

THE SPS AGREEMENT AND BIOSAFETY

**BY
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**FAO
LEGAL PAPERS
ONLINE #65**
March 2007

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The SPS Agreement and biosafety

This paper was presented at a regional training workshop on drafting secondary biosafety regulations, organized by the United Nations Environment Programme (UNEP) and funded by the Global Environment Facility (GEF) (10-13 October 2006, Hanoi, Vietnam). The purpose of the workshop was to enable key government staff from Cambodia, Thailand and Vietnam to draft secondary biosafety regulations that are consistent with *inter alia* the Cartagena Protocol on Biosafety (the Protocol) and other international treaties and arrangements. The paper includes a general introduction to the World Trade Organization (WTO), its objectives, functions and structure, and to the relevant WTO Agreements in the biosafety area, notably the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). In addition, it presents the findings of the Panel Report in the recent *Biotech* dispute and identifies some areas of potential conflict between the Protocol and WTO rules, in particular the SPS Agreement. The concluding remarks contain some practical considerations on drafting biosafety legislation.

The World Trade Organization

The World Trade Organization is a global international organization dealing with the rules of international trade between states. At its heart are many specific agreements, which were negotiated and signed by governments and ratified in their parliaments. At present, the WTO has 150 Members, including Cambodia, Thailand and Vietnam.¹

History

The WTO was created in 1995 after the culmination of long, intense negotiations, which took place under the auspices of the General Agreement on Tariffs and Trade (GATT), and are known as the "Uruguay Round" of multilateral trade negotiations. Formally, the GATT was not an international organization but simply an international

¹ Following the training workshop, Vietnam became WTO's 150th Member on 11 January 2007.

agreement, concluded in 1947. It contained rules and obligations that governed the trade in goods for almost fifty years between the countries that were party to the agreement. However, the Secretariat of the GATT took up many responsibilities throughout the years, which led to the GATT being called a *de facto* international organization. Therefore, while the WTO is still young, the multilateral trading system that was originally set up under the GATT is well over 50 years old.

Participants in the Uruguay Round concluded the Round by adopting the "Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations". The Final Act includes the "Marrakesh Agreement Establishing the World Trade Organization" (the Marrakesh Agreement), which contains provisions on establishment, scope, functions and structure of the WTO. It defines the WTO relationship with other organizations, its secretariat, budget and contributions, legal status, and decision-making and amendment procedures (including special voting procedures). Additionally, it presents information on the definition of original Members, accession, non-application, acceptance, entry into force and deposit, denunciation and final provisions.

Objectives and functions

The Preamble to the Marrakesh Agreement encapsulates the organization's objectives, which are to improve the welfare of the peoples of its Members (standard of living, employment, income, etc.) by expanding the production of, and trade in, goods and services. Article III expounds the functions of the WTO in this regard, which are to:

- administer trade agreements;
- serve as a forum for trade negotiations;
- settle trade disputes;
- review Members' trade policies;
- assist developing countries with trade policy issues, through technical assistance and training programmes; and
- cooperate with other international organizations.

Annexed to the Marrakesh Agreement are the agreements on goods, services and intellectual property, dispute settlement and the trade policy review mechanism (Annexes 1, 2 and 3). Together these agreements are termed "Multilateral Trade Agreements". They are applicable to all Members and as such have to be complied with simultaneously, without the possibility for the Member of choosing just this or that agreement to be bound by. This is called the "single undertaking" principle. The Schedules of Commitments also form part of the agreements. The schedules contain the commitments made by individual WTO Members allowing specific foreign products or service-providers access to their markets. Finally, Annex 4 is termed "Plurilateral Trade Agreements", which bind only those Members party to the agreement. There are currently two plurilateral agreements in force, namely on civil aircraft and government procurement. Two other plurilateral agreements, on dairy products and bovine meat, were terminated at the end of 1997. **Table 1** below further clarifies the basic structure of the WTO Agreements.

Organization

The Ministerial Conference is the highest authority in the WTO and can take decisions on all matters under all Multilateral Trade Agreements. Its sessions must take place at least once every two years. To date, six sessions of the Ministerial Conference have been held. Of particular relevance was the fourth session in November 2001 in Doha (Qatar), where the Ministers adopted a Ministerial Declaration (also referred to as the Doha Development Agenda) containing a work programme for a new round of trade negotiations (the Doha Round). These negotiations take place in the Trade Negotiations Committee and its subsidiary bodies, i.e. Special Sessions of the various committees that carry a mandate to

negotiate (such as Agriculture, Trade and Environment, Subsidies, etc.). The Doha Round was originally scheduled to be completed by 1 January 2005 but this deadline was missed. At the sixth Ministerial Conference in December 2005 in Hong Kong (China), Members agreed to finish the negotiations by the end of 2006. Ministers met again at the end of June 2006 in order to advance, and if possible, conclude trade talks under the Doha Round. However, an agreement was not reached and trade negotiations were subsequently suspended. At present, the importance of resuming the negotiations is becoming increasingly clear. The costs of failure, and the missed opportunity to rebalance the multilateral trading system, would particularly hurt developing countries.

The General Council constitutes the second tier in the WTO structure. It comprises representatives from all Member countries, usually Ambassadors/Permanent Representatives based in Geneva, Switzerland, where the WTO Headquarters are located. It meets regularly (approximately once a month) to adopt Decisions, mostly on behalf of the Ministerial Conference when the Conference is not in session. The General Council has authority over the Trade Negotiations Committee and, in addition, it meets as:

- the Trade Policy Review Body (TPRB), with its own Chairperson, to carry out trade policy reviews as mandated by the Trade Policy Review Mechanism (Annex 3 of the WTO Agreement); and
- the Dispute Settlement Body (DSB), with its own Chairperson, to administer the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) (Annex 2 of the WTO Agreement).

Box 1: Basic structure of the WTO Agreements

The basic structure of the WTO Agreements: how the six main areas fit together — the umbrella Marrakesh Agreement, goods, services, intellectual property, disputes, trade policy reviews and the plurilateral agreements.

