

UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

**TRAINING MODULE ON THE  
WTO AGREEMENT ON  
SANITARY AND  
PHYTOSANITARY MEASURES**



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## ABBREVIATIONS

- AIA:** Advance informed agreement
- ALOP:** Appropriate level of sanitary or phytosanitary protection
- CAC:** Joint FAO/WHO Codex Alimentarius Commission
- CCFL:** Codex Committee on Food Labelling
- CCGP:** Codex Committee on General Principles
- FAO:** Food and Agriculture Organization
- GATT:** General Agreement on Tariffs and Trade
- GMOs:** Genetically modified organisms
- ICPM:** Interim Commission on Phytosanitary Measures
- IPPC:** International Plant Protection Convention
- ISPMs:** International Standards for Phytosanitary Measures
- JECFA:** Joint FAO/WHO Expert Committee on Food Additives
- JMPR:** Joint FAO/WHO Meetings on Pesticide Residues
- LDC:** Least developed countries
- LMOs:** Living modified organisms
- MEAs:** Multilateral environmental agreements
- NPPOs:** National plant protection organizations
- OECD:** Organization for Economic Co-operation and Development
- OIE :** Office International des Epizooties / International Office of Epizootics
- PPMs:** Processes and production methods
- S&D:** Special and differential treatment
- SPS:** Sanitary and phytosanitary measures
- STDF:** Standards and Trade Development Facility
- TBT:** Technical barriers to trade
- TNCDB:** Trade Negotiations and Commercial Diplomacy Branch
- UNCTAD:** United Nations Conference for Trade and Development
- UNDP:** United Nations Development Programme
- UNIDO:** United Nations Industrial Development Organization
- UR:** Uruguay Round of Trade Negotiations
- WHO:** World Health Organization
- WTO:** World Trade Organization



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This training module is for information and training purposes only and does not intend to state the official position of Member States of the WTO.

It aims to provide training materials and inputs for developing countries' trainers, lecturers and government officials involved in training and research tasks on the multilateral rules governing the application of sanitary and phytosanitary (SPS) measures in international trade.



## INTRODUCTION

Governments make use of a wide-range of measures to safeguard public health. Through the adoption of rules and regulations that govern food safety and animal and plant health, they seek to maintain the trust of consumers and mitigate losses from pests, diseases and contaminants, as well as from harmful, non-indigenous species. Governments set standards to fulfil a variety of purposes, including the traditional ones such as minimizing risks and raising efficiency, as well as others, such as encouraging technological progress. Rules and regulations are also established in response to changes in public demand. For example, as standards of living rise, so too does consumers' willingness to shoulder the economic costs of providing increasingly complex sanitary and phytosanitary regulations.

While rules and regulations can facilitate and enhance trade by increasing the confidence of consumers in imported products, they may also serve as barriers to trade, particularly for exporters in countries where the lack of monitoring, testing, and certification infrastructure makes it difficult to demonstrate compliance with import requirements. Indeed, developing countries have long been concerned by their trading partners' use of health, safety and environment measures for protectionist purposes.

The Uruguay Round Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) allows governments to implement border measures in pursuit of objectives relating to human, animal and plant life or health. Members have the right to determine the appropriate level of health and environmental protection that they afford to their citizens, animals and plants. The SPS Agreement establishes a series of procedural and substantive disciplines to ensure that SPS measures are not misused for protectionist purposes and that they do not result in unnecessary barriers to international trade. SPS measures thus vary, often substantially, from country to country, reflecting differences in desired levels of protection. These differences stem from a number of factors, such as geography, demography, the prevalence of diseases in a certain territory or area, cultural and religious values and the financial resources available for Governments to maintain and effectively enforce quarantine regimes. The diversity of SPS measures resulting from the independent development of national food laws can adversely affect developing countries in so far as they often lack not only the financial and technical capacity to comply with these diverse measures, but also the complete information on the number of measures affecting their exports.

The SPS Agreement encourages Governments to use international standards and to recognize other countries' compliance procedures as equivalent to their own if the same level of sanitary and phytosanitary protection is achieved. Should Members wish to adopt measures that provide a higher level of sanitary and phytosanitary protection than international standards, they must ensure that their measures are based on an assessment of the risks to human, animal and plant health in conformity with the standards, guidelines or recommendations of the relevant international organizations, namely the Codex Alimentarius Commission (Codex), which addresses issues concerning food safety, the International Office of Epizootics (OIE) for matters pertaining to animal health, and the Secretariat of the International Plant Protection Convention (IPPC) for plant health. The objective of minimizing negative trade effects is to be taken into account when determining the appropriate level of sanitary and phytosanitary protection.

Previous work in UNCTAD on SPS measures and trade examined the role of standards and regulations within the WTO context and the main issues of concern for developing countries

in the SPS Agreement and analysed the legal framework of the SPS Agreement by examining its substantive and procedural disciplines and the jurisprudence of the WTO panels and Appellate Body (Prévost, 2003<sup>1</sup>). This module, which is part of a series of training modules on trade negotiations, prepared by TNCDB<sup>2</sup>, draws on these works, identifies the main issues and presents them in a format suitable for training purposes. It aims to provide up-to-date background information on of SPS Committee's work on implementation and related issues.

The first section of this module identifies the basic principles of the SPS Agreement from a development perspective. It describes the scope of application of the SPS Agreement, the main rights and obligations it creates and how the international standard-setting bodies work. It explains the importance of transparency and notification obligations with regard to market access and the problems of implementing the special and differential treatment provisions for developing countries, and it reviews the recommendations WTO Members put forward to enhance them. In so doing, section I sets the stage for a further, more detailed examination of selected problems faced by developing countries in implementing the SPS Agreement, contained in section 2.

Section 2 addresses the participation of developing countries in the international standardization process, the provisions on equivalence and on regionalization, and specific trade concerns. It finishes with an overview of dispute settlement cases under the SPS Agreement

Section 3 provides additional reference materials that may be useful for trainers and researchers in developing countries for further investigation. In section 3, annex I provides relevant extracts from official SPS texts. Annex II contains a list of WTO dispute settlement cases relevant to the SPS Agreement. Finally, Annex III focuses on international trade in biotechnology products, in particular genetically modified organisms (GMOs), with a summary of domestic GMO regulations, the WTO legal framework applicable to trade in Biotechnology products, other applicable legal regimes, such as the Cartagena Protocol on Biosafety, and associated concerns.

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<sup>1</sup> Prévost, D., Dispute Settlement. World Trade Organization: SPS Measures, footnote 1.

<sup>2</sup> Previous Training Modules can be found at <http://www.unctad.org/tradenegotiations>.

## CHAPTER I

### BASIC PRINCIPLES OF THE SPS AGREEMENT AND ISSUES FOR DEVELOPING COUNTRIES

#### I.1. Scope of Application of the SPS Agreement

The SPS Agreement regulates the conditions under which national regulatory authorities may set and enforce health and safety standards that directly or indirectly affect international trade. In particular, it applies to any measure, regardless of the specific form it may take, which is adopted with the aim to:

- Protect consumers and animals from food- and feed-borne risks (SPS Annex A, para. 1(b)) and;
- Protect consumers, animals and plants from pest- or disease-related risks (SPS Annex A, paras. 1(a), (c) and (d)).<sup>3</sup>

In the case of food safety, for example, the SPS Agreement applies to risks deriving from additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs. For more details on the definition of SPS measures and risks involved, see Annex A of the Agreement, which is reproduced in Annex I of the present module.

It is clear from the above that in order to determine whether a measure falls under the SPS Agreement or under other WTO disciplines, such as the Agreement on Technical Barriers to Trade (TBT) or the General Agreement on Tariffs and Trade (GATT), the basic criterion is the purpose for which the measure is put in place. Measures which address health risks other than those mentioned above (such as a ban on asbestos products) or which are aimed at other policy objectives are not SPS measures. The distinction is significant, since the legal disciplines of the SPS Agreement are substantially different from, and in part stricter than, those applying to technical standards and regulations under the TBT Agreement or generally under GATT.<sup>4</sup>

Typical policy instruments used to achieve SPS protection are import bans, technical specifications, including process and product standards, and information tools, including labeling requirements. Process standards are the most commonly used SPS measures.

The SPS Agreement also covers measures adopted before its entry into force, i.e. 1 January 1995, which are still in place. There is thus a general obligation for Members to re-examine their existing SPS measures in order to ensure that they are in compliance with the new rules

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<sup>3</sup> The distinction between the two categories of risk, i.e. food-borne risks and pest or disease risks is important, since the kind of risk assessment to be conducted is different for each of these risk categories. See section I.2.3 Risk Analysis Obligations (Article 5).

<sup>4</sup> While the TBT Agreement explicitly excludes SPS measures from its application, so that there is no overlap in scope of application, Article 2.4 of the SPS Agreement clarifies that measures conforming to the SPS Agreement are presumed to comply with the relevant obligations under GATT, in particular the provisions of Article XX(b).

under the SPS Agreement, in particular in light of the obligation to base health regulations on risk assessment.

The SPS Agreement sets out both substantive and procedural requirements with the aim of preventing food safety and animal and plant health regulations from unnecessarily hindering international trade and from being misused for protectionist purposes.

## **I.2. Basic Rights and Obligations**

The following paragraphs address basic substantive provisions of the SPS Agreement.

While the Agreement recognises the right of each Member to adopt SPS measures for the protection of human, animal or plant life or health, based on the level of risk each Member deems appropriate, it tries to ensure that these measures are not used for protectionist purpose. It does so by imposing a number of obligations, including:

- a. The obligation that any SPS measure must be based on scientific principles and not be maintained without sufficient scientific evidence;
- b. The obligation to base SPS measures either on a relevant international standard or on a scientific assessment of the risk;
- c. The obligation to apply regulations only to the extent necessary to protect human, animal or plant life or health; and
- d. The obligation not to arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.

Other substantive provisions of the Agreement, such as those on recognition of equivalence and regionalization, which pose particular implementation problems for developing countries, are reviewed in Section II below.

### **I.2.1. Right to Take SPS Measures (Article 2)**

In principle, the Agreement allows Members to set their own food safety and animal/plant health regulations, provided certain requirements are respected.<sup>5</sup> Limitations on Members' rights to adopt SPS measures are to be found in paragraphs 2 and 3 of Article 2 of the Agreement and further qualified in other provisions, in particular Article 5.

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<sup>5</sup> This implies that, in the event of a dispute, it is up to the complaining party to prove that the measure is inconsistent with the provisions of the Agreement.

**THE RIGHT TO TAKE SPS MEASURES:** Members have the right to adopt SPS measures necessary for the protection of human, animal or plant life or health (Article 2.1).

**LIMITS ON THE USE OF SPS MEASURES:** Article 2.2 states that such measures must:

- 1) Be applied only to the extent necessary;
- 2) Be based on scientific principles, and not be maintained without sufficient scientific evidence, except as provided for in Article 5.7.

In addition, SPS measures must not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members (Article 2.3).

The requirement under Article 2.2 that SPS measures have a scientific basis and not be maintained without sufficient scientific evidence is the cornerstone of the SPS Agreement and it is further elaborated in Article 5.1 on risk assessment. Scientific evidence is required to identify the likelihood of risk and the means by which a particular requirement may reduce or eliminate that risk. Such evidence must be “sufficient”, i.e. there must be a rational relationship<sup>6</sup> between the measure and the risk assessment, and the results of the risk assessment have to sufficiently warrant the SPS measure.

The only qualified exception to this rule is provided by Article 5.7, which allows Members to adopt provisional SPS measures in cases where the scientific evidence available is not sufficient, provided other requirements are fulfilled.<sup>7</sup>

The exercise of the right to impose SPS measures is further limited by a non-discrimination requirement, in Article 2.3, where “Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail”. This broad non-discrimination provision is complemented by Article 5.5, according to which “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”.

### **1.2.2. Promotion of International Harmonization of Standards (Article 3)<sup>8</sup>**

One of the main objectives of the SPS Agreement is to further the widest possible use of harmonized measures based on internationally agreed standards so as to minimize the measures' negative impact on international trade.

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<sup>6</sup> Appellate Body Report, *EC - Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, 13 February 1998. Paragraph 193 clarifies that the requirement for SPS measures to be “based on” risk assessment required a rational relationship between the measure and that the results of the risk assessment had to sufficiently warrant the SPS measure.

<sup>7</sup> See section I.2.3 Risk Analysis Obligations (Article 5).

<sup>8</sup> For a detailed discussion of issues related to trade and international standards, including in the SPS context, see World Trade Organization, *The World Trade Report, Exploring the links between trade, standards and the WTO*, published on 30 June 2005, available under <http://www.wto.org>.

**MEASURES BASED ON INTERNATIONAL STANDARDS:** Members are encouraged to *base* their SPS measures *on* international standards, guidelines and recommendations, where these exist (Article 3.1).

- For an SPS measure to be “based on” a relevant international standard, the measure must be derived from it.

**INTERNATIONAL STANDARD-SETTING BODIES:** As defined in Annex A.3 of the SPS Agreement, the international standards, guidelines and recommendations referred to in Article 3.1 are those promulgated by the so-called "three sister organizations", namely:

- The *Codex Alimentarius Commission* (Codex) for food safety;
- The *International Office of Epizootics* (Office International des Epizooties - OIE) for animal health and zoonoses, and;
- The Secretariat of the *International Plant Protection Convention* (IPPC) for plant health.<sup>9</sup>

Members are not obliged to harmonize their SPS standards. International standards, guidelines and recommendations are, by their very nature, non-binding norms. However, through their explicit recognition in the SPS Agreement, such norms do indeed, acquire a certain force, most importantly, by creating a presumption of WTO/SPS compatibility.

**MEASURES CONFORMING TO INTERNATIONAL STANDARDS:** National SPS measures which *conform* to international standards, guidelines and recommendations are presumed to be in conformity with the provisions of the SPS Agreement and the GATT (Article 3.2).

- For an SPS measure to be “in conformity with” a relevant international standard, the measure must completely embody it.

By granting such rebuttable presumption of conformity, the Agreement provides a substantial incentive to Members to make fuller use of internationally harmonized standards, where they exist, and to promote the development of new standards in areas of interest to them, where these are lacking.

The benefits of harmonizing SPS measures based on international standards are evident:

- Trade is facilitated, since exporters will face uniform requirements in their export markets;
- The likelihood of a measure being challenged by trading partners is substantially reduced, since it is in principle considered WTO-consistent; and
- Member countries lacking the human and financial resources to carry out their own risk assessment will be able to refer to the authoritative science-based work done by the relevant international standard-setting body.

Nevertheless, in certain cases, especially when significant differences exist among Members in geographic, climatic and health conditions, risk perceptions, tastes, income levels and

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<sup>9</sup> For matters not covered by the Codex, OIE or IPPC, the SPS Committee may identify appropriate standards, guidelines and recommendations promulgated by other relevant international organizations.

technological endowment, the use of harmonized standards may not appear as a desirable option and equivalence of SPS measures could thus play a crucial role.<sup>10</sup>

In accordance with the basic right set out in Article 2.1, the SPS Agreement permits Members to depart from international harmonization if they have legitimate reasons.

**THE RIGHT TO TAKE MEASURES RESULTING IN A HIGHER LEVEL OF PROTECTION:** Members retain the autonomous right to adopt SPS measures which result in a higher level of protection than would be achieved by applying the relevant international standard. The Agreement reiterates that Members have the right to choose their own level of sanitary and phytosanitary protection, determined in accordance with the relevant rules of the SPS Agreement (see below).

**LIMITS TO THE RIGHT TO TAKE MEASURES RESULTING IN A HIGHER LEVEL OF PROTECTION:** In accordance with Article 2.2, the Member choosing a higher level of protection, thus deviating from an internationally agreed standard, must fulfill its obligations under the SPS Agreement - in particular Article 5 on risk assessment (Article 3.3).

Members adopting SPS measures deviating from relevant international standards must thus justify such measures by means of a scientific assessment of the risk.

Under Article 5.8, a Member may request another Member to provide reasons for the latter's SPS measure when the latter is not based on international standards and constrains or could potentially constrain the Member's exports. The importing Member is then obliged to provide such explanations.

The three sister organizations were selected by the drafters of the SPS Agreement for the high standards of their guidelines and recommendations, which are based on sound scientific analysis and evidence and involve a thorough review of all relevant evidence and information.

### **The Joint FAO/WHO Codex Alimentarius Commission (CAC)**

The *Codex Alimentarius Commission (CAC)* is an intergovernmental body, established in 1963, under the co-sponsorship of two UN organizations: the World Health Organization (WHO) and the Food and Agriculture Organization (FAO). The CAC has recently decided to meet once a year (previously it met on a biannual basis), in either Rome or Geneva. The CAC's primary mission is to administer the Joint WHO/FAO Food Standards Programme with the aim of protecting the health of consumers and promoting fair practices in food trade. The Commission is charged with establishing food safety and agricultural trade standards, codes of practice and maximum limits for additives, contaminants, pesticide residues and veterinary drugs, for the use of its 169 participating Governments in drafting their own national regulations. This task is performed through a network of committees, composed of delegates from member countries, each hosted by an agreed-to Government.

There are two types of committees: general subject committees, such as the one on food labeling, and commodity committees, such as the one on milk and milk products. In 1999, the Commission established three *ad hoc* intergovernmental task forces – on biotechnology,

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<sup>10</sup> See section II.2 Recognition of Equivalence of SPS Measures.

animal feeding and fruit juices. The technical work is carried out in cooperation with scientific bodies, such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meetings on Pesticide Residues (JMPR), while six regional Codex committees ensure coordination and promote region-specific needs. Finally, an Executive Committee oversees the Commission's work (for more details and Codex documentation, see: <http://www.codexalimentarius.net>).<sup>11</sup> Codex Committees and Task Forces are organized by host Governments, who pay for the operating costs of the meetings. However, the costs of delegates' participation are borne by the Governments concerned. This obviously poses a constraint on the participation of developing countries. Participation by correspondence is also allowed.<sup>12</sup>

In order for a new food standard to be adopted by the Commission, it has to proceed through an eight-step procedure, allowing time for members to comment, which should not take more than five years overall (with extensions permitted based on cause). An accelerated five-step procedure is also available. Adopted standards and guidelines are then compiled in the *Codex Alimentarius*. The entry into force of the WTO SPS Agreement has strengthened the role of Codex standards as a reference point for food quality and safety. By creating a presumption of WTO/SPS compatibility, these norms do, indeed, acquire a certain force. To avoid past occurrences where standards proposed by a relatively small group of interested countries were adopted by a simple majority vote, since 1999 the CAC has committed itself to making every effort to reach agreement on the adoption or amendment of standards by consensus.

### **The International Office of Epizootics (Office International des Epizooties – OIE)**

Created in 1924, the International Office of Epizootics is an intergovernmental organization, based in Paris, engaged in the prevention and control of the spread of zoonoses (animal diseases). Its mandate is to promote transparency and knowledge of the world's animal health situation, collect, analyse and disseminate veterinary scientific information, provide expertise and strengthen international cooperation and coordination. It develops standards and guidelines for use by its 164 Member countries to protect themselves against incursions of diseases or pathogens during trade in animals and animal products, while, at the same time, avoiding unjustified trade barriers. OIE standards are developed by internationally renowned scientific experts from Member countries, meeting in Specialist Commissions and Working Groups, with support from a network of 162 Reference Laboratories and Collaborating Centres. Five Regional Commissions are devoted to studying specific problems encountered by local veterinary services and promoting cooperation activities at regional level. International standards, guidelines and recommendations on animal health are finally adopted

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<sup>11</sup> In 2002, an evaluation of the Codex Alimentarius and other FAO and WHO Food Standards was undertaken by an independent Evaluation Team supported by an Expert Panel, with the aim of ensuring that these programmes best serve the concerns of all countries regarding health, safety and trade in food. The review process included a call for public comments. The report, completed in December 2002, confirmed that Codex Food Standards are given very high importance by member countries as a vital component of food control systems. The Report of the evaluation of the Codex Alimentarius can be accessed at: <http://www.fao.org/docrep/meeting/005/y7871e/y7871e00.htm>.

<sup>12</sup> The 26<sup>th</sup> Session of the Codex Alimentarius Commission met in Rome from 30 June to 7 July 2003 and was attended by delegates from 127 member countries, at that time the most ever to attend a Codex session. It adopted more than 50 new food safety and quality standards and, in particular, guidelines on how to assess the risks to consumers from food derived from biotechnology. Discussions were held on the "Codex Trust Fund", launched in January 2003, to enhance the participation in Codex by developing countries and countries with economies in transition. Members focused on the proposed criteria for eligibility and allocation of funds, based on World Bank indicators. Applications to the Fund will be entertained as soon as possible, subject to the availability of sufficient funding. Many delegations emphasized the importance of utilizing the Fund to support attendance of developing country members at the annual sessions of the Commission. See the Progress Report on the FAO/WHO Project and Fund for Participation in Codex, available at: <http://www.fao.org/docrep/meeting/006/y9487e.htm>.

by consensus by the OIE's highest authority, the International Commission, which meets once a year. OIE bears the costs of experts' participation in the Specialist Commissions and Working Groups, as well as that of delegates attending the annual General Session of the International Committee, where standards are adopted.

OIE standards undergo a regular updating process and are incorporated into the following codes and manuals: the "Terrestrial Animal Health Code" (12<sup>th</sup> edition, 2003) and the "Aquatic Animal Health Code" (6<sup>th</sup> edition, 2003) - containing detailed recommendations designed to prevent the introduction of infectious agents and diseases pathogenic to animals and humans into the importing country during trade in animals, animal genetic material and animal products; and their companion volumes the "Manual of Standards for Diagnostic Tests and Vaccines" and the "Diagnostic Manual for Aquatic Animal Diseases" - providing a uniform approach to disease diagnosis and vaccine control methods.<sup>13</sup>

### **The International Plant Protection Convention (IPPC)**

The International Plant Protection Convention is a multilateral treaty which aims to secure common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control. It currently has 120 contracting parties. The IPPC is administered through the IPPC Secretariat, located in FAO Headquarters, Rome, and is responsible for coordination of the work programme for the global harmonization of phytosanitary measures. Implementation is ensured through a network of regional and national plant protection organizations. Wide-ranging amendments to the Convention were adopted in 1997 to reflect contemporary phytosanitary concerns and the evolving role of the IPPC in relation to the SPS Agreement, but the New Revised Text of the IPPC (1997) has not yet entered into force. The implementation of the Convention is thus temporarily governed by an Interim Commission on Phytosanitary Measures (ICPM), composed of representatives from the National Plant Protection Organizations (NPPOs) from both IPPC contracting parties and FAO members.

The ICPM meets annually to direct the work programme of the Secretariat, lay down the priorities for standard setting and the harmonization of phytosanitary measures, review the state of global plant protection and approve standards. The Secretariat's main tasks are to develop International Standards for Phytosanitary Measures (ISPMs – to date, 19 ISPMs have been adopted), provide information and facilitate information exchange between contracting parties and provide technical assistance. An Interim Standards Committee, a group of phytosanitary experts from around the world, meets annually to review and comment on the suitability of documents prepared by the Secretariat. In April 2003, the 5<sup>th</sup> ICPM approved guidelines for the use of irradiation as a phytosanitary measure (ISPM 18), guidelines on a list of regulated pests (ISPM 19) and revised ISPM 15 on wood packaging in international trade to incorporate a new wood packaging mark.<sup>14</sup> Funding for the travel and subsistence of participants in expert working group meetings is provided by the IPPC Secretariat through the regular programme budget of FAO, except when such meetings are organized by a donor.

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<sup>13</sup> These codes and manuals are available on the OIE's Website at [http://www.oie.int/eng/normes/en\\_norm.htm](http://www.oie.int/eng/normes/en_norm.htm).

<sup>14</sup> Further details are available at the IPPC's website: <http://www.ippc.int/>.

### **I.2.3. Risk Analysis Obligations (Article 5)**

At the outset, it is important to underline that the SPS disciplines implicitly take into account a fundamental distinction between two aspects of the regulatory process relating to risk analysis: risk assessment and risk management. Risk assessment is the scientifically based process of determining the existence of a hazard and the likelihood of its occurrence. Based on the scientific results of the risk assessment and taking into account other factors relevant for the health protection of consumers, animal and plants, including societal value judgments, risk management involves a policy choice of weighing different alternatives, in consultation with all interested parties, with a view to identifying the desired level of health protection and, if necessary, the kind of risk mitigating (SPS) measure required to achieve that goal. However, it is worth noting that the distinction is not absolute, and non-scientific factors may also have an important role to play in risk assessment procedures.

Under the SPS Agreement, whereas the choice of an appropriate level of protection is regarded as an autonomous right of each Member, the design and adoption of an SPS measure must be based on science, and the applicable disciplines dealing with the process of scientific assessment of the risks are rather strict.

**NOTION OF APPROPRIATE LEVEL OF SANITARY OR PHYTOSANITARY PROTECTION (ALOP):** Annex A.5 defines ALOP as the level of protection deemed appropriate by a Member establishing an SPS measure.

Members may decide what level of protection they wish to afford their citizens, animals and plants. In choosing their ALOP, however, Members should take into account the objective of minimizing negative trade effects (Article 5.4). The use of the word “should” indicates that there is no binding obligation upon Members. In paragraphs 5 and 6 of Article 5, the SPS Agreement establishes obligations for applying the concept of appropriate level of protection (e.g. consistency and non-discrimination in the application of measures or that measures shall not be not more trade-restrictive than necessary to achieve the appropriate level of protection).

