Chapter 28

International Standard Setting on Biosafety: An Introduction to Some Other International Agreements and Forums

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THIRD WORLD NETWORK

1. The international regulatory regime governing biosafety

The Cartagena Protocol on Biosafety, as the first international law to specifically regulate genetically modified organisms (GMOs) and genetic engineering, is an extremely important development in the international biosafety regulatory regime (see Chapter 26). There are, however, also other international laws and forums that are part of the international regulatory regime and which establish standards for biosafety.

In Chapter 27, the biosafety-relevant World Trade Organization (WTO) Agreements, which are legally binding for its Members, were discussed. This chapter will describe in further detail the three bodies that are recognized by the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures (1994) (SPS Agreement) as international standard-setting bodies – the Codex Alimentarius Commission for food safety, the International Plant Protection Convention (IPPC) for plant health, and the World Organisation for Animal Health (OIE) for animal health and zoonoses – and some of the key elements of their work in relation to biosafety.

The standards, guidelines and recommendations established by these international standard setting bodies are explicitly recognized in the SPS Agreement as international standards, guideline and recommendations, on which WTO Members shall base their sanitary or phytosanitary measures. Often, countries adopt these standards, guidelines and recommendations at the national level, but very importantly, the SPS Agreement has flexibilities for Members to introduce or maintain higher standards if there is scientific justification for doing so. Furthermore, according to Article 3(2) of the SPS Agreement (1994), 'sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994'. Thus, the standards, guidelines and recommendations established by the three bodies, are presumed to be WTO consistent, potentially shielding WTO Members that conform to such standards from challenge at the WTO's Dispute Settlement Body.

For matters not covered by the above three organizations, the SPS Agreement recognizes as international standards, guidelines and recommendations, the appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the SPS Committee. This means that international biosafety standards can be set in other relevant international organizations. Moreover, standard-setting bodies should also be guided by the principles and standards established under the Cartagena Protocol on Biosafety.

There are also other international efforts to set up standards and guidelines for GMOs, which are not discussed in this chapter. These include the UNEP International Technical Guidelines for Safety in Biotechnology and the FAO Draft Code of Conduct on Biotechnology as it relates to genetic resources for food and agriculture. In addition, the International Organization for

Standardization (ISO) has developed international standards related to the detection methods for GMOs and derived products in foodstuffs.

2. Codex Alimentarius Commission

The Codex Alimentarius Commission has 175 member governments (including the European Community). It was created in 1963 to develop food standards, guidelines and related texts such as codes of practice under the Joint Food and Agriculture Organization/World Health Organization Food Standards Programme. The main purposes of this Programme are to protect the health of consumers, to ensure fair trade practices in the food trade, and to promote coordination of all food standards work undertaken by international governmental and non-governmental organizations. Thus, the Commission basically provides for the international regulation of food matters.

The standards, guidelines and recommendations established by the Codex Alimentarius Commission relate to 'food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice'. They are non-binding, but are recognized in the SPS Agreement as international standards, guidelines and recommendations for food safety.

2.1 Ad–hoc Intergovernmental Task Force on Food Derived from Biotechnology

In 1999, governments established the Ad-hoc Intergovernmental Task Force on Food Derived from Biotechnology to deal with the issue of genetically modified (GM) food or in the language used by the Codex Alimentarius Commission, 'food derived from biotechnology', in particular their health and nutrition implications. One key mandate of the Task Force was to elaborate standards, guidelines or other principles, as appropriate, for foods derived from biotechnology. The Task Force worked for four years, and adopted the following in 2003 (Codex Alimentarius Commission 2004):

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology
- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants
- Guideline for the Conduct of Food Safety Assessment on Foods Produced using Recombinant-DNA Microorganisms.

2.2 Some significant elements of the Codex Principles and Guidelines

The Principles and Guidelines adopted by the Task Force recognize that a pre-market safety assessment (the part of a risk assessment that identifies whether a hazard, nutritional or other safety concern is present) should be undertaken on a case-by-case basis for GM foods. They also acknowledge that there are unintended effects related to GM foods that have to be risk assessed, prior to their market approval (Haslberger 2003). This is in addition to an evaluation of their potential direct health effects such as toxicity and allergenicity.

The unintended effects (reflected by the loss or modification of acquired or existing traits) that need to be evaluated arise from the process of insertion of DNA sequences into the plant genome (Codex Alimentarius Commission 2004). This may cause disruption or silencing of existing genes, activation of silent genes, or modifications in the expression of existing genes. New or changed patterns of metabolites may also result. Moreover, environmental factors and genetic background may affect the expression of the transgenes (Haslberger 2003).

