

# **International Agreements and Instruments that impact on the use of Living Modified organisms**

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There are many international agreements that impact on the use of modern biotechnology. Some are primarily 'trade agreements' whilst others are primarily concerned with protection of the environment and sustainability. The primary agreements that may need to be taken into account are listed in this short paper which attempts, where practicable, to provide the wording that is used in the agreement itself. Wherever appropriate, references to the original documents are provided.

Most countries will have implemented some, or many of the international agreements or guidelines in their own national legislation, and a careful consideration is needed of that which is in place and that which is needed to fill any gaps is needed.

A very detailed analysis of legal instruments that apply to Genetically Modified Organisms may be found in "The Role of Law in Realising the Potential and Avoiding the Risks of Modern Biotechnology: Selected Issues of Relevance to Food and Agriculture" by Lyle Glowka, Biodiversity Strategies International, in 2002 and prepared for the FAO Commission on Genetic Resources for Food and Agriculture.<sup>1</sup> The document has a slightly different emphasis to this paper and is very much longer.

## **1. Agenda 21**

Concern over the way in which human activity was affecting the planet and the need to take conservation and sustainability seriously led to a declaration by 178 Countries in June 1992 at a meeting in Rio de Janeiro, Brazil<sup>2</sup>. The 'agenda' for the 21<sup>st</sup> century was to be a comprehensive plan of action to be undertaken by governments and international organisations in every area where human activity interacted with the environment. Agenda 21 was adopted by 178 Countries in Rio de Janeiro in June 1992. In Chapter 16 of the document Biotechnology was seen as an important tool for the 21<sup>st</sup> Century. The new techniques offered visions of improving sustainability and conservation in a manner that had not yet been achieved using conventional technology, even though it was recognised that it alone could not solve all the problems that faced the world:

"Biotechnology is the integration of the new techniques emerging from modern biotechnology with the well-established approaches of traditional

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<sup>1</sup> <ftp://ext-ftp.fao.org/ag/cgrfa/BSP/bsp19e.pdf>

<sup>2</sup> <http://www.un.org/esa/sustdev/documents/agenda21/english/agenda21toc.htm>

biotechnology. Biotechnology, an emerging knowledge-intensive field, is a set of enabling techniques for bringing about specific man-made changes in deoxyribonucleic acid (DNA), or genetic material, in plants, animals and microbial systems, leading to useful products and technologies. By itself, biotechnology cannot resolve all the fundamental problems of environment and development, so expectations need to be tempered by realism. Nevertheless, it promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, improved supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes. Biotechnology also offers new opportunities for global partnerships, especially between the countries rich in biological resources (which include genetic resources) but lacking the expertise and investments needed to apply such resources through biotechnology and the countries that have developed the technological expertise to transform biological resources so that they serve the needs of sustainable development. 1/ Biotechnology can assist in the conservation of those resources through, for example, ex situ techniques. The programme areas set out below seek to foster internationally agreed principles to be applied to ensure the environmentally sound management of biotechnology, to engender public trust and confidence, to promote the development of sustainable applications of biotechnology and to establish appropriate enabling mechanisms, especially within developing countries, through the following activities:

- (a) Increasing the availability of food, feed and renewable raw materials;
- (b) Improving human health;
- (c) Enhancing protection of the environment;
- (d) Enhancing safety and developing international mechanisms for cooperation;
- (e) Establishing enabling mechanisms for the development and the environmentally sound application of biotechnology."

In defining areas in which action had to be taken, the Declaration provided a blueprint for action without any legally binding structures, but it provided the aims and objectives of the actions that governments needed to take.

## ***2. Rio Declaration on Environment and Development***

The Rio Declaration on Environment and Development was agreed at the same time<sup>3</sup>. It identified 27 principles which taken together were meant to ensure the goals of sustainability and conservation of our environment. Principle 1 identifies the primacy of human rights in this context:

"Human beings are at the centre of concerns for sustainable development. They are entitled to a healthy and productive life in harmony with nature."

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<sup>3</sup> <http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm>

The principle that has caused the most controversy is that which has been termed the “precautionary Principle”, Principle 15:

“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.”

### **3. Convention on Biological Diversity**

The Convention on Biological Diversity<sup>4</sup> was one of the key agreements adopted at the Earth Summit in Rio de Janeiro in 1992 and it came into force in 1994. The convention aims at conserving biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits from the use of genetic resources.

187 countries are party to the Convention. The countries that have chosen not to be full members of the Convention are Brunei, Iraq, Thailand and United States of America. Two Articles specifically refer to modern biotechnology which is defined as

“*Biotechnology*” means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.”