<i>Umbrella</i>	MARRAKESH AGREEMENT		
	Goods (Annex 1 A)	Services (Annex 1 B)	Intellectual property (Annex 1 C)
<i>Basic principles</i>	GATT	GATS	TRIPS
<i>Additional details</i>	Other goods agreements and annexes ⁱ	Services annexes ⁱⁱ	
<i>Market access commitments</i>	Countries' schedules of commitments	of Countries' schedules of commitments (and Most Favoured Nation (MFN) exemptions)	
<i>Dispute settlement</i>	DISPUTE SETTLEMENT (Annex 2)		
<i>Transparency</i>	TRADE POLICY REVIEWS (Annex 3)		
<i>Plurilateral commitments</i>	Plurilateral Agreements (Annex 4)		

i. The agreements that disciplines the trade in goods, which are contained in Annex 1 A, are the: [General Agreement on Tariffs and Trade \(GATT 1994\)](#); [Agreement on Agriculture \(AoA\)](#); [Agreement on the Application of Sanitary and Phytosanitary Measures \(SPS\)](#); [Agreement on Textiles and Clothing \(ATC, terminated on the 1st of January 2005\)](#); [Agreement on Technical Barriers to Trade \(TBT\)](#); [Agreement on Trade Related Investment Measures \(TRIMS\)](#); [Agreement on Anti-Dumping \(AA\)](#); [Agreement on Customs Valuation](#); [Agreement on Preshipment Inspection](#); [Agreement on Rules of Origin](#); [Agreement on Import Licensing](#); [Agreement on Subsidies and Countervailing Measures](#); [Agreement on Safeguards](#).

ii. The Agreement that disciplines the trade in services, which is contained in Annex 1 B, is the [General Agreement on Trade in Services](#). This Agreement has several annexes of its own, which are the: [Annex on Article II Exemptions](#); [Annex on Movement of Natural Persons Supplying Services under the Agreement](#); [Annex on Air Transport Services](#); [Annex on Financial Services](#) and [Second Annex on Financial Services](#); [Annex on Telecommunications](#) and [Annex on Negotiations on Basic Telecommunications](#); [Annex on Negotiations on Maritime Transport Services](#).

The DSB has the authority to establish panels on an *ad hoc* basis, at the request of a Member (or Members). It is responsible for adopting Panel and Appellate Body Reports, overseeing the implementation of rulings and recommendations, and authorizing the suspension of concessions and other obligations under the agreements for which disputes can be settled by the DSU - the "covered agreements." The DSB also appoints persons to serve on the Appellate Body. When adopted by the DSB, the Panel Report as upheld, amended, or reversed by the Appellate Body becomes binding on the disputing Members.

The Councils - being subsidiary bodies to the General Council – constitute the third tier in the WTO structure. They are composed of all WTO Members. There are three:

- the Council for Trade in Goods (the Goods Council) oversees all the issues related to the agreements on trade in goods;
- the Council for Trade in Services (the GATS Council) oversees all issues related to the GATS; and
- the Council for Trade-Related Aspects of Intellectual Property Rights (the TRIPS Council) administers the TRIPS Agreement.

Finally, both the Goods and the GATS Council have subsidiary bodies. The Goods Council for instance has 11 committees composed of all Members working on specific subjects (such as agriculture, market access, subsidies, anti-dumping measures, etc.). One of these committees is the Committee on Sanitary and Phytosanitary Measures (the SPS Committee), which will be further discussed below.

Trade and the environment

It has been widely recognized by both environmental and trade policy-makers that multilateral solutions to transboundary environmental problems, whether regional or global, are preferable to unilateral solutions. Resort to unilateralism runs the risk of arbitrary discrimination and disguised protectionism, which could damage the multilateral trading system. Whilst Multilateral Environmental Agreements (MEAs), such as the Convention on Biological Diversity (CBD) and the Protocol,

are to be encouraged, the WTO has wrestled with the issue of how to address the trade provisions which several of these agreements contain.² These include trade measures agreed to amongst parties to MEAs, as well as measures adopted by parties to MEAs against non-parties.

Some WTO Members have expressed the fear that MEA-related disputes could be brought to the WTO dispute settlement system. Whereas disputes between two parties to an MEA, who are both WTO Members, would most likely be settled in the MEA, disputes between an MEA party and a non-party (both of whom are WTO Members) would most probably come to the WTO since the non-party would not have access to the dispute settlement provisions of the MEA. They have argued that the WTO should not wait until it is requested to resolve an MEA-related dispute and a Panel is asked to examine the relationship between WTO rules and MEAs. It is WTO Members that should themselves, through negotiations, clarify this relationship.

In discussing the compatibility between the trade provisions contained in MEAs and WTO rules, it should be observed that of the approximately 200 MEAs currently in force, only about 20 contain trade provisions. It has been argued, therefore, that the dimension of the problem should not be exaggerated. Until now, these MEAs and WTO rules have co-existed without conflicts, in particular because the MEAs have a very narrow scope and there seems to be a transatlantic agreement on the regulatory principles to be used to deal with specific issues. Thus far, no disputes have come to the WTO regarding trade provisions contained in an MEA.

² The CBD does not define the term "living modified organisms" but it is understood to include genetically modified organisms (GMOs), provided they are live. There are two distinct kinds of LMOs. The first category includes organisms whose genetic material has been modified by traditional or conventional techniques such as plant breeding or artificial insemination. The second category includes organisms whose genetic material has been modified more directly, e.g. through recombinant DNA technology, and these are the ones generally referred to as GMOs. The term GMOs will normally be used in this paper.

Some WTO Members have argued that the existing principles of public international law suffice in governing the relationship between WTO rules and MEAs. The 1969 Vienna Convention on the Law of Treaties as well as principles of customary law can themselves define how WTO rules interact with MEAs. The legal principles of “lex specialis” (the more specialized agreement prevails over the more general) and of “lex posterior” (the agreement signed later in date prevails over the earlier one) emanate from public international law, and some have argued that these principles could help the WTO in defining its relationship with MEAs. Others, however, have argued that there is a need for greater legal clarity.

