be sufficient scientific evidence for a definitive decision on safety, or in emergency situations? Can unsafe products be banned?

Three different types of precautions are provided for in the SPS Agreement. First, the process of risk assessment and determination of acceptable levels of risk implies the routine use of safety margins to ensure adequate precautions are taken to protect health. Second, as each country determines its own level of acceptable risk, it can respond to national concerns regarding what are

³ Codex also develops standards with respect to food quality, nutrition and labelling. These other standards are not directly relevant to the SPS Agreement, however they are relevant to the TBT Agreement.

necessary health precautions. Third, the SPS Agreement clearly permits the precautionary taking of measures when a government considers that sufficient scientific evidence does not exist to permit a final decision on the safety of a product or process. This also permits immediate measures to be taken in emergency situations.

There are many examples of bans on the production, sale and import of products based on scientific evidence that they 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?

It is accepted in the SPS Agreement that food safety and animal and plant health regulations do not necessarily have to be set by the highest governmental authority and that they may not be the same throughout a country. Where such regulations affect international trade, however, they should meet the same requirements as if they were established by the national government. The national government remains responsible for implementation of the SPS Agreement, and should support its observance by other levels of government. Governments should use the service 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 there is a demonstrable scientific basis for their food safety and health requirement. Each country has the right to determine what level of food safety and animal and plant health it considers appropriate, based on an assessment of the risks involved.

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). In choosing among such alternatives, the SPS Agreement requires that a government use those

measures which are no more trade restrictive than required to achieve its health protection objectives, if these measures are technically and economically feasible. For example, although a ban on imports could be one way to reduce the risk of entry of an exotic pest, if requiring treatment of the products could also reduce the risk to the level considered acceptable by the government, this would normally be a less trade restrictive requirement.

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 GATT began in 1948, it has been possible for a government to challenge another country's 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 supporting the need for the trade restriction. The SPS Agreement provides greater certainty for regulators and traders alike, enabling them to avoid potential conflicts.

The WTO is an inter-governmental organization and 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 find a mutually acceptable bilateral solution through formal consultations. If the governments cannot resolve their dispute, they can choose to follow any of several means of dispute

settlement, including good offices, conciliation, mediation and arbitration. Alternatively, a government can request that an impartial panel of trade experts be established to hear all sides of the dispute and to make recommendations.

In a dispute on SPS measures, the panel can seek scientific advice, including by convening 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), where all WTO member countries are represented. Unless the DSB decides by consensus not to adopt the panel's report, or unless one of the parties appeals the decision, the defending party is obliged to implement the panel's recommendations and to report on how it has complied. Appeals are limited to issues of law and legal interpretations by the panel.

Although only one panel was asked to consider sanitary or phytosanitary trade disputes during the 47 years of the former GATT dispute settlement procedures, during the first seven years of the SPS Agreement 18 complaints were formally lodged with reference to the new obligations. This is not surprising as the agreement clarifies, for the first time, the basis for challenging sanitary or phytosanitary measures which restrict trade and may not be scientifically justified. The challenges have concerned issues as varied as inspection and quarantine procedures, animal diseases, "use-by" dates, the use of veterinary drugs in animal rearing, and disinfection treatments for beverages. Dispute settlement panels have been requested to examine four of the complaints; the other complaints have been or are likely to be settled following the obligatory process of bilateral consultations.

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

The decision to start the Uruguay Round trade negotiations was made after years of public debate, including debate in national governments. The decision to negotiate an agreement on the application of sanitary and phytosanitary

measures was made in 1986 when the Round was launched. The SPS negotiations were open to all of the 124 governments which participated in the Uruguay Round. 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 the FAO, the Codex and the OIE.

Developing countries participated in all aspects of the Uruguay Round negotiations to an unprecedented extent. In the negotiations on sanitary and phytosanitary measures, developing countries were active participants, often represented by their national food safety or animal and plant health experts. Both before and during the Uruguay Round negotiations, the GATT Secretariat assisted developing countries to establish effective negotiating positions. The SPS Agreement calls for assistance to developing countries to enable them to strengthen their food safety and animal and plant health protection systems. FAO and other international organizations already operate programmes for developing countries in these areas.

Was there public participation in the Uruguay Round negotiations? Were private sector interests or consumer interests excluded?

GATT was an intergovernmental organization and it was governments which participated in GATT trade negotiations; neither private business nor non-governmental organizations participated directly. But as the scope of the Uruguay Round was unprecedented, so was the public debate. Many governments consulted with both their public and private sectors on various aspects of the negotiations, including the SPS Agreement. Some governments established formal channels for public consultation and debate while others did so on a more ad hoc basis. 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.

The WTO is, likewise, an intergovernmental organization. Private business and non-governmental organizations do not directly participate in its work, but can influence the work of the WTO through their contacts with their own

governments. In addition, the WTO Secretariat regularly has contacts with many non-governmental organizations.

What is the SPS Committee and who is on it? What does it do?