Article 8 addresses *in-situ* conservation. Sub-article 8(g) requires parties to set up legal systems to regulate, manage or control any risks that may arise from the use and release of living modified organisms “which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health

“Each Contracting Party shall, as far as possible and as appropriate:

...

g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;”

This ensures that where organisms are likely to be used and released within a country’s borders appropriate action needs to be taken if they are likely to have adverse effects as identified in the Convention. Many countries have adopted legal systems or modified existing systems to ensure that regulation is in place.

The parties to the convention recognized that regulation itself was not enough, and that there were many more actions that needed to be taken to provide for the sustainable use of biotechnology. Article 19 requires parties to take measures to provide for research that would permit the effective use of biotechnology, especially for and by developing countries.

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<sup>4</sup> <http://www.biodiv.org/convention/articles.asp>

"1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms."

Paragraphs 3 and 4 of Article 19 called on Parties to the Convention to consider whether an additional treaty (a Protocol) should be enacted that would set out the procedures for the safe transfer, handling and use of living modified organisms resulting from biotechnology that might have adverse effects on the conservation and sustainable use of biological diversity.

"3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced."

The Conference of the Parties to the Convention set up an open-ended ad-hoc group of experts to examine the need for a protocol in the terms of Article 19(3) and at the second meeting of the Parties to the CBD adopted a decision to proceed to attempt to negotiate a protocol to the Convention that focussed particularly on transboundary movement of living modified organisms as defined in Article 19(3). It set up an open-ended ad-hoc working group to achieve this end. In doing so, the Conference of the Parties recognised that

"modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,"

"although considerable knowledge has accumulated, significant gaps in knowledge have been identified, specifically in the field of interaction between living modified organisms (LMOs) resulting from modern biotechnology and the environment, taking into account the relatively short period of experience with releases of such organisms, the relatively small number of species and traits used, and the lack of experience in the range of environments, specifically those in centres of origin and genetic diversity"

*It also noted* "that that there is a need for further analysis of existing national, regional and international regulations and legally binding instruments of relevance to the impact of LMOs on the conservation and sustainable use of biological diversity".

There were to be two parallel sets of negotiation. One would attempt to identify a protocol that would achieve the objectives set out, particularly in relation to transboundary movement of living modified organisms. A second would try to set up a set of International Technical Guidelines on Safety in Biotechnology.

After difficult and bitter discussion (6 meetings of the Working Group), including the collapse and adjournment of an extraordinary meeting of the Parties to the Convention in Cartagena, Colombia in 1999, a Protocol to the CBD was agreed in 2000 in Montreal. It should be noted that only Parties to the Convention could be Party to the Protocol.

The relationship of this treaty to other treaties already in existence was considered when adopting the Convention; Article 22 states that

"1. The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity."

The Convention requires that there be public participation. In Article 13 (titled Public Education and Awareness) the Parties are enjoined to:

(a) Promote and encourage understanding of the importance of, and the measures required for, the conservation of biological diversity, as well as its propagation through media, and the inclusion of these topics in educational programmes; and

(b) Cooperate, as appropriate, with other States and international organizations in developing educational and public awareness programmes, with respect to conservation and sustainable use of biological diversity.

The Cartagena Protocol on Biosafety provides much clearer guidance to countries as to public participation.

With respect to liability and redress, the Parties were to examine, on the basis of studies to be carried out, the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is a purely internal matter. (Article 14.2). No action has yet been taken on this, with a report due to be made to the next meeting of the Conference of the Parties in 2004. The decision at the 5<sup>th</sup> Meeting of the Conference asked for a working group to consider:<sup>5</sup>

Clarifying basic concepts and developing definitions relevant to paragraph 2 of Article 14 (such as the concept of damage to biological diversity, its

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<sup>5</sup> Decision VI/11

valuation, classification, and its relationship with environmental damage, the meaning of "purely internal matter");

Proposing the possible introduction of elements, as appropriate, to address specifically liability and redress relating to damage to biological diversity into existing liability and redress regimes;

Examining the appropriateness of a liability and redress regime under the Convention on Biological Diversity, as well as exploring issues relating to restoration and compensation;

Analysing activities and situations that contribute to damage to biological diversity, including situations of potential concern; and

Considering preventive measures on the basis of the responsibility recognized under Article 3 of the Convention.