The Doha Round

Trade and environment issues in the WTO are generally addressed in the Committee on Trade and Environment (CTE), whose mandate broadly covers the relationship between trade and environmental measures to promote sustainable development and who is to make recommendations on whether modifications of the provisions of the multilateral trading system are required. The work programme of the CTE, which reports directly to the General Council, is contained in a separate Ministerial Decision on Trade and Environment adopted by ministers at the meeting of the Uruguay Round Trade Negotiations Committee in Marrakech on 14 April 1994.³ In addition, trade and environment issues are high on the Doha Development Agenda. The negotiations fall under the remit of the CTE Special Session (CTESS), whose mandate is contained in Paragraph 31 of the Doha Ministerial Declaration.⁴ The CTES reports to the Trade Negotiations Committee.

Paragraph 31(i) of the Doha Ministerial Declaration mandates Members to negotiate on the relationship between WTO rules and specific trade obligations set out in MEAs. However, there are important qualifications to this mandate. First, it is limited in scope to specific trade obligations (excluding for instance MEA provisions that leave discretion to parties as to the type of measure that may be adopted to ensure compliance). Second, it states that the negotiations are without prejudice to the rights of any Member to the extent that it is

not a party to an MEA. In other words, the mandate does not cover party/non-party issues. These qualifications are sometimes perceived as having effectively enabled the CTES to side-step the areas where conflicts between the WTO and MEAs are most likely to arise. Indeed, to date no real progress on the issue has been made. A majority of WTO Members supports the status quo and considers that the existing rules provide the necessary flexibility to take MEAs into account. Some Members - including countries that have not ratified the CBD and/or the Protocol - also seem reluctant to further negotiate in this area, as there is fear that the rules of MEAs may become predominant over trade rules. At present, the only Members pushing for a substantive output from the negotiations are the European Communities (EC) and Switzerland.

Paragraph 31(ii) mandates negotiations on procedures for information exchange between MEAs and the relevant WTO committees, and on the criteria for the granting of observer status in WTO bodies. Here, Members have identified various avenues that could be further explored to strengthen mechanisms of cooperation between the WTO and MEA Secretariats, including organizing joint WTO, UNEP and MEA technical assistance and capacity building projects. In fact, WTO's participation in this training workshop can be cited as an example in this respect. There has been no dedicated discussion of specific criteria that could be applied by WTO bodies when dealing with requests for observer status from MEAs.⁵

Paragraph 31(iii) mandates negotiations on the reduction or, as appropriate, the elimination of tariff and non-tariff barriers to environmental goods and services. Negotiations in this area have been the main focus in CTES discussions over the last years and technical work has focused on two main areas: renewable/clean energy and air pollution control. The negotiations provide a good example of a possible win-win for trade, environment and development, as they may lead to greater access to products and technologies that have clear environmental benefits.

⁵ Some general criteria for the granting of observer status to international inter-governmental organizations are set out in Annex 3 of the Rules of Procedure of the General Council.

³ LT/UR/D-6/2.

⁴ WT/MIN(01)/DEC/1.

Finally, worth mentioning is the end of paragraph 32, which adds that "the outcome... of the negotiations carried out under paragraph 31(i) and (ii) shall be compatible with the open and non-discriminatory nature of the multilateral trading system, shall not add to or diminish the rights and obligations of Members under existing WTO agreements, in particular the Agreement on the Application of the Sanitary and Phytosanitary Measures, nor alter the balance of these rights and obligations, and will take into account the needs of developing and least-developed countries". This qualification was added to caution against altering through the negotiations the balance of rights and obligations of WTO Members under the existing agreements.

Relevant WTO Agreements

Most relevant in the biosafety area, as will be further discussed below, is the SPS Agreement, which underlying objective is - in short - to ensure that Members do not use food safety, animal and plant health regulations as unjustified trade barriers to protect their domestic agricultural industries from competitive imports. However, apart from the SPS Agreement, several other WTO agreements are also directly relevant in the biosafety area.

GATT 1994

The original General Agreement on Tariffs and Trade (GATT 1947) was revised as part of the Uruguay Round and the revised text, GATT 1994, constitutes an integral part of the WTO. GATT 1994 is the umbrella agreement for trade in goods and covers the basic principles that form the foundation of the multilateral trading system. Its rules continue to apply where not superseded by a more specific WTO Agreement. Article I prohibits discrimination between products imported by Members, also referred to as the Most Favoured Nation (MFN) principle. Article III prohibits discrimination between imported and domestic goods, also referred to as the principle of national treatment, and Article XI prohibits quantitative restrictions on trade.

Exceptions to the basic principles are contained in Article XX (b) and (g). They permit Members to take measures necessary to protect human, animal and plant health, or relating to the conservation

of exhaustible national resources, as long as they do not arbitrarily or unjustifiably discriminate between countries where the same conditions prevail or constitute a disguised restriction on international trade. In other words, Article XX gives Members the legal means to balance their trade obligations with non-trade objectives such as health protection or the environment. As will be further discussed below, the SPS Agreement builds on the general exception of Article XX (b) and provides additional rules in this regard.

TBT Agreement

Technical regulations and industrial standards are important but vary from country to country. Having too many different standards may create difficult situations for producers and exporters. If standards are set arbitrarily, they could be used as an excuse for protectionism. The Agreement on Technical Barriers to Trade (the TBT Agreement) aims to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles to trade. However, the TBT Agreement recognizes Members' rights to adopt the standards they consider appropriate - for instance to protect human, animal or plant life or health, or the environment, or to meet other consumer interests.