Notably, the Guidelines broaden risk assessment to encompass not only the health effects of GM foods, but also the indirect effects of GM foods on human health, for example, as mediated

through the environment. Under such an approach, herbicide residues from GM herbicide resistant crops (Codex Alimentarius Commission 2004) or potential risks associated with gene flow, for example, of a transgene coding for the production of biopharmaceuticals (Haslberger 2003), also need to be considered.

The Task Force also clarifies that the concept of 'substantial equivalence' is not a safety assessment in itself, but is only a starting point for any GM food safety assessment, to identify similarities and differences between the GM food and its conventional counterpart (Codex Alimentarius Commission 2004). This is in line with the limitations increasingly associated with the concept (for example, see the analysis by the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology (Expert Panel on the Future of Food Biotechnology 2001)).
In relation to the use of antibiotic resistance marker genes, the Guidelines discourage their use and instead recommend that alternative transformation technologies be used in the future development of GM plants or GM microorganisms (Codex Alimentarius Commission 2004). This is because the possibility of horizontal gene transfer to intestinal microorganisms or human cells (see Chapter 13) is an occurrence that cannot be completely discounted. For food derived from GM plants, the Task Force recommends that 'If evaluation of the data and information suggests that the presence of the antibiotic resistance marker gene or gene product presents risks to human health, the marker gene or gene product should not be present in food. Antibiotic resistance genes used in food production that encode resistance to clinically used antibiotics should not be used in foods'. For food produced using GM microorganisms, the Task Force makes several recommendations, including the avoidance of genes in the genetic construct that could provide a selective advantage.

Legislation in the European Union already implements this, as there is an obligation in its Directive 2001/18 (see Chapter 22) to phase-out antibiotic resistance markers in GMOs by 2004 in the case of GMOs placed on the market and by 2008 for experimental GMOs. This applies to antibiotic resistance marker genes that may have adverse effects on human health and the environment. The Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority in 2004 evaluated the potential risks associated with specific antibiotic resistance marker genes, taking into account their current usage in clinical and veterinary medicine, and has issued guidance on this issue for EU Member States (Scientific Panel on Genetically Modified Organisms 2004).

The Codex Guidelines further recommend that foods derived from GM plants or produced using GM organisms that have been intentionally modified to alter their nutritional quality or functionality should be subjected to additional nutritional assessment and may require additional testing (Codex Alimentarius Commission 2004). The nutrient profile may change, affecting the nutritional status of individuals consuming the food, or there could be unexpected alterations in the nutrients. The need for stringent risk assessment on such GM foods is becoming more urgent, as there are more GM crops with such modifications in the pipeline, which regulatory authorities will have to assess. In response to this, the Task Force is currently undertaking work to develop a guideline on food safety assessment of foods derived from GM plants modified for nutritional or health benefits (see Section 2.3).

The Codex Principles also underline that risk management should take into account the uncertainties identified in the risk assessment, and that measures could include food labelling conditions for marketing approvals and post-market monitoring (Codex Alimentarius Commission 2004). In particular, post-market monitoring may be needed to verify conclusions about the absence or possible occurrence, impact and significance of potential health effects, and

to monitor changes in nutrient intake levels to determine human health impact (for GM foods likely to significantly alter nutritional status). (See also Chapters 32 and 33 on monitoring.)

2.3 Ongoing work of the Task Force

In July 2004, government members of the Codex Alimentarius Commission approved the re-establishment of the Ad-hoc Intergovernmental Task Force on Food Derived from Biotechnology. When the Task Force met in 2005, it agreed to initiate new work on the following:

- A guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals
- An annex to the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants regarding food safety assessment of foods derived from recombinant-DNA plants modified for nutritional or health benefits.
- Two Working Groups were established for this purpose:
- A physical Working Group to prepare a Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals, co-chaired by Australia and Japan
- An electronic Working Group led by Canada to formulate a scoping document on the Proposed Draft Annex on Food Safety Assessment of Food Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits.