**RISK ASSESSMENT PARADIGM:** Members are required to ensure that their SPS measures are based on a scientific assessment of the risks involved to human, animal and plant health or life, taking into account risk assessment techniques developed by relevant international organizations (Article 5.1).

A risk assessment is the necessary foundation for all national SPS measures, unless such measures conform to international standards, as discussed above (Article 3.2): as such, risk assessment is a key yardstick by which SPS measures may be appraised as necessary and justified.<sup>15</sup>

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<sup>15</sup> The requirement to base SPS measures on a risk assessment draws on the assumption that full and objective, i.e. scientific, characterization of the probability and consequences of risks will narrow information gaps between exporters and importers and facilitate common judgements about the necessity for and design of any risk-mitigating, trade-restrictive SPS measure imposed. See Roberts, Orden and Josling, “WTO Disciplines on Sanitary

The requirement that SPS measures be “based on” a risk assessment presupposes a rational or objective relationship between the two elements, namely the SPS measure and the risk assessment. The results of the risk assessment must “reasonably support” or “sufficiently warrant” the relevant SPS measure.

Members are not required to engage in their own risk assessment, and may base their measures on other relevant risk assessments, such as those carried out by other Members or by a relevant international organization. Developing countries and economies in transition experiencing difficulties in conducting their own thorough scientific assessments of the risks due to technical and resource constraints, may find it more appropriate or convenient to “borrow” the relevant risk assessment from other Members, regional bodies or international organizations.

**CONCEPT OF RISK ASSESSMENT:** Annex A.4 defines two types of risk assessment, depending on the purpose of the SPS measure, namely protection from food-borne risks and protection from pest and disease risks.

In respect of *food-borne risks*, the definition of risk assessment requires 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. This involves:

- (a) Identifying the adverse effects; and
- (b) If any such effect exists, evaluating the potential of occurrence.

In respect of *disease or pest risks*, the definition of risk assessment, arguably more difficult to conduct, requires the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of the importing Member, according to the SPS measure which might be applied, and of the associated potential biological and economic consequences. In the animal/plant health area, a risk assessment is subject to a three-pronged test: It must:

- (a) Identify the pest(s) or disease(s) whose entry, establishment or spread the measure is intended to prevent, as well as the associated potential biological and economic consequences;
- (b) Evaluate the likelihood of entry, establishment or spread of such pest(s) or disease(s) as well as the associated potential biological and economic consequences; and
- (c) Evaluate the likelihood of entry, establishment or spread of such pest(s) or disease(s) according to the SPS measure which might be applied.

The risk assessment must be comprehensive and the risk that is being assessed must be "an identifiable risk", not just a theoretical one: Quantification of the risk is not required: it may be expressed in qualitative terms.

Finally, Members are not obliged to set their health policy according to what at a given time may constitute a majority scientific opinion. A divergent, i.e. minority, opinion coming from qualified and respected sources may also be taken into account.

The Agreement does not provide for a specific methodology to be followed when conducting a risk assessment. Members are required to refer to the relevant techniques developed by

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and Phytosanitary Barriers to Agricultural Trade: Progress, Prospects and Implications for Developing Countries”, draft paper prepared for the World Bank, 1999, p. 6, available at: <http://www.cid.harvard.edu/cidtrade/issues/spstbtpaper.html>.

international organizations. Article 5.2, however, lists, in a non-exhaustive manner, certain factors to be taken into account. These range from the available scientific evidence to prevalence of specific diseases or pests, or existence of pest- or disease-free areas, to relevant ecological and environmental conditions. The effectiveness of quarantine and control mechanisms can also be taken into account. Article 5.3 identifies the economic factors that Members shall take into account when assessing risks to animal or plant life or health.

In addition to the science-based requirements considered so far, Articles 5.5 and 5.6 lay down certain trade-related disciplines applicable to SPS measures. Thus, even if an SPS measure is based on science, it might still be deemed WTO-inconsistent under the consistency requirement of Article 5.5, the necessity tests of Articles 5.6 and 2.2, and the prohibition on arbitrary or unjustifiable discrimination in Article 2.3.

**CONSISTENCY IN THE APPLICATION OF THE CONCEPT OF APPROPRIATE LEVEL OF PROTECTION:** Although Members enjoy great latitude in choosing their ALOP, this choice is subject to several requirements, including a consistency requirement. Article 5.5 requires Members to avoid arbitrary or unjustifiable distinctions in the levels of protection they consider appropriate, if such distinctions would result in a disguised restriction on international trade.

The Article 5.5 consistency requirement consists of two key elements, namely:

- 1) The *goal* of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection; and
- 2) The *legal obligation* to avoid arbitrary or unjustifiable distinctions in the levels of protection considered to be appropriate in different situations, if these distinctions result in discrimination or disguised trade restrictions.<sup>16</sup>

Warning signals that a discrimination or a disguised restriction in international trade exists could be: substantial differences in the ALOPs for comparable situations and the absence of a scientific justification for the SPS measure allegedly applied to achieve the ALOP.<sup>17</sup>

Once the assessed risk is found to be unacceptable relative to the chosen ALOP, risk-mitigating measures may be imposed. In doing so, Members are required by the SPS Agreement to ensure that such measures are not more trade-restrictive than required to achieve their ALOP (Article 5.6).

According to Article 5.6, an SPS measure may be found to be WTO-inconsistent if an alternative, significantly less trade-restrictive measure which would achieve the Member's ALOP is reasonably available, taking into account technical and economic feasibility.

#### **1.2.4. Provisional SPS Measures (Article 5.7) and the Precautionary Principle**

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<sup>16</sup> Prévost, D., Dispute Settlement. World Trade Organization: SPS Measures, page 31.

<sup>17</sup> See the “Guidelines to further the practical implementation of Article 5.5”, adopted by the SPS Committee, G/SPS/15, 18 July 2000.

Precaution as a concept is the basis for taking action to prevent harm.<sup>18</sup> The precautionary principle or approach, as embodied in the Rio Declaration, specifically addresses the use of government action which goes beyond the prevention of known dangers. Governments may face situations where little or even only unreliable evidence is available for the assessment of risks to health or the environment, and in such cases the precautionary principle provides Governments with the right to adopt appropriate provisional SPS measures to protect against risks until the time when the appropriate information becomes available.

As shown below – and as indicated by the Appellate Body – the precautionary principle is reflected, to a certain extent, in several provisions of the SPS Agreement. For instance, Article 5.7 of the SPS Agreement provides for a qualified exception from the obligation not to maintain SPS measures without sufficient scientific evidence. In addition, Article 3.3 of the Agreement relates to the right of Members to adopt – in certain situations – SPS standards that may be higher than international standards. Lastly, there is the sixth recital of the Agreement's preamble, which on the one hand reflects the desire of Members to harmonize SPS measures, but on the other clearly states that this does not require Members to change their appropriate level of protection of human, animal or plant life or health.

**PROVISIONAL SPS MEASURES:** Under Article 5.7, Members may enact a provisional SPS measure if such measure is:

- Imposed in respect of a situation where “relevant scientific information is insufficient”; and
- Adopted “on the basis of available pertinent information”.

**LIMITS TO THE ADOPTION OF PROVISIONAL SPS MEASURES:** However, such provisional measure may not be maintained unless the Member which has adopted it:

- Seeks to obtain the additional information necessary for a more objective assessment of risk; and
- Reviews the measure accordingly within a “reasonable period of time”.

The above-mentioned four requirements of Article 5.7 are cumulative in nature. If one of these is not met, then the “provisional” SPS measure will be found to be inconsistent with the SPS Agreement. For instance, in the recent *Apples* case, the Panel found that Japan’s defense under Article 5.7 could not be upheld since the measure at issue was not imposed with respect

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<sup>18</sup> The precautionary principle can be traced back to the German *Vorsorgeprinzip* (“principle of foresight-planning”), a founding criterion of German environmental policy in the 1970s and 1980s. At the international level, the precautionary principle emerged in the context of marine pollution and its regulation by the North-Sea Inter-ministerial Conferences (Bremen, 1984, and London, 1987). Since then and with increasing pace over time, it has become a corner stone of many international environmental and natural resource treaty regimes and it has been adopted by several national systems. Most importantly, it can be found in Principle 15 of the Rio Declaration on Environment and Development (UN Conference on Environment and Development, 1992), which reads as follows: “In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation”. The precautionary principle has been embodied in many different international agreements, each time in slightly different forms. Differences exist as to the level of risk that justifies precautionary action, as to what kind of action should be taken when the situation triggers that level of risk or uncertainty and, finally, as regards the level of scientific certainty that may be used to avoid precautionary action. Often, treaties addressing issues where there are large potential risks from the activity with impacts on the environment, but also smaller benefits (such as dumping of wastes), include less stringent requirements that make resort to precautionary action easier.

to a situation where little or unreliable scientific evidence was available on the matter. On the contrary, the specific situation under scrutiny was one where “a wealth of information” was available. The first requirement of Article 5.7 had thus not been met.<sup>19</sup>

What constitutes a “reasonable period of time” (according to Article 5.7) is to be established on a case-by-case basis with regard to the specific circumstances of each case, taking into account the difficulty of obtaining the additional information for reviewing the provisional measure.

Furthermore, and as stated by the Appellate Body in the *Hormones* case: “... representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned. ... However, the precautionary principle does not, by itself, override the provisions of Articles 5.1 and 5.2 of the SPS Agreement”.<sup>20</sup>

### **I.3. Procedural Provisions: Transparency and Notification Obligations**

One of the main difficulties developing country exporters face when entering their trading partners’ markets is the lack of complete information on the number and kind of SPS measures applicable to their products. The procedure to obtain such information may be lengthy and burdensome. The correct implementation of transparency and notification obligations is thus vital for the purpose of facilitating market access and achieving the other objectives of the SPS Agreement.

**PUBLICATION AND NOTIFICATION OBLIGATIONS:** Article 7 and Annex B of the SPS Agreement require Members to notify amendments to SPS measures, provide any other relevant information and make sure that all adopted SPS measures are published so as to enable all interested parties to become acquainted with them.

Except for urgent circumstances, Annex B.2 obliges Members to provide a “reasonable interval of time” (now understood to mean not less than six months) between the publication and the entry into force of an SPS measure, in order to allow time for exporters in other Members, and particularly in developing country Members, to adapt their processes and products to, and thus comply with, the requirements of the importing Member.

As for new SPS measures, where a proposed regulation deviates from the relevant international standard, or no such standard exists, and the measure may have a significant impact on trade of other countries, the procedure under Annex B.5 provides that the notification should be made when a draft text is available. The notification must include a reasonable period of time (normally at least 60 days) to be granted to other Members to enable them to comment. Comments made at an early stage in the adoption process may trigger amendments to the proposed measures.

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<sup>19</sup> Panel Report, *Japan – Measures Concerning the Importation of Apples*, doc. WT/DS245/R, 15 July 2003, at paras. 8.216-8.222.

<sup>20</sup> Appellate Body Report, *EC – Measures Concerning Meat and Meat Products (Hormones)*, doc. WT/DS26/AB/R, 1998, at paras. 124-125.

In case of emergency, the above consultation process may be reduced or eliminated. “Where urgent problems of health protection arise or threaten to arise” for the Member implementing the emergency measure, the notification may take place before or immediately after its entry into force, but an explanation of the reasons for resorting to emergency action shall be provided.

The WTO Secretariat circulates copies of all notifications received to all Member countries and draws the attention of developing country Members to any notification of special interest to them (Annex B.9). SPS notifications can be found in the official document series G/SPS/N/Notifying Member/#. A monthly list of notifications is also circulated regularly to all Members.

**WTO SECRETARIAT GUIDELINES:** Member countries may find it useful to refer to the Secretariat’s handbook on “How to Apply the Transparency Provisions of the SPS Agreement” of November 2000.

In the area of transparency obligations, developing countries face major difficulties in dealing with the flood of notifications submitted by trading partners. The complexity of issues behind these notifications puts an additional burden on developing countries' scarce resources. It has been estimated that, in 2002, only 47 of the 145 Members submitted one or more of the 663 SPS notifications that were submitted in total.<sup>21</sup>

Other recurring problems in the implementation of the transparency provisions relate to variations in the quality and content of the information provided by countries in their notifications, comment periods shorter than 60 days, delays in responding to requests for documentation and insufficient time-frames for compliance.

At the June 2003 SPS Committee meeting, delegations discussed China’s proposal to have the sixty-day comment period commence from the date of circulation of a notification by the Secretariat, so as to allow effective implementation of the relevant provision. Some Members indicated that such a proposal would not be consistent with their domestic regulatory procedures. One developed country Member, however, sought to increase the comment period to 65 days from the date of notification.

Moreover, developing countries have noted that even when a comment period is allowed, their comments or suggestions for amendment do not find reflection in the final text adopted by the notifying Member. A possible improvement could be to require the notifying Member to provide an explanation of the reason for refusing to take into account the comments made.<sup>22</sup>

In the context of S&D treatment discussions, Members adopted a procedure in October 2004 to enhance the provision and the transparency of S&D treatment and technical assistance. Among other things, the procedure (set out in G/SPS/33<sup>23</sup>) is intended to ensure that the importing Member consults with any developing country Member that has expressed a

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<sup>21</sup> See “Report of the Analysis on SPS Notifications in 2002”, Submission by China, doc. G/SPS/GEN/378, 31 March 2003.

<sup>22</sup> *Ibid.*, p. 18.

<sup>23</sup> “Procedure to Enhance Transparency of Special and Differential Treatment in Favour of Developing Country Members”, doc. G/SPS/33, 2 November 2004.

concern regarding the potential effect of the newly proposed or modified measure on its exports. The aim is to find a means for addressing their concerns. Subsequently, the solution must be notified. This is to ensure greater transparency for developing country Members as well (see chapter on special provisions for developing countries below).

**NOTIFICATION AUTHORITY AND ENQUIRY POINTS:** Each Member is required to establish the necessary national infrastructure for the implementation of the transparency obligations. Annex B.10 mandates Members to designate a single central government authority charged with the responsibility of implementing the notification procedures. Furthermore, a National Enquiry Point must be established with the task of providing (a) answers to all reasonable questions from trading partners and (b) relevant documentation regarding, inter alia, any adopted or proposed SPS measure, control and inspection procedures, quarantine treatment, pesticide tolerance and food additive approval procedures (Annex B.3 and 4).

Lists of Members' National Authorities and National Enquiry Points (often combined in the same agency) are regularly updated and circulated for information to all Members (see the official document series G/SPS/NNA/# and G/SPS/ENQ/#).<sup>24</sup> As of June 2005, out of 148 WTO Members, 135 had notified their Enquiry Point, whereas 129 had notified their National Notification Authority.<sup>25</sup> The countries that had not yet established/notified their Enquiry Points and/or National Authorities were developing and least developed countries as well as economies in transition.

Another obstacle to the effective capacity of developing countries to provide adequate comments on proposed regulations arises from the different languages Members use in the process. To minimize the impact of this problem, agreement has been reached on a specific set of recommended procedures encouraging translations of notified documents, or summaries thereof, to be notified as well. In addition, developed country Members are required to supply, upon request, a translation of the document when this is not available in a WTO working language. Finally, Members possessing an "unofficial" translation of another Member's proposed regulation should share it with other interested Members.<sup>26</sup>

#### **I.4. The SPS Committee**

The Agreement established a Committee (hereinafter, the SPS Committee) to serve as the regular forum for consultations among Members on food safety and animal and plant health issues which affect trade. It meets in Geneva usually three times per year in formal sessions, and may convene informal or special meetings and workshops as necessary. All 148 WTO Members may participate in the work of the Committee, either through their representatives in Geneva or by sending the appropriate officials, such as representatives of their food safety, veterinary or plant health authorities.

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<sup>24</sup> Links to Members' SPS-related websites are available at:  
[http://www.wto.org/english/tratop\\_e/sps\\_e/spslinks\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/spslinks_e.htm).

<sup>25</sup> See "Implementation of the Transparency Obligations as of 24 June 2005", Note by the Secretariat, doc. G/SPS/GEN/27/Rev.14, 24 June 2005.

<sup>26</sup> See paras. 18-22 of the "Recommended Procedures for Implementing the Transparency Obligations of the SPS Agreement (Article 7)", Revision, doc. G/SPS/7/Rev.2, 2 April 2002.

The Committee's activities are aimed at furthering the implementation of the provisions of the Agreement, by encouraging, in particular, the harmonization of standards. Representatives from the relevant standard-setting bodies are also regular observers.

The Committee considers submissions and statements by Members on their relevant regulatory processes, their use of risk assessment in designing SPS measures and their status regarding the spread of certain diseases, such as BSE, foot and mouth disease or fruit fly.

During SPS meetings, delegates from Member countries have the opportunity to raise issues and concerns regarding the implementation of the SPS disciplines. In order to ensure that a Member's national interests and positions on specific issues at SPS Committee meetings are well represented, effective channels of communication must be established between the Geneva-based delegation and the Government's regulatory authorities, which, on their part, also have to ensure the efficient gathering, analysis and transmittal of relevant information between and among local producers and exporters and national/regional food safety, veterinary or plant health agencies.

Extensive discussions on particular implementation problems voiced by Members in the SPS Committee have helped to draw attention to 100 and to avoid potential trade conflicts (for further analysis on this point, see section II.4 below).

## **I.5. Special Provisions for Developing Countries**

The concept of more favourable treatment for developing countries under the GATT/WTO legal system has undergone various mutations over time. In particular, before the Uruguay Round (UR), special and differential (S&D) treatment for least developed and developing countries was largely restricted to dispensation related to tariffs. The UR incorporated new issues beyond tariffs, and S&D expanded in scope. Under the WTO Agreements, S&D essentially consists of time-limited derogations from the multilateral rules, some exemptions and flexibilities, mainly for LDCs, and technical assistance, in order for national legislation, institutions and economic policy to adjust to the new standards.<sup>27</sup> However, many S&D provisions were couched in "best endeavour" language and have – to date – not been implemented effectively.

**SPECIAL AND DIFFERENTIAL TREATMENT IN WTO AGREEMENTS:** The WTO secretariat has undertaken a detailed analysis of all S&D provisions (roughly 155) with a view to providing Members with an overview of their implementation. The various S&D provisions have been classified according to the following typology:

- (i) Provisions aimed at increasing trade opportunities of developing countries;
- (ii) Provisions under which WTO Members should safeguard the interests of developing countries;

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<sup>27</sup> For further discussion, see Tortora M., "Special and Differential Treatment and Development Issues in the Multilateral Trade Negotiations: the Skeleton in the Closet", UNCTAD, doc. WEB/CDP/BKGD/16, January 2003, searchable at: <http://www.unctad.org>, p. 5.

- (iii) Flexibility of commitments, actions, and use of policy instruments;
- (iv) Transitional time periods;
- (v) Technical assistance;
- (vi) Provisions related to the least developed countries (provisions in this category fall into one or the other of the previous five categories, with the characteristic that their application relates exclusively to LDCs).

S&D provisions have also been further classified according to whether they require Members to achieve a certain result (obligations of result) or to engage in a certain conduct (obligations of conduct).

Recognizing the financial and technical resource constraints of developing countries and their lack of skilled manpower to comply with trading partners' SPS measures, the SPS Agreement includes certain more favourable provisions relating to the provision of special and differential treatment, as well as to technical assistance in their favour.

More specifically, four paragraphs under Article 10 deal with special and differential treatment in favour of developing country Members, while two paragraphs under Article 9 are concerned with technical assistance.

It is worth mentioning that also some of the SPS disciplines discussed above incorporate S&D features, in particular Annex B.2 on reasonable adaptation period between the date of publication of an SPS measure and its entry into force (a mandatory S&D provision containing an obligation of result), and Annex B.9, whereby the Secretariat is requested to draw the attention of developing country Members to any notification of special interest to them.<sup>28</sup>

During the preparatory process for the Third Ministerial Conference, developing countries raised numerous "implementation" issues, revealing that their expectations to reap greater benefits from trade had not materialized and that many of the new rules imposed obligations that their legal, institutional and economic capacities were unable to meet. Many also questioned the effectiveness of the WTO Agreements' S&D provisions.

At the Fourth Ministerial Conference Member Governments agreed that "all special and differential treatment provisions shall be reviewed with a view to strengthening them and making them more precise, effective and operational" (paragraph 44 of the Doha Ministerial Declaration<sup>29</sup>). Subsequently, in May 2003, the so-called category II proposals were referred to the relevant WTO bodies for consideration. Five such proposals were submitted to the SPS Committee. They mostly concerned Articles 9 and 10 of the SPS Agreement. The Committee considered them<sup>30</sup> and completed its work programme for 2003 as envisaged, but could not

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<sup>28</sup> See section I.3 Procedural Provisions: Transparency and Notification Obligations.

<sup>29</sup> See "Ministerial Declaration", adopted on 14 November 2001, Fourth Ministerial Conference, Doha, doc. WT/MIN(01)/DEC/1, 20 November 2001.

<sup>30</sup> S&D related work in the SPS Committee has been pursued through different tracks: (i) issues raised in the SPS Committee under the agenda item on S&D, specifically relating to Article 10; (ii) issues raised in the SPS Committee in the context of other specific topics discussed in the Committee; and (iii) issues referred to the SPS Committee by the General Council. In addition, (iv) there have been relevant actions and decisions taken in bodies

reach any decision on any of the specific issues raised.<sup>31</sup> In 2004, the so-called July Package<sup>32</sup> mandated the SPS Committee (as well as other specific bodies) to expeditiously complete the consideration of the S&D proposals and to report to the General Council, with clear recommendations for a decision no later than July 2005. Again, the relevant proposals have been subject to discussions in both formal and informal meetings. In July 2005, the SPS Committee adopted a report to be submitted to the General Council.

While some argue that progress has been made (e.g. adoption of Decision G/SPS/33 or improvement of technical assistance) in terms of addressing the concerns underlying the original proposals, Members still could not reach consensus on any of the five proposals submitted for consideration. This is reflected in the recommendations of the July 2005 report,<sup>33</sup> in which the SPS Committee asks the General Council, among other things, to take note of the report and to take note of the Committee's commitment to continue to examine the proposals before it and revisions thereof, with the aim of making specific recommendations. It remains to be seen whether Members will achieve more substantial progress in the future.<sup>34</sup> Some of the proponents have indicated that they will submit revised versions of their proposals in due course.

### **1.5.1. Special and Differential Treatment (Article 10)**

Articles 10.1 and 10.4 of the SPS Agreement fall under the second category of the WTO six-fold typology, whereas paragraphs 2 and 3 pertain to the fourth.<sup>35</sup> The WTO Secretariat has identified paragraph 1 as a mandatory provision and paragraphs 2 and 4 as non-mandatory provisions.<sup>36</sup>

#### **ANALYSIS OF ARTICLE 10 OF THE SPS AGREEMENT**

- 1. *As regards the Preparation and Application of SPS Measures:*** Members are required to take account of the special needs of developing and least developed countries in the preparation and application of SPS Measures. These needs must be considered in the regulatory process, but there is no obligation to actually adapt measures in accordance with those needs. Proposals to review this provision can be found below.
- 2. *Phased-in Introduction of Measures:*** Members are encouraged, not obliged, to allow

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other than the SPS Committee. See also doc. G/SPS/W/173 including its revisions, "Review of the Operation and Implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures."

<sup>31</sup> See, for example, "Implementation and Special and Differential Treatment", Report by the Chairman to the General Council, doc.G/SPS/30, 20 November 2003.

<sup>32</sup> See "Doha Work Programme: Decision Adopted by the General Council on 1 August 2004," doc. WT/L/579, 2 August 2004.

<sup>33</sup> See "Report on Proposals for Special and Differential Treatment", Note by the Secretariat, 30 June 2005, doc. G/SPS/W/175/Rev.2, 30 June 2005.

<sup>34</sup> For reviews and summary notes on S&D prepared by the WTO Secretariat, please see "Elaboration of the Proposal to Enhance Transparency of Special and Differential Treatment in Favour of Developing Country Members," doc. G/SPS/W/132/Rev.2, 19 March 2004 Rev.3, 26 March 2004 and "Proposals and Progress on Special and Differential Treatment" doc. G/SPS/GEN/543, 28 February 2005.

<sup>35</sup> See "Implementation of Special and Differential Treatment Provisions in WTO Agreements and Decisions", doc. WT/COMTD/W/77/Rev.1/Add.2, 21 December 2001, p.9, and Add.3, 4 February 2002, p.6.

<sup>36</sup> See "Implementation of Special and Differential Treatment Provisions in WTO Agreements and Decisions – Mandatory and Non-Mandatory Special and Differential Treatment Provisions", doc. WT/COMTD/W/77/Rev.1/Add.1/Corr.1, 4 February 2002.

developing country Members longer time frames for compliance with new SPS measures, where the importing Member's ALOP allows scope for this. The Doha Decision on Implementation clarifies that the "longer period for developing countries to comply" is now understood to mean, normally, at least six months. Where phased introduction is not envisaged, but a Member government has problems complying, the two sides should consult with a view to finding a mutually acceptable solution, "while continuing to achieve the importing Member's appropriate level of protection".