At the outset, it is important to understand that the scope of the TBT Agreement and the SPS Agreement are different. As will be further discussed below, the SPS Agreement covers all measures whose purpose is to protect (i) human or animal health from food-borne risks; (ii) human health from animal- or plant-carried diseases; (iii) animals and plants from pests or diseases; and (iv) the territory of a country from other damage caused by the entry or spread of pests. This protection applies regardless whether these are technical measures or not. The TBT Agreement covers all technical regulations, voluntary standards and procedures, except when these are SPS measures as defined by the SPS Agreement (Article 1.5 of the TBT Agreement). It is the type of measure which determines whether the measure 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 may 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 can include pharmaceutical restrictions, or the labelling of cigarettes. Most measures related to human disease control are in fact under the TBT Agreement, unless they concern diseases which are carried by plants or animals. In terms of food, labelling requirements, nutrition claims, quality and packaging regulations, etc. are generally not considered to be SPS measures and hence are normally subject to the TBT Agreement. However, if the packaging and labelling requirements are directly related to the safety of the food, then they are 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 (or "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, animal and 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 technological problems or geographical factors.

Additionally, SPS 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 establish whether a measure is an SPS measure, or a measure subject to the TBT Agreement.

TRIPS Agreement

Finally, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which establishes minimum levels of protection that each Member has to give to the intellectual property of other Members, should be noted. In particular, the issue of obtaining patents on live plants and animals, including biotechnological inventions and plant varieties, is a heatedly debated topic. Concerns are expressed in particular about the economic, social, environmental and ethical impacts of life patenting. In addition, developing countries are concerned that life patenting could affect their development prospects and have an impact on their food security situation. A detailed analysis of the issues, however, falls outside the scope of this paper.

The SPS Agreement

One objective of the Uruguay Round was to further reduce barriers to agricultural trade. In fact, an agriculture specific agreement was included in the multilateral trade negotiations for the first time and the aim was to reduce tariffs for agriculture products and to eliminate to a large extent the agriculture-specific trade barriers that existed. This led to the creation of the Agreement on Agriculture, which prohibits the use of agriculture-specific non-tariff measures such as import quotas and discretionary licenses, reduces the use of export subsidies and disciplines the use of production subsidies that may distort trade. Some countries, however, were concerned that the reduction of tariffs and other barriers would be circumvented by disguised protectionist measures in the form of sanitary and phytosanitary regulations. In fact, a sanitary or phytosanitary restriction which is not required for health reasons can be a very effective protectionist device, and because of its technical complexity, a difficult barrier to challenge. To close this loophole, another - complementary - agreement, the Agreement on the Application of Sanitary and Phytosanitary Measures was created.⁶ Both the Agreement on Agriculture and the SPS Agreement are serviced by the Agriculture and Commodities Division of the WTO.

Scope

The SPS Agreement ensures that governments can give health protection priority over trade. It grants governments the explicit right to impose restrictions on international trade when these are necessary to protect human, animal or plant health from certain risks (Article 2.1). The scope of the SPS Agreement is further defined in Annex A. The Agreement does not apply to all risks to human health, only those from unsafe food or beverages, or risks from diseases carried by animals or plants.

The Agreement also applies to the protection of animal health from contaminated feed, or from pests and diseases, and to the protection of plant health from pests or diseases. Finally, measures to protect the territory of a country from damage from the spread of pests, even if these do not bring a disease threat, are covered by the SPS Agreement. This includes what are now popularly referred to as "invasive species". The Agreement covers all plants and animals, not just commercially important species, and includes fish, wild fauna and flora (see **Box 2**).

⁶ At the time of the Uruguay Round, an Agreement on Technical Barriers to Trade, adopted in 1979, was already in place. However, this agreement was not developed primarily for the purpose of regulating SPS measures but nonetheless covered technical requirements resulting from food safety and animal and plant health measures. It was generally felt that the relationship between health protection and trade measures required more in depth coverage than the TBT Agreement provided, i.e. through the adoption of a separate agreement on sanitary and phytosanitary measures. As a result of the Uruguay Round, the 1979 TBT Agreement was superseded by the current TBT Agreement.

Box 2: The SPS Agreement applies to all measures taken by governments:**to protect****from**

human health and life

risks arising from additives, contaminants, toxins or disease-causing organisms in foods and beverages; or

risks arising from disease carried by animals, plants or their products, or from the entry and spread of pests

animal health and life

risks arising from the entry, establishment or spread of pests, diseases, disease-causing or disease-carrying organisms; or

risks arising from additives, contaminants, toxins or disease-causing organisms in feedstuffs

plant life and health

risks arising from the entry, establishment or spread of pests, diseases, disease-causing or disease-carrying organisms

the territory of the country

damage from the entry, establishment or spread of pests

Scientific justification

Governments should be able to demonstrate that a trade restriction is indeed necessary to protect health, i.e. that there is scientific evidence of a potential risk to health (Article 2.2). There is one exception to this requirement which will be discussed later. Essentially two options are available to governments in order to provide a scientific justification for a trade barrier. The first, and most encouraged by the WTO, is for governments to make use of internationally developed standards, guidelines and recommendations (Article 3.1). This process is often referred to as "harmonization". In terms of international standards, the SPS Agreement identifies three organizations as being relevant (Annex A). For food safety, the Agreement identifies the standards and guidelines adopted by the Codex

Alimentarius Commission, established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The standards and guidelines of the Office International des Epizooties (OIE, now the World Organization for Animal Health) are considered as the reference for animal health protection and zoonoses. The standards and guidelines adopted under the auspices of the FAO's International Plant Protection Convention (IPPC) provide the reference for plant protection. The work of these three "sister" organizations on GMOs is summarized in **Box 3** below. It is important to note that governments who base their SPS measures on international standards benefit from a legal presumption of having complied with the SPS Agreement (Article 3.2).

Box 3: GMOs and the three sisters

Codex:	- Principles for the risk analysis of foods derived from modern biotechnology - Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants - Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA micro-organisms
IPPC	- Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms (ISPM 11)
OIE	- Working group on biotechnology

In those cases where there is no relevant international standard, or a government chooses not to use one, the government must be able to show that its measure is based on an assessment of the potential health risks (Article 5.1). Risk assessment is proving to be one of the most critical and most difficult provisions of the SPS Agreement. Although the Agreement sets out some general criteria for risk assessments, it does not detail the methodology to be used, though governments should at least consider the risk assessment methodologies developed by Codex, OIE and IPPC.