#### **4. United Nations Environment Programme International Technical Guidelines on Safety in Biotechnology**

After many meetings that permitted all countries party to the CBD to participate, the UNEP Technical Guidelines on Safety in Biotechnology were adopted in Cairo in 1995. They were to be used as an interim mechanism during the development of the protocol and to complement it after its completion, for the purposes of facilitating the development of national capacities to assess and manage risks, establish adequate information systems and develop expert resources in biotechnology<sup>6</sup>. These technical Guidelines are intended as a contribution to the implementation of Agenda 21 commitments and aim to assist Governments, intergovernmental, private-sector and other organizations in the establishment and maintenance of national capacities to provide for safety in biotechnology, to assist in developing expert human resources and for international exchange of information. The Guidelines were "developed on the basis of common elements and principles derived from relevant existing regional and international instruments and national regulations and guidelines, and drawing upon experience already gained through their preparation and implementation"<sup>7</sup>. They were "based on the premise that adequate mechanisms for risk assessment and risk management and capacity-building through - among others - the exchange of information and the use of these Guidelines at national, regional and international levels can contribute significantly to safety in biotechnology." They addressed "the human health and environmental safety of all types of applications of biotechnology, from research and development to commercialization of biotechnological products containing or consisting of organisms with novel trait(s)." It was noted that they could be implemented through existing legal and administrative structures or new ones.

The principles that underlay the Guidelines were to

(a) Identify any hazards;

(b) Assess the risks - which involved taking into account the consequences and the likelihood of the hazard being realized.

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<sup>6</sup> [http://www.iisd.ca/linkages/biodiv/cop3/cop3\\_28vfinal.doc](http://www.iisd.ca/linkages/biodiv/cop3/cop3_28vfinal.doc)

<sup>7</sup> <http://www.unep.org/unep/program/natres/biodiv/irb/unepgds.htm>

(c) Manage the risks: "either by applying adequate management strategies, including designing procedures and methods to minimize risks and their consequences, or by deciding not to proceed. Management strategies should be commensurate with the results of the risk assessment. Therefore, there might be cases where very few, if any, risk management measures will be necessary."

The Guidelines provided an indication of the manner in which these principles could be implemented. In particular, it was noted that "An organism with novel traits which is considered to be harmless in one region might be potentially harmful in another region which offers different environmental conditions. Therefore, there is a need for the exchange and supply of scientific information in cases where organisms with novel traits are intended to be released into new environments and when transfer of such organisms across national boundaries is being considered, particularly in those cases in which organisms with novel traits are intended to be released in the environment."

The UNEP International Guidelines have not been 'repealed' as they apply widely to the use of living modified organisms within the boundaries of a country whereas the Protocol applies mainly to the transboundary movement of living modified organisms.

## **5. Cartagena Protocol on Biosafety**

The Cartagena Protocol on Biosafety<sup>8</sup> was adopted as a supplementary agreement to the Convention on Biological Diversity in January 2000. It primarily deals with transboundary movement of living modified organisms<sup>9</sup> that might have adverse effects on biological diversity

"In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development<sup>10</sup>, the objective of this Protocol is 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."<sup>11</sup>

Importantly, the Protocol is both a Trade and Environment treaty. The recitals stress that the treaty is neither subordinate to any other international agreements nor is it to be taken as over-riding any other commitments (in particular, those agreed in the agreements setting up the WTO).

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<sup>8</sup> <http://www.biodiv.org/biosafety/protocol.asp>

<sup>9</sup> A Living Modified Organism (LMO) is defined in the Cartagena Protocol on Biosafety as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. The Protocol also defines the terms 'living organism' and 'modern biotechnology' (see [Article 3](#)). In everyday usage LMOs are usually considered to be the same as GMOs (Genetically Modified Organisms), but definitions and interpretations of the term GMO vary widely. Common LMOs include agricultural crops that have been genetically modified for greater productivity or for resistance to pests or diseases. Examples of modified crops include tomatoes, cassava, corn, cotton and soybeans.

<sup>10</sup> See above

<sup>11</sup> Article 1, Cartagena Protocol on Biosafety - see

“Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements,”

The Protocol does not apply to pharmaceuticals intended for human use where there are other international agreements or organisations that address their use. It also exempts (if countries do not decide otherwise) LMOs in transit or those used in containment from the terms of the “Advance Informed Agreement Procedure”.

There are three main strands to the Protocol. It identifies LMOs intended for direct use as food, feed or for processing for particular treatment; other LMOs that are intended to be released into the environment involve an advance informed agreement procedure; and it sets up a “Biosafety Clearing House” that holds information that must be provided by member countries about their decision, their decision making processes and their laws and regulations. Risk Assessment and Risk Management are clearly identified in two separate Articles and in Annex III.