3. *Time-Limited Exceptions*: The SPS Committee may grant, upon request, developing countries specified, time-limited exemptions from all or some of their obligations under the Agreement. No developing country has requested such an exemption to date.
4. *Facilitation of Participation in International Standard-Setting Organizations*: Members should encourage and facilitate the active participation of developing countries in the relevant international organizations (see above).

In formal and informal sessions on S&D, the SPS Committee undertook a preliminary consideration of specific proposals on Article 10.

It has been proposed that Article 10.1 be adjusted in favour of developing countries, *requiring* importing developed country Members intending to apply SPS measures that adversely affect any developing or least developed countries (or which are difficult to comply with) to enter into consultations with them with a view to finding a mutually satisfactory solution. In addition, it is suggested that Members shall either withdraw any such measures or provide technical and financial resources to assist adversely affected developing countries to comply with the measures. In the SPS Committee, however, a number of Members noted that a legitimate, justified SPS measure should not be withdrawn simply because some trading partners might have difficulties meeting its requirements.<sup>37</sup>

Another proposal is to establish that Article 10.4 a mandatory obligation, obliging Members to facilitate the participation of developing countries in the relevant organizations.

As for Article 10.3, it has been proposed that any grant of time-limited exemptions from the SPS obligations should be accompanied by a package of technical and financial assistance aimed at strengthening national capacity to comply with the scientific requirements of the Agreement and/or at facilitating needed adjustments in the production processes for products to comply with the export markets' standards. While the effective implementation of S&D in the SPS Agreement would, therefore, be closely interlinked with the provision of technical assistance,<sup>38</sup> it is important to recall that technical assistance is not the only way to respond to calls for making S&D provisions more specific, precise and operational.

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<sup>37</sup> See "Implementation and S&D Treatment", Report by the Chairman to the General Council, doc. G/SPS/27, 4 July 2003.

<sup>38</sup> See Zarrilli S., *The Sanitary and Phytosanitary Agreement, Food Safety Policies and Product Attributes in "Agriculture and WTO; creating a trading system for development"*. Editors: Merlinda D. Ingco and John D. Nash, World Bank-Oxford University Press (2004), pp. 11-12.

***1.5.2. Technical Assistance and Capacity Building (Article 9)***

In order for Members to conduct risk assessments and/or gain market access by meeting the required standards of importers, they require advanced scientific national infrastructures, adequate human and financial resources, and a thorough system of control, inspection and approval procedures. Technical cooperation represents a tool that can help countries modernize their food safety and phytosanitary systems and thus upgrade their capacity to implement the SPS Agreement effectively.

Technical cooperation should begin with a country diagnosis in order to define the country's own needs and capacities, and once the needs have been defined, to identify priorities. For this purpose, and in order to ensure that the system is demand-driven, the WTO Secretariat has circulated a detailed questionnaire to all developing country Members requesting them to submit specific requests for technical assistance.<sup>39</sup>

In the area of SPS, the technical assistance needs of developing countries range from improving their understanding of the applicable rules to the provision of practical training for scientific and technical personnel and the development of a national regulatory framework. In order to be able to meet their obligations and to be able to enforce their rights under the Agreement, developing countries need to acquire technical and scientific capacity as well as adequate field equipment and infrastructure, including technology transfer.<sup>40</sup> Technical assistance should also focus on strengthening the functioning of SPS enquiry points in developing countries and the links between the government/regulatory authorities and other relevant actors at the national level, so as to facilitate exchanges of information, identification of problems and a better representation of national interests at Committee meetings.

Article 9.1 states that the provision of technical assistance in favour of developing countries shall be facilitated on a bilateral basis or through the appropriate international organizations. This assistance may take various forms, such as credits, grants and donations. Article 9.2 refers to the more specific case where substantial investments are needed for a developing country exporting Member to comply with an importing Member's SPS requirements. In such circumstances, the importing Member must consider providing technical assistance that will enable the developing country to maintain and expand its market access opportunities.

The above are considered to be mandatory obligations, and their effective and coherent implementation would be highly conducive to the establishment of the necessary infrastructural, human resources and regulatory preconditions that would allow developing countries to fully implement and benefit from the SPS disciplines.

Although it refers only to least developed countries, the Doha Decision on Implementation deals with the issue of technical assistance by urging Members to provide, as far as possible, LDCs with the necessary financial and technical assistance to enable them to effectively

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<sup>39</sup> See doc. G/SPS/W/113, 15 October 2001. Responses to this questionnaire submitted by Members are circulated as addenda to doc. G/SPS/GEN/295.

<sup>40</sup> The WTO Secretariat has identified four broad categories of technical assistance needs: information, training, "soft" infrastructure development and "hard" infrastructure development (see doc. G/SPS/GEN/206, 18 October 2000).

implement the SPS disciplines and respond adequately to the introduction of SPS measures that might adversely affect their exports.<sup>41</sup>

As technical cooperation in the SPS area is undertaken by WTO Members, the WTO Secretariat and several relevant international organizations, a high degree of coherence and coordination among these different actors will ensure better results. The creation of the Standards and Trade Development Facility (STDF) responds, in part, to this need.

In the SPS Committee, technical assistance is discussed as a regular agenda item, under which Members are invited to identify any specific technical assistance needs that they may have, and/or to report on any SPS-related capacity building activities in which they are involved. The WTO Secretariat, as well as observer organizations, report on their assistance activities. The WTO Secretariat has also prepared a note on a typology of technical assistance.<sup>42</sup> The Report of the SPS Committee on the Review of the Operation and Implementation of the SPS Agreement also contains an overview of technical-assistance-related issues.<sup>43</sup>

### **1.5.3 Enhancing Transparency in Special and Differential Treatment**

One of the specific issues raised in the Committee has been the need to enhance transparency regarding the provision of S&D treatment. In March 2002, in the context of the Committee's review of the recommended notification procedures, Egypt proposed adding a new "S&D box" in the notification format, with the aim of identifying, "ex-ante", i.e. at the time a measure is being developed or modified, the developing countries which might be affected and the availability of S&D.<sup>44</sup> Egypt suggested that one form of S&D could be the application of international standards, or if these did not exist, the continued application of previous measures on imports from developing countries until technical assistance permitted developing countries to meet the new requirements.<sup>45</sup>

In June 2002, building on the Egyptian proposal, Canada suggested that special and differential treatment be notified "ex post" in the form of an addendum (once the importing Member and the developing exporting Member had found a solution to a problem identified by the exporting country). The Canadian proposal<sup>46</sup> was adopted in principle by the Committee at its March 2003 meeting, subject to further elaboration of the relative eight-step procedure.<sup>47</sup>

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<sup>41</sup> See Decision of 14 November 2001, "Implementation-Related Issues and Concerns", doc. WT/MIN(01)/17, 20 November 2001, para. 3.6, reproduced in Annex 1 of this module.

<sup>42</sup> See "Technical Assistance Typology", Note by the Secretariat, doc. G/SPS/GEN/206, 18 October 2000.

<sup>43</sup> See "Review of the Operation and Implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures", draft Report of the Committee, doc. G/SPS/W/173/Rev 2, 28 June 2005.

<sup>44</sup> See "Report to the Committee on Trade and Development on S&D", doc. G/SPS/23, 15 November 2002.

<sup>45</sup> See also the statement by Egypt at the November 2002 meeting of the SPS Committee, "Comments on the Canadian Proposal", doc. G/SPS/GEN/358, 15 November 2002.

<sup>46</sup> See the submission by Canada, "Enhancing Transparency of S&D Treatment within the SPS Agreement", doc. G/SPS/W/127, 30 October 2002.

<sup>47</sup> See "Elaboration of the Proposal to Enhance Transparency of S&D in favour of Developing Countries", Note by the Secretariat, doc. G/SPS/W/132/Rev.1, 8 July 2003.

According to the then recommended transparency provisions, a Member preparing a new or revised measure shall submit a notification to the WTO Secretariat. Box 4 shall, to the extent practicable, identify the regions or countries likely to be affected by the notified regulation (step 1). The WTO Secretariat will circulate the notification with the minimal delay possible (step 2). Any concerned exporting Members should contact the notifying Member, within the comment period, to seek additional information. A thirty-day extension of the comment period should be granted, upon request, to the concerned exporting Member (step 3). The notifying Member should acknowledge receipt of the request for an extension of comment period or for additional information, and explain, at the earliest possible date. If requested, the notifying Member should also provide additional relevant information on the proposed SPS measures concerned (step 4).

If the latter identifies potential difficulties with the proposed regulation that might hamper its exports, the notifying Member would enter into discussions to try and resolve the issue of concern (step 5). Bilateral discussions may be also initiated after the entry into force of the notified measure (step 6). When a decision is taken on whether and how S&D might be provided, the notifying Member should submit to the WTO Secretariat an addendum to its original notification (step 7). These discussions may lead an exporting developing country Member to request S&D and the importing Member to examine how the identified problem could best be addressed, taking into account the special needs of concerned exporting developing countries. With the conclusion of the bilateral discussions, the notifying Member would submit an addendum to its original notification, specifying any modifications to the regulation, whether S&D has been requested, the requesting country(ies), the nature of such treatment, if provided, and an explanation if S&D was not provided (step 8).

At the June 2003 meeting of the SPS Committee, Members were not able to agree on whether the importing Member, referred to in the procedure above, should be defined as an “importing *developed* country Member” or simply as “importing Member”. This second option would leave the door open for other developing country Members to provide transparency in S&D under Article 10.1.

In October 2004, Members adopted the elaboration of the steps to implement this procedure (G/SPS/33).<sup>48</sup> This decision by the Committee requires an importing Member to consider any request for special and differential treatment or technical assistance which is made in response to the importing Member's notification of a new or modified SPS measure.

In step 6, the procedure outlines different options for resolving the concern that is identified. These include: (1) a change in the measure to be applied on an MFN basis; (2) the provision of technical assistance to the exporting Member; (3) the provision of S&D treatment; or a combination thereof. Should special and differential treatment be provided, it would apply equally to all developing country Members.

Subsequently, the importing Member has to submit a specific addendum to its notification. This has to indicate: that S&D treatment or technical assistance has been requested; the Member(s) affected; the concerns identified; whether S&D treatment has been provided, and

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<sup>48</sup> See “Procedure to Enhance Transparency of Special and Differential Treatment in Favour of Developing Country Members”, doc. G/SPS/33, 2 November 2004.

if so, the type of treatment provided. The procedure is intended to ensure that the importing Member consults with any developing country Member that has expressed a concern regarding the potential effect of the proposed new/modified measure on its exports with the aim of finding a means to address these concerns.

It is important to recall that the Committee, when adopting the procedure, recognized that it would not fully resolve the issue of S&D treatment, and that it was one step in addressing the problem of implementation of the SPS-related S&D provisions.<sup>49</sup> For example, the Decision does not fully correspond to the objectives and suggestions laid out in certain specific S&D proposals of developing countries. Amongst others, this is the case with proposals that had suggested requiring Members to initiate consultations in the SPS Committee or requiring Members to provide specific "ex-ante" information (including on the type of technical requirements probably needed to comply with the notified measure or the type of S&D treatment that the notifying country is ready to provide). More broadly, the Decision also stops short of fulfilling some of the broader objectives behind the S&D proposals, namely to secure and enhance current levels of exports from developing countries and LDCs; to require the importing Member to withdraw measures that adversely affect a developing country or LDC; or to provide technical and financial resources where necessary when "special needs of developing country Members are affected".

The Committee agreed to review the notification process one year after its adoption, evaluate its implementation, and determine whether changes are required and/or its continuance is warranted. The Committee also agreed to consider other proposals and possible actions.

## **I.6. Overview of Dispute Settlement Cases under the SPS Agreement**

### **I.6.1 Dispute Settlement under the WTO: Basics<sup>50</sup>**

Under the WTO legal framework, dispute settlement procedures<sup>51</sup> are available to Members who believe that a trade policy measure adopted by another Member is violating one or more provisions of the WTO Agreements.

The most desirable way of solving a trade dispute under the WTO is for the two parties to reach an agreed solution through bilateral discussions on the issue. Such discussions may be given a more formal character if the complaining party decides to request the other party to

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<sup>49</sup> See paragraph 5 of the "Procedure to Enhance Transparency of Special and Differential Treatment in Favour of Developing Country Members", doc. G/SPS/33, 2 November 2004.

<sup>50</sup> For a more comprehensive overview of procedural issues relating to WTO Dispute Settlement, see UNCTAD's training modules on Panels, the Appellate Body and Implementation and Enforcement, available under <http://r0.unctad.org/disputesettlement/course.htm>.

<sup>51</sup> See the "Understanding on rules and procedures governing the settlement of disputes" (DSU), which, as the bulk of the WTO Agreements, is an outcome of the Uruguay Round negotiations, available together with all WTO legal texts at: [http://www.wto.org/english/docs\\_e/legal\\_e/legal\\_e.htm](http://www.wto.org/english/docs_e/legal_e/legal_e.htm). The DSU provides the legal infrastructure for enforcement of rights and obligations under all WTO Agreements. The description of the dispute settlement procedures in this section of the Module is only a very brief summary and does not intend to be exhaustive.

enter into official consultations. Once this first stage is reached, WTO rules ensure that the complaining party, if not satisfied with the outcome of the consultations after a certain period of time, has the right, if it so desires, to obtain the establishment of a panel of experts to rule on the issue. The panel's findings may be appealed by either side and, in this case, the final conclusions will be those contained in the report of the Appellate Body. The final report (of the panel, as amended by the Appellate Body) is then adopted by the WTO Dispute Settlement Body (DSB) by "reverse consensus". If the report concludes that the measure at stake violates one or more WTO provisions, the classic recommendation is for the losing defendant party to bring its measure into conformity with its obligations under the relevant WTO agreements. Prompt compliance with the rulings is expected. Should this not materialize within a reasonable period of time, the disputing parties may agree to determine a mutually acceptable compensation (such as tariff reductions in an area of interest to the complaining side). If the parties fail to agree, then the complaining party may request authorization from the DSB to retaliate by suspending concessions or obligations.

### **1.6.2 Formal Disputes Concerning SPS measures**

In order to enforce their rights under the SPS Agreement, Members may consider it appropriate to have recourse to the above-outlined dispute settlement procedures.

In more than 10 years of operation, there have been 30 formal complaints over more than 24 different SPS issues.<sup>52</sup> Of these, three advanced to the stage of panel rulings, subsequently being appealed to the Appellate Body (Australian measures on salmon, EU measures on hormone-treated beef and Japanese varietal testing requirements), while in July 2003, a panel report was issued on Japanese import measures on apples. In all of these four cases,<sup>53</sup> both complaining and defending parties were developed country Members. In recent developments, two developing countries have requested the establishment of a panel to judge certain measures of developed countries under the SPS rules: the Philippines over certain Australian import measures on fresh fruit and vegetables, and Argentina (together with the US and Canada) over EU biotech regulations. Unless the parties manage to solve the dispute bilaterally (an option which is always open, even during panel procedures), these will be the first SPS disputes involving a developing country to be settled judicially.

As for the burden of proof, in an SPS dispute, as generally in any WTO dispute, the initial burden lies with the complaining party, which must establish a prima facie case of inconsistency with a particular provision of the SPS Agreement of the defending party's SPS measure at issue. Typically, disputes focus on claims of non-compliance with the basic obligations in Articles 2 and 5, i.e. it is claimed that the measure is maintained without sufficient evidence (see above section I.2.1 on Article 2 requirements) and that it is not based on a risk assessment (see above section I.2.3).

All panel and Appellate Body reports have addressed the obligation of Members to base their sanitary and phytosanitary measures on an objective assessment of risks. They have held that

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<sup>52</sup> Until June 2005, out of these 30 complaints, 12 reached the stage of the establishment of a panel.

<sup>53</sup> For more information on these four disputes, see Annex 1 of this module which contains a summary of the current status of formal dispute settlement cases relating to SPS measures.

there must be a rational relationship between the policy choices made by Governments and objective (risk) assessments that go beyond mere hypothesis.

Given the high complexity of the problems inherent with the evaluation of scientific evidence, panels are authorized to seek information and technical advice from experts chosen in consultation with the parties (Article 11.2 SPS). For this purpose, an advisory expert group may be set up, or relevant international organization may be consulted by the panel. All panels dealing with issues under the SPS Agreement have so far consulted individual experts.

## CHAPTER II

# SELECTED PROBLEMS OF IMPLEMENTATION AND DISPUTE SETTLEMENT UNDER THE SPS AGREEMENT

### II.1 Participation in International Standard-Setting Bodies

The active participation of Members in the process by which international standards relevant to the SPS Agreement are set is required in order to ensure sound and fair decision-making, transparency and the avoidance of situations where the process of standardization is determined by special interests. For this purpose, the SPS Agreement instructs all WTO Members to promote maximum membership and participation, within the limits of their financial and human resources, in preparing such standards. However, the weak regulatory systems and infrastructure in developing countries and economies in transition constitute a major limitation to their effective participation in international standardization bodies.

As stated by J. Michael Finger and Philip Schuler in their article,<sup>54</sup> not only does implementing the obligations taken on by developing countries for sanitary and phytosanitary standards have a substantial cost, but *“the WTO obligations reflect little awareness of development problems and little appreciation for the capacities of least developed countries to carry out the functions that SPS regulations address (...) Because of their limited capacity to participate in the Uruguay Round negotiations, the WTO process has generated no sense of “ownership” of the reforms to which WTO membership obligates them. From their perspective, the implementation exercise has been imposed in an imperial way, with little concern for what it will cost, how it will be done, or if it will support their development efforts.”*

The recognition of this critical situation is embodied in Article 10.4 of the SPS Agreement on Special and Differential Treatment, which states that "Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations". However, developing countries have repeatedly pointed out that this “best endeavor” clause has not been implemented. It is generally agreed that developing countries (particularly the least developed countries) have not fully participated in the work of the three sister organizations. In particular, attendance at the meetings of the committees or working groups responsible for drafting proposed standards is significantly lower than the level of participation in the plenary sessions of executive bodies where standards are formally adopted.

While it has to be pointed out that, over the years, due to increased awareness of the importance of international standards under the SPS disciplines, developing countries have

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<sup>54</sup> Finger J.M., and Schuler P., “Implementation of Uruguay Round commitments: the development challenge” countries is available at <http://econ.worldbank.org/docs/941.pdf>

become more active in this regard, major constraints on their effective participation at all stages of the standard-setting process remain. These have been identified as follows.<sup>55</sup>

1. Lack of effective technical infrastructures and human capabilities at the national level for the evaluation of draft standards and the formulation of positions in consultation with other interested members; and
2. Cost of travel and attendance at relevant meetings.

It is clear that the first constraint is even more critical than the second one. This is because the effective participation of developing countries and economies in transition can only be achieved through sustainable development (at the local level) of the technical capacity to substantially contribute to the standard-setting process. This in turn would require submitting proposals, on issues of interest to them, for scientifically sound draft solutions, consistent with their level of technological endowment.

Developing countries might find it desirable to coordinate efforts and resources at the regional or sub-regional level so as to:

- ▶ Reduce the cost of participation of their representatives in international standard-setting organizations;
- ▶ Effectively promote the development of standards in their common interest; and
- ▶ Invest in the necessary regional or sub-regional control, inspection and accreditation bodies.

As an implementation issue, developing countries' participation in setting international SPS standards was discussed during the Third WTO Ministerial Meeting in Doha. In the Doha "Decision on Implementation-Related Issues and Concerns",<sup>56</sup> Ministers took note of the actions taken to date by the Director-General<sup>57</sup> to facilitate the increased participation of Members at different levels of development in the work of the relevant international standard setting organizations, as well as his efforts to coordinate with these organizations and financial institutions in identifying SPS-related technical assistance needs and how best to address them; and urged the Director-General to continue his cooperative efforts with these organizations and institutions in this regard by according priority to the effective participation of least-developed countries and facilitating the provision of technical and financial assistance for this purpose.

Reinforcing these views, the Executive Heads of the FAO, OIE, WHO, WTO and World Bank issued a joint statement in Doha, expressing their commitment to strengthening developing countries' capacity both to establish and implement SPS measures and to participate fully in the standard-setting bodies. Building on this commitment, the five

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<sup>55</sup> See the Summary Report of the "Workshop on the International Standard-Setting Organizations: Process and Participation", organized by the WTO Secretariat on 13 March 2001, doc. G/SPS/GEN/250 and the relevant submissions by Codex "Note on Developing Country Participation in Codex Bodies", doc. G/SPS/GEN/236, and IPPC, "Developing Country Participation in IPPC Standard-Setting", doc. G/SPS/GEN/227.

<sup>56</sup> See Decision on Implementation Issues, doc. WT/MIN(01)/17, 20 November 2001, para. 3.5.

<sup>57</sup> See the Reports by the WTO Director-General on "Actions to increase the participation of developing country members in the work of the relevant sanitary and phytosanitary international standard-setting organization", docs. WT/GC/42, 45, 46/Rev.1 and 54.

institutions established in September 2002 a “Standards and Trade Development Facility” (STDF) to facilitate inter-agency collaboration in enhancing the capacity of developing countries to meet SPS standards. Furthermore, the STDF will fund projects on capacity building both in individual countries and through regional initiatives, involving both the public and the private sector.<sup>58</sup>

According to Article 3.5,<sup>59</sup> in 1997 the Committee adopted a provisional procedure<sup>60</sup> to monitor the process of international harmonization and the use of international standards. Based on this procedure, Members have drawn only eleven standard-related concerns to the attention of the Committee and of the relevant standard-setting bodies, which have regularly reported on their subsequent actions. Unlike the growing number of specific trade concerns raised by Members at the meetings of the Committee, the use of this procedure has progressively diminished, with only two issues raised in the last two years.<sup>61</sup> In light of the difficulties developing countries face in participating effectively in the international harmonization process, they should be encouraged to make greater use of this mechanism to address their concerns in relation to specific standards, or the need for new standards, so as to receive useful and prompt feedback from the representatives of the relevant bodies and so as to better ensure that their interests are taken into account in such complex international processes.

## II.2 Recognition of Equivalence of SPS Measures

The SPS Agreement encourages Member countries to accept their trading partners' different standards provided these afford a similar level of protection, through equivalence arrangements. Equivalence, in fact, is an understanding reached through formal or *ad hoc* arrangements between two or more countries. It is a means by which trading partners mutually recognize that their different national SPS measures are equivalent in terms of health and food safety protection requirements. This kind of arrangement thus helps promote and facilitate trade among the countries involved.

**EQUIVALENCE:** The SPS Agreement recognizes that different measures can provide equivalent levels of protection. A Member is required to allow imports from an exporting Member applying different SPS measures from its own, if the exporting Member objectively demonstrates that its measures achieve the importer's appropriate level of protection. For this purpose, the latter is to provide, upon request, reasonable access to the importing Member for inspection, testing and other relevant procedures (Article 4.1).

Recognition of equivalence may take different forms: acceptance of SPS measures as equivalent on a product-by-product basis or formal system-wide or broad-ranging agreements. It can be negotiated in bilateral, regional or multilateral agreements. According

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<sup>58</sup> For further details, see the “Standards and Trade Development Facility”, Note by the Secretariat, doc. G/SPS/GEN/371, 18 February 2003.

<sup>59</sup> Article 3.5 of the SPS Agreement requires the SPS Committee to monitor the work of the relevant international standard setting bodies and to coordinate with them.

<sup>60</sup> This procedure was recently extended up to July 2005. See doc. G/SPS/25, 1 July 2003.

<sup>61</sup> See “Review of the Provisional Procedure to Monitor the Process of International Harmonization”, Note by the Secretariat, doc. G/SPS/W/134, 10 June 2003.

to Article 4.2, Members are required, upon request, to enter into consultations with a view to achieving such agreements

Equivalent regulatory systems need not be identical. Countries normally require an equivalency assessment of national control systems for a particular product or industry prior to a determination of equivalence of individual measures. The existence in the exporting country of an efficient regulatory framework of conformity assessment certification bodies, quarantine settings, laboratory infrastructure and sufficient human resources to provide scientific information to support the equivalence claim is thus a necessary prerequisite for entering into equivalence arrangements.

The equivalence obligation has the potential to yield significant benefits in international markets for food and agricultural products where process standards are crucial components of risk managing programmes (for instance, the Hazard Analysis and Critical Control Point – HACCP – regulations for food products are mandatory in a growing number of countries). However, in this field, developing countries face great difficulties.

Developing countries' concerns in relation with the implementation of Article 4 provisions have been on the agenda of the SPS Committee since late 2000.<sup>62</sup> Developing countries argue that in practice developed countries often require “sameness”, i.e. compliance, rather than equivalence of SPS standards and control and inspection systems. This is considered a major impediment, depriving developing country Members of the flexibility to choose their measures. In addition, compliance may unfairly disadvantage exporters if the risks are substantially lower in their countries than in the importing country.<sup>63</sup> Overall, experience has shown that recognition of equivalence is reached only in limited cases, and mostly between developed countries. Members have noted the administrative burdens associated with formal equivalence agreements. In this context, some Members, especially developed countries, claim that the negotiation of equivalence agreements is too costly, too resource-intensive and too time-consuming relative to the small anticipated trade benefits, while developing countries have stressed the importance of gaining improved market access through acceptance of equivalence. Especially, this is the case as their exports are often heavily concentrated in a few products.