The risk assessment should identify potential health hazards and consequences but is not expected to answer the question of whether these risks are "acceptable". The Agreement allows governments to decide the acceptable level of risk or, to use the terms of the Agreement, the appropriate level of health protection (also referred to as "ALOP"). In making this decision, the SPS Agreement obliges governments to be open and to ensure that their acceptance of higher levels of risk in one case and lower levels in another is not arbitrary or a disguised restriction to trade (Article 5.5).⁷

Once a government has determined what level of risk it will accept, it should put in place that measure which ensures the necessary health protection but which is also

the least restrictive to international trade (while technically and economically feasible) (Article 5.6). For example, fumigation treatment to ensure that imported apples do not bring dangerous insects with them is less trade restrictive than an outright prohibition of apples from countries where such insects exist. There may be circumstances where a prohibition is the only feasible way to ensure health protection - but the importing government must be able to justify its measures.

The only exception to the requirement of scientific justification is the possibility for governments to take provisional measures when the scientific evidence is insufficient to demonstrate a health risk. In these cases, however, the government must actively seek further scientific information and review its provisional measure within a reasonable period of time (Article 5.7).

Equivalence and regionalization

The SPS Agreement requires governments to recognise that there may be more than one way to ensure a product is equally safe. If an exporting country can demonstrate that the safety of its product is equivalent to that required by the importing country, then the product should be permitted, even though it was not produced according to the standards or processes normally required by the importing country (Article 4).⁸ The initial

⁷ The SPS Committee has adopted guidelines to help governments ensure consistency in their levels of health protection (G/SPS/15). The guidelines are available on the WTO website.

⁸ The SPS Committee has developed guidelines to assist governments implementing this provision (G/SPS/19/Rev.2). The guidelines are available on the WTO website.

burden is on the exporting country to provide the necessary evidence to show that its product is equally safe, and on the importing country to objectively assess this claim.

When considering, in particular, protection of plant and animal health, the prevalence of particular pests or diseases in the exporting country is of critical importance. However, pests or diseases may occur only in a certain part of a country, or in a region, which encompasses parts of several countries and, with proper controls, other areas of the country may be considered as pest- or disease-free. Conversely, a particular pest or disease may pose a risk only for certain areas in the importing country and be of no concern to other areas due to lack of suitable hosts or climatic or geographical conditions. The SPS Agreement requires that importing countries adapt their requirements according to the pest or disease status of the region from which the product is coming and according to the conditions in the region to which the product is destined (Article 6). As with equivalence, the burden is initially on the exporting country to demonstrate the pest- or disease-free status of a particular area, and on the importing country to objectively assess this claim.

Control, inspection and approval procedures

In addition to imposing disciplines on the selection of SPS measures, the SPS Agreement also requires that testing and inspection procedures used by governments to enforce these measures do not themselves act as unnecessary trade barriers. The basic requirement is that any such procedures should not be less favourable for imported products than they are for domestic goods, and should be no more than what is necessary to ensure compliance. This applies for time delays, information requirements, fees, sampling procedures, siting of facilities, etc. (Article 8 and Annex C).

Transparency

One of the basic principles of the WTO is that trading partners should be able to identify what requirements and restrictions may affect their products. A basic obligation for transparency is also included in the SPS Agreement (Article 7 and Annex B). First, the Agreement requires governments to

publish all of their SPS measures so that they can be known by trading partners. Following publication, governments should allow a reasonable period of time (normally at least 6 months) before the measure enters into force so that exporting countries can adapt to the new measure.

Second, there is an obligation for governments to notify the WTO whenever a new or modified measure has been proposed, if this measure may have an effect on international trade and is not based on an international standard. Trading partners should be provided with a period of at least 60 days to comment on the proposed measure. The advance notification is not required for provisional measures taken under urgent circumstances but these must be immediately notified and comments taken into consideration. By October 2006, of the 7,200 SPS notifications circulated since the SPS Agreement took effect in 1995, close to 170 notifications related to GMOs.

A third transparency obligation is for each WTO Member to establish an "enquiry point" with the responsibility of providing information regarding SPS measures. Lists with the names, addresses and contact details for national enquiry points are circulated by the WTO Secretariat, and any interested trading partner can contact an enquiry point to request copies of regulations, bilateral agreements and risk assessments. Although the SPS Agreement does not require it, most national enquiry points will also respond to requests from interested exporters and other private sector groups.⁹

Developing countries

It is clear that implementation of the various obligations of the SPS Agreement may require considerable technical, administrative and financial resources. The Agreement contains some provisions to facilitate implementation by developing countries, while still ensuring that health

⁹ The SPS Committee has adopted recommended procedures regarding all aspects of the transparency provisions, as well as standard formats for regular and emergency notifications (G/SPS/7/Rev.2 and Add.1). A practical guide on how to notify measures to the WTO, establish an enquiry point and respond to enquiries ("Transparency Handbook") is available on the WTO website.

protection is not compromised (Article 10). It provides that governments should phase in new requirements, to the extent potential health risks permit, on products of particular interest to developing countries. They should also provide technical assistance to developing countries to enable them to meet new requirements on their products. In addition, a developing country may seek a waiver from its obligations under the Agreement. WTO Members should assist developing countries to receive the technical assistance they may need to implement the SPS Agreement (Article 9). The assistance may take the form of training, credit, donations, etc. and can be provided either directly by countries or through the relevant international organizations. The WTO Secretariat also undertakes training activities to ensure that developing countries are familiar with both their rights and their obligations under the Agreement.

The SPS Committee

The SPS Committee has been established to oversee the implementation of the Agreement and provide a forum for the discussion of any trade issues related to SPS measures (Article 12). Like other WTO committees, all WTO Members have the right to participate in the work and decision-making of the SPS Committee. Decisions are taken by consensus. The SPS Committee has accepted Codex, OIE and IPPC as observers, as well as a number of other international and regional intergovernmental organisations with activities in food safety, animal health and plant protection. A request for observer status from the CBD Secretariat is currently pending. The SPS Committee normally holds meetings three times each year, usually at the WTO Headquarters in Geneva. In addition to considering specific trade concerns raised by governments, the SPS Committee reviews virtually all of the provisions of the Agreement at its meetings, with standing agenda items on monitoring the use of international standards, transparency, equivalence, regionalization, technical assistance and special and differential treatment.