LMOs that are intended only for direct use as food, feed or for processing are treated differently in the Protocol than are those which are intended for release into the environment. These organisms are addressed primarily in Article II. There is no requirement to follow an “advance informed agreement procedure”. Rather, the country that first decides to permit their use must inform a “Biosafety Clearing House” of the decision specifying the information required in Annex II of the Protocol. Countries must then take a decision on whether or not to permit the importation of these products on the basis of their domestic regulatory framework that is consistent with the objectives of the Protocol. This includes a risk assessment report consistent with Annex III. The precautionary approach is taken into account in Article 11(8):

“Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.”

LMOs that are intended for release into the environment may be subject to an elaborate procedure identified in Articles 7 through 10 and Article 12 of the Protocol. It applies prior to the first trans-boundary movement of the LMO. In the first instance

“The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of

import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I." (Article 8(1))

Articles 9 and 10 provide a timetable for action, and identify the decisions that may be made by the country of import.

Risk Assessments must be carried out in a scientifically sound and transparent manner (Annex III(3)), they are required and Article 15 provides that

"1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires."

Risk management is addressed in Article 16.

"Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import."

The biosafety clearing house (BCH) is an important mechanism for implementing the Protocol. It is intended, amongst other, to "facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms". It should assist Parties to implement the protocol (and is to take account of the needs of developing countries, "in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity." Much information has to be placed on the BCH including details of laws and regulations, decisions and risk assessments (Article 20).

The Parties are enjoined to facilitate public awareness, education and participation in the various processes leading up to decisions (Article 23). The terms are much more specific than those in the CBD:

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

Socio-economic considerations may in some limited areas be taken into account by parties to the Protocol:

“The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.”<sup>12</sup>

A number of provisions of the Protocol came into effect on the 11<sup>th</sup> September:

- a. “Countries shipping LMOs for intentional introduction into the environment will have to give prior notification to the importing country that is a party to the Protocol, under what is known as the advance informed agreement (AIA) procedure, and provide sufficient information for the first shipment to enable them to make informed decisions. Those shipments will have to be identified in accompanying documentation as LMOs with specification of the LMO identity and characteristics and with a declaration that “the movement is in conformity with the requirements of the Protocol”.
- b. Likewise, shipments of LMO commodities intended for direct use for food, feed or processing will have to be identified in accompanying documentation as “may contain” LMOs and as “not intended for intentional introduction into the environment”.
- c. Parties will be required to use the Biosafety Clearing-House (BCH) to fulfill a number of obligations. Specific information that must be made available through the BCH includes: national biosafety laws; risk assessment summaries; and final decisions by importing Parties with supporting reasons. The pilot phase of the BCH, which is largely Internet-based, has been developed by the

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<sup>12</sup> Article 26(1)

Secretariat of the Convention and is available at <http://bch.biodiv.org/Pilot/Home.aspx>.

- d. Any Party that approves for domestic use and marketing LMOs intended for direct use as food, feed or processing that may be exported will be required to communicate this decision and details about the LMO to the world community via the Biosafety Clearing-House (BCH).<sup>13</sup>

The Secretariat of the CBD (and of the Protocol) have produced a document listing requirements that need to be fulfilled as at the date of entry into force of the Cartagena Protocol on Biosafety which should be consulted at <http://www.biodiv.org/doc/notifications/2003/ntf-2003-093-cpb-en.pdf>.

Liability and redress are addressed in Article 27 of the Protocol, where

"the Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analyzing and taking due account of ongoing processes in international law on these matters, and shall endeavour to complete this process within four years"

The first meeting of the Parties will be in February 2003 in Kuala Lumpur. Under international law, the term "liability" is normally associated with the obligation to provide for compensation for damage caused to persons, property and the environment. Liability and redress in the context of the Protocol concern the question of what would happen should the transboundary movement of LMOs results in damage.<sup>14</sup> A workshop on this issue was held in Rome in December 2002 and the papers for the meeting may be found at <http://www.biodiv.org/doc/meeting.asp?wg=BSWSLR-01>.

## **6. Agreement setting up the WTO**

The World Trade Organization (WTO) is the only international organization dealing with the global rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably and freely as possible.<sup>15</sup> The World Trade Organization came into being in 1995. One of the youngest of the international organizations, the WTO is the successor to the General Agreement on Tariffs and Trade (GATT) established in the wake of the Second World War.