Another critical element in the process of recognition of equivalence is the determination of the importing Member's ALOP and the satisfactory demonstration by the exporting Member that its measure can achieve that level.<sup>64</sup>

In October 2001, in response to the above-mentioned concerns, the SPS Committee adopted a “Decision on the Implementation of Article 4 SPS” (commonly known as the Equivalence Decision).<sup>65</sup> The decision sets out some guidelines for exporting Members requesting recognition of equivalence of their SPS measures and for importing Members receiving such

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<sup>62</sup> In October 2002, the General Council requested the SPS Committee “to examine the concerns of developing countries regarding the equivalence of SPS measures and to come up with concrete options as to how to deal with them”. See para. 2 of the “Summary of the Special Meeting on Equivalence held on 18-19 September 2001”, Note by the Secretariat, doc. G/SPS/R/23, 22 October 2001.

<sup>63</sup> See Roberts, Orden and Josling, p.11.

<sup>64</sup> See “Equivalence”, Note by the Secretariat, doc. G/SPS/W/111, 4 July 2001.

<sup>65</sup> See doc. G/SPS/19, 26 October 2001.

requests.<sup>66</sup> Subsequently, in March 2004, the Committee completed its work programme on equivalence. This included clarifications on the Decision on equivalence.<sup>67</sup> These clarifications related to: facilitating the recognition of equivalence based on historic trade (paragraph 5); the effect of a request for recognition of equivalence on trade (paragraph 6); and the importance of scientific information in evaluating the impact of exporting countries' measures (paragraph 7). Equivalence remains a standing agenda item for the SPS Committee.

**DECISION ON EQUIVALENCE:** The importing Member should assist the exporting Member to provide an objective demonstration of the equivalence of its own measure. In particular, upon request, the importing Member should provide information regarding the objective and rationale of its measure, identify clearly the risks it addresses, indicate the ALOP its measure is supposed to achieve and supply the underlying risk assessment (para. 2). The exporting Member must provide science-based and technical information to support an objective demonstration that its measure achieves the importing Member's ALOP and provide reasonable access for inspection and testing (para. 4). In the case of historically traded products, the importing Member should accelerate its procedure for determining equivalence (para.5).<sup>68</sup> The importing Member should analyse the scientific and technical information with a view to evaluating equivalence (para. 7) and must give full consideration to requests for technical assistance to facilitate implementation of Article 4 (para 8). The importing Member is expected to respond in a timely manner to an equivalence request (normally six months – para. 3 – although no provision is made regarding the need to justify a refusal).

In discussing the problems of implementation in Article 4, several Members have stressed the need for the elaboration of internationally harmonized guidelines on equivalence, which would facilitate the systematic application of the principle. The three sister organizations have been formally encouraged to engage in such activity.<sup>69</sup>

With a view to clarifying paragraph 7 of the Decision on Equivalence, it has been suggested that the importing Member should specify an objective basis for the comparison of alternative measures. This issue is addressed in the Codex "Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems".<sup>70</sup> These guidelines provide for the following supporting information to be supplied by the importing country: (a) the aim of the measure, including identification of the specific risks addressed; (b) the relationship of the measure to the ALOP; (c) an expression of the level of control of the hazard in a food achieved by the measure; (d) the scientific basis for the measure; and (e) any additional information that may assist the exporting country in presenting an objective demonstration of equivalence. The OIE "Guidelines for Reaching a Judgment of Equivalence

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<sup>66</sup> In Doha, Ministers instructed the SPS Committee to develop expeditiously the specific programme to further the implementation of these equivalence provisions. See para. 3.3 of the Doha Decision on Implementation, doc. WT/MIN(01)/17, 20 November 2001. The SPS Committee's programme of further work on equivalence is contained in doc. G/SPS/20, 21 March 2002.

<sup>67</sup> See "Decision on the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures, Revision", doc. G/SPS/19/Rev.2, 23 July 2004. See also Rev.1.

<sup>68</sup> See Addendum to the Equivalence Decision, containing a clarification of paragraph 5, doc. G/SPS/19/Add.1, 15 November 2002, p.1.

<sup>69</sup> Prepared by the Codex Committee on Food Import and Export Inspection and Certification System (CCFICS), the guidelines on the judgement of equivalence of sanitary measures were adopted by the CAC at its 26<sup>th</sup> Session, in June/July 2003 (see Alinorm 03/30A, available at: <http://www.codexalimentarius.net>).

<sup>70</sup> See paragraph 7 of the "Clarification of Paragraph 7 of the Decision on Equivalence, Note by the Secretariat, doc. G/SPS/W/128/Rev.3, 2 July 2003.

of Sanitary Measures” also take a similar approach.<sup>71</sup> The SPS Committee, in its meeting in June 2003, endorsed a recommendation that “if the exporting Member demonstrates by way of an objective basis of comparison or similar approach established by a relevant international organization that its measure has the same effect in achieving the objective as the importing Member’s measure, the importing Member should recognize both measures as equivalent”.<sup>72</sup>

Members have also stressed the importance of access to information regarding equivalence agreements and discussions. In the SPS Committee, developing countries have criticized the lack of transparency in this area, which has not allowed them to participate in existing agreements between developed countries unless they are able to comply with all the relevant conditions. Responding to this concern, the SPS Committee restated that it is up to each Member’s Enquiry Point to provide information, upon request, on the participation in any bilateral or multilateral equivalence agreements of the Member concerned. Based on the Equivalence Decision, the SPS Committee also agreed to revise its recommended notification procedures to provide for the notification of conclusion of equivalence agreements between Members.<sup>73</sup> The proposed format for this kind of notification was adopted at the June 2002 meeting by the Committee.<sup>74</sup> A notification shall be submitted when a decision on recognition of equivalence is reached, modified or rescinded, by formal agreement or by another less formal arrangement.

While desirable, equivalence agreements may be difficult to secure, even between developed countries, due to institutional disorganization, bureaucratic intransigence, or even conflict of authority within the respective countries. The costs related to the procedure of equivalence assessment could also have an impact on the competitiveness of the exported product. The existence of a trading relationship between two Members may facilitate the determination of equivalence of a new SPS measure, primarily because of the availability of information regarding the exporting country’s infrastructure and regulatory systems, and the historic contacts between the relevant regulatory officials of the exporting and importing countries.<sup>75</sup> In the context of the discussions on clarification of paragraph 5 of the Equivalence Decision (accelerated procedure for historically traded products), one Member underscored the importance of detailed knowledge of the inspection and certification services of the exporting country as being the cornerstone of confidence between the national competent authorities engaged in a negotiation on equivalence.<sup>76</sup>

In order to benefit from the equivalence provisions of the SPS Agreement, developing countries need to reinforce their scientific capacities, laboratory facilities and certification and accreditation authorities. The establishment and strengthening of regional or sub-regional laboratories, certification and accreditation bodies should be pursued and supported by internationally financed technical assistance. Provisions concerning equivalence of SPS measures should also be included and implemented in the framework of regional or sub-regional trade arrangements.

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<sup>71</sup> See doc. G/SPS/GEN/406, 19 June 2003.

<sup>72</sup> Recommendation (f), paragraph 9 of the “Clarification of Paragraph 7 of the Decision on Equivalence”, Note by the Secretariat, doc. G/SPS/W/128/Rev.3, 2 July 2003.

<sup>73</sup> See Equivalence Decision, para. 11, doc. G/SPS/19, 26 October 2001

<sup>74</sup> See “Notification of Determination of the Recognition of Equivalence of SPS Measures”, doc. G/SPS/7/Rev.2/Add.1, 25 July 2002.

<sup>75</sup> See paragraph 8 of “Clarification of Paragraph 5 of the Decision on Equivalence”, Note by the Secretariat, doc. G/SPS/W/121, 7 October 2002.

<sup>76</sup> See “Comments on Argentina’s Proposal (G/SPS/W/123/ADD.1)”, Submission by the European Communities, doc. JOB(03)/110, 11 June 2003.

### II.3 Adaptation to Regional Conditions

Within a single country, the prevalence of pests or diseases may differ between regions. Such differences may stem from climatic or environmental conditions or from the efforts of regulatory authorities to eradicate a disease or a pest from a specific area. In order to improve and preserve a country's sanitary and phytosanitary status, national regulatory bodies invest large resources in surveillance, eradication and control of pests and diseases in part or all of their territory. By ensuring that importing countries adapt their SPS measures to the conditions prevailing in the region of origin of the product, the regionalization provision of the SPS Agreement provides the trade-gain motivation for greater investment in eradication and control measures.

**REGIONALIZATION:** Article 6.1 requires Members to ensure that their measures are adapted to the SPS conditions of the area from which the product originated and to which the product is destined. Factors to be taken into account in assessing the SPS characteristics of a region are, inter alia, the level of prevalence of specific pests or diseases, the existence of eradication or control programmes and appropriate criteria or guidelines developed by relevant international organizations.

The implementation of the Article 6 provision on regionalization is particularly important for developing countries, especially large developing countries, where conditions vary substantially from region to region (see below for responses to implementation problems). The principle was largely developed from IPPC and OIE guidelines.

Cases of outbreaks of animal diseases, such as foot and mouth disease, classical swine fever and avian influenza, and of plant pests, such as fruit flies, are rather common, and regulatory authorities devote great efforts to achieving the status of disease- or pest-free area.

**PEST- OR DISEASE-FREE AREAS AND AREAS OF LOW PEST OR DISEASE PREVALENCE:** Article 6.2 embodies an obligation for Members to recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such status shall be based on factors such as geography, ecosystems, epidemiological surveillance and the effectiveness of SPS controls.

**OBLIGATIONS OF EXPORTING MEMBERS:** Exporting Members claiming that certain regions of their territories have achieved the status of pest- or disease-free areas or of areas of low pest or disease prevalence, must provide the necessary evidence of such facts to the importing Member. For this purpose, it must give the Importing Member reasonable access for inspection, testing and other relevant procedures (Article 6.3).

Once a certain SPS status has been achieved, evidence must be provided with a guarantee that that status will be maintained. Some developing countries reporting negative experiences with the recognition process have pointed out that this is delayed primarily for two reasons: (a) importing countries do not acknowledge the recognition granted by the relevant international organization; and (b) the administrative procedures required by the importing countries are too slow and complex and deviate from the procedures developed by the

relevant international organization.<sup>77</sup> They have also proposed certain stages to expedite the recognition procedure, urging the SPS Committee to undertake further work on this matter in order to clarify the valid procedures to be followed in such cases, in an effort to back up the work of the OIE and IPPC.

The IPPC standards relate to the requirements for the establishment of pest-free areas (ISPM 4) and pest-free places of production and production sites (ISPM 10). The general approach involves a system to establish freedom, phytosanitary measures to maintain freedom and checks to verify that freedom is maintained. A number of supporting standards are also relevant, such as those on guidelines for surveillance and pest eradication programmes. A standard on low pest prevalence is being developed. As for OIE, the Terrestrial Code includes the concept, principles and practice of zoning. Requirements for obtaining disease-free status include a system of surveillance and monitoring. In addition, OIE Members have agreed on a new concept of management-based delineation at the enterprise level, avian influenza being the first disease for consideration. The OIE also provides for verification of disease-free status for a certain number of diseases, while IPPC is not involved in verification of pest or disease status. Their further involvement in this activity might be desirable but Members should consider the inevitable resource implications.<sup>78</sup>

Despite the OIE and the IPP guidance, exporting countries still suffer from delayed recognition of their pest- or disease-free status by importing countries. In response, some Members would like the SPS Committee to draft administrative guidelines on the topic (e.g. Chile, Argentina, Peru, Brazil and the EU), and one Member suggested that regionalization be a permanent agenda item for the Committee (Chile). Other Members would prefer to wait until the IPPC and the OIE complete their own technical guidelines on the issue (e.g. New Zealand, Canada and the United States). So far, there has not been a decision to start working on a draft text on regionalization. However, during the course of the second Review of the operation and implementation of the SPS Agreement, the issue was discussed in a series of formal and informal meetings.

## II.4 Specific Trade Concerns

Since 1995, when the SPS Agreement came into force, Members have brought a number of specific trade concerns to the SPS Committee's attention. By raising a specific trade issue, Members can draw attention to a particular concern, which may help to avoid disputes between trading partners or potential future trade problems.

A wide range of specific trade concerns have been raised, including policy measures taken in response to foot-and-mouth disease outbreaks, BSE, maximum levels for certain food contaminants, and measures taken that affect trade in particular commodities. According to the WTO Secretariat, from 1995 to October 2004, altogether 204 specific trade concerns were raised. Of these, 27 per cent related to food safety; 29 per cent related to plant health and 4

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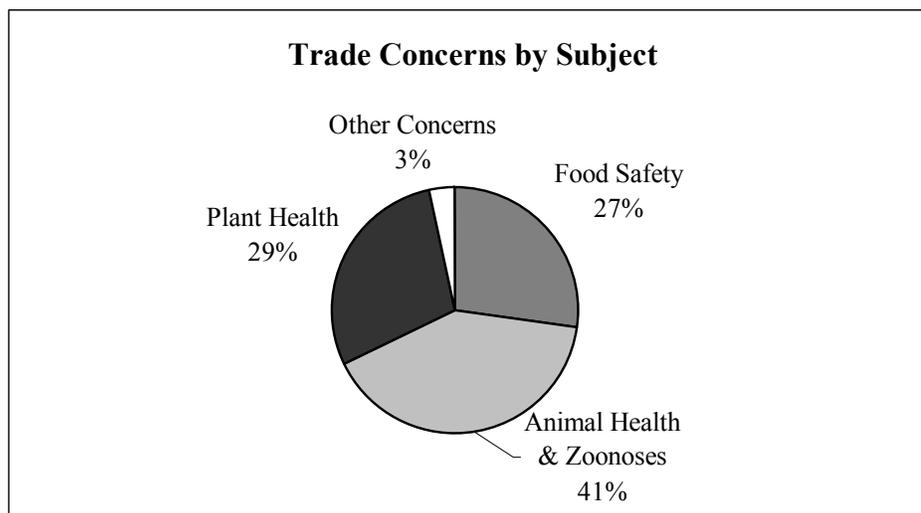
<sup>77</sup> See the submissions by Chile and Mexico, docs. G/SPS/W/129, 21 March 2003, and G/SPS/GEN/388, 1 May 2003.

<sup>78</sup> See the Chairperson's summary.

per cent concerned other issues such as certification requirements or translation. About 40 per cent of concerns raised related to animal health and zoonoses.<sup>79</sup>

In 124 cases, the measures for which trade concerns had been raised were maintained by a developed country Member, and in 99 cases by a developing country Member. No specific trade concerns regarding measures maintained by least developed country Members have been raised. In 2002, a growing number of trade concerns were raised by developing countries, an indication that participation of these countries in the work of the Committee is improving. By October 2004, 101 specific trade concerns had been raised by developing countries, as opposed to 134 by developed and 2 by least developed country Members. In 149 cases, a developing country Member has supported another Member raising an issue.<sup>80</sup>

**Figure 1**



*Source*, WTO, G/SPS/GEN/204/Rev.5, 2005, page ii

While there is growing recourse to the Committee, there remains the problem of reaching solutions. Out of these 204 concerns, 56 (i.e. 27 per cent) are reported to have been resolved in the same period of time.<sup>81</sup> Excluding the 21 new issues raised in 2004, there are 116 specific trade concerns that are at least one year old and for which no solution has been reported. However, it may well be that some of these concerns have been resolved without the Committee being aware of it.<sup>82</sup> For cases that remain unresolved, Members have, as a last resort, the right to resort to the dispute settlement mechanism of the WTO and to request formal consultations, as examined in the Dispute Settlement section.

Major food safety scares, such as dioxin contamination and BSE ("mad cow disease"), as well as concerns about genetically modified foods and the use of growth promoting hormones

<sup>79</sup> See doc. G/SPS/W/173, including Rev. 1 and 2.

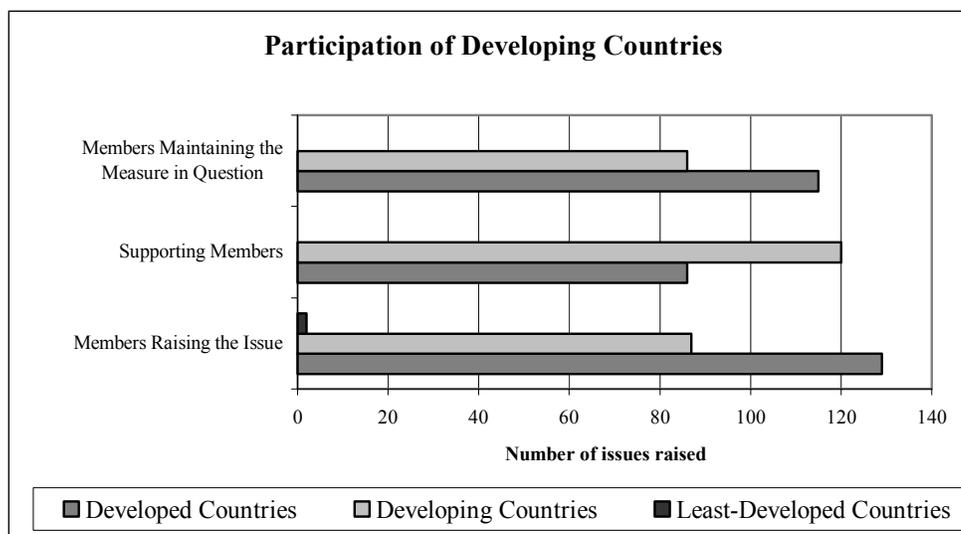
<sup>80</sup> See page iv "Specific Trade Concerns", Note by the Secretariat, doc. G/SPS/GEN/204/Rev.5, 25 February 2005.

<sup>81</sup> See para 84 "Review of the Operation and Implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures", Draft Report of the Committee, doc. G/SPS/W/173 Rev 2, 28/06/2005.

<sup>82</sup> See page v, "Specific Trade Concerns", Note by the Secretariat, doc. G/SPS/GEN/204/Rev.4, 2 March 2004.

in beef, have increased consumer anxiety, particularly in Europe, about domestic food safety systems. Within the context of the SPS Committee there were detailed discussions on various trade restrictions imposed in response to these disease outbreaks and other food safety concerns. Annex II deals in detail with the important issue of genetically modified organisms. Most developing countries have not yet passed legislation in this field and believe that their limited scientific capacities, their recurrent problems with checking products at the border, and their restricted ability to make their own assessment of the risks and benefits involved do not allow them to manage properly the challenges that GMOs pose.

**Figure 2**



Source, WTO, G/SPS/GEN/204/Rev.5, 2005, page iii

**PROBLEMS IN EXPORT MARKETS: WHAT CAN BE DONE?**

Whenever a Member believes that another Member's draft or existing SPS measure is adversely affecting its exports and is not in conformity with the relevant provisions of the SPS Agreement, the following steps should be undertaken:

- 1) Request a draft copy of the measure in question from the SPS Enquiry Point of the notifying Member;
- 2) Disseminate the text among local exporters/producers;
- 3) Get comments;
- 4) Send comments to the notifying Member;

Should this not suffice, Members may consider the following:

- 5) **Political profile:** Raise the issue in the SPS Committee (from 1995 to 2002, out of a total of 154 specific trade concerns, 77 were raised by developing country Members and 2 by LDCs).

And, only as a last resort:

- 6) **Dispute Settlement:** Request formal consultations.

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## ANNEX I

### EXTRACTS FROM THE WTO SPS AGREEMENT AND RELEVANT DECISIONS

#### **Annex A of the SPS Agreement: Definition of sanitary or phytosanitary measures**

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

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

#### **Decision on "Procedure to Enhance Transparency of Special and Differential Treatment in Favour of Developing Country Members", adopted by the SPS Committee on 27 October 2004 (G/SPS/33)**

1. At its meeting of 2-3 April 2003, the Committee on Sanitary and Phytosanitary Measures ("the Committee") adopted, in principle, the Canadian proposal to enhance transparency of special and differential treatment within the Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement") (G/SPS/W/127), as one step for immediate implementation by Members, subject to further elaboration of the procedures to be followed. This proposal builds upon a proposal by Egypt for enhanced transparency through modification of the notification formats (G/SPS/GEN/358).
2. The Committee hereby agrees on the procedures to be followed.
3. The proposed procedure essentially follows the relevant current practices and recommendations regarding the submission and handling of notifications as described in G/SPS/7/Rev.2, with new actions included as Steps 5, 6 and 7.

4. Following one year of the adoption of this procedure, the Committee shall review the proposed notification process to evaluate its implementation, and determine whether changes are required and/or its continuance is warranted.

5. This procedure is without prejudice to the rights and obligations of Members under Article 10.1 of the SPS Agreement. In adopting the Canadian proposal, Members reaffirmed that in the preparation and application of sanitary and phytosanitary (SPS) measures, Members shall take account of the special needs of developing country Members and in particular of the least-developed country Members. The Committee recognized that this would not fully resolve the issue of special and differential treatment, but that this was one step in addressing the problem of implementation of the special and differential treatment provisions of the Agreement. The Committee also agreed to consider other proposals and possible actions.

Step 1. A Member preparing a new or a revision to an existing SPS regulation shall submit a notification to the WTO Secretariat, following the guidance provided in G/SPS/7/Rev.2. The notification should be made when a draft with the complete text of the proposed regulation is available, and when amendments can still be introduced and comments taken into account. The notifying Member should provide in Box 3 of the notification format a clear description of the products covered, including tariff item numbers where possible. The notifying Member should also complete Box 4, identifying the geographical regions or countries likely to be affected by the notified regulation to the extent relevant or practicable. The notifying Member should identify in Box 12 the final date for receiving comments and the agency responsible for handling comments. The Member shall normally allow a period of at least 60 days for comment, except for proposed measures which facilitate trade. Any Member which is able to provide a time-limit beyond 60 days is encouraged to do so.

Step 2. The Secretariat will circulate the notification with the minimal delay possible. The Secretariat will provide paper copies of the notification to the permanent missions of all WTO Members, and mail paper copies to one other designated address if so requested by a Member. The notification will be posted on both the "Members' Only" and the public web sites of the WTO, and will be electronically sent within one week of circulation to all addresses on the SPS self-subscribing electronic mailing list (in the language received by the Secretariat). The notification will be included in the monthly summary of SPS notifications circulated by the Secretariat. If a developing country Member has difficulties in receiving and distributing notifications after receipt, the Member should inform the Secretariat thereof and propose how the national enquiry point could be improved.

Step 3. If a Member with an interest in exporting the products affected by the notification identifies a concern with the content of the notification, the exporting Member should contact the notifying Member, within the comment period, to seek additional information with respect to the notified measure and to identify their concerns. If the exporting Member requests an extension of the comment period, the notifying Member should grant requests for extension of the comment period wherever practicable, in particular with regard to notifications relating to products of particular interest to developing country Members, where there have been delays in receiving and translating the relevant documents or where there is a need for further clarification of the measure notified. A 30-day extension should normally be provided.

Step 4. The notifying Member should acknowledge receipt of the request for an extension of the comment period, or for additional information, and explain within a reasonable period of time, and at the earliest possible date before the adoption of the measure, to any Member from which it has received comments, how it will take these comments into account and, where appropriate, provide additional relevant information on the proposed sanitary or phytosanitary regulations.

Step 5. If an exporting Member identifies significant difficulties with the proposed measure, that Member may, in its comments, request an opportunity to discuss and resolve the potential difficulty with the notifying Member. In response to such a written request, the notifying Member will contact the appropriate officials of the exporting Member and enter into bilateral discussions to attempt to resolve the issue of concern. In the case of such a request from an exporting developing country Member, the notifying Member would in any discussions examine whether and how the identified problem could best be addressed to take into account the special needs of the interested exporting developing country Member. Resolution of the concern identified could include one of the following, or a combination thereof: (1) a change in the measure to be applied on a MFN basis; (2) the provision of technical assistance to the exporting Member; or (3) the provision of special and differential treatment. Should special and differential treatment be provided, it would apply equally to all developing country Members.

Step 6. If, following the entry into force of a new regulation (including an emergency measure), an exporting Member identifies significant difficulties which its exports face in complying with the new regulation, it may request an opportunity to discuss its difficulties with the importing Member to attempt to resolve the issue of concern, especially where no time, or an insufficient period of time, has been provided for comments. In the case of such a request from an exporting developing country Member, the importing Member would, in any discussions, examine whether and how the identified problem could best be addressed to take into account the special needs of the interested exporting developing country Member, so as to enable it to satisfy the requirements of the measure. Resolution of the concern identified could include one of the following, or a combination thereof: (1) a change in the measure to be applied on a MFN basis; (2) the provision of technical assistance to the exporting Member; or (3) the provision of special and differential treatment. Should special and differential treatment be provided, it would apply equally to all developing country Members.

Step 7. When a decision is taken on whether and how special and differential treatment may be provided for a final measure in response to specific requests, the notifying Member should promptly submit to the WTO Secretariat an Addendum to its original notification. The Addendum shall indicate: (1) if special and differential treatment was requested; (2) the name(s) of Member(s) that requested special and differential treatment; (3) if special and differential treatment was provided, the form of such treatment; and (4) if not provided, the Addendum shall indicate why special and differential treatment was not provided and whether technical assistance or any other solution was found to address the identified concern. A format for the Addendum is contained in Annex 1.