Dispute resolution

The WTO procedures for resolving trade disputes apply to disputes arising from the application of SPS measures (Article 11). The procedures require initial bilateral

consultations and provide for the establishment of an independent panel of trade experts to examine the case. The parties to the dispute have the opportunity to make both written and oral arguments, and the panel issues its legal findings and recommendations in a publicly available report. The findings of the panel can be appealed and legal issues re-examined by the WTO's Appellate Body. When the dispute involves SPS measures, the panel of trade experts often may seek scientific and technical advice. The advice can be sought either from individual experts or through the establishment of an advisory group.

To date, five disputes involving SPS measures have been considered by WTO panels:

- the EC's prohibition of imports of meat from animals treated with growth-promoting hormones from the United States (US) and Canada (*Hormones*);¹⁰
- Australia's restrictions on imports of fresh chilled or frozen salmon from Canada (*Salmon*);¹¹
- Japan's testing requirements for different varieties of US fruits to ensure the effectiveness of treatment against codling moth (*Varietals*);¹²
- Japan's requirements on apples imported from the US relating to fire blight (*Fire blight*);¹³
- the ECs' measures affecting the approval and marketing of biotech products from the US, Canada and Argentina (*Biotech*).¹⁴

In all of these cases, scientific and technical advice was sought from several experts on an individual basis. Additionally, other disputes regarding SPS measures have formally been brought to the WTO. Some have subsequently been resolved, while bilateral consultations are continuing for others. At present, one dispute regarding the continued suspension of obligations in

¹⁰ WT/DS26 and WT/DS48.

¹¹ WT/DS18 [WT/DS21].

¹² WT/DS76.

¹³ WT/DS245.

¹⁴ Following the training workshop, the Dispute Settlement Body on 21 November 2006 formally adopted the Panel Report in the *Biotech* dispute (WT/DS291, WT/DS292 and WT/DS293). The Panel Report is available on the WTO website.

the *Hormones* dispute is still underway.¹⁵ In this case, the EC has complained *inter alia* about the failure by the US and Canada to remove retaliatory measures despite the EC's claim that it has removed WTO-inconsistent measures and about their unilateral determination that the new EC legislation is a continued violation of WTO rules. A meeting of the panel with experts recently took place in Geneva, which was open for observation by the public.

The *Biotech* dispute

One of the most awaited cases in WTO history has undoubtedly been the *Biotech* dispute. Because of its complexity, the dispute encountered several delays but on 29 September 2006, just a few days before the start of the training workshop, the Panel Report was issued to the public. It was the lengthiest report in WTO history. Publication of the report was followed by much debate, in particular within the EC, which eventually decided not to appeal the report. On 21 November 2006, as mentioned above, the DSB formally adopted the report. Given its relevance for trade in GMOs and GM products, a brief presentation of the dispute and references to the most important paragraphs are included below. The conclusions of the panel are contained in paragraphs 8.1 to 8.64 of the report.

In the beginning of the 90s, in accordance with its legislation, the EC authorized a number of GMOs for commercial release into the environment for different uses, some for cultivation, others as food or feed. By the mid-90s, however, several EC member states started to express concerns. They believed that the existing regulatory framework was not adequate, in particular with regard to issues such as risk assessment, labelling and traceability. As a result of these concerns, and in reaction to rapid scientific developments and the negotiation of the Protocol, no new GMOs were approved under the legislation in force during the period October 1998 until May 2004. By that time, the EC had adopted a new set of rules, which have been discussed by another key speaker at the training workshop, Mr Veit Koester from Denmark.

However, in August 2003, just a few weeks before the Protocol entered into force, the US, Canada and Argentina, all major GMO

producers and exporters, requested the establishment of a panel under the WTO dispute settlement procedure. In short, the countries claimed that:

- the EC had implemented a general de facto moratorium;
- the EC had failed to approve specific GM products;
- the EC member states had prohibited products which had been approved by the EC after consideration by its own scientific regulatory approval process;
- the moratoria and the national prohibitions constituted an unjustified barrier to their trade in agricultural and food products, thus violating the SPS Agreement as well as GATT. Some of the complaints also alleged violations of the TBT Agreement.

The panel analyzed the scope of the SPS Agreement and found that the EC approval procedures were - in fact - SPS measures. It also found that the EC had "de facto" established a moratorium, however that this moratorium was not an SPS measure *per se* but rather affected the operation and application of the EC approval procedures. In addition, it found that the EC's failure to complete its approval procedures without "undue delay" was inconsistent with the Agreement's provisions on control, inspection and approval procedures (Article 8 and Annex C).

The panel also ruled on the prohibitions that a number of EC member states – Austria, France, Germany, Greece, Italy, Luxemburg and the UK - had imposed on the importation, marketing or sale of a number of biotech products which had already been approved at Community level. The panel found that these prohibitions were also SPS measures and could not be regarded as provisional SPS measures (Article 5.7) - as the EC had argued - because there was sufficient scientific evidence available to conduct a risk assessment. In fact, risk assessments had been conducted under the EC scientific regulatory approval process and resulted in positive opinions. Consequently, the prohibitions were not based on these risk assessments and although some member states submitted

¹⁵ DS320 and DS321.

additional reports and studies, the panel considered that the additional documentation did not constitute a proper risk assessment. These prohibitions thus violated the SPS Agreement (Article 5.1).

Of particular interest is that the panel took a wide view of the SPS Agreement and found that a broad range of measures to protect biodiversity fall within its scope, including cross-contamination of plants by GM plants, reduction of the economic value of crops, effects on non-target insects and plants, etc. The panel considerations on the applicability of the SPS Agreement are contained in paragraphs 7.147 to 7.437 of the report.