The Working Group on GM animals met twice in 2006 and discussed draft text. Among the contentious issues were how to address non-food safety concerns, such as environmental risks, animal welfare and ethical issues, and the use of antibiotic resistance marker genes (ICTSD 2006a). A Joint FAO/WHO Expert Consultation was held in early 2007 to seek scientific advice on the Proposed Draft Guideline and in particular to address questions related to the development and use of marker and reporter genes, and the non-heritable applications of recombinant DNA techniques to the production of animals, such as the safety of GM vaccines and gene therapy. In relation to the proposed draft annex regarding food safety assessment of foods derived from GM plants modified for nutritional or health benefits, Canada sent out a questionnaire to Codex delegations and interested organizations, to gather information, in order to assist in drafting the document. The scope of the work is, with respect to any additional safety and nutritional considerations, related to the assessment of foods derived from GM plants with enhanced nutrition. Regrettably, it does not cover plants expressing pharmaceuticals or other non-food related substances, the rationale being that the primary purpose of these plants is not food use but rather as factories to produce industrial or pharmaceutical compounds.

The Biotechnology Task Force met again in November 2006 and continued discussions on the two issues (GM animals and GM crops modified for nutritional and health benefits). A physical Working Group was established to elaborate the proposed draft annex on the safety assessment of foods derived from GM plants modified for nutritional or health benefits. In addition, several discussion papers were tabled, including on 'Safety Assessment of Foods Derived from Animals Exposed to Protection against Disease through Gene Therapy or Recombinant-DNA Vaccines'. Moreover, the United States requested the inclusion of a new item to the agenda and proposed new work on 'Food Safety Assessment of Low-Level Presence of Recombinant-DNA Plant Material in Food Resulting from Asynchronous Authorizations'. This deals with the low-level presence of unapproved transgenic material in food, in other words, transgenic contamination. At the November 2006 meeting, a Working Group to deal with this issue was established, chaired by the United States, Germany and Thailand. It will draft an annex on 'Low-Level Presence of

rDNA Plant Material to the existing Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants' (ICTSD 2006b).

The United States' proposal was revised to remove reference to 'asynchronous approvals', which had implicitly assumed that the importing country would eventually approve the contaminant (nothing in the document actually questions the right of an importing country to reject the contaminated shipment), and the focus expanded to include a requirement for supplying adequate data and information on the shipment and the contamination (such as the primers and other detection methodologies needed to detect the contamination) (personal communication, Philip L. Bereano and Michael Hansen 2006). The annex will not replace a full risk assessment under the Guideline for any GM foods that would be marketed in a country. It also does not preclude countries from having zero tolerance for unapproved GMOs and exporters must still meet a country's relevant import requirements.

There was disagreement in terms of the scope of the work, with the United States targeting GM plants under development being field-tested or plants that are no longer used commercially but may still be present in the food supply, and the European Union preferring to limit the work to cases where a GM plant has been approved in one country but not another (ICTSD 2006b). In the end, the terms of reference for the Working Group are to develop recommendations to the Task Force on performing a safety assessment in situations of low-level presence in which the GM plant has been authorized for commercialization for food by one or more countries, but the importing country has not determined its food safety, and on the requisite data and information sharing systems to facilitate this process. The work of this Working Group will undoubtedly attract much interest, given the increasing number of cases of transgenic contamination of food supplies that have occurred, the latest being of unapproved experimental GM rice.

2.4 Other biosafety-related work of Codex

The Codex Committee on Food Labelling has been discussing a Draft Proposed Guideline for the Labelling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Modification-Genetic Engineering for many years now. It has yet to come to agreement on an international standard for mandatory labelling, largely due to opposition from the United States, Canada and Argentina, the major GM crop producing countries. Nonetheless, the draft standard on GM labelling has support from the majority of countries, both developed and developing. In May 2006, to try and move the discussion forward, a new Working Group was established to prepare guidance on GM food labelling. It will consider all relevant issues in order to identify the main problems, and take into account the experience of countries that have established relevant regulations on mandatory and voluntary labelling, including communication aspects. Some 40 countries already have laws requiring labelling of GM food. The Working Group met in January 2007 in Oslo, and is co-chaired by Norway, Ghana and Argentina.

Other biosafety-relevant discussions at Codex include the ongoing discussions on risk analysis under the Committee on General Principles, which also touch on issues such as precaution, risk assessment, risk management, and risk communication; discussions on traceability/product tracing under the Committee on General Principles and the Committee on Food Import and Export Inspection and Certification Systems; and discussions under the Committee on Methods of Analysis and Sampling on the criteria for the detection and identification of foods derived from biotechnology.

3. International Plant Protection Convention

The International Plant Protection Convention (IPPC) is an international treaty that sets phytosanitary standards for plants. It has 158 Parties (as of 20 December 2006) and the secretariat is hosted by the UN Food and Agriculture Organization.