Step 8. The Addendum to the notification shall be circulated by the WTO Secretariat in the same manner as the notification.

Addendum

The following communication, dated DD/MM/YY has been received from [Member].

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Title outlining what the SPS measure or product is

[Text describing any modification to the notified measure.]

*Special and Differential Treatment*

Text (1) indicating if special and differential treatment was requested; (2) providing the name(s) of the Member(s) that requested special and differential treatment; (3) if special and differential treatment was provided, describing how such treatment was provided, including what form it took; and (4) if special and differential treatment was not provided, indicating why it was not provided and whether technical assistance or any other solution was found to address the identified concern.

Where the notified document can be obtained from – include contact name, agency, full address, telephone, facsimile, and e-mail as appropriate.

**"Decision on the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures", adopted by the SPS Committee (G/SPS/19/Rev.2)**

Revision<sup>83</sup>

The Committee on Sanitary and Phytosanitary Measures,

*Having regard* to paragraph 1 of Article 12 of the Agreement on the Application of Sanitary and Phytosanitary Measures;

*In response* to the request from the General Council that the Committee examine the concerns of developing country Members regarding the equivalence of sanitary or phytosanitary measures and develop concrete options as to how to deal with them;

*Reaffirming* the right of Members to establish sanitary and phytosanitary measures necessary to ensure the protection of human, animal and plant life or health and the protection of their territory from other damage caused by the entry, establishment or spread of pests, in accordance with the Agreement on the Application of Sanitary and Phytosanitary Measures;

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<sup>83</sup> This revision provides updated information with respect to actions taken pursuant to the Decision as adopted on 26 October 2001. This information is provided in footnotes to the relevant provisions in the Decision.

*Desiring* to make operational the provisions of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures;

*Noting* that equivalence of sanitary or phytosanitary measures does not require duplication or sameness of measures, but the acceptance of alternative measures that meet an importing Member's appropriate level of sanitary or phytosanitary protection;

*Recognizing* that equivalence can be applied between all Members, irrespective of their level of development;

*Noting* that Members have faced difficulties applying the provisions of Article 4 recognizing the equivalence of sanitary and phytosanitary measures;

*Taking into account* the specific concerns raised by developing country Members, and particularly the least developed among them, regarding their difficulties in having the equivalence of their sanitary or phytosanitary measures accepted by importing Members;

*Recognizing* the importance of minimizing possible negative effects of sanitary or phytosanitary measures on trade and of improving market access opportunities, particularly for products of interest to developing country Members;

*Recognizing* that transparency, exchange of information and confidence-building by both the importing and exporting Member are essential to achieving an agreement on equivalence;

*Recognizing* that there may be other less resource-intensive and time-consuming means for Members to enhance trade opportunities;

*Decides as follows:*

1. Equivalence can be accepted for a specific measure or measures related to a certain product or categories of products, or on a systems-wide basis. Members shall, when so requested, seek to accept the equivalence of a measure related to a certain product or category of products. An evaluation of the product-related infrastructure and programmes within which the measure is being applied may also be necessary.<sup>84</sup> Members may further, where necessary and appropriate, seek more comprehensive and broad-ranging agreements on equivalence. The acceptance of the equivalence of a measure related to a single product may not require the development of a systems-wide equivalence agreement.
2. In the context of facilitating the implementation of Article 4, on request of the exporting Member, the importing Member should explain the objective and rationale of the sanitary or phytosanitary measure and identify clearly the risks that the relevant measure is intended to address. The importing Member should indicate the appropriate level of protection which its sanitary or phytosanitary measure is designed to achieve.<sup>85</sup> The explanation should be accompanied by a copy of the risk assessment on which the sanitary or phytosanitary measure is based or a technical justification based on a relevant international standard, guideline or recommendation. The importing Member should also provide any additional information which may assist the exporting Member to provide an objective demonstration of the equivalence of its own measure.
3. An importing Member shall respond in a timely manner to any request from an exporting Member for consideration of the equivalence of its measures, normally within a six-month period of time.

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<sup>84</sup> Product-related infrastructure and programmes is in reference to testing, inspection and other relevant requirements specific to product safety.

<sup>85</sup> In doing so, Members should take into account the *Guidelines to Further the Practical Implementation of Article 5.5* adopted by the Committee on Sanitary and Phytosanitary Measures at its meeting of 21-22 June 2000 (document G/SPS/15, dated 18 July 2000).

4. The exporting Member shall provide appropriate science-based and technical information to support its objective demonstration that its measure achieves the appropriate level of protection identified by the importing Member. This information may include, *inter alia*, reference to relevant international standards, or to relevant risk assessments undertaken by the importing Member or by another Member. In addition, the exporting Member shall provide reasonable access, upon request, to the importing Member for inspection, testing and other relevant procedures for the recognition of equivalence.

5. The importing Member should accelerate its procedure for determining equivalence in respect of those products which it has historically imported from the exporting Member.

*The Committee agrees that historic trade provides an opportunity for an importing Member to become familiar with the infrastructure and measures of an exporting Member, and to develop confidence in the regulatory procedures of that Member. This information and experience, if directly relevant to the product and measure under consideration, should be taken into account in the recognition of equivalence of measures proposed by the exporting Member. In particular, information already available to the importing Member should not be sought again with respect to procedures to determine the equivalence of measures proposed by the exporting Member.*

*An importing Member should consider the relevant information and experience that the sanitary and phytosanitary services have on the measure(s) for which recognition of equivalence is requested as applied to the product for which that request relates.*

*This information and experience refers to:*

(i) *The historic knowledge and confidence that the competent authority of the importing Member has of the competent authority of the exporting Member.*

(ii) *The existence of an evaluation and recognition of the products-related system of inspection and certification of the exporting Member by the importing Member.*

(iii) *The available scientific information supporting the request for the recognition of equivalence.*

*The more such relevant information and experience is available to the importing Member, the more rapid should be the procedure for recognition of equivalence by that Member.*

*A Member should consider the existence of information between competent authorities related to sanitary and phytosanitary measures of other products (different from the one for which equivalence is requested) when this information is useful.*

*A Member should consider the risk of the product to which the sanitary and phytosanitary measures are applied, in order to reduce requirements and accelerate the procedure in cases of low risk.*

*The importing Member should not seek again information already available with respect to the determination of the equivalence of sanitary and phytosanitary measures proposed by the exporting Member, unless this information needs to be updated.*

*For accelerated procedures, the importing Member should estimate the steps that the demonstration of equivalence will require, and inform the exporting Member, when it is possible, of an estimated time schedule for the whole process. These steps should be considered between the exporting and importing Members, on an issue-by-issue basis, in order to give predictability to the process of determination of equivalence.*

*When more than one agency is involved, the relevant requirements of all of these agencies must be taken into account and included in the steps and timetable identified above.*

*The Committee notes that the importance of this knowledge based on historic trade has been fully recognized in the draft FAO/WHO Joint Codex Alimentarius Commission Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems.<sup>86</sup> The Committee further notes that the importance of such prior experience is also recognized in the draft paper of the World Organization for Animal Health (OIE) on the Judgement of Equivalence of Sanitary Measures relating to International Trade in Animals and Animal Products.<sup>87</sup> The Committee encourages that further elaboration of specific guidance by these organizations should ensure that such recognition is maintained.*

*The Committee draws the attention of the Interim Commission on Phytosanitary Measures (ICPM) to the Decision on Equivalence (G/SPS/19), and to the above clarification with respect to Paragraph 5 of the Decision. The Committee requests that the ICPM take into consideration the Decision and this clarification in its future work on judgement of equivalence with regard to sanitary measures to address plant pests and diseases.<sup>88</sup>*

6. The consideration by an importing Member of a request by an exporting Member for recognition of the equivalence of its measures with regard to a specific product shall not be in itself a reason to disrupt or suspend on-going imports from that Member of the product in question.

*The Committee agrees that since a request for recognition of equivalence does not in itself alter the way in which trade is occurring, there is no justification for disruption or suspension of trade. If an importing Member were to disrupt or suspend trade solely because it had received a request for an equivalence determination, it would be in apparent violation of its obligations under the SPS Agreement (e.g. under Article 2).*

*At the same time, a request for recognition of equivalence does not impede the right of an importing Member to take any measure it may decide is necessary to achieve its appropriate level of protection, including in response to an emergency situation. However, if the decision to impose some additional control measure were to coincide with consideration by the same Member of a request for recognition of equivalence, this might lead an exporting Member whose trade is affected to suspect that the two events were linked. To avoid any misinterpretation of this kind, the Committee recommends that the importing Member should give an immediate and comprehensive explanation of the reasons for its action in restricting trade to any other Members affected, and that it should also follow the normal or emergency notification procedures established under the SPS Agreement.*

*The Committee notes that this issue has been addressed also in the draft Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems, and should encourage the maintenance of*

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<sup>86</sup> The Codex Alimentarius Commission adopted the Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems at its 26<sup>th</sup> Session held in Rome, Italy, from 30 June to 7 July 2003.

<sup>87</sup> The International Committee of the OIE adopted the Guidelines for Reaching a Judgement on Equivalence of Sanitary Measures at its 71<sup>st</sup> General Session held in Paris, France, from 18 to 23 May 2003.

<sup>88</sup> The Interim Commission on Phytosanitary Measures (ICPM) noted the request of the SPS Committee at its 5<sup>th</sup> Session held in Rome, Italy, from 7 to 11 April 2003. The ICPM agreed to include Equivalence and Efficacy of Measures, considered a pre-requisite to an ISPM on Equivalence, as priorities in its work programme. Work on these two issues is currently underway.

*such a provision in the further elaboration of specific guidance by the Codex. The Committee draws the attention of the World Organization for Animal Health (OIE) and the Interim Commission on Phytosanitary Measures (ICPM) to the above clarification with respect to Paragraph 6 of the Decision on Equivalence, and requests that the OIE and the ICPM take this clarification into consideration in their future work on equivalence with regard to sanitary or phytosanitary measures.*

7. When considering a request for recognition of equivalence, the importing Member should analyze the science-based and technical information provided by the exporting Member on its sanitary or phytosanitary measures with a view to determining whether these measures achieve the level of protection provided by its own relevant sanitary or phytosanitary measures.

*The Committee notes that conscientious implementation of the Guidelines to Further the Practical Implementation of Article 5.5 (G/SPS/15) will assist Members in determining equivalence.*

*The Committee further notes that the relationship between the level of protection provided by the importing Member's own measures and what it requires from imported products has been explicitly addressed in the draft Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems.<sup>89</sup> The Committee notes that the OIE Guidelines for Reaching a Judgement of Equivalence of Sanitary Measures also recognizes the importance of facilitating comparison of the exporting and importing Members' measures. The Committee agrees that Members should consider the Codex approach of establishing an objective basis for comparison or the similar OIE approach when determining the equivalence of sanitary measures.*

*The Committee encourages the FAO/WHO Codex Alimentarius Commission and the World Organization for Animal Health to ensure that the recognition of the importance of facilitating comparison of the exporting and importing Members' measures is maintained in any elaboration of guidance by these organizations.*

*The Committee requests that the Interim Commission on Phytosanitary Measures (ICPM) take into consideration the Decision on Equivalence and this clarification in its future work on judgement of equivalence with regard to measures to address plant pests and diseases.*

*The Committee agrees that where the objective basis for comparison, or a similar approach established by a relevant international organization, demonstrates that the level of protection achieved by the importing Member's sanitary or phytosanitary measure differs from its appropriate level of protection, the importing Member should resolve this difference independently of the procedure for determination of equivalence.*

*If the exporting Member demonstrates by way of an objective basis of comparison or similar approach established by a relevant international organization that its measure has the same effect in achieving the objective as the importing Member's measure, the importing Member should recognize both measures as equivalent.*

8. In accordance with Article 9 of the Agreement on the Application of Sanitary and Phytosanitary Measures, a Member shall give full consideration to requests by another Member, especially a developing country Member, for appropriate technical assistance to facilitate the implementation of Article 4. This assistance may, *inter alia*, be to help an exporting Member identify and implement measures which can be recognized as equivalent,

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<sup>89</sup> The Committee recognizes that the Codex Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems are also relevant in this regard.

or to otherwise enhance market access opportunities. Such assistance may also be with regard to the development and provision of the appropriate science-based and technical information referred to in paragraph 4, above.

9. Members should actively participate in the ongoing work in the Codex Alimentarius Commission on the issue of equivalence, and in any work related to equivalence undertaken by the World Organization for Animal Health and in the framework of the International Plant Protection Convention. Bearing in mind the difficulties faced by developing country Members to participate in the work of these bodies, Members should consider providing assistance to facilitate their participation.

10. The Committee on Sanitary and Phytosanitary Measures recognizes the urgency for the development of guidance on the judgement of equivalence and shall formally encourage the Codex Alimentarius Commission to complete its work with regard to equivalence as expeditiously as possible. The Committee on Sanitary and Phytosanitary Measures shall also formally encourage the World Organization for Animal Health and the Interim Commission on Phytosanitary Measures to elaborate guidelines, as appropriate, on equivalence of sanitary and phytosanitary measures and equivalence agreements in the animal health and plant protection areas. The Codex Alimentarius Commission, the World Organization for Animal Health and the Interim Commission on Phytosanitary Measures shall be invited to keep the Committee on Sanitary and Phytosanitary Measures regularly informed regarding their activities relating to equivalence.

11. The Committee on Sanitary and Phytosanitary Measures shall revise its recommended notification procedures to provide for the notification of the conclusion of agreements between Members which recognize the equivalence of sanitary and phytosanitary measures.<sup>90</sup> Furthermore, the procedures shall reinforce the existing obligation in paragraph 3(d) of Annex B of the Agreement on the Application of Sanitary and Phytosanitary Measures for national Enquiry Points to provide information, upon request, on the participation in any bilateral or multilateral equivalence agreements of the Member concerned.

12. Members should regularly provide to the Committee on Sanitary and Phytosanitary Measures information on their experience regarding the implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures. In particular, Members are encouraged to inform the Committee on Sanitary and Phytosanitary Measures of the successful conclusion of any bilateral equivalence agreement or arrangement. The Committee on Sanitary and Phytosanitary Measures shall consider establishing a standing agenda item for its regular meetings for this purpose.

13. The Committee on Sanitary and Phytosanitary Measures shall develop a specific programme to further the implementation of Article 4, with particular consideration of the problems encountered by developing country Members.<sup>91</sup> In this respect, the Committee on Sanitary and Phytosanitary Measures shall review this decision in light of the relevant work undertaken by the Codex Alimentarius Commission, the World Organization for Animal Health and the Interim Commission on Phytosanitary Measures, as well as the experience of Members.

14. The Committee on Sanitary and Phytosanitary Measures requests that the General Council take note of this decision.

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<sup>90</sup> G/SPS/7/Rev.2 and Rev.2/Add.1.

<sup>91</sup> In the light of this paragraph and the decision at the Fourth Ministerial Conference regarding implementation-related issues and concerns (WT/MIN(01)17, paragraph 3.3), the SPS Committee adopted a programme for further work on equivalence at its meeting of 19-21 March 2002 (G/SPS/20). The Committee completed this work programme in March 2004 but agreed that equivalence would be a standing agenda item for its regular meetings.

### **Paragraph 3 of the Doha Decision on Implementation Related Issues and Concerns**

#### Agreement on the Application of Sanitary and Phytosanitary Measures

3.1 Where the appropriate level of sanitary and phytosanitary protection allows scope for the phased introduction of new sanitary and phytosanitary measures, the phrase "longer time-frame for compliance" referred to in Article 10.2 of the Agreement on the Application of Sanitary and Phytosanitary Measures, shall be understood to mean normally a period of not less than 6 months. Where the appropriate level of sanitary and phytosanitary protection does not allow scope for the phased introduction of a new measure, but specific problems are identified by a Member, the Member applying the measure shall upon request enter into consultations with the country with a view to finding a mutually satisfactory solution to the problem while continuing to achieve the importing Member's appropriate level of protection.

3.2 Subject to the conditions specified in paragraph 2 of Annex B to the Agreement on the Application of Sanitary and Phytosanitary Measures, the phrase "reasonable interval" shall be understood to mean normally a period of not less than 6 months. It is understood that timeframes for specific measures have to be considered in the context of the particular circumstances of the measure and actions necessary to implement it. The entry into force of measures which contribute to the liberalization of trade should not be unnecessarily delayed.

3.3 Takes note of the Decision of the Committee on Sanitary and Phytosanitary Measures (G/SPS/19, including Rev.1 and 2) regarding equivalence, and instructs the Committee to develop expeditiously the specific programme to further the implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures.

3.4 Pursuant to the provisions of Article 12.7 of the Agreement on the Application of Sanitary and Phytosanitary Measures, the Committee on Sanitary and Phytosanitary Measures is instructed to review the operation and implementation of the Agreement on Sanitary and Phytosanitary Measures at least once every four years.

3.5 (i) Takes note of the actions taken to date by the Director-General to facilitate the increased participation of Members at different levels of development in the work of the relevant international standard setting organizations as well as his efforts to coordinate with these organizations and financial institutions in identifying SPS-related technical assistance needs and how best to address them; and

(ii) urges the Director-General to continue his cooperative efforts with these organizations and institutions in this regard, including with a view to according priority to the effective participation of least-developed countries and facilitating the provision of technical and financial assistance for this purpose.

3.6 (i) Urges Members to provide, to the extent possible, the financial and technical assistance necessary to enable least-developed countries to respond adequately to the introduction of any new SPS measures which may have significant negative effects on their trade; and

(ii) urges Members to ensure that technical assistance is provided to least-developed countries with a view to responding to the special problems faced by them in implementing the Agreement on the Application of Sanitary and Phytosanitary Measures.

## ANNEX II

### OVERVIEW OF FORMAL DISPUTES UNDER THE SPS AGREEMENT, 1995-2003 (UP TO AUGUST 2003), PANEL/APPELLATE BODY REPORTS

For more details, see WTO documents in the *WT/DS series* and, in particular the “Update of WTO Dispute Settlement Cases”, doc. WT/DS/OV/19, 6 February 2004, or any more recent version of this summary document, searchable at:

[http://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm).

**Table 1: Cases that have proceeded to the panel stage or where rulings (by the Panel or the Appellate Body) have been issued**

Case No.	Measure	Complaining Party (Third Parties)	Ruling
DS 291/292/293	European Communities – Measures Affecting the Approval and Marketing of Biotech Products	United States, Canada and Argentina	Request for establishment of Panel (August 2003)  <i>Alleged violations<sup>92</sup>: Articles 2.2, 2.3, 5.1, 5.2, 5.5, 5.6, 7, 8, and paragraphs 1, 2 and 5 of Annex B, and paragraphs 1(a), 1(b), 1(c), and 1(e) of Annex C</i>
DS 245	Japan – Measures Affecting the Importation of Apples  Complex set of phytosanitary measures restricting the importation of US apples to protect Japan against fire blight bacteria	United States	Panel Report (July 2003)  <i>Ruling:</i> The measure was judged as inconsistent with Article 2.2. It could not be justified as a precautionary measure under Article 5.7 (the relevant scientific evidence was not insufficient). Finally, it was not based on a risk assessment within the meaning of Article 5.1, as defined in Annex A.4 (panels were established in the context of procedures according to Articles 21.5 and 22.6 of the DSU, with the 21.5 panel pending and the 22.6 panel process suspended).
DS 270	Australia – Certain Measures Affecting the Importation of Fresh Fruit and Vegetables	Philippines	Request for establishment of Panel (July 2003)  <i>Alleged violations: Articles 2.2, 2.3, 3.1, 5.1, 5.2, 5.3, 5.5, 5.6, 6.1, 6.2 and Annex A.4.</i>

<sup>92</sup> The alleged violations listed in tables 1, 2 and 3 on dispute settlement cases are those indicated in the requests for formal consultations (or for the establishment of a panel) and only refer to cited violations of the SPS Agreement. This is without prejudice to claims of violations under other Agreements, such as GATT, TBT and the Agreement on Agriculture, which are not mentioned in this table.

TRAINING MODULE ON THE WTO AGREEMENT  
ON SANITARY AND PHYTOSANITARY MEASURES

Case No.	Measure	Complaining Party (Third Parties)	Ruling
DS 76	<p>Japan – Measures Affecting Agricultural Products (varietal testing requirements)</p> <p>Phytosanitary measures, requiring testing on each new variety of fruit and walnuts to protect orchards from codling moth</p>	<p>United States</p> <p><i>(Brazil, European Communities, Hungary)</i></p>	<p>Completed Appellate Body proceedings (1999)</p> <p><i>Ruling:</i> Japan's varietal testing requirements were maintained without sufficient scientific evidence (Article 2.2). They could not be justified as a precautionary measure under Article 5.7 (Japan did not fulfill the obligation to seek additional information). The measures were not based on a risk assessment (Article 5.1). Finally, they were not transparent (i.e. the measures had not been published, Article 7 and Annex B). The Parties notified a mutually agreed solution in September 2001.</p>
DS 26/49	<p>European Communities – Measures Affecting Meat and Meat Products (hormones)</p> <p>Ban on imports of meat and meat products from cattle treated with any of six specific hormones for growth promotion purposes (to protect human health)</p>	<p>United States and Canada</p> <p><i>(Australia, New Zealand, Norway)</i></p>	<p>Completed Appellate Body proceedings (1998)</p> <p><i>Ruling:</i> The ban was not based on a risk assessment (Article 5.1). The EC did not produce scientific evidence to support its claim that the measure provided a high level of health protection (higher than Codex standard, Article 3.3). Given the non-compliance by defendant with DSB's recommendation to bring measure into conformity, in July 1999, concessions were suspended at a level of US\$ 116.8 million (USA) and CN\$11.3 million (Canada)</p>
DS 18/21	<p>Australia – Measures Affecting the Importation of Salmon</p> <p>Ban on salmon imports (while allowing imports of other fish potentially vectors of the same, or even more virulent, diseases)</p>	<p>Canada</p> <p><i>(European Communities, India, Norway, United States)</i></p>	<p>Completed Appellate Body proceedings (1998)</p> <p><i>Ruling:</i> The measures were not based on a risk assessment (Article 5.1). The ban on salmon imports provided a level of protection that was higher than other measures used to protect fish stocks, and this variation resulted in a disguised restriction on trade (Article 5.5). The Parties notified a mutually agreed solution in May 2000.</p>

**Table 2: Pending consultations**

Case No.	Measure	Complaining Party	Alleged SPS Violations
DS 297	Croatia – Measures Affecting Imports of Live Animals and Meat Products	Hungary	Pending consultations (since July 2003) Articles 2.2, 2.3, 3.1, 5.1, 5.2, 5.3, 5.6, 6.1, 6.2, 7 and Annex B
DS 287	Australia – Quarantine Regime for Imports	European Communities	Pending consultations (since April 2003) Articles 2.2, 2.3, 3.3, 4.1, 5.1, 5.6 and, if applicable, 5.7, 8 and Annex C
DS 271	Australia – Certain Measures Affecting the Importation of Fresh Pineapple	Philippines	Pending consultations (since October 2002) Articles 2, 3, 4, 5, 6 and 10
DS 256	Turkey – Import Ban on Pet Food from Hungary	Hungary	Pending consultations (since 2002) Articles 2.2, 2.3, 5.1, 5.2, 5.6, 6.1, 6.2 and 7 and Annex B
DS 237	Turkey – Certain Import Procedures for Fresh Fruit	Ecuador	Pending consultations (since 2001) Articles 2.3 and 8 and Annexes B and C
DS 205	Egypt -Import Prohibition on Canned Tuna with Soybean Oil	Thailand	Pending consultations (since 2000) Articles 2,3,5 and Annex B, para 5
DS 203	Mexico – Measures Affecting Trade in Live Swine	United States	Pending consultations (since 2000) Articles 2.2, 2.3, 3, 5.1, 5.6, 7 and 8
DS 144	United States – Certain Measures Affecting the Import of Cattle, Swine and Grain from Canada	Canada	Pending consultations (since 1998) Articles 2, 3, 4, 5, 6, 13 and Annexes B and C
DS 137	European Communities – Measures Affecting Imports of Wood of Conifers from Canada	Canada	Pending consultations (since 1998) Articles 2, 3, 4, 5 and 6
DS 134	European Communities - Measures Affecting Import Duties on Rice	India	Pending consultations (since 1998) Article 2
DS 133	Slovak Republic - Measures Concerning the Importation of Dairy Products and the Transit of Cattle (BSE restrictions)	Switzerland	Pending consultations (since 1998) Article 5
DS 100	United States – Measures Affecting the Importation of Poultry Products	European Communities	Pending consultations (since 1997) Articles 2, 3, 4, 5, 8 and Annex C

**Table 3: Settled Cases (mutually agreed solutions)**

Case No.	Measure	Complaining Party	Alleged SPS Violations
DS 284	Mexico – Certain Measures Preventing the Importation of Black Beans from Nicaragua	Nicaragua	Pending consultations (since March 2003) Articles 2.1, 2.2, 2.3, 5.1, 7 and paragraph 1 of Annex B; withdrawal of request for consultations in spring 2004.
DS 205	Egypt – Import Prohibition on Canned Tuna with GM Soybean Oil	Thailand	Informally settled by mutually agreed solution Consultations (2000) Articles 2, 3 and 5, and Annex B, paragraph 2 and paragraph 5
DS 96	India – Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products	European Communities	Settled by mutually agreed solution (1998) Articles 2, 3 and 5
DS 21	Australia – Measures Affecting the Importation of Salmonids	United States	Consultations (1995): same measure at issue in case DS/18 (above) Establishment of panel (1999); suspension pending DS/18 proceedings Settled by mutually agreed solution (2000) Articles 2, 5
DS 20	Korea – Measures Concerning Bottled Water	Canada	Consultations (1995) Settled by mutually agreed solution (1996) Articles 2, 5
DS 5	Korea – Shelf-life Measures	United States	Consultations (1995) Settled by mutually agreed solution (1995) Articles 2, 5
DS 3/41	Korea – Measures Concerning the Testing and Inspection of Agricultural Products	United States	Pending consultations (since 1995/96) Article 5. Mutually satisfactory solution notified in July 2001

## ANNEX III

# INTERNATIONAL TRADE IN BIOTECHNOLOGY PRODUCTS

### **Annex III.1. Modern Biotechnology and its Applications in the Field of Agriculture**

Genetically modified organisms (GMOs) are obtained through the use of modern techniques of genetic modification, which allow changes to biological organisms beyond what would be attainable through natural selection and controlled breeding.<sup>93</sup> The ability to change the genetic make-up of crops using a wider gene pool offers the possibility of providing such products with new beneficial traits that conventional products lack. Transgenic crops (such as soybeans, cotton, corn, canola, potatoes and rice, to cite a few) can already be genetically modified to better resist environmental and biological stress, such as heat, drought or frost, to remain fresh longer, to resist insects and diseases and to tolerate herbicides.<sup>94</sup> The same biotechnology tools can be also applied to livestock, so as to improve the quality and quantity of milk, eggs, meat and wool, and to produce healthier and faster-growing animals.