Over three quarters of WTO members are developing or least-developed countries. All WTO agreements contain special provision for them, including longer time periods to implement agreements and commitments, measures to increase their trading opportunities and support to help them build the infrastructure for WTO work, handle disputes, and implement technical standards<sup>16</sup>

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<sup>13</sup> <http://www.biodiv.org/biosafety/ratification.asp>

<sup>14</sup> <http://www.biodiv.org/biosafety/liability.asp>

<sup>15</sup> [http://www.wto.org/english/thewto\\_e/whatis\\_e/inbrief\\_e/inbr00\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr00_e.htm)

<sup>16</sup> [http://www.wto.org/english/thewto\\_e/whatis\\_e/inbrief\\_e/inbr04\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr04_e.htm)

Most of the WTO agreements are the result of the 1986–94 Uruguay Round negotiations, signed at the Marrakesh ministerial meeting in April 1994. There are about 60 agreements and decisions totalling 550 pages.

The Agreement setting up the WTO specifies that there is a need to ensure that trade should be conducted with a view to raising standards of living and, in particular allowing for the optimal use of resources in accordance with the objective of sustainable development:

*"Recognizing* that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development,

The agreement is also cognisant of the needs of developing countries:

*Recognizing* further that there is need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development,"<sup>17</sup>

Three of the WTO Agreements have particular significance for those implementing regulation of living modified organisms: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), the Agreement on Technical Barriers to Trade and the agreement on Trade-Related Aspects of Intellectual Property Rights Measures (TRIPS). In addition the Disputes Settlement Understanding is important<sup>18</sup> On the 7<sup>th</sup> August 2003 the United States, Canada and Mexico requested the creation of a formal World Trade Organisation (WTO) dispute panel over the issue of the *de facto* moratorium on GM food and products within Europe.

At the meeting of the WTO Dispute Settlement Body (DSB) on the 18<sup>th</sup> August the United States requested the establishment of a panel to rule on its complaint against the EU's *de facto* moratorium on the approval of new genetically modified organisms. The US is also challenging a number of marketing and import bans in certain EU member states, including Austria, France, Greece and Italy where the importation and marketing of GM products is prohibited although they have been approved for sale in the EU. Panel requests were also submitted by Argentina, a third party to the US case, and Canada, which is initiating a separate dispute. The US asked that the complaints be assessed by a single panel.

There are 3 institutions that are named in the treaty as having responsibilities for setting standards – Codex Alimentarius, the International Plant Protection Convention and the World Organisation for Animal Health (OIE).

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<sup>17</sup> [http://www.wto.org/english/docs\\_e/legal\\_e/04-wto.doc](http://www.wto.org/english/docs_e/legal_e/04-wto.doc)

<sup>18</sup> [http://www.wto.org/english/docs\\_e/legal\\_e/legal\\_e.htm](http://www.wto.org/english/docs_e/legal_e/legal_e.htm)

## **7. Codex Alimentarius**

"The Codex Alimentarius Commission was created in 1963 by the Food and Agriculture Organisation of the United Nations and the World Health Organisation to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations."<sup>19</sup>

The Codex is a collection of internationally adopted food standards presented in a uniform manner. These are developed in order to attempt to ensure that products meet internationally accepted minimum acceptable quality levels, are safe and do not present a health hazard. Standards are prescribed for individual foods and food groups. General standards have also been adopted, for example, for labelling pre-packaged foods.

In addition to specific standards, the Codex also includes "related texts". Related texts include advisory instruments: statements of principle, codes of practice, guidelines and codes of technological practice. Some of these instruments apply to food and food products that have been derived from biotechnology (genetically modified).

The General Principles of the Codex Alimentarius state:

"The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade."<sup>20</sup>

The [Codex Alimentarius Commission \(CAC\)](#), at its 23rd session held from 28 June to 3 July 1999, established the ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology to consider the health and nutritional implications of such foods. In particular, the Task Force would develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology.

The scientific basis for the work of Task Force is provided by FAO and WHO through a series of scientific expert consultations on the safety and nutritional aspects of GM foods. These expert consultations while addressing issues which are closely related to the work of the Task Force, are completely independent from the inter-government negotiation process, and treat the subject from a pure scientific perspective.<sup>21</sup>

In July 2003 the Codex Alimentarius Commission approved draft principles for the risk analysis of foods derived from Modern Biotechnology, a Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and Draft Annex on the Assessment of Possible Allergenicity to the Draft Guideline

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<sup>19</sup> <http://www.codexalimentarius.net/>

<sup>20</sup> <http://www.fao.org/docrep/w9114e/W9114e06.htm#TopOfPage>

<sup>21</sup> [http://www.fao.org/es/ESN/food/risk\\_biotech\\_en.stm](http://www.fao.org/es/ESN/food/risk_biotech_en.stm)

for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants<sup>22</sup>

## **8. International Plant Protection Convention**

The IPPC is an important treaty that seeks to prevent the spread of (and introduction to new countries) of pests of plant and plant products around the world. It attempts to promote appropriate measures to control these pests. It addresses natural flora and plant products, not solely concerned with transborder transfer, and covers direct and indirect damage by pests, including weeds. There are three legal texts, 1952, 1979 and 1997.<sup>23</sup>

As in so many relatively new treaties, the 1997 text includes (Article III)

“Nothing in this Convention shall affect the rights and obligations of the contracting parties under relevant international agreements.”