The panel also addressed the issue of the application of the CBD and the Protocol (paragraphs 7.49 to 7.96). Generally, claims under the WTO dispute settlement mechanism can only be based upon violation of WTO Agreements but - under certain circumstances - other international agreements can be taken into account in the interpretation of WTO Agreements or be used as a defence. For instance, a country can admit to have violated the SPS Agreement but declare that it did so because it had to implement another international agreement to which it is a party. The panel considered that if a rule of international law is not applicable to one of the parties to the dispute, it is not applicable in the relations between all WTO Members. Given that the US was not a party to the CBD, the panel ruled that it was not required to take the CBD into account in interpreting the WTO Agreements at issue in the dispute. Similarly, the panel considered that it was not required to take the Protocol into account since Argentina, Canada and the US were not parties to it. Moreover, the panel noted that the Protocol had entered into force after the panel was established.

Apart from the panel findings on the applicability of the SPS Agreement, it should be noted that the report in itself is a narrow and specific ruling. The panel did not rule on a number of important questions that remain outstanding. For instance, it did not examine:

- whether biotech products in general are safe or not;
- whether the biotech products at issue in the dispute are "like" their conventional counterparts; Although

this claim was made by the complaining parties in relation to some aspects of their complaints, the panel did not find it necessary to address those aspects of the complaints since the EC and the member states violated the SPS Agreement; The thorny "like" issue would certainly have come up in considering violations of the TBT Agreement and/or GATT.

- whether the EC has a right to require pre-marketing approval of biotech products;
- whether the EC approval procedures are consistent with the EC's obligations under the WTO Agreements;
- the conclusions of the relevant EC scientific committees regarding the safety evaluation of specific biotech products.

The Protocol and WTO rules: conflict or co-existence?

The Protocol was adopted in 2000 and entered into force in September 2003. It stipulates the rules for the safe transfer, handling and use of living modified organisms (LMOs), both where it concerns LMOs for voluntary introduction into the environment - such as seeds and live fish - and LMOs for direct use as food or feed, or for processing (FFP). The latter represents the bulk of GMO trade, including crops - such as soybean, cotton and maize. It should be noted that the Protocol does not cover products that may be derived from GMOs - such as processed foods, cotton clothes, etc.

This paper will not discuss the Protocol in detail, which has been done by other key speakers at the training workshop. However, its provisions raise a number of questions with respect to their relationship to WTO rules - since both disciplines regulate the transboundary movement of GMOs. Tensions between the two regimes are also reflected in the Preamble to the Protocol. On the one hand, it states that the Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international

agreement - such as the SPS Agreement - and, on the other hand, that the Preamble is not intended to subordinate the Protocol to other international agreements.

Generally, the main concern of GMO producing and exporting countries, such as the US, Canada and Argentina, is to have reliable access to foreign markets. Other countries or regions, such as the EU, have adopted what they consider to be a pragmatic precautionary approach. Both sides claim to have strict import and approval measures to guarantee a high level of health and environmental protection. Developing countries are often "caught in the middle". They are of course concerned about health and environmental risks, but at the same time, they wish to preserve their export opportunities, in particular to markets that are sceptical about GMOs. There are examples of developing countries that wish to stay GMO-free for these reasons – as can be illustrated by the recent controversy around GMO food aid being refused by certain countries in Africa.

The different trade concerns and perspectives on GMOs may lead to different trade regimes, which may in turn give rise to disputes between GMO-exporting countries and potential importers. If all countries in such a conflict are not only WTO Members but also parties to the Protocol, then the conflict is likely to be addressed through mechanisms established under the Protocol itself. However, if the exporting country is not a party to the Protocol, then the case is more likely to be decided before the WTO. The risk of such potential conflict further increases as the parties to the Protocol adopt more detailed rules and implementation requirements over time.

Nevertheless, as mentioned above, to date there has been no dispute before the WTO regarding trade measures taken pursuant to an MEA, so it is difficult to predict how such conflict would be handled by a WTO panel, or what weight might be given to the provisions of the Protocol in the context of a trade dispute.¹⁶ There are also commentators who believe that the risk of conflict is perhaps being overstated. Others, however, underline that the Protocol has a much wider application than most existing MEAs and that there are big differences on both sides of the Atlantic Ocean on how to

¹⁶ As mentioned above, the *Biotech* dispute applies to measures that pre-date the entry into force of the Protocol.

deal with GMOS. Selected issues that might be the source of a potential conflict with WTO rules, in particular the SPS Agreement, are highlighted below.

Precaution

The Protocol is based on application of the precautionary principle. It allows for trade restrictions to be taken where there is a lack of scientific certainty regarding potential adverse effects of LMOs that are intended to be released into the environment. This seems to go beyond the scope of the SPS Agreement, which permits the taking of provisional SPS measures (Article 5.7) in cases where relevant scientific evidence is insufficient and on the basis of available pertinent information. In addition, Members should seek to obtain additional information necessary for a more objective assessment of the risk and review the SPS measure accordingly within a reasonable period of time. Although the precautionary principle thus finds some reflection in Article 5.7, the Appellate Body on several occasions noted that insufficient scientific evidence is not the same as scientific uncertainty. They should be regarded as two different concepts. It also noted that inconclusiveness of scientific evidence cannot, in itself, justify the application of Article 5.7 and that scientific uncertainty always exists.

Risk assessment

Both the Protocol and the SPS Agreement contain similar language as to the importing country ensuring that decisions are based on risk assessment. According to the Protocol, the importing party may carry out the risk assessment, or request the exporting party to do so. If the risk assessment is performed by the importer, it can recover the cost from the potential exporter. In case of the SPS Agreement, it is also the importing country which must ensure that its decision is based on a proper risk assessment. However, the Agreement does not oblige the importing country to carry out the assessment itself. It may rely on assessments carried out by the exporting country or by any other Member or by international organizations if these are appropriate to the circumstances. Thus, at first sight, the main difference seems to be in the cost. Under the SPS Agreement, it is the importing country that eventually bears the cost of the risk assessment, while under

the Protocol the exporting party might be required to finance the assessment.