#### **Annex III.1.1. Opportunities and Risks**

The above-mentioned technological improvements present significant opportunities for agriculture and farmers. These include more flexibility in crop management, reduced dependency on conventional chemicals, higher yields and potential increased returns through savings in production costs. Furthermore, nutritionally enhanced food products can offer increased levels of nutrients and vitamins (such as protein-enhanced sweet potatoes and rice, high-vitamin A canola oil, increased antioxidant fruits and vegetables, etc.). The possibilities for transgenic modification appear almost infinite.

These developments have alarmed consumer advocates and a wide range of environmental and food safety groups. While GM crops may offer great benefits to agriculture, there are many uncertainties linked to perceived threats to human, animal and plant health and the environment at large. Although there is not yet any definite scientific evidence of harm to humans, it is held by many that adverse effects may be revealed in the future by more extensive research. The fear is that GMOs may change the toxicity and allergenicity of food,

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<sup>93</sup> Basically, there are two types of genetic modification: within-species genetic modification and transgenic modification. Within-species genetic modification uses biotechnological techniques to cross similar plants or animals to create new varieties, thus speeding up the traditional slow process of scientific breeding. Transgenic, or more precisely trans-species genetic modification differs from conventional breeding techniques, since it allows crops to receive genetic transfers from another plant species, animal or bacterium (traditional breeding can only combine genes between similar species). This process, which consists in joining DNA fragments from different sources to create recombinant DNA (rDNA), is also called genetic engineering and makes it possible to take a valued quality of one organism and combine it with the valued quality of another organism.

<sup>94</sup> For an updated list of agricultural biotech products on the market and for those expected to be available within the next six years, see the Biotechnology Industry Organization (Bio) Website, at: [http://www.bio.org/er/agri\\_products.asp](http://www.bio.org/er/agri_products.asp). See also World Health Organization, “20 Questions on GM Foods”, available at: <http://www.who.int/fsf/GMfood/>.

fostering allergic reactions or altering antibiotic resistance. A major environmental concern relates to potential consequences of gene flow from GM to non-GM individuals of the same species and to the possibility of unpredictable crosses with other species. Some claim that crops modified so as to be tolerant to herbicides could foster the development of “super weeds”. Another related concern is that GMOs could threaten the world’s biological diversity and lead to excessive dependence on a few crop varieties, thereby increasing the vulnerability of crops to diseases. Finally, some also argue that modern biotechnology techniques may touch on religious infringements and ethical issues.

## **Annex III.2. Access to International Markets**

Questions and uncertainty about the food and environmental safety of transgenic products have raised warning flags in several countries, most notably in Europe, where consumers and government authorities do not accept GM foods uncritically as equivalent to their conventional counterparts.

Although GM crop plantings have expanded in the last few years, they have remained confined to a rather small number of countries. By 2002, the global area of GM crops had reached 58.7 million hectares, cultivated by almost six million farmers in sixteen countries.<sup>95</sup> Herbicide-tolerant soybean was the dominant transgenic crop grown in seven countries – USA, Argentina, Canada, Mexico, Romania, Uruguay and South Africa. The second most dominant GM crop was Bt maize and the third one herbicide-tolerant canola. Four principal countries accounted for 99 per cent of the global transgenic crop area (USA, 66 per cent of global total; Argentina, 23 per cent; Canada, 6 per cent; and China, 4 per cent). Minor plantings could be found in South Africa, Australia, Romania, Mexico, Bulgaria, Spain, Germany, Uruguay, Indonesia and Colombia.<sup>96</sup>

Apart from suspected or scientifically proven biosafety hazards, the reason for the restricted global uptake of GM crops may find its rationale in fear of export loss due to the political and regulatory environment in many countries outside North America which oppose GMOs.

The large-scale production and commercialization of GM crops has further complicated an already difficult international regulatory trade system for agricultural products. On the one hand, countries producing and exporting transgenic crops seek to reap the commercial benefits of their heavy investments in new technologies and continue their business unimpeded by unnecessary and unjustified trade-restrictive measures. On the other hand, for importing countries, the main question is whether they should be notified before any GMOs enter their territory and whether, and on what grounds, once informed, they should be able to refuse or otherwise regulate such trade. In this context, segregated markets for non-GM products are developing in several countries to accommodate consumer preferences, with some countries supplying the markets for non-GM products and some major importers increasingly sourcing in countries known to be free of transgenic crop plantings.

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<sup>95</sup> In the period from 1996 to 2002, the global area of transgenic crops increased by 35 fold, from 1.7 to 58.7 million hectares, and the number of countries growing transgenic crops more than doubled, increasing from 6 in 1996, to 9 in 1998, to 12 in 1999 and to 16 in 2002. See James C., “Report: GM Crop Update 2002”, International Service for the Acquisition of Agri-biotech Applications (ISAAA), available at: <http://www.isaaa.org/>.

<sup>96</sup> Ibid.

In order to manage these tensions, an increasing number of national biosafety systems have been (or are being) developed, and international efforts have multiplied. However, given the great complexity of the debate over agricultural biotechnology, which involves delicate issues such as science and precaution, free trade requirements, economic interests and consumer perceptions, national and international responses have not so far provided a coherent framework.

As a matter of fact, diverging domestic regulations relating to the approval of GMOs and GM food and related issues, such as traceability and labeling requirements, have emerged in the WTO context, which has become the battleground for trading partners having different perceptions of risks, different economic interests and, consequently, different legislative approaches to this matter.

Furthermore, outside the WTO context, the beginning of the new millennium brought to a positive conclusion the complex, five-year-long negotiations, over the first protocol to the Convention on Biological Diversity, the Cartagena Protocol on Biosafety (hereinafter, the Biosafety Protocol) on the transboundary movement of living modified organisms. Since then, the relevant rights and obligations of contracting parties to this Protocol have been debated against the background of the existing WTO rules, as well as the impact that the Cartagena Protocol might have on the WTO rules.

### **Annex III.2.1. Domestic Regulations Applicable to GMOs and GM Products: Selected Countries**

In approaching GMO regulation, countries normally adopt an approach based on one or the other of the following two key concepts: the equivalence principle or the precautionary principle. Countries adhering to the first paradigm rely on the concept of substantial equivalence of GM foods with conventional counterparts and the notion that bioengineered foods are generally regarded as safe. Countries favouring the precautionary principle consider biotechnology products as inherently different and thus subject them to stricter regulatory controls.<sup>97</sup> While the United States, Canada and Argentina, major agricultural exporters, have substantially adopted the first approach, thus widely authorizing most GM products for production and consumption, regulators in Europe and Japan have taken up consumers' concerns and imposed tough control measures and labeling requirements. Australia and New Zealand have processes for pre-market approval and, although their regulations refer to the concept of substantial equivalence, implement mandatory labeling of GMOs.

As for the developing countries, China is the only country having planted GM cotton on a substantial acreage, but even there, after an initial quick adoption of biotechnology agricultural techniques, the Government has decided to slow down the approval process, mainly for fear of export sales loss. Other developing countries are showing reluctance to approve the commercial growing of GM corn, soya or rice in order not to lose their valued status of GM-free exporters.

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<sup>97</sup> See Sheldon I. and Josling T., "Biotechnology Regulations and the WTO", Working Paper No. 02.2, International Agricultural Trade Research Consortium, January 2002. See also International Agricultural Trade Research Consortium, "The Role of Product Attributes in the Agricultural Negotiations", Commissioned Paper No. 17, May 2001, p. 37 ff.

However, many developing and least developed countries, especially in Africa, still lack, or are in the process of developing, comprehensive regulatory systems to deal with the challenges of agricultural biotechnology. Developing a regulatory framework concerning GMOs may be a costly and lengthy process. Areas for regulation include: (a) research and development (R&D), for example conditions under which laboratory experiments take place and conditions for testing in contained facilities or in the field; (b) approval processes for commercial release, including prior scientific assessment of risks to human health and the environment, minimum distance from organic agriculture or non-GM fields, labeling, post-commercialization monitoring, liability; and (c) import regulations.<sup>98</sup>

Many developing and least developed countries have already ratified the Cartagena Protocol on Biosafety on the transboundary movement of living modified organisms, which will enter into force shortly. In order to successfully implement the Protocol's provisions, countries that have not yet done so will have to establish biosafety systems and develop the necessary national capacity to regulate, manage and control risks derived from transgenic organisms.

Table 4 below summarizes selected countries' current approaches to GM regulation.<sup>99</sup> A more detailed overview is provided below of the relevant EU and US legislation. The next section reviews the main provisions of the Cartagena Protocol on Biosafety.

### **The European Union**

Starting in the early 1990s, the European Union has developed and continuously refined a rather complex legislative framework related to GMOs and GM food. With a view to preserving a high level of health and environmental protection throughout the Community, horizontal legislation enacted in 1990, established a system of compulsory notification to be followed prior to the deliberate release and placing on the market of any GMOs for research and commercial purposes.<sup>100</sup> In addition, the 1997 Novel Foods Regulation provided for mandatory labeling of food consisting of or containing GMOs.<sup>101</sup> Under this legislation, food produced from GMOs but no longer containing any GM material is deemed substantially equivalent to conventional food and does not trigger labeling requirements.

While a small number of transgenic crops are in an approval process under that system,<sup>102</sup> growing demands across Europe for a ban or, at least, some restrictions both on planting GM

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<sup>98</sup> The International Service for National Agriculture Research (ISNAR) and FAO, in consultation with UNEP/GEF, have developed a web-based "Decision Support Toolbox for Biosafety Implementation", which describes the key elements to be considered when developing a regulatory framework. The toolbox is designed to assist policy makers, biosafety managers and other stakeholders in understanding and applying a biosafety framework for capacity-building and regulatory decision-making (<http://www.isnar.cgiar.org/ibs/biosafety/regulatory.cfm>).

<sup>99</sup> A rich and easy-to-use collection of domestic GM regulations by country is available at the Website of the Biosafety Information Network and Advisory Service (BINAS), a service of the United Nations Industrial Development Organization: <http://binas.unido.org/binas/regs.php>. The OECD "Biosafety - Biotrack" also offers an overview of biotechnology regulatory developments in OECD Member countries, available at: [http://www.oecd.org/document/17/0,2340,en\\_2649\\_34393\\_1890001\\_1\\_1\\_1\\_37437,00.html](http://www.oecd.org/document/17/0,2340,en_2649_34393_1890001_1_1_1_37437,00.html).

<sup>100</sup> See Council Directive 90/220/EEC, 23 April 1990, laying down rules for the contained use of GM micro-organisms for experimental purposes or as commercial products, Official Journal (OJ) L 117, 8 March 1990, pp. 15 ff.

<sup>101</sup> See Regulation 258/97, of January 1997, OJ L 043, 14 February 1997, pp. 1 ff.

<sup>102</sup> Under the 1990 Directive system, a total eighteen GMOs and fifteen GM foods have been authorized up to 1998. For a complete list, see: [http://www.europa.eu.int/comm/food/fs/gmo/list\\_author\\_gmo\\_en.pdf](http://www.europa.eu.int/comm/food/fs/gmo/list_author_gmo_en.pdf). In 2000, France, Spain and Germany had small areas of Bt corn.

crops and on importing GM commodities caused several Member States to implement, what some call a de facto moratorium,<sup>103</sup> which, since October 1998, has brought the GMO approval procedure in the Community to a provisional halt.

In order to recuperate some of the credibility lost in the 1990s because of multiple food safety scandals (mad cow disease, dioxin in chicken, etc.), European regulators have since struggled to keep reinforcing the institutional and legislative framework relating to public health protection and food scares in general.

In February 2000, the European Commission published a Communication on the “precautionary principle”<sup>104</sup> aiming at informing the public and other EU institutions of the Commission’s approach to the use of this principle in Community legislation and action. According to the Communication, precaution has to be used whenever a potential risk has been identified, scientifically studied and such studies result in mixed or inconclusive evidence. In these cases, the appropriate response is “an eminently political decision, a function of the risk that is acceptable to the society on which the risk is imposed”.<sup>105</sup> Potential threats must be managed cautiously and, consequently, by reversing the burden of proof, certain products should not be placed in the market until they are proven safe.

In line with the precautionary approach briefly described above, a whole set of new legislation on GMOs has been developed. An updated Directive 2001/18 entered into force on 17 October 2002<sup>106</sup> and replaced the 1990 Directive by establishing harmonized procedures and criteria for the case-by-case evaluation of potential risks arising from the deliberate release of GMOs into the environment. Under the new regime, prior notification by applicants for market placement must be accompanied by: a full environmental risk assessment, detailed information on the GMO, its release conditions, interaction with the environment, monitoring, waste and contingency plans, labeling and packaging proposals. The Directive further provides for a complicated approval procedure involving both national competent authorities and Community bodies.<sup>107</sup> Nevertheless, despite these strengthened rules, several Member States declared they would keep blocking the approval procedure of new GMOs, unless additional, stricter rules on labeling and traceability of GM food and feed were enacted.

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<sup>103</sup> Article 16 of Directive 90/220 allows a Member State to provisionally restrict or prohibit the use and sale of an approved product, if there are justifiable reasons to consider that the product constitutes a risk to human health or the environment.

<sup>104</sup> See Communication from the Commission on the Precautionary Principle, COM(2000) 1 final, 2 February 2000. The communication was submitted to the SPS Committee in doc. G/SPS/GEN/168, 14 March 2000.

<sup>105</sup> *Ibid.*, para. 5.2.1.

<sup>106</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.04.2001. See the EU website on GMOs at: [http://www.europa.eu.int/comm/food/fs/gmo/gmo\\_index\\_en.html](http://www.europa.eu.int/comm/food/fs/gmo/gmo_index_en.html).

<sup>107</sup> From the institutional point of view, a 2002 regulation established a brand new European Food Safety Authority (EFSA), which fills a long-standing gap in the EU framework, along the lines of the United States Food and Drug Administration (FDA). General principles and requirements of food law have also been laid down as a basis for the assurance of a high level of protection of human health and consumers’ interests. The EFSA is entrusted with the task of carrying out scientific risk assessments. See Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 February 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002. Further details on the EFSA are available at: <http://www.efsa.eu.int/>.

In response, Community institutions have proposed and only recently agreed on two new regulations: one that specifically applies to GM food and feed and another one concerning the traceability and labeling of GMOs and traceability of GM food and feed (i.e. the tracking of the movement of GM products throughout the production and distribution chains).<sup>108</sup> Consequently, as of 22 July 2003, the EU legislation on GMOs may be said to be complete. The two new regulations address the most pressing concerns of the public regarding the environmental and health effects of GMOs, providing a reinforced safeguard system and enabling consumers to choose, through comprehensive, compulsory labeling. Once the regulations enter into force, it is expected that the *de facto moratorium* on GMO approval will be lifted.<sup>109</sup>

However, these new, much tougher rules have not appeased US, Canadian and Argentinian farmers and industry trade bodies, which, on the contrary, have pushed the respective administrations to take further steps in the context of the WTO dispute settlement procedures against the five-year EU moratorium, claiming that the EU legislation system is adversely affecting their agricultural biotechnology products. Consultations were held on 19 and 25 June 2003, but failed to settle the dispute. A lengthy and very emotive trade battle over GMOs is thus drawing closer to a judicial settlement.<sup>110</sup>

Under the new EU rules on traceability, operators using or handling GM products are required to transmit and retain (for five years) information at each stage of the placing on the market. GMOs are assigned a code (unique identifier), which will be passed in writing to involved operators. Traceability is regarded as a safety net in case of unforeseen effects on human health, animal health or the environment and it is established to facilitate accurate implementation of labeling requirements.

The law also adds, relative to previous rules, compulsory labeling of all food and food ingredients produced from GMOs, irrespective of whether there is DNA or protein of GM origin in the final product, and for the first time to all GM feed.<sup>111</sup> The presence of GM material in conventional food<sup>112</sup> does not have to be labeled if it is below 0.9 per cent and if it can be shown to be adventitious (or unintended) and technically unavoidable. Furthermore, the threshold for adventitious presence of unapproved GMOs that have been assessed as risk-free is 0.5 per cent, provided the operator can prove it was technically unavoidable. Above this threshold the product will not be allowed on the market. Finally, the authorization

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<sup>108</sup> While publication of final texts is still pending, see the two Common Positions (EC) Nos 21 and 22/2003, adopted by the Council on 17 March 2003, with a view to adopting, respectively, a Regulation concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, and a Regulation on genetically modified food and feed (OJ C113 E, 13.5.2003).

<sup>109</sup> Nevertheless, it is reported that some EU Member Governments have hinted that they will block a restart of the approval process until strict environmental liability legislation is also in place.

<sup>110</sup> In particular, the three complainants claim that the EU measures relating to the suspension of consideration of applications for endorsement or approval of biotech products, together with undue delays in finalizing consideration of various applications and national marketing and import bans maintained by member States infringe WTO rules. For further details, see the requests for the establishment of a panel by the US, Canada and Argentina, in docs. WT/DS291/23, DS/292/17 and DS/291/17, of 8 August 2003.

<sup>111</sup> The label has to indicate: "This product contains GMOs" or "... produced from GM (name of organism)".

<sup>112</sup> In related developments, the Commission has recently adopted recommended guidelines on co-existence, i.e. strategies and best practices, such as on-farm measures, to ensure that the production of organic and conventional crops can co-exist with GM crops. The recommendation builds on experience with segregation practices. See Commission Recommendation 2003/556/EC, of 23 July 2003, OJ L189, 29 July 2003, searchable at: [http://europa.eu.int/eur-lex/en/search/search\\_oj.html](http://europa.eu.int/eur-lex/en/search/search_oj.html).

process has been simplified. The newly established European Food Safety Authority is charged with carrying out scientific risk assessment.

### **United States of America**

The United States' regulatory system relative to biotechnology products is rather different from the one put in place in the European Union. Discrepancies mainly reflect the different approach taken by the US governmental authorities, citizens and firms towards GMOs and GM food, especially in the initial years. In the United States, genetically engineered crops have been sold since 1994 and in 2002 were already planted on 39 million hectares. Based on the approach that GM products are essentially an extension of "normal" products (equivalence principle), the US Government has made use of existing laws to ensure the safety of GM products. Three federal agencies are primarily responsible for regulating biotechnology: the Food and Drug Administration (FDA)<sup>113</sup> responsible for food and feed safety; within the Department of Agriculture (USDA), the Animal and Plant Health Inspection Service (APHIS), responsible for assessing the environmental safety of GM crops;<sup>114</sup> and the Environmental Protection Agency (EPA), responsible for development and release of GM plants with pest control properties.

Under the 1992 FDA "Statement of Policy: Foods Derived from New Plant Varieties",<sup>115</sup> developers have the responsibility to ensure that the foods they offer to consumers are safe and comply with all applicable requirements. For this purpose, food producers using new biotechnology techniques should work cooperatively with FDA to assess the safety of bioengineered foods under a prudent, but not obligatory, practice of consultations that allows FDA to gather the information necessary to address any safety, nutritional or other regulatory issues before commercialization. In 1996, FDA provided further guidance to the biotech industry on procedures for these consultations. In 1999, public meetings were held by the agency with the aim of sharing its experience regarding bioengineered foods and soliciting views on whether its policies and procedures should be modified. Public comments indicated considerable public support for a mandatory and more transparent process. After accurate analysis of the evolving and increasingly broader use of rDNA techniques to develop foods for human and animal use, the FDA resolved to subject bioengineered foods to greater regulatory scrutiny to ensure that the agency obtains the maximum amount of relevant information. In 2001, the agency issued a proposed rule and a draft guidance document concerning food developed through biotechnology. The proposed "Pre-market notice concerning bioengineered foods"<sup>116</sup> would require, on a mandatory basis, the submission to the agency of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals, to be made available at least 120 days prior to the commercial distribution of such foods. The draft guidance on labeling will assist manufacturers who wish to voluntarily label their foods as being made with or without the use of bioengineered ingredients.<sup>117</sup> As of 11 October 2002, the FDA reported having concluded consultations for 54 GM foods.<sup>118</sup>

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<sup>113</sup> FDA, Center for Food Safety and Applied Nutrition: <http://www.cfsan.fda.gov/~lrd/biotechm.html>.

<sup>114</sup> USDA, APHIS, Biotechnology Permits Branch, at: <http://www.aphis.usda.gov/brs/>.

<sup>115</sup> Available at: <http://www.cfsan.fda.gov/~lrd/biotechm.html#reg>.

<sup>116</sup> Available at: <http://www.cfsan.fda.gov/~lrd/fr010118.html>.

<sup>117</sup> See US FDA, Center for Food Safety and Applied Nutrition: "Voluntary labelling indicating whether foods have or have not been developed using bioengineering", January 2000, available at: [www.cfsan.fda.gov/~dms/guidance.html](http://www.cfsan.fda.gov/~dms/guidance.html).

<sup>118</sup> The list of completed consultations is available at: <http://www.cfsan.fda.gov/~lrd/biocon.html#list>.

In 2002 the US General Accounting Office (GAO) issued a report on GM foods stating that GM foods share the same types of health risks as conventional foods and that the current regulatory regime of safety tests is viewed by biotechnology experts as adequate.<sup>119</sup> However, according to the GAO report, FDA's evaluation process could be enhanced by randomly verifying the test data that companies provide and by increasing the transparency in the evaluation process.<sup>120</sup>

In recent years, consumer resistance to GM food has been growing also in the United States, where the public is increasingly demanding that GM food be appropriately labeled.<sup>121</sup> In Congress, Representative Kucinich has been pushing new legislation on mandatory labeling for GM food since 2000. More recently, he re-introduced six bills in the House of Representatives dealing with the regulation of bioengineered crops. The proposed "Genetically Engineered Food Right to Know Act of 2003" (H.R. 2916) intends to protect consumers by requiring food companies to label all foods that contain or are produced with GM materials and instructing the FDA to conduct periodic tests to ensure compliance.<sup>122</sup>

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<sup>119</sup> See US General Accounting Office (GAO), "Genetically Modified Foods", GAO-02-566, May 2002, available at: <http://www.gao.gov/new.items/d02566.pdf>.

<sup>120</sup> *Ibid.*, p. 18.

<sup>121</sup> According to a survey conducted by ABC News in July 2003, with safety concerns widespread, while a third of Americans already try to avoid buying food that has been genetically modified or treated with antibiotics or hormones, 55 per cent would avoid buying GM food if it were so labelled. See ABC News article available at: [http://abcnews.go.com/sections/business/Living/poll030715\\_modifiedfood.html](http://abcnews.go.com/sections/business/Living/poll030715_modifiedfood.html).

<sup>122</sup> See Kucinich's press release available at: <http://www.thecampaign.org/leg2003summary.php>. All draft Acts are searchable at: <http://www.gpoaccess.gov/bills/index.html>.