The IPPC aims to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control. The international standards, guidelines and recommendations developed under the auspices of the Secretariat of the IPPC in cooperation with regional organizations operating within the framework of the IPPC are recognized by the SPS Agreement as international standards, guidelines and recommendations for plant health. Phytosanitary measures that conform to IPPC standards, guidelines and recommendations are deemed necessary to protect plant life or health and are presumed WTO consistent. International standards for phytosanitary measures (ISPMs) are developed through the work programme of the Commission on Phytosanitary Measures. Non-contracting parties to the IPPC are encouraged to observe these standards.

3.1 Pest Risk Analysis for Quarantine Pests including Analysis of Environmental Risks and LMOs
In April 2004, the then Interim Commission on Phytosanitary Measures endorsed a supplement on pest risk analysis for genetically or living modified organisms (LMOs), resulting in an integrated standard: *ISPM No. 11: Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*. It includes guidance on evaluating potential phytosanitary risks to plants and plant products posed by LMOs.
Annex 3 of ISPM No. 11 (ISPM 2004) identifies the potential phytosanitary risks from LMOs when associated with some characteristic or property related to the genetic modification, as including the following:

(a) Changes in adaptive characteristics which may increase the potential for introduction or spread, for example, alterations in:

- tolerance to adverse environmental conditions (e.g. drought, freezing, salinity, etc.)
- reproductive biology
- dispersal ability of pests
- growth rate or vigour
- host range
- pest resistance
- pesticide (including herbicide) resistance or tolerance

(b) Adverse effects of gene flow or gene transfer including, for example:

- transfer of pesticide or pest resistance genes to compatible species
- the potential to overcome existing reproductive and recombination barriers resulting in pest risks
- potential for hybridization with existing organisms or pathogens to result in pathogenicity or increased pathogenicity

(c) Adverse effects on non-target organisms including, for example:

- changes in host range of the LMO, including the cases where it is intended for use as a biological control agent or organism otherwise claimed to be beneficial
- effects on other organisms, such as biological control agents, beneficial organisms, or soil fauna and microflora, and nitrogen-fixing bacteria, that result in a phytosanitary impact (indirect effects)

- capacity to vector other pests
- negative direct or indirect effects of plant-produced pesticides on non-target organisms beneficial to plants

(d) Genotypic and phenotypic instability including, for example:

- reversion of an organism intended as a biocontrol agent to a virulent form

(e) Other injurious effects including, for example:

- phytosanitary risks presented by new traits in organisms that do not normally pose phytosanitary risk
- novel or enhanced capacity for virus recombination, trans-encapsidation and synergy events related to the presence of virus sequences
- phytosanitary risks resulting from nucleic acid sequences (markers, promoters, terminators, etc.) present in the insert

3.2 Some significant elements of the IPPC standard

ISPM No. 11 (ISPM 2004) harmonizes and standardizes the way countries analyse risks that LMOs may post to plant health. A country may use the standard to determine which LMOs pose a threat and if necessary can subsequently (as a last resort) prohibit or restrict their import and domestic use. The standard is not just restricted to GM plants, but also covers other LMOs that may be harmful to plants, such as GM insects, fungi and bacteria. Direct and indirect effects on plants or plant products are both considered.

The standard includes the assessment of the risks of LMOs to plants, in so far as they are pests of plants (e.g. if a GM plant subsequently becomes a weed). Phytosanitary risks may result from certain traits introduced into the organism, such as those that increase the potential for establishment and spread, or from inserted gene sequences that do not alter the pest characteristics of the organism but that might act independently of the organism or have unintended consequences. In cases of phytosanitary risks related to gene flow, the term 'pest' is understood to include the potential of a LMO to act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk, rather than the LMO acting as a pest in and of itself.

Under the assessment process, LMOs are essentially considered a potential phytosanitary risk/quarantine pest, until decided otherwise. Thus, for LMOs, the aim of the first, initiation stage is to identify those LMOs that have the characteristics of a potential pest and need to be assessed further, and those which need no further assessment under ISPM No. 11.
Furthermore, in most cases, the parent organism is not normally considered to be a plant pest but an assessment may need to be performed to determine if the genetic modification (i.e. gene, new gene sequence that regulates other genes, or gene product) results in a new trait or characteristic that may present a plant pest risk.

Even if it is determined that the LMO does not need further assessment under the standard, the IPPC recognizes that this only relates to the assessment and management of phytosanitary risks and that LMOs may present other risks (to the environment, or to human or animal health) not falling within its scope. It thus encourages the notification of relevant authorities if potential non-phytosanitary risks come to light.

Once an LMO is determined to be a potential pest, it then goes through a pest risk assessment process, involving three inter-related steps:

Pest categorization, to determine whether the criteria for a quarantine pest are satisfied. This would include defining the identity of the pest, which requires information regarding characteristics of the recipient or parent organisms, the donor organism, the genetic construct, the gene or transgene vector, and the nature of the genetic modification.