Countries are obliged to institute a regulatory system that has responsibilities in assuring the safety of plants, plant products and other regulated products for import and export, surveillance of plants throughout their territory (Article IVb) and inspection of plants “moving in international traffic”. They must protect endangered areas, designate and maintain pest free areas (or areas of low pest prevalence). The system must have a means of doing risk analyses of pests – defined as

“Pest risk analysis” - the process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it;

The risk analysis procedures required of countries have some similarities to that required for implementing a Biosafety regime, however Article VII requires that

“Contracting parties shall institute only phytosanitary measures that are technically justified, consistent with the pest risk involved and represent the least restrictive measures available, and result in the minimum impediment to the international movement of people, commodities and conveyances.”

## **9. World Organisation for Animal Health (OIE)**

The OIE is an intergovernmental organisation created by the International Agreement of 25 January 1924, signed by 28 countries. In May 2003, the OIE totalled [164 Member Countries](#).

The OIE has the responsibility to guarantee the transparency of animal diseases throughout the world, and member countries are required to report diseases that are current in their territory, including diseases that may be transferred to humans. It also has a responsibility to guarantee the sanitary safety of world trade by

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<sup>22</sup> <ftp://ftp.fao.org/docrep/fao/meeting/006/y6705e.pdf> and <ftp://ftp.fao.org/docrep/fao/meeting/006/y9220e.pdf>

<sup>23</sup>

[http://www.ippc.int/servlet/BinaryDownloaderServlet/13742\\_English.pdf?filename=/publications/13742.New\\_Revised\\_Text\\_of\\_the\\_International\\_Plant\\_Protection\\_Convention.2001-3-26.pdf&refID=13742](http://www.ippc.int/servlet/BinaryDownloaderServlet/13742_English.pdf?filename=/publications/13742.New_Revised_Text_of_the_International_Plant_Protection_Convention.2001-3-26.pdf&refID=13742)

developing rules for trade in animals and animal products that are recognised by the WTO as reference standards.

"The OIE develops normative documents relating to rules that Member Countries can use to protect themselves from diseases, without setting up unjustified sanitary barriers. The main normative works produced by the OIE are: the [International Animal Health Code](#)<sup>24</sup>, the [Manual of Standards for Diagnostic Tests and Vaccines](#)<sup>25</sup>, the [International Aquatic Animal Health Code](#)<sup>26</sup> and the [Diagnostic Manual for Aquatic Animal Diseases](#)."

Most countries will have sanitary and phytosanitary regulations and/or specific legislation that deals with the issues for which the standards are developed and which are likely to impinge on possible legislation for the control of modified organisms.

## **10. Agreement on the Application of Sanitary and Phytosanitary Measures**

The SPS Agreement provides conditions under which members can erect barriers to trade in order to assure the safety of their general and agricultural environment.

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

Members of the Agreement have the right to take action to protect human, animal or plant life or health taking into account the provisions of the agreement.

In order to ensure that members only take actions that are necessary, the agreement sets out the system for harmonising the sanitary and phytosanitary procedures as far as possible, In particular, only

"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" unless there is a scientific justification.

Like the Cartagena Protocol, member countries may take action based on a risk assessment "of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations". The wording here is almost identical to that in Annex III of the Cartagena Protocol.<sup>27</sup>

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<sup>24</sup> [http://www.oie.int/eng/publicat/en\\_code.htm](http://www.oie.int/eng/publicat/en_code.htm)

<sup>25</sup> [http://www.oie.int/eng/publicat/en\\_standards.htm](http://www.oie.int/eng/publicat/en_standards.htm)

<sup>26</sup> [http://www.oie.int/eng/publicat/en\\_aqua.htm](http://www.oie.int/eng/publicat/en_aqua.htm)

[http://www.oie.int/eng/publicat/en\\_aqua.htm](http://www.oie.int/eng/publicat/en_aqua.htm)

<sup>27</sup> "Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations."