In deciding whether and under which conditions to accept the import of LMOs, the Protocol allows countries to take into account "socio-economic considerations" arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities. Under the SPS Agreement, an assessment of the risks to animal and plant health should take into account the following relevant economic factors: (i) 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; (ii) the costs of control or eradication in the territory of the importing Member; and (iii) the relative cost-effectiveness of alternative approaches to limiting risks (Article 5.3). The list is exhaustive and does not apply to the assessment of risks to human health, for which the inclusion of economic factors was considered inappropriate at the time of writing the SPS Agreement.

Documentation requirements

One of the most contentious issues discussed under the Protocol are the documentation requirements for the shipment of LMOs destined for direct use as food or feed, or for processing (FFP). According to the Protocol, LMOs intended for FFP must clearly identify that they "may contain" LMOs and that they are not intended for release into the environment. Parties to the Protocol recently adopted a Decision which further elaborates this requirement. It provides that when the identity of the LMO is known through identity preservation systems, the shipment should be labelled as "contains" LMOs. This seems to go beyond the original requirement in the Protocol and might prove burdensome for the industry, which must establish strict traceability systems (identification and segregation). That being said, reportedly the new requirements do not apply to transboundary movements of LMOs between parties and non-parties to the Protocol (at the request of Mexico who imports LMOs from the US).

Nevertheless, the documentation requirements could be challenged before the WTO by an exporting Member on the ground

that they impose an unjustified barrier to trade. In the *Biotech* dispute the Panel ruled that labelling requirements related to the safety (or safe use) of a product fall within the scope of the SPS Agreement. If not, labelling regulations for LMO shipments are likely to fall under the TBT Agreement (for instance when the objective of the regulation is to inform the consumer) and/or GATT. Since the TBT Agreement restates the basic principle of non-discrimination (as contained in GATT) with regard to imported products and "like" products of domestic origin, the issue would thus be whether GMOs and GM products should be considered "like" their conventional counterparts. If this is the case, then there might be no ground for applying any special treatment, including mandatory labelling and traceability requirements.

Concluding remarks

Given the Panel Report in the *Biotech* dispute, a wide range of measures to protect biodiversity fall within the scope of the SPS Agreement. This in turn requires governments to consider and implement the relevant provisions of the Agreement in their biosafety regulatory frameworks, in particular in relation to risk assessment. Prohibitions on the importation, marketing or sale of biotech products should be based on a proper risk assessment and approval procedures should be completed without "undue delay". Nevertheless, the panel's considerations do not prohibit countries to have approval procedures in place. Moreover, in accordance with Article 5.7 of the Agreement, governments have a right to take provisional measures if there is insufficient scientific evidence to evaluate the risk although in such a case governments must seek further scientific evidence and review their provisional measure within a reasonable period of time.

That being said, a number of practical considerations deserve further attention. First, "proof" of a proper risk assessment would only be required when a formal complaint is brought to the WTO that a particular measure violates the SPS Agreement. Although to date several complaints have been brought to the WTO, most of these complaints have been resolved through bilateral consultations. Only five disputes involving SPS measures have been considered by WTO panels. To date, no SPS panel was established to

consider an SPS measure maintained by a developing country. Initiating a dispute before the WTO is usually expensive and only opportune if substantial economic interests are at stake. Thus, the probability of Cambodia, Thailand or Vietnam becoming formally involved in a trade dispute before the WTO on GMOs is at this stage actually low - although the possibility cannot be ruled out altogether.

Further reflecting upon the compatibility of the Protocol and the SPS Agreement, the Agreement does not require the importing country to carry out the risk assessment itself. It can use an assessment done by the exporting or another country or by an international organization, as long as it is appropriate. In particular in the case of food safety assessments (i.e. the bulk of GMO trade) it might be practical to rely on other assessments. If a GM product is known to have negative effects on human health, it makes little difference if the humans in question live in Vietnam, Switzerland or the US. The situation would be different in the case of risks to plant and animal health or the environment, since disease conditions, climate, geography, etc. would usually be different. Although seeking scientific evidence is ultimately the responsibility of the importing country, exporters could be requested in the national legislation of the importing country to submit all the relevant documentation in order for the importing country to be able to perform a proper risk assessment. In terms of cost, Annex C allows Members to impose fees for the procedures on imported products - as long as the fees are equitable in relation to fees charged on "like" domestic products and no higher than the actual cost of the service.

Countries have a sovereign right to set their appropriate level of protection (ALOP), i.e. decide to be more or less risk-averse. Where a risk assessment can only be based on scientific evidence and take into account a limited list of economic factors (in the case of animal and plant health), the process of deciding whether the identified risks are acceptable provides countries with a possibility to take other "socio-economic" considerations into account - as long as

governments are open and avoid the acceptance of higher levels of risk in one case and lower levels in another if this is arbitrary and results in a disguised restriction to trade.

In complying with the SPS Agreement, governments should also be aware of the transparency requirements. This includes an obligation to notify in advance other countries of any proposed new or changed regulation that might affect international trade in GMOs and GM products and to answer reasonable questions of their trading partners about those regulations through their enquiry points. Related to the notification requirement is another important issue, namely that governments should consider and identify what the objective or purpose of any particular regulation will be. If the objective is only technical, for instance to inform consumers through GMO labeling, then the regulation should be notified under the TBT Agreement. However, if a government seeks to protect human health from the alleged harmful effects of GMOs or any other sanitary or phytosanitary objective (see **Box 1**), then the measure should be notified under the SPS Agreement. It is of course possible that a single regulation addresses both objectives. In those circumstances, the regulation must be notified twice, both under the TBT and the SPS Agreement.

Finally, governments are bound by the "single undertaking" principle, i.e. all multilateral trade agreements have to be complied with simultaneously. In particular, governments should be aware of their obligation to incorporate the basic non-discrimination principles of the multilateral trading system, as embodied in the SPS Agreement and GATT. For instance, regulations should not only stipulate the requirements on imported GMOs and GM products but also ensure that these requirements are similarly applicable to domestic products. Although in the short run Cambodia, Thailand and Vietnam are expected to be mainly importers of GMOs and GM products, in the near future they might also become producers and exporters.

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