The SPS Agreement established a Committee on Sanitary and Phytosanitary Measures (the “SPS Committee”) to provide a forum for consultations about food safety or 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. Governments which have an observer status in the higher level WTO bodies (such as the Council for Trade in Goods) are also eligible to be observers in the SPS Committee. The Committee has agreed to invite representatives of several international intergovernmental organizations as observers, including Codex, OIE, IPPC, WHO, UNCTAD and the International Standards Organization (ISO). Governments may send whichever officials 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 holds occasional joint meetings with the TBT Committee on notification and transparency procedures. Informal or special meetings may be scheduled as needed.

During its first year, the SPS Committee developed recommended procedures and a standardized format for governments to use for the required advance notification of new regulations. Over 2,600 notifications of sanitary and phytosanitary measures were submitted and circulated by the end of 2001. The Committee considered information provided by governments regarding their national regulatory procedures, their use of risk assessment in the development of sanitary and phytosanitary measures and their disease-status, notably with respect to foot-and-mouth disease and fruit-fly. In addition, a considerable number of trade issues were discussed by the SPS Committee, in particular with regard to bovine spongiform encephalopathy (BSE). As required by the SPS Agreement, the SPS Committee developed a provisional procedure to monitor the use of international standards. The SPS Committee has agreed guidelines to ensure consistency in risk management decisions, in order to reduce possible arbitrariness in the actions taken by governments. In 1998, the SPS Committee undertook its first review of the operation of the SPS

Agreement; further reviews are scheduled every four years. A decision to facilitate the implementation of Article 4 (equivalence) was taken by the SPS Committee.

Who benefits from the implementation of the SPS Agreement? Is the agreement in the interest of developing countries?

Consumers in all countries benefit. The SPS Agreement helps ensure, and in many cases enhances, the safety of their food as it encourages the systematic use of scientific information in this regard, thus reducing the scope for arbitrary and unjustified decisions. More information will increasingly become available to consumers as a result of greater transparency in governmental procedures and on the basis for their food safety, animal and plant health decisions. The elimination of unnecessary trade barriers allows consumers to benefit from a greater choice of safe foods and from healthy international competition among producers.

Specific sanitary and phytosanitary requirements are most frequently applied on a bilateral basis between trading countries. **Developing countries** benefit from the SPS Agreement as it provides an international framework for sanitary and phytosanitary arrangements among countries, irrespective of their political and economic strength or technological capacity. Without such an agreement, developing countries could be at a disadvantage when challenging unjustified trade restrictions. Furthermore, under the SPS 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 SPS Agreement.

Exporters of agricultural products in all countries benefit from the elimination of unjustified barriers to their products. The SPS Agreement reduces uncertainty about the conditions for selling to a specific market. Efforts to produce safe food for another market should not be thwarted by regulations imposed for protectionist purposes under the guise of health measures.

Importers of food and other agricultural products also benefit from the greater certainty regarding border measures. The basis for sanitary and phytosanitary measures which restrict trade are made clearer by the SPS Agreement, as well

as the basis for challenging requirements which may be unjustified. This also benefits the many processors and commercial users of imported food, animal or plant products.

What difficulties do developing countries face in implementing the SPS Agreement? Will they receive any assistance in this regard? 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 these, the requirements of the SPS Agreement present a challenge to improve the health situation of their people, livestock and crops which may be difficult for some to meet. Because of this difficulty, the SPS Agreement delayed all requirements, other than those dealing with transparency (notification and the establishment of Enquiry Points), until 1997 for developing countries, and until 2000 for the least developed countries. This means that these countries are not required to provide a scientific justification for their sanitary or phytosanitary requirements before that time. Countries which need longer time periods, for example for the improvement of their veterinary services or for the implementation of specific obligations of the agreement, can request the SPS Committee to grant them further delays.

Many developing countries have already adopted international standards (including those of Codex, OIE and the IPPC) as the basis for their national requirements, thus avoiding the need to devote their scarce resources to duplicate work already done by international experts. The SPS Agreement encourages them to participate as actively as possible in these organizations, in order to contribute to and ensure the development of further international standards which address their needs.

One provision of the SPS Agreement is the commitment by members to facilitate the provision of technical assistance to developing countries, either through the relevant international organizations or bilaterally. FAO, OIE and WHO have considerable programmes to assist developing countries with regard to food safety, animal and plant health concerns. A number of countries also have extensive bilateral programmes with other WTO members in these areas. The WTO Secretariat has undertaken a programme of regional seminars to provide developing countries (and those of Central and Eastern Europe) with detailed information regarding their rights and obligations stemming

from this agreement. These seminars are provided in cooperation with the Codex, OIE and IPPC, to ensure that governments are fully aware of the role these organizations can play in assisting countries to meet their requirements and fully enjoy the benefits resulting from the SPS Agreement. The seminars are open to participation by interested private business associations and consumer organizations. The WTO Secretariat also provides technical assistance through national workshops and to governments through their representatives in Geneva.

TEXT:
AGREEMENT ON THE APPLICATION OF
SANITARY AND PHYTOSANITARY MEASURES

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 I
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.

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

*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.
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.

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

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.

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

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.

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.

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

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

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

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 non-governmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement.

Article 14
Final Provisions

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

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.

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;
- (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;

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

- (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.

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,

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.

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.

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;

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

- (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;
- (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.