**Table 4: Summary of domestic GM regulations in selected countries (as of August 2003)<sup>123</sup>**

<i>Countries</i>	<i>Regulatory system and agency(ies) responsible</i>	<i>GM products approved</i>	<i>Labeling requirements</i>
<b>European Union</b> (see more details in text)	<p><u>Directive 2001/18 on deliberate release into the environment of GMOs</u> entered into force on 17 October 2002:</p> <p>→ Harmonized procedures and criteria for case-by-case evaluation of potential risks: mandatory prior notification by applicants, accompanied by full environmental risk assessment, detailed information on the GMO, its release conditions, interaction with the environment, monitoring, waste and contingency plans, labeling and packaging proposals. Complex approval procedure involving competent national authorities, the EU Commission and Council.</p> <p><u>Regulation on GM food and feed</u>, adopted on 22 July 2003, amending Directive 2001/18 (not yet in force):</p> <p>→ Authorization procedure for market placement of GM food and feed, including food and feed produced from GMOs, irrespective of whether there is DNA or protein of GM origin in the final product. Approval procedure simplified. The European Food Safety Authority (EFSA) is charged with carrying out scientific risk assessment.</p> <p><u>Regulation on traceability and labeling of GMOs</u>, adopted on 22 July 2003 (not yet in force):</p> <p>→ Strengthened rules on (1) mandatory traceability and (2) mandatory labeling.</p>	<p>As of March 2001, 18 GMOS and 15 GM foods had been approved.</p> <p>Currently 12 applications for authorization are pending.</p>	<p><i>Mandatory labeling</i> for all GMOs and GM products, including food and feed produced from GMOs but no longer containing GM material, unless presence of GM material is adventitious and below 0.9%</p> <p>0.5% threshold for adventitious presence of unapproved GMOs, assessed as risk-free.</p>

<sup>123</sup> This summary table is not intended to be comprehensive. While every effort was made to provide correct information, the correctness of the information in this table cannot be guaranteed. For a database on products derived from biotechnology, see the OECD Biotech Database, available at: <http://webdomino1.oecd.org/ehs/bioprod.nsf>.

TRAINING MODULE ON THE WTO AGREEMENT  
ON SANITARY AND PHYTOSANITARY MEASURES

<b>Countries</b>	<b>Regulatory system and agency(ies) responsible</b>	<b>GM products approved</b>	<b>Labeling requirements</b>
<b>Australia and New Zealand</b>	<p><u>Commonwealth Gene Technology Act 2000</u> took effect on June 2001:</p> <p>→ General prohibition of any dealings with GMOs (e.g. research, manufacture, production, commercial release and import) unless licensed for contained use or intentional release into the environment by the Gene Technology Regulator, based on rigorous scientific risk assessment and extensive consultation with expert advisory committees, Government agencies and the public (<a href="http://www.health.gov.au/ogtr/index.htm">http://www.health.gov.au/ogtr/index.htm</a>)</p> <p><u>Australia New Zealand Food Standards Code</u> regulates the sale of GM food:</p> <p>→ Standard 1.5.2 (1999, amended in 2000) provides for (1) mandatory pre-market safety assessment and (2) mandatory labeling. Food Standards Australia New Zealand (FSANZ) is charged with case-by-case assessment of all GM food applications (<a href="http://www.foodstandards.gov.au/whatsinfo/gmfoods/index.cfm">http://www.foodstandards.gov.au/whatsinfo/gmfoods/index.cfm</a>)</p>	As of April 2003, numerous field trials are under way. Approved GM crops are: soybean (2 varieties), canola (3), corn (7), potato (3), sugarbeet (1) and cotton (4).	<i>Mandatory</i> for all GM food and ingredients (containing novel DNA and/or novel protein in final product, or having altered characteristics)
<b>United States</b> (see more details in text)	<p><u>Statement of Policy: Foods Derived from New Plant Varieties</u>, Food and Drug Administration (FDA) 1992:</p> <p>→ Concept of substantial equivalence: developers are encouraged to work cooperatively with FDA under a practice of (non mandatory) consultations to allow FDA to obtain information necessary to assess safety before commercialization</p> <p><u>Draft Pre-market Notice Concerning Bioengineered Foods</u>, FDA 2001</p> <p><u>Draft Guidance for Industry Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering</u>, FDA 2001</p>	As of October 2001, consultations were concluded for 54 GM foods	Proposal on <i>voluntary labeling</i>

<i>Countries</i>	<i>Regulatory system and agency(ies) responsible</i>	<i>GM products approved</i>	<i>Labeling requirements</i>
<b>Canada</b>	<p><u>Canadian Food Inspection Agency (CFIA)</u> regulates the confined field trial evaluation of all novel crops based on a case-by-case environmental safety assessment (<a href="http://www.inspection.gc.ca/english/toc/bioteche.shtml">http://www.inspection.gc.ca/english/toc/bioteche.shtml</a>)</p> <p><u>Health Canada</u> is responsible for biotechnology-derived products, as a class of novel foods, regulated under Division 28 of the Food and Drug Regulations (<a href="http://www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_division28.html">http://www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_division28.html</a>):</p> <p>→ Mandatory pre-market notification to the Novel Foods Office, which coordinates a full scientific safety assessment of the product, based on substantial equivalence.</p> <p>In response to the 2001 Royal Society of Canada Expert Panel Report, "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada", the Government of Canada has prepared a comprehensive action plan with a view to enhancing its regulatory processes and protocols. The Expert Panel Report has in particular introduced elements of precaution in risk assessment and stressed the need to replace the current regulatory reliance on "substantial equivalence" as a decision threshold with testing based on rigorous scientific assessment of potential of transgenic products for causing harm to the environment or to human health. In order to keep up with advances in knowledge and technology, Health Canada has revised its 1994 Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms, to reflect the risk analysis principles and safety assessment guidelines developed by the Codex Ad Hoc Intergovernmental Task Force of Foods derived from Biotechnology. (<a href="http://www.hc-sc.gc.ca/english/protection/royalsociety/index.htm">http://www.hc-sc.gc.ca/english/protection/royalsociety/index.htm</a>)</p> <p><u>Health Canada and the CFIA</u> carry joint responsibility for federal food labeling policies in Canada under the Food and Drugs Act (<a href="http://www.inspection.gc.ca/english/sci/biotech/tech/labelie.shtml">http://www.inspection.gc.ca/english/sci/biotech/tech/labelie.shtml</a>):</p> <p>→ A standards committee established by the Canadian General Standards Board (CGSB), with the participation of food, manufacturing and retailing groups, has developed a draft Canadian standard for voluntary labeling of GM foods to address non-health and safety labeling (rather, labeling for method of production). The process started in early 2000. The draft standard has not been made public yet, but a decision is expected soon. (<a href="http://www.pwgsc.gc.ca/cgsb/032_025/intro-e.html">http://www.pwgsc.gc.ca/cgsb/032_025/intro-e.html</a>)</p>	In the 1994-2003 period, more than 60 GM crops have been approved.	Draft standard for <i>voluntary labeling</i>

<i>Countries</i>	<i>Regulatory system and agency(ies) responsible</i>	<i>GM products approved</i>	<i>Labeling requirements</i>
<b>Argentina</b>	<p><u>Resolutions n. 656 (1992) and 289 (1997)</u> of Secretariat of Agriculture, Livestock, Fisheries and Food (SAGyP):</p> <p>→ National Advisory Committee on Agricultural Biotechnology (CONABIA), as advisor to SAPyA: Risk assessment for field trials and commercial applications based on technical and biosafety requirements (focused on characteristics and risks of transgenic products, not on process of production). “Flexibilisation” licence for authorized GM products to allow future releases. (<a href="http://siiap.sagyp.mecon.ar/">http://siiap.sagyp.mecon.ar/</a>)</p> <p>National Service of Health and Agrofood Quality (SENASA): Requirements for marketing licence: safety assessment for human and animal consumption based on substantial equivalence. (<a href="http://www.senasa.gov.ar/">http://www.senasa.gov.ar/</a>)</p> <p>National Seed Institute (INASE): Registration on National Crop Register</p>	In the 1991-2001 period, release permits were granted to 495 GMO trials (mainly corn, soybean, cotton and sunflower)	
<b>Brazil</b>	<p><u>Brazilian Biosafety Law (Law n. 8974, 1995)</u> prohibits imports and entry of GMOs without prior approval. It is implemented by the National Technical Biosafety Committee (CTNBio), under the Ministry of Science and Technology, responsible for establishing standards and regulations for dealings with GMOs and for issuing final technical opinions on the release of GMOs. (<a href="http://binas.unido.org/binas/regulations/ctnbio_1.doc">http://binas.unido.org/binas/regulations/ctnbio_1.doc</a>)</p> <p>Legal and political opposition from NGOs has held up the approval process for commercial release of GM soybeans. However, it is reported that illegal planting of GM soy is widespread in southern areas of the country.</p> <p>An April 2003 decree requires all GM foods and food ingredients with GM content of more than 1 percent to be labeled<sup>124</sup></p>	Approval of GM soybean suspended.	Mandatory labeling above 1% threshold

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<sup>124</sup> See “Bridges Trade BioRes”, 1 May 2003, at: <http://www.ictsd.org>

<i>Countries</i>	<i>Regulatory system and agency(ies) responsible</i>	<i>GM products approved</i>	<i>Labeling requirements</i>
<b>Philippines</b>	<p><u>Regulations on the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology</u>, Administrative Order No. 8, April 2002 (<a href="http://binas.unido.org/binas/regs.php">http://binas.unido.org/binas/regs.php</a>):</p> <p>→ Import restrictions imposed to prevent the entry of harmful pest and disease in the country (doc. G/SPS/N/PHL/41, 22 April 2002). All GM products must undergo a safety assessment carried out by regulatory bodies of the Department of Agriculture (Bureau of Plant Industry and Scientific Technical Review Panel).</p>	Insect protected GM corn approved in 2002 for commercial release <sup>125</sup>	
<b>Thailand</b>	<p><u>Biosafety Guidelines in Genetic Engineering and Biotechnology For Field Work and Planned Release</u>, Ministry of science, Technology and Environment 1992 (<a href="http://binas.unido.org/binas/regulations/thai_field.doc">http://binas.unido.org/binas/regulations/thai_field.doc</a>)</p> <p>→ Thailand Biodiversity Center was established in 2000 and is responsible for the implementation of biosafety legislation for sustainable utilization of Thailand's natural resources and is the national focal point for the Cartagena Protocol.</p>		

<sup>125</sup> See Monsanto Press Release, "Monsanto's Insect-Protected Corn Approved for Planting in the Philippines", 5 December 2002, <http://www.monsanto.com/monsanto/layout/media/02/12-05-02.asp>.

<i>Countries</i>	<i>Regulatory system and agency(ies) responsible</i>	<i>GM products approved</i>	<i>Labeling requirements</i>
<b>China</b>	<p><u>Regulations on Safety Control on GM Animals, Plants and Microorganisms, their Products and By-products</u>, Ministry of Agriculture (MOA) 2002, and relative implementation regulations (see translated text at BINAS UNIDO: <a href="http://binas.unido.org/binas/regs.php">http://binas.unido.org/binas/regs.php</a>):</p> <ul style="list-style-type: none"> <li>→ Safety assessment: to be carried out by the Agricultural GMO Safety Committee, based on 4 classes of safety (from “no danger” to “high degree of danger”). Final decision taken by MOA.</li> <li>→ Safety of Import: different approval procedures (entry approval, testing, safety evaluation) depending on intended use of GMOs. Final decision taken by MOA.</li> <li>→ Labeling for listed GM products</li> </ul> <p>These regulations were supposed to enter into force in March 2002, but have been temporarily waived under MOA Circular N. 190. An interim rule on imports of GM crops has been extended to 20 April 2004. Since 20 July 2003, the GMO Safety Regulatory Office under MOA has started accepting applications for imports of GM crops from 20 September 2003 to 20 April 2004. Applications must be accompanied by a safety assessment carried out in the country of origin</p> <p><u>Administrative Measures on Hygiene of GM Foodstuffs</u>, Ministry of Health, 2001:</p> <ul style="list-style-type: none"> <li>→ All GM foods and food additives must undergo a safety assessment, carried out by the GMO Food Expert Commission.</li> </ul>	<p>Altered tobacco genes released in 1990.</p> <p>Between 1996 and 2000, 45 GM plant applications for field trials, 65 for environmental release and 31 for commercialization (mainly cotton) had been approved.<sup>126</sup></p> <p>Approval process slowed down since 2000.</p>	<i>Mandatory labeling</i>

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<sup>126</sup> See R. Paarlberg, “The Contested Governance of GM Foods: Implications for U.S.-EU Trade and the Developing World”, Working Paper, Weatherhead Center for International Affairs, Harvard University, 2002, p. 13.

<i>Countries</i>	<i>Regulatory system and agency(ies) responsible</i>	<i>GM products approved</i>	<i>Labeling requirements</i>
<b>India</b>	<p><u>Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms Genetically engineered organisms or cells</u>, Ministry of Environment and Forests (MEF) 1989, (<a href="http://envfor.nic.in/legis/hsm/hsm3.html">http://envfor.nic.in/legis/hsm/hsm3.html</a>)</p> <p>→ The Review Committee on Genetic Manipulation (RCGM) in the Department of Biotechnology (DBT) is responsible for monitoring the safety related aspects in respect of on-going research projects and activities involving GMOs and laying down procedures restricting or prohibiting their production, sale, importation and use.</p> <p>→ The Genetic Engineering Approval Committee (GEAC) under the Department of Environment Forests and Wildlife is responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experiment field trials.</p> <p><u>Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts</u>, DBT 1998 (<a href="http://binas.unido.org/binas/regulations/indiaguide.doc">http://binas.unido.org/binas/regulations/indiaguide.doc</a>)</p> <p>→ RCGM is responsible for clearance of imports of GM material.</p>	<p>In 2002, 3 varieties of GM cotton approved.</p> <p>Field trials for several GM crops.</p>	
<b>Egypt</b>	<p><u>Ministerial Decrees Nos. 85 and 136</u>, Biosafety Guidelines and Regulations, Ministry of Agriculture and Land Reclamation (MALR) 1995 (<a href="http://binas.unido.org/binas/regulations/egypt_bs.pdf">http://binas.unido.org/binas/regulations/egypt_bs.pdf</a>)</p> <p>→ National Biosafety Committees (NBC) is responsible for the implementation of Egypt's Biosafety Guidelines, conducts risk assessments, and issues for field tests and commercial release of GM plants permits (in collaboration with the Supreme Committee for Food Safety, Ministry of Health, and the Seed Registration Committee, MALR).</p>	<p>Almost 40 GM field trials have been authorized</p>	
<b>Zimbabwe</b>	<p>Under the <u>Statutory Instrument 20/2000 Biosafety Regulations</u>, the Research Council established the Biosafety Board to oversee the conduct of biotechnology in Zimbabwe, including approving the safety of imports of GM products. While initially rejecting GM food aid, Zimbabwe later accepted it, provided all GM maize was milled immediately upon arrival<sup>127</sup>.</p>		

<sup>127</sup> See "Bridges Trade BioRes", 11 July 2002, at: <http://www.ictsd.org>.

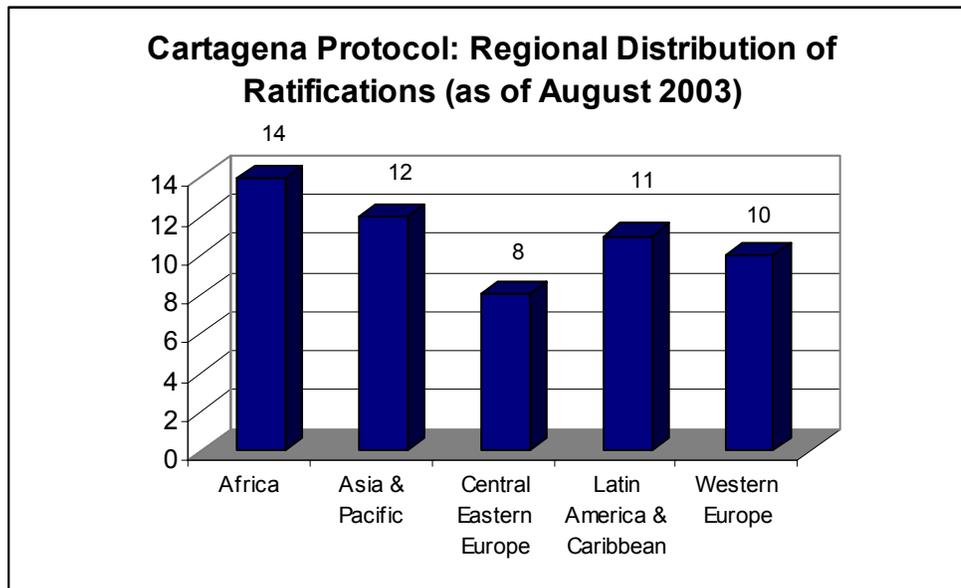
<i>Countries</i>	<i>Regulatory system and agency(ies) responsible</i>	<i>GM products approved</i>	<i>Labeling requirements</i>
<b>South Africa</b>	<p>Genetically Modified Organisms Act 1997, implemented in 1999 (<a href="http://www.africabio.com/policies.shtml">http://www.africabio.com/policies.shtml</a>)</p> <p>→ <u>Executive Council for GMOs</u>, charged with approving imports and release of GMOS. A Scientific Advisory Committee reviews the human and environmental safety of GMOs and advises the Executive Council. A Registrar administers the GMO Act on behalf of the Minister of Agriculture, issues permits at the request of the Executive Council. An Inspectorate is responsible for monitoring and inspecting local work with GMOs.</p> <p><u>Draft Regulations Governing the Labeling of Foodstuffs Obtained Through Certain Techniques of Genetic Modification</u>, Department of Health, Government Notice No. 366, 4 May 2001 (<a href="http://www.africabio.com/policies/GMlabellingE.htm">http://www.africabio.com/policies/GMlabellingE.htm</a>).</p>	4 GM crops approved: pest resistant maize for animal feed, herbicide tolerant and pest resistant varieties of cotton, GM soybeans	<i>Mandatory labeling</i> requirements for GM foods that are significantly different and that contain allergens from a list of specific products. Label “not genetically modified” only if produced with an identity preservation system.
<b>NEPAD</b>	<p>NEPAD is planning to set up an Advisory Panel on Biotechnology and Biosafety charged with developing an African strategy on biotechnology and bioengineered crops. The Panel will also attempt to harmonize Biosafety regulations between African countries in order to facilitate trade (25 July 2003, NEPAD website: <a href="http://www.nepad.org">http://www.nepad.org</a>).</p>		
<b>SADC</b>	<p>As directed by the 2002 SADC Council of Ministers, a SADC Advisory Committee on Biotechnology and Biosafety was established on 16 April 2003. The Committee will “develop guidelines to safeguard Member States against potential risks in the areas of human and animal food safety, contamination of genetic resources taking into account ethical, and trade-related issues including consumer concerns”.</p> <p>The 2002 Council also urged all Member States to develop their national legislations by 2004 taking into account the Cartagena Biosafety Protocol and the Draft OAU Biosafety Model Legislation as a guide.<sup>128</sup> It was also noted that, while retaining freedom to accept or reject GM maize as food aid, Member States accepting it should undertake awareness campaigns to ensure that all GM maize is not planted and that it is milled into flour before distribution (see paras. 33-35 of the 2002 SADC Summit Final Communiqué, available at: <a href="http://www.sadc.int">http://www.sadc.int</a>). The Advisory Committee is expected to use as working tools the findings of the Zambian biotechnology mission report<sup>129</sup> and SADC fact-finding mission report to the US, Europe and South Africa and make appropriate recommendations to be submitted to SADC Council of Ministers meeting scheduled for August 2003 in Tanzania.</p>		

<sup>128</sup> Available at the Africabio Website at: <http://www.africabio.com/policies.shtml>.

<sup>129</sup> In August 2002, Zambia declined a US offer of maize, some of which contained GM products. Main Zambian concerns related to uncertainty regarding the safety of GM maize for human consumption and the possible contamination of local varieties. The debate focused also on fears that EU countries would reject Zambian food exports as result of possible contamination. The report of the USAID-sponsored Zambian fact-finding tour is available at: <http://www.zamtie.org/pdfreports/zamfactfindingmissionbiotechfoods.pdf>.

### Annex III.3 The Cartagena Protocol on Biosafety

The international environmental community has been deeply concerned with the spread of GMOs in the environment and the risks related to the conservation of biodiversity. In order to respond to its concerns, the “Cartagena Protocol on Biosafety” (Biosafety Protocol or BP) was negotiated under the auspices of the Convention on Biological Diversity (CBD) and adopted on 29 January 2000. The Protocol entered into force on 11 September 2003. As of August 2003, 54 countries and the European Community have become parties to it (see figure below on regional distribution of ratifications).<sup>130</sup>



The Biosafety Protocol, administered by the CBD secretariat, establishes a multilateral framework with the following objective: “to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements” (Article 1 BP).

The Protocol requires each party to designate a national focal point, responsible for liaison with the Secretariat, and one or more national competent authorities, responsible for performing the administrative functions under the Protocol. A single entity may fulfill both functions.

Under the Protocol, two categories of living modified organisms (LMOs)<sup>131</sup> are regulated in a substantially different way:

<sup>130</sup> Website of the Cartagena Protocol on Biosafety: <http://www.biodiv.org/biosafety/default.aspx>.

<sup>131</sup> For an organism to be living, it must be a biological entity capable of transferring or replicating genetic material. LMOs are thus a sub-category of GMOs. Given the focus of the Protocol on the protection of biological diversity, its scope of application excludes inanimate products of LMOs, such as corn cereal or soybean oil that

- (1) LMOs for “intentional introduction into the environment” of the importing party (e.g. seeds for planting, microorganisms for bioremediation or live fish for release into lakes). These are subject to an Advance Informed Agreement (AIA) procedure, which lays down detailed rules for decision making on imports and incorporates a different approach to precautionary measures from the one reflected in Article 5.7 of the SPS Agreement, by providing importing countries with more leeway to unilaterally restrict trade in case of insufficient scientific evidence;
- (2) LMOs “intended for direct use as food or feed, or for processing” (LMOs-FFP, e.g. commodities, such as modified corn, soya and tomatoes, which represent the large majority of traded LMOs). These are subject to a less rigorous procedure.

*Advanced Informed Agreement procedure.* Under the AIA (Articles 7 to 10 BP), an exporter must give advance notice and seek the consent of the party of import prior to the first shipment of an LMO intended to be introduced in the environment of that party. The exporter’s notification<sup>132</sup> must include, inter alia, detailed information on the technique used, the characteristics of the resulting LMO, the regulatory status of the LMO in the country of export and a risk assessment report (Annex I BP). The competent national authority of the party of import then decides whether and on what conditions to provide authorization for the shipment. Failure to communicate the decision within the stated time limits (270 days from the date of receipt of notification) will not imply consent on the part of the importing country. Import decisions must be based on a risk assessment to be undertaken, by the exporting country if the importing country so requires, “in a scientifically sound manner”, taking into account recognized risk assessment techniques (Article 15 and Annex III BP). Any decision taken by the import party must be notified to the (web-based) Biosafety Clearing House (BCH) established under the BP to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs.<sup>133</sup>

*Precaution.* In application of the precautionary principle contained in Principle 15 of the Rio Declaration on Environment and Development, the Protocol provides that “lack of scientific certainty due to insufficient relevant scientific information and knowledge ... shall not prevent that Party from taking a decision, as appropriate ... in order to avoid or minimize ... potential adverse effects” (Article 10.6 BP for LMOs and, with identical language, Article 11.8 BP for LMOs-FFP). In contrast with the SPS provisions, in case of an import-restrictive measure, the Protocol imposes no obligation to seek further information necessary in order to achieve scientific certainty, and thus a ban may be in force without time limits.

*Requirements for commodities.* Parties are required to inform the other parties, through the BCH, on any decision they take regarding domestic use, including placing on the market, of LMOs that may be exported for direct use as FFP (Article 11 BP). An importing party may then decide on the import of LMOs-FFP under its domestic regulatory framework. Developing country parties or parties with economies in transition may, in the absence of such domestic framework, declare that their import decisions on LMOs-FFP will be either based on a risk assessment or taken within a predictable timeframe (not exceeding 270 days).

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might be made from GM corn or soybeans. Thus, GM products derived from but no longer containing GMOs are not covered by the Protocol. The Protocol also expressly excludes pharmaceuticals for humans from its ambit (Article 5 BP) and LMOs transiting third countries or destined for contained use (Article 6 BP).

<sup>132</sup> The exporter is responsible for the accuracy of the information in the notification. The exporting party is required to take the necessary and appropriate legal measures to implement this obligation (Articles 8.2 and 11.2 BP).

<sup>133</sup> The pilot-phase of the BCH is available at: <http://bch.biodiv.org/Pilot/Home.aspx>

Failure of such parties to communicate their decisions does not imply consent (Article 11.6 and 7).

*Review of decisions.* In light of new scientific information, an importing party may review and change its decision on import (Article 12.1 BP). As for an exporting party, if a change of circumstances has occurred that may influence the outcome of the relevant risk assessment, or if additional scientific or technical information has become available, it may request an importing party to review its decision under the AIA procedure. The party of import is required to respond to such request, providing the reasons for its decision, within ninety days (Article 12.2 and 3 BP).

*Documentation.* The Protocol includes provisions regarding documentary requirements for the transboundary movement of all LMOs. Documentation accompanying LMOs intended to be introduced into the environment must: clearly identify them as living modified organisms; specify their relevant traits/characteristics and any requirement for safe handling, storage and use; and contain a declaration of compliance with the Protocol (Article 18.2(c) BP). As for LMOs-FFP, the requirement is less strict: the container need only indicate that it “may contain” LMOs (Article 18.2(a) BP).