However, in performing the risk assessment Members may 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.” (Article 5(3)). The major difference is in the approach to risk assessment where there is insufficient evidence to determine the risk:

“In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.” (Article 5(7)).

The full Agreement may be found at [http://www.wto.org/english/docs\\_e/legal\\_e/15-sps.doc](http://www.wto.org/english/docs_e/legal_e/15-sps.doc).

## **11. Agreement on Technical Barriers to Trade**

The TBT Agreement is relevant to biotechnology products because it applies to technical regulations and standards, including packaging, marking and labelling requirements. The TBT Agreement recognises that “no country should be prevented from taking measures necessary” to ensure the quality of its exports; to protect human, animal or plant life or health, of the environment; or prevent deceptive practices.

*“Recognizing that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement;”*<sup>28</sup>

The TBT Agreement applies to all products except that it does not apply to sanitary and phytosanitary measures<sup>29</sup>. The SPS Agreement would, therefore, apply where a product could be a risk to human, plant or animal health. The TBT Agreement probably would apply where, for example, a product is merely labelled as containing GMOs.<sup>30</sup> Technical regulations should not create unnecessary obstacles to

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<sup>28</sup> Preamble to the TBT Agreement.

<sup>29</sup> Article 1.5 of the TBT Agreement: “1.5 The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures.”

<sup>30</sup> See Lyle Glowka (2002) *The Role of Law in Realising the Potential and Avoiding the Risks of Modern Biotechnology: Selected Issues of Relevance to Food and Agriculture* - <ftp://ext-ftp.fao.org/ag/cgrfa/BSP/bsp19e.pdf>

international trade and should not be more trade-restrictive than necessary to fulfil a "legitimate objective, taking account of the risks of non-fulfilment" (Article 2.2).

Legitimate objectives include *inter alia* preventing deceptive trade practices, protecting human health or safety, animal or plant life or health, or the environment. Relevant elements are suggested for assessing the risks.

Article 12 refers specifically to Developing Countries, and Article 12.4 is of particular interest in that it provides for the preservation of indigenous technology and production methods and processes and requires all members to take into account the special needs of developing countries so as not to put obstacles in the way of their export trade:

"12.3 Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members.

12.4 Members recognize that, although international standards, guides or recommendations may exist, in their particular technological and socio-economic conditions, developing country Members adopt certain technical regulations, standards or conformity assessment procedures aimed at preserving indigenous technology and production methods and processes compatible with their development needs. Members therefore recognize that developing country Members should not be expected to use international standards as a basis for their technical regulations or standards, including test methods, which are not appropriate to their development, financial and trade needs."

## **12. International Treaty on Plant Genetic Resources**

The Food and Agriculture Organisation (FAO) has agreed a new International Treaty on Plant Genetic Resources for Food and Agriculture<sup>31</sup>. The treaty was opened for signature on the 3<sup>rd</sup> November 2001.

Under Article 26, the Treaty is subject to ratification, acceptance or approval by the Members and non-Members of FAO (Members of the United Nations, or any of its specialized agencies or of the International Atomic Energy Agency). Thirty two instruments of ratification, acceptance, approval or accession had been deposited with the Director-General of FAO by the end of September 2003. The objectives of the treaty are stated in Article 1:

"1.1 The objectives of this Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with

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<sup>31</sup> The text of the treaty is on <ftp://ext-ftp.fao.org/ag/cgrfa/it/ITPGRRe.pdf> and a primer published by the CGIAR centres may be found at [http://www.sgrp.cgiar.org/SgrpTreaty\\_final.pdf](http://www.sgrp.cgiar.org/SgrpTreaty_final.pdf)

the Convention on Biological Diversity, for sustainable agriculture and food security.

1.2 These objectives will be attained by closely linking this Treaty to the Food and Agriculture Organization of the United Nations and to the Convention on Biological Diversity.”

Plant genetic resources for food and agriculture are defined as "any genetic material of plant origin of actual or potential value for food and agriculture". `Countries have agreed to establish an efficient, effective and transparent Multilateral System to facilitate access to plant genetic resources for food and agriculture, and to share the benefits in a fair and equitable way. The Multilateral System applies to over 64 major crops and forages. The Governing Body of the Treaty, which will be composed of the countries that have ratified it, will set out the conditions for access and benefit-sharing in a "Material Transfer Agreement"<sup>32</sup>.

Members of the Treaty are expected to develop and maintain appropriate procedures for assuring the sustainable use of plant genetic resources (Article 6). Examples of mechanisms to achieve this end are given, including broadening the genetic base of crops and increasing the range of genetic diversity available to farmers.