Assessment of the probability of introduction and spread, including an analysis of both intentional and unintentional pathways of introduction, and intended use. The probability of gene flow and gene transfer should be considered, when there is a trait of phytosanitary concern that may be transferred, as should the probability of expression and establishment of that trait. Moreover, the survival capacity without human intervention of the LMO should also be assessed. Other factors to be considered include specific cultural, control or management practices for GM plants, genotypic and phenotypic instability, and the proposed production and control practices related to the LMO in the country of import.

Assessment of potential economic consequences (including environmental impacts); in the case of LMOs, this relates to the pest nature (injurious to plants and plant products) of the LMO. Additionally, the potential economic consequences that could result from adverse effects on non-target organisms that are injurious to plants or plant products, as well as the economic consequences that could result from pest properties, should be considered.

The analysis of unintentional pathways of introduction is particularly significant with respect to LMOs, as experience has shown that these can play significant roles, no matter what the intended use. For example, in the Cartagena Protocol on Biosafety, a regulatory distinction is made between how LMOs for intentional introduction into the environment and those intended for direct use as food or feed, or for processing, are treated. This distinction is actually an artificial one, given that a GM grain intended for use as food or feed, or for processing, may also germinate and end up in the environment. It is thus important also to consider unintentional pathways with equal weight as intentional pathways of introduction.

With regard to economic impact, while some scientists argue that the assessment of potential economic consequences are not part of scientific risk assessments, it is clear from the IPPC standard that these have to be taken into account. The WTO SPS Agreement (1994), which the IPPC standard has a relationship with, states in Article 5.3:

> *In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.*

(See also Chapter 27 for a discussion on the biosafety relevant WTO Agreements.) Moreover, 'risk assessment' is defined in the SPS Agreement (1994) as:

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

The conclusions from the pest risk assessment are then used to decide whether pest risk management measures should be taken. These measures should be cost-effective and feasible, not more trade restrictive than necessary, be applied to the minimum area necessary, allow for alternatives if the effect of different measures are the same, and be non-discriminatory. No additional measures should be imposed if existing measures are effective.

In addition to options such as inspection and testing, and restrictions on end use, distribution, and periods of entry of a commodity, measures may also be applied to restrict the import of consignments, if the plants are considered to be pests. Moreover, the measures may include procedures for the provision of information on the phytosanitary integrity of consignments (e.g. tracing systems, documentation systems and identity preservation systems). This issue had been intensively discussed under Article 18.2(a) of the Cartagena Protocol on Biosafety, when in 2006 a decision was adopted on the identification requirements for shipments of LMOs intended for direct use as food or feed, or for processing (see Chapter 26).

Importantly, if no satisfactory measure is available to reduce risk to an acceptable level, ISPM No. 11 (ISPM 2004) acknowledges that the final option may be to prohibit importation of the relevant commodities. This is viewed as a measure of last resort. Nonetheless, the implementation of phytosanitary measures are not considered permanent, and should be monitored, reviewed and modified if necessary.

4. World Organisation for Animal Health

The World Organisation for Animal Health (OIE) is an intergovernmental organization, and as of May 2006, totalled 167 Member Countries. It is recognized by the SPS Agreement as the international organization responsible for standard-setting related to animal health. Within this mandate, it aims to safeguard world trade by publishing health standards for international trade in animals and animal products.

4.1 Ad Hoc Group on Biotechnology

In May 2005, at the 73rd General Session, OIE members adopted Resolution No. XXVIII: Applications of Genetic Engineering for Livestock and Biotechnology, which requested the constitution of an Ad Hoc Group on Biotechnology.
Members also asked the OIE to develop and adopt standards, recommendations and guidelines (ICTSD 2005) for:

- research on the use of live attenuated vaccines in animal health
- use of DNA vaccines
- animal health risks linked to cloning
- assessing the health of embryos and production animals derived from cloning, and associated safety of cloned production animals and their products
- exclusion of unapproved animals and products from the livestock population and segregation from the feed and food supply
- identification, testing, and certification for international trade in production animals and their products for which biotechnology procedures have been employed.

The work of the Ad Hoc Group is ongoing.

5. Conclusion

The work of the three standard-setting bodies described in this chapter is part of the international regulatory system for biosafety. It is important for countries to be aware of the developments in

these other international agreements and forums, and to ensure coordination and coherence at the national level when developing biosafety law, policy and regulation.

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