Despite notable achievements, the Protocol is obviously a compromise text, the result of lengthy and complex negotiations, where several opposing negotiating groups emerged. In particular, the “Miami Group”, which included the main exporters of GM seeds and crops and principal holders of the related technology (United States,<sup>134</sup> Argentina, Canada, Chile, Uruguay and Australia), called for a narrow scope for the Protocol by keeping GM commodities out of it and limiting the references to the precautionary principle in the decision-making process. The main opponent of the Miami Group was the European Union, which was facing food safety scandals and, supported by the “Like-Minded Group”, sought to include risks to human health, GM commodities and a strong formulation of the precautionary principle.<sup>135</sup>

The text of the Protocol reflects the complexity of the issue at stake. Several issues have been left unresolved. The CBD Conference of the Parties (COP), serving as the meeting of the parties to the Protocol, will have to finalize/operationalize a number of provisions. For example, it may identify certain LMOs as being not likely to have adverse effects on biological diversity, thus exempting them from the application of the AIA procedure (Article 7.4 BP). The COP will also have to work out the details of the requirements relating to the documentation for shipments of LMOs-FFP. More generally, in the area of documentation, the Protocol fails to establish concrete standards and thus calls on the COP to consider the need for and modalities of developing standards for identification, handling, packaging and transport practices, in collaboration with relevant international bodies.

The first COP meeting took place in Kuala Lumpur, Malaysia on 9-20 February 2004. One challenging substantive item on its agenda was the issue of liability and redress. In Article 27, the Biosafety Protocol instructed the first COP to adopt, and complete within four years, a

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<sup>134</sup> The United States is not a party to the CBD, and cannot be a party to the Protocol, since participation to the CBD is a necessary pre-condition.

<sup>135</sup> For more details on the negotiating history of the Protocol, see S. Zarrilli, “International Trade in Genetically Modified Organisms and Multilateral Negotiations: a New Dilemma for Developing Countries”, UNCTAD, document UNCTAD/DITC/TNCD/1, 5 July 2000, available at: <http://www.unctad.org>.

process with respect to the elaboration of international rules and procedures in the field of liability and redress from damage resulting from the transboundary movements of LMOs, taking into account ongoing processes in international law.

The relationship between the provisions of the Biosafety Protocol and the relevant rules under WTO Agreements has been amply discussed in academic and trade circles. In particular, the difference between the largely precautionary approach taken by the Protocol and the evidence-based Article 5.7 of the SPS Agreement emerged as clear at the time the BP was being negotiated, and its preamble sought to resolve this issue by stating that the BP “shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements” (such as the SPS Agreement). However, the preamble also adds that the BP shall not be considered “subordinate” to these other agreements. The BP’s preambular language is not an example of clarity and shows how difficult it is to clearly define the relationship between multilateral environmental agreements (MEAs) and WTO rules. On the basis of an approach of mutual supportiveness, and taking into account the general rules of international law, the Protocol provisions should be interpreted as compatible with WTO rules.

### **Annex III.4 The WTO Legal Framework Applicable to Trade in Biotechnology Products**

The legal WTO framework for trade in GMOs is not straightforward. The SPS and TBT Agreements do not contain rules that deal specifically with products of modern biotechnology. Which Agreement applies to a trade-restrictive national regulation related to GMOs depends primarily on the measure's objective and on the precise nature of the risk that the regulation is addressing.<sup>136</sup>

As discussed in the first chapter, a national measure laying down pre-market approval requirements in order to assess, for example, the possible risks deriving from increased levels of toxins in GM food would fall under the scope of application of the SPS Agreement. The same would apply to a measure designed to minimize risks caused by the potential allergenicity of GM food (e.g. a label informing consumers about allergens). As for environmental purposes, a trade-restrictive regulation intended to avoid the spread of GMOs or their breeding with wild relatives would still be considered an SPS measure, since it relates to the prevention of damage from entry, establishment or spread of pests.

Labeling requirements related to nutritional characteristics, or intended to give consumers information on whether a product contains GMOs or was produced from GMOs would, instead, be covered by the TBT Agreement.

<p><b>THE TBT AGREEMENT</b> applies to product requirements (except for measures falling within the scope of application of the SPS Agreement, so that there can be no overlap in coverage) and conformity assessment procedures. Governments introduce technical regulations and standards when necessary to meet a number of legitimate objectives, including the prevention of deceptive practices and health and environmental protection.</p>
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<sup>136</sup> *Ibid.*

WTO Members must ensure that their TBT measures are not more trade-restrictive than necessary to fulfill a legitimate policy objective and that they do not discriminate between “like” imported and domestically produced goods. The TBT discipline does not require that all measures be based on scientific principles, but the latter may be taken into account as a relevant element when assessing risks. The use of international standards is also encouraged.

Labelling of GM products has been frequently debated at the TBT Committee. Some Members consider that informing consumers through labeling of GM products is a legitimate objective that justifies a trade restriction within the TBT discipline. Consumers have the right to know what they are buying and labels allow them to make informed choices. Other WTO Members argue that, given the emotional character of consumers, labeling would stigmatize GM products, mislead consumers to think that GM-products may be unsafe or substantially different from conventional counterparts, even if there is no scientific proof of any health risk.<sup>137</sup> Moreover, some Members oppose mandatory labeling of GMOs since its enforcement requires the setting up of costly procedures to ensure segregation from non-modified products.

However, labeling is a less trade-restrictive measure than import bans. Unless there is evidence of health or environmental risks, an import ban on GMOs might be difficult to maintain as SPS or TBT consistent, given that under both disciplines measures are required to restrict trade only to the extent necessary to attain a legitimate objective.

The first WTO dispute regarding a GM-related measure concerned an import ban enacted by Egypt on canned tuna from Thailand, allegedly because the tuna was canned in GM oil. The two parties have reportedly agreed to resolve the case through a certification that Thai tuna is not canned in GM oil.

There are high expectations that the dispute settlement process initiated by the US, Canada and Argentina, concerning the EU de facto moratorium that has blocked the approval of new agricultural biotechnology products since 1998 will shed light on the application of the global multilateral trade rules to the complex relations between the world's biggest exporters of genetically modified crops and the strongly precautionary approach of the EU. It is worth noting that the complaints currently do not cover hotly debated issues such as the new EU traceability and labeling provisions.

### **Annex III.5 The Relevant Work of Standard-Setting Organizations**

Codex has three committees that are considering various issues related to GM food: (i) the Committee on Food Labelling (CCFL); (ii) the Committee on General Principles (CCGP);

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<sup>137</sup> The GM labelling discussion falls into a broader and long unresolved debate about whether different treatment based on requirements related to processes and production methods (PPMs) that do not alter the characteristics of the final product is covered by GATT/WTO law. The product/process distinction is highly controversial and still an open issue, since the jurisprudence is not conclusive and there are ample divisions on this subject among scholars. Under the TBT Agreement, an important topic to be analysed is therefore the issue of “likeness” of GM-products and their conventional counterparts.

and more specifically, (c) the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (Task Force).<sup>138</sup>

While the Committee on Food Labeling<sup>139</sup> is continuing its work on the development of guidelines on the labeling of GM foods and food ingredients, the Committee on General Principles has the task of developing a definition of “traceability/product tracing”, a concept which is extremely relevant for biotechnology products. The May 2003 draft working definition, subject to further amendments, is as follows: “The implementation of measures to ensure, at any stage of the food chain, that the movement of a food and the relevant informations about it (pertaining to food safety and/or fair practices in its trade) are known, including: product identification, product information (how it was changed - if appropriate, where it came from and where it was sent - one step backward and one step forward and the linkages between product identification and product information. These informations are recorded by each business involved and are stored in a well organized and readily accessible format.”<sup>140</sup>

The Task Force on biotechnology food was established in 1999 with the aim of: (a) elaborating standards, guidelines, or other principles, as appropriate, for foods derived from biotechnology; (b) coordinating and closely collaborating, as necessary, with appropriate Codex Committees within their mandate as relates to foods derived from biotechnology; and, (c) taking full account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.

The 26<sup>th</sup> Session of the Codex Alimentarius Commission, which was held in July 2003, adopted all texts brought forward from the Task Force, which include:

- (1) Principles for the Risk Analysis of Foods Derived from Modern Biotechnology;
- (2) Guideline for the Food Safety Assessment of Foods Derived from r-DNA Plants;
- (3) Guideline for the Conduct of Food Safety Assessment of r-DNA Microorganisms; and
- (4) Annex on the Assessment of Possible Allergenicity (placed in both the r-DNA Plant and Microorganism documents).

These guidelines lay out broad general principles intended to make the analysis and management of risks related to foods derived from biotechnology uniform across Codex 172 member countries. It is worth noting that these guidelines do not concern environmental risks.

The guidelines require the scientific assessment of both GM micro-organisms and GM foods derived from GM micro-organisms. Furthermore, provisions of the guidelines include pre-market safety evaluations and “product tracing” for recall purposes and post-market monitoring. Should “product tracing” as a risk management tool be considered the same as traceability, then the adoption of this Codex standard could be extremely important in the

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<sup>138</sup> For full details, see: [http://www.fao.org/es/ESN/food/risk\\_biotech\\_en.stm](http://www.fao.org/es/ESN/food/risk_biotech_en.stm).

<sup>139</sup> See the latest Report of the CCFL 31<sup>st</sup> session, Ottawa, May 2003, Alinorm 03/22A, available at: <http://www.codexalimentarius.net>.

<sup>140</sup> The CCGP 18<sup>th</sup> session took account of the divergence of opinions expressed by members on the issue and established an open-ended electronic working group under the direction of the Delegation of France to develop a draft definition of traceability/product tracing for consideration at the next regular session of the Committee in 2004. See Alinorm 03/33A, available at: <http://www.codexalimentarius.net>.

debate over labeling and traceability for GM products. It is reported that the US has attempted to distinguish between the two terms, arguing that “product tracing” is limited to “one step forward and one step back”.<sup>141</sup>

As for the IPPC, an International Standard for Phytosanitary Measure (ISPM) aiming to provide guidance on the criteria for evaluating potential risks to plants and plant health posed by living modified organisms was approved in 2004 by the Standards Committee of the Interim Commission on Phytosanitary Measures (the IPPC governing body).<sup>142</sup>

**Table 5: WTO Notifications under the SPS Agreement related to Biotech Products (up to March 2005)**<sup>143</sup>

Country	Doc. G/SPS/N/	Product Covered	Date
United States of America	USA/15 Rev.1 and	Genetically engineered plants	05/09/1995 12/09/1995
Japan	JPN/7	Food and food additives produced by recombinant DNA techniques	06/11/1995
Mexico	MEX/97	Organisms manipulated by genetic engineering	23/01/1996
Japan	JPN/10	Feed produced by recombinant DNA techniques	08/02/1996
Japan	JPN/11	Feed additives produced by recombinant DNA techniques	08/02/1996
Czech Republic	CZE/2	Seed and seedlings of crops	27/03/1996
United States of America	USA/64	Veterinary Biological Products	02/09/1996
Canada	CAN/14	Biotechnology	26/09/1996
Switzerland	CHE/2	Foodstuffs which contain genetically modified organisms or which are produced from these	19/06/1997
Japan	JPN/27	Feed Additives produced by the recombinant DNA techniques	28/08/1998
United States of America	USA/126	Export of animal drugs, biologics, food additives as well as the importation of components for incorporation or further processing into articles intended for export	24/06/1998
New Zealand	NZL/19	Novel Foods	08/09/1998
Australia	AUS/73	Novel Foods	02/10/1998
Canada	CAN/41	Novel Foods	21/10/1998
Switzerland	CHE/17	Foodstuffs	12/01/1999
Colombia	COL/25	Rice	31/03/1999
United States of America	USA/152	Veterinary Biological Products	16/04/1999
Korea, Republic of	KOR/55	Foods and Food Additives	21/05/1999
United States of America	USA/157	Animal Drugs, Human Drugs, Biologics and Devices	08/02/2000
Canada	CAN/56	Biotechnology Substances	08/02/2000

<sup>141</sup> See Bridges Trade BioRes, 21 March 2003, available at: <http://www.ictsd.org>.

<sup>142</sup> These ISPM are available at: <http://www.ippc.int/servlet/CDSServlet?status=ND0zMjU0OCY2PWVuJmZPSomMzc9a29z>.

<sup>143</sup> This table was last updated on 18 July 2005 and is based upon the WTO Table, “SPS Notifications Related to GMOs,” 7 January 2005.

TRAINING MODULE ON THE WTO AGREEMENT  
ON SANITARY AND PHYTOSANITARY MEASURES

Country	Doc. G/SPS/N/	Product Covered	Date
New Zealand	NZL/52	Food Produced using Gene Technology	22/02/2000
Japan	JPN/51	Foods and food additives produced by recombinant DNA techniques	14/03/2000
Japan	JPN/52	Foods and food additives produced by recombinant DNA techniques	01/05/2000
United States of America	USA/228	Biotechnological/Biological Veterinary Medicinal Products	02/22/2000
United States of America	USA/237	Pesticide: Cry1F Plant Pesticide	03/14/2000
Korea, Republic of	KOR/66	Foods	05/01/2000
New Zealand	NZL/58	Food produced from insect-protected corn line	27/06/2000
New Zealand	NZL/59	Food produced from glyphosate-tolerant corn line	27/06/2000
New Zealand	NZL/60	Food produced from glyphosate-tolerant cotton line	27/06/2000
New Zealand	NZL/61	Food produced from high oleic acid soybean lines	27/06/2000
New Zealand	NZL/62	Food produced from glyphosate-tolerant canola line	27/06/2000
Australia	AUS/119	Processed foods in general (see NZL/58-62)	03/07/2000
Indonesia	IDN/9	Food in General	07/26/2000
Japan	JPN/56	Foods containing organisms derived from biotechnology, processed foods	04/08/2000
United States of America	USA/315	Pesticides	08/15/2000
Indonesia	IDN/9/Add.1	Food in General	09/11/2000
New Zealand	NZL/66	Food derived from insect and virus Y - protected potato lines	09/14/2000
New Zealand	NZL/67	Food derived from insect and potato leaf roll virus - protected potato lines	09/14/2000
New Zealand	NZL/68	Food derived from insect-protected potato lines	09/14/2000
Australia	AUS/120	Processed food derived from potatoes	09/25/2000
New Zealand	NZL/71	Food derived from insect-protected Bt-176 corn	06/10/2000
New Zealand	NZL/72	Food derived from insect-protected, herbicide tolerant Bt-11 corn	06/10/2000
Australia	AUS/121	Processed corn food (derived from insect-protected, herbicide tolerant Bt-11 corn and from insect-protected Bt-176 corn)	11/10/2000
United States of America	USA/348	StarLink Corn Cry 9C Bt Corn Plant-Pesticide	03/11/2000
Japan	JPN/63	Foods and food additives produced by recombinant DNA techniques	22/01/2001
United States of America	USA/384	Bioengineered foods	24/01/2001
Japan	JPN/63/Add.1	Foods and food additives produced by recombinant DNA techniques – Availability of additional safety assessments	23/03/2001
Chile	CHL/74 and Add.1	Live genetically modified plant products for propagation	27/03/2001
United States of America	USA/384/Add.1	Bioengineered foods – extension of comment period	09/04/2001
Thailand	THA/55	Foods contaminated with Cry 9C sequence (maize)	26/04/2001

## ANNEX III: INTERNATIONAL TRADE IN BIOTECHNOLOGY PRODUCTS

Country	Doc. G/SPS/N/	Product Covered	Date
South Africa	ZAF/9	Labelling of foodstuffs obtained through certain techniques of genetic modification	30/05/2001
Korea, Republic of	KOR/94	Genetically modified organisms	11/06/2001
Korea, Republic of	KOR/95	Safety evaluations for genetically modified foods	11/06/2001
Korea, Republic of	KOR/96	Labelling of genetically modified foods	11/06/2001
Sri Lanka	LKA/1	Restrictions on imports of food derived from DNA recombinant technology	19/07/2001
Sri Lanka	LKA/1/Add.1	Deferment of restrictions on imports of food derived from DNA recombinant technology	10/09/2001
Thailand	THA/55/add.1	Modification of prohibition measures on maize imports with Cry 9C DNA and certification of non-presence	12/09/2001
Thailand	THA/70	Labelling of food and food products (soya, corn)	12/09/2001
Thailand	THA/71	Labelling of food obtained through certain techniques of genetic modification	05/10/2001
Japan	JPN/77	Feed and feed additives produced by recombinant DNA techniques	09/11/2001
Brazil	BRA/59	Labeling requirements for packed food products containing genetically modified organisms	26/11/2001
New Zealand	NZL/161	Legislation to restrict, for a period of two years, consideration and approval by the relevant agency of applications to release GMOs into the environment	16/12/2001
Japan	JPN/80	Processed food made from genetically modified potatoes	15/01/2002
New Zealand	NZL/165	Start of pre-market safety assessment for food products derived from corn line NK603 (glyphosate tolerant)	12/02/2002
New Zealand	NZL/166	Start of pre-market safety assessment for food products derived from GM corn line DBT41 (insect protected and glufosinate ammonium tolerant)	12/02/2002
New Zealand	NZL/167	Start of pre-market safety assessment for food products derived from GM canola line (Navigator bromoxynil herbicide tolerant)	12/02/2002
European Communities	EEC/149	Genetically modified organisms (GMOs), for food and feed use, food feed containing, consisting of or produced from GMOs	14/02/2002
European Communities	EEC/150	Products that contain or comprise genetically modified organisms and food and feed products produced from genetically modified organisms	14/02/2002
Australia	AUS/136	Scientific assessments on imported GM corn or canola	19/02/2002
Australia	AUS/137	Scientific assessments on imported GM corn – (glyphosate tolerant)	19/02/2002
South Africa	ZAF/11	Genetically modified foods - Hypersensitivity	22/02/2002
Japan	JPN/80/Corr.1	Processed foods made from genetically modified potatoes	21/03/2002

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Country	Doc. G/SPS/N/	Product Covered	Date
China	CHN/P/136 to 140 <sup>144</sup>	Genetically modified animals, plants and micro-organisms, their products and by-products – Regulations on safety control; – Implementation regulations on safety assessment; – Implementation regulations on labelling; – Provisional measures on safety control	14/04/2002
China	CHN/P/111	Plant propagating materials	19/04/2002
Philippines	PHL/41	Plant or plant products altered or produced through the use of modern biotechnology	22/04/2002
New Zealand	NZL/173	Foods derived from cotton lines containing event 15985	22/05/2002
Australia	N/AUS/140	Foods derived from cotton lines containing event 15985	29/05/2002
China	CHN/10	Foodstuffs and food additives produced with genetically modified organisms (GMO)	26/06/2002
China	CHN/15	GMO products	25/07/2002
New Zealand	NZL/161/Add.1	Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002	02/08/2002
Australia	AUS/143	Processed foods in general	12/11/2002
New Zealand	NZL/187	Processed foods in general	27/11/2002
Canada	CAN/156	Enzyme - Xylanase	10/12/2003
Malaysia	MYS/12	Genetically modified food and food ingredients	19/12/2002
Japan	JPN/77/Add.1	Feed and feed additives produced by recombinant DNA techniques	16/01/2003
Slovenia	SVN/18	Genetically modified organisms	24/01/2003
Slovenia	SVN/19	Genetically modified soya and genetically modified maize	24/01/2003
Slovenia	SVN/20	Genetically modified organisms	24/01/2003
Korea, Republic of	KOR/123	Food additives, apparatus, packaging and containers for food	27/01/2003
Slovenia	SVN/21	Genetically modified organisms, microorganisms, plants, animals, feed and seed	17/02/2003
Japan	JPN/98	Uses of living modified organisms	26/03/2003
Korea, Republic of	KOR/125	Transboundary movement of living modified organisms	07/04/2003
European Communities	EEC/149/Add.1	Genetically modified organisms (GMOs) for food or feed use, food and feed containing, consisting of or produced from GMOs	02/04/2003
European Communities	EEC/150/Add.1	Products that contain or comprise genetically modified organisms and food and feed products produced from genetically modified organisms	02/04/2003
European Communities	EEC/149/Add.2	Genetically modified organisms (GMOs) for food or feed use, food and feed containing, consisting of or produced from GMOs	11/04/2003
European Communities	EEC/150/Add.2	Products that contain or comprise genetically modified organisms and food and feed products produced from genetically modified organisms	11/04/2003

<sup>144</sup> These notifications by China were submitted pursuant to Section 14 of the Protocol of Accession of the People's Republic of China, document WT/L/432

## ANNEX III: INTERNATIONAL TRADE IN BIOTECHNOLOGY PRODUCTS

Country	Doc. G/SPS/N/	Product Covered	Date
Canada	CAN/156/Add.1	Regulations amending the food and drug regulations (1259 - Xylanase)	29/04/2003
European Communities	EEC/149/Add.2/Corr.1	Genetically modified organisms (GMOs) for food or feed use, food and feed containing, consisting of or produced from GMOs	20/05/2003
European Communities	EEC/150/Add.2/Corr.1	Products that contain or comprise genetically modified organisms and food and feed products produced from genetically modified organisms	20/05/2003
Korea, Republic of	KOR/130	Revision of Safety Evaluation Guidelines for Genetically Modified Foods and Food Additives	17/06/2003
Australia	AUS/145	Processed foods	20/06/2003
Canada	CAN/177	Maltogenic amylase	30/06/2003
Australia	AUS/147	Processed foods	30/07/2003
Guatemala	GTM/12	Establishments of requirements for the importation, transport, handling and field trials of agricultural GMO's	28/08/2003
Canada	CAN/183	Pectinase enzyme in the manufacture of cider, wine, fruit juices and unstandardized fruit and vegetables products	29/08/2003
Australia	AUS/147/Add.1	Processed foods	12/09/2003
Japan	JPN/107	Living modified organisms (LMOs)	25/09/2003
All countries	THA/107	Genetically modified plants	10/10/2003
Philippines	PHL/49	Live fish and fishery/aquatic products, aquatic micro-organisms, biomolecules including GMOs and endangered species	15/10/2003
European Communities	EEC/149/Add.3	GMOs for food or feed use etc.	19/11/2003
European Communities	EEC/150/Add.3	Products consisting of or containing GMOs – labelling & traceability	19/11/2003
United States	USA/835	Products using pesticide plant-incorporated protectant Bacillus thuringiensis Cry1 Ab protein	1/12/2003
European Communities	EEC/149/Add.4 EEC/150/Add.4	GMOs for food or feed use	19/12/2003
European Communities	EEC/149/Add.5	GMOs for food or feed use	23/12/2003
Canada	CAN/195	Pullulanase enzyme in bakery products	06/01/2004
Philippines	PHL/61	Any altered plant product for consumption - Guidelines for importation	18/02/2004
Philippines	PHL/62	Any altered plant product for consumption - Additional signatories to the Declaration of GMO Content	18/02/2004
United States	USA/878	Products using ZMIR39 x MON810 combined insecticidal trait stacked corn hybrids, etc.	17/03/2004
Philippines	PHL/63	Any altered plant product for consumption - Guidelines for phytosanitary inspection	18/03/2004
Australia	AUS/159	Processed foods, foods derived from insect-protected cotton line COT102	22/03/2004
New Zealand	NZL/284	Processed foods, foods derived from insect-protected cotton line COT102	23/03/2004
United States	USA/898	Hygromycin B phosphotransferase (APH4) marker protein	06/04/2004

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Country	Doc. G/SPS/N/	Product Covered	Date
United States	USA/899	Bacillus thuringiensis Cry2Ab2 protein in cotton	06/04/2004
New Zealand	NZL/294	Food derived from insect-protected glufosinate ammonium-tolerant cotton line MXB-13	25/05/2004
Canada	CAN/206	Various food additives	01/06/2004
European Communities	EEC/149/Add.6	Genetically modified organisms for food and feed and products that contain or comprise GMOs and food and feed products produced from GMOs	03/06/2004
United States	USA/898/Add.1	Hygromycin B phosphotransferase	03/06/2004
Australia	AUS/162	Processed foods	09/06/2004
United States	USA/914	Phosphomannose isomerase	09/06/2004
China	CHN/15/Add.1	Genetically modified products	13/07/2004
Switzerland	CHE/37	Foods derived from GMOs	29/07/2004
Switzerland	CHE/38	Feedstuff derived from GMOs	01/09/2004
United States	USA/972	Corn – Registration Applications	08/09/2004
United States	USA/973	Corn - Registration Applications	08/09/2004
United States	USA/979	Corn – Exemption from the requirement of a tolerance for modified Cry3A protein	08/09/2004
United States	USA/982	Corn – Exemption from the requirement of a tolerance for Cry34Abl and Cry35Abl	08/09/2004
United States	USA/987	Bacillus thuringiensis VIP3A insect control protein	27/09/2004
Korea	KOR/173	GM crops and related foods	15/12/2004
New Zealand	NZL/312	Sugar derived from sugar beet	20/12/2004
Norway	NOR/11	Genetically modified organisms	23/12/2004
Australia	AUS/172	Sugar derived from sugar beet	04/01/2005
Chinese Taipei	TPKM/46	Transgenic plants	09/02/2005
New Zealand	NZL/319	Food derived from insect-protected Glufosinate Ammonium-tolerant Corn Line DAS-59122-7	18/03/2005
Australia	AUS/174	Food derived from Insect-protected Glufosinate Ammonium-tolerant Corn Line DAS 59122-7	21/03/2005