The Treaty recognizes the contribution that farmers and farming communities make to the conservation and development of plant genetic resources (Article 9). This is the basis for that which is called Farmers' Rights, - including the protection of traditional knowledge, and the right to participate equitably in benefit-sharing and in national decision-making about plant genetic resources. It gives governments the responsibility for implementing these rights.

The crops covered by the treaty are named in Annex 1, and range from asparagus and coconut to all commonly farmed brassicas, maize, rice and wheat. Many forage crops are also included.

### **13. Agreement on Trade-Related Aspects of Intellectual Property Rights Measures**

The TRIPS agreement is one of the most hotly disputed measures introduced in the Uruguay round that saw the introduction of the World Trade Organisation. The most controversy lies in the application of its requirements which may limit the availability of medicines in developing countries. It is primarily those articles of the Agreement that relate to patents that may impact on a regulatory system introduced for the safe use of living modified organisms.

Article 27 identifies that which should be patentable. Patents may cover products or processes or both, and must be new, involve an inventive step (non-obvious) and be capable of commercial exploitation (useful). They must not discriminate on the basis of place of invention, the field of technology or whether the invention is locally produced or imported. Countries have the right to exclude from patentability those inventions whose commercial exploitation may affect *ordre public* or morality including the protection of "human, animal or plant life or health or to avoid serious prejudice to the environment".

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<sup>32</sup> <http://www.fao.org/ag/cgrfa/itpgr.htm#text>

In recognition of patent laws and agreements that already existed, the TRIPS agreement allowed for the exclusion of

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

The specific system for the protection of intellectual property for plant varieties that most countries use is the UPOV system explained below. The main difference is that a patent requires a written description of the invention whereas a plant variety system requires the actual plant to be provided with evidence that it is distinct, uniform and stable.

It should be noted that patents are national rights for which redress must be sought in the country in which an infringement occurs and therefore, if the patentor has not chosen to protect the invention in a particular country (or to maintain the protection) there are no rights which forbid the use of the invention within those borders. It is when there is an attempt to export products which are not protected in a country to one in which it is protected that the exported must be sure not to infringe the patent.

"A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process."

#### **14. Union for the Protection of Plant Varieties (UPOV)**

UPOV was established by the International Convention for the Protection of New Varieties of Plants. The Convention was adopted in Paris in 1961 and it was revised in 1972, 1978 and 1991<sup>33</sup>. The objective of the Convention is the protection of new varieties of plants by an intellectual property right.

A patent requires that a written description of the invention is provided to the authorities; a plant variety is physically submitted for inclusion in a national list of permitted varieties. As for patents, a plant variety right is a national right, and national law is drafted to implement the conventions. A listing of National Plant Variety Protection Laws can be examined at the UPOV website<sup>34</sup>; there is also a list of countries that have registered varieties under the UPOV system<sup>35</sup>. In order to

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<sup>33</sup> <http://www.upov.int/en/publications/conventions/1991/pdf/act1991.pdf>

<sup>34</sup> <http://www.upov.int/en/publications/npvlaws/index.htm>

<sup>35</sup> [http://www.upov.int/en/documents/c/36/c\\_36\\_7.pdf](http://www.upov.int/en/documents/c/36/c_36_7.pdf)

obtain listing, applicants have to demonstrate that their new variety is distinct, uniform and stable. A variety is distinct (D) from any other variety whose existence is a matter of common knowledge at the time of the filing of the application. An introduction to the concepts of distinct, uniform and stable is available<sup>36</sup>. The 1991 act added an extra concept – “essentially derived” – if a plant is ‘essentially derived’ from a protected variety, then its use requires permission from the owner of the listed variety. An essentially derived variety is one which is predominantly derived from the initial variety (or from one that has been produced from a protected variety) and retains the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety. It must however, be clearly distinguishable from the initial variety and “except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety” (Article 14). The 1991 Act also modifies ‘farmer’s rights’ but permits countries to provide in their national laws for the retention of seed (Article 15) – note should be taken of the paragraphs of the International treaty on Plant genetic resources in relation to Farmer’s rights.

“Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder’s right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14(5)(a)(i) or (ii).”

It is possible to protect all varieties of flora using this system. A listing of all the varieties covered can be found on the website<sup>37</sup>

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<sup>36</sup> [http://www.upov.int/en/publications/tg-rom/tg001/tg\\_1\\_3.pdf](http://www.upov.int/en/publications/tg-rom/tg001/tg_1_3.pdf)

<sup>37</sup> [http://www.upov.int/en/documents/c/36/c\\_36\\_6.pdf](http://www.upov.int/en/documents/c/36/c_36_6.pdf)