

Foreign Policy Bulletin

The Documentary Record of United States Foreign Policy



SPECIAL DOUBLE ISSUE

An Uneasy Transition to a New Century

Features

- *U.S Foreign Policy into the 21st Century: The Opportunities and Obligations of Leadership in the Global Era*
- *China and the WTO: The U.S. and China Reach Agreement on Terms for China's Accession to the WTO*
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Cover and page 72 photo of Russian soldiers loading shells into their tank as smoke rises in the background from a burning oil plant the outskirts of Grozny, Chechnya, December 26, 1999.
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The Cartagena Protocol on Biosafety

Parties to the U.N. Convention on Biological Diversity Reach Accord Regulating Importation of Genetically Modified Organisms

Greenpeace Press
Statement, September 15,
1999¹

Greenpeace today demanded the international delegates gathered in Vienna to set strong environmental controls for genetically modified organisms (GMOs). The organization demonstrated in front of the United Nations building in Vienna where the Biosafety Protocol negotiations are being held. Activists dressed as genetically engineered maize and tomato waltzed with Bill Clinton and Tony Blair and held up banners demanding, "Stop GMOs—Biosafety Now!", "Stop playing dirty games".

"Governments have so far dodged their responsibility to protect the environment from genetic pollution," said Greenpeace political advisor Louise Gale. "Even though citizens in a growing number of countries across the world are rejecting genetically engineered food, governments have done precious little to draft global rules to address the public's concerns. International biosafety rules are needed now more than ever to give countries the right to say no to GMOs."

The U.S. along with other grain exporting countries like Canada, Australia and Argentina have been the strongest opponents of all environmental clauses in the Biosafety Protocol. The previous round of protocol negotiations collapsed in Colombia earlier this year mainly due to the opposition of the group.

Greenpeace is calling for precaution to be the basis of all decisions on GMOs since the long term effects of this new technology are mostly unknown and what

is known causes concern. Any government should have a right to stop any import of GMOs if it suspects there may be environmental or health risks.

The Biosafety Protocol is the first attempt by the international community to set binding rules for the use, transport and handling of GMOs. The U.S. is not a party to the process since it has not ratified the Biodiversity Convention.

Global Industry Coalition
Press Statement, January
24, 2000²

The Global Industry Coalition (GIC) is an association of over 2,200 firms in more than 130 countries that develop or use biotechnology. The GIC issued its press release in advance of informal consultations in Vienna.

The Global Industry Coalition today urged negotiators to conclude a practical and workable Biosafety Protocol that will protect biological diversity and lead to enhanced social and economic benefits through the use of biotechnology.

"The challenge facing negotiators is to develop a practical and workable agreement that will truly protect biodiversity without disrupting research, innovation and trade unjustifiably" said Joyce Groote, chair of the Global Industry Coalition which represents some 2,200 companies that employ more than one million people in more than 130 countries. "These people are working to sustainably improve agricultural production, enhance nutritional benefits of food, protect our environment and generate breakthroughs in health care

and renewable resources," said Ms. Groote.

"A workable Protocol will lead to clear measures that will protect biological diversity and provide predictability so that government, industry and the research community can allocate the resources needed for the development of biotechnology and realize the social and economic benefits it will produce," said Ms. Groote.

Such a protocol should:

- Be grounded in science;
- Include timely and efficient procedures;
- Exclude those products intended for food, feed or processing that have no effect on the environment, and;
- Preserve countries' rights and obligations under existing international agreements.

Representatives of more than 130 nations are meeting in Montreal to open the first of five days of formal negotiating sessions sponsored by the United Nations. In the past five years, considerable progress has been made through international negotiations for a Protocol following commitments made at the 1992 Earth Summit in Rio de Janeiro. The Coalition has been fully supportive and involved in this process.

Greenpeace Press
Statement, January 27, 2000³

Greenpeace today urged the U.S. and Canada to stop their obstruction of the UN Biosafety negotiations and agree with the majority of countries to set up international rules to control genetically engineered organisms (GMOs). Activists dressed as

CONTEXT

The Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety was finalized in January 2000 after four years of contentious negotiation. The centerpiece of the Protocol is an obligation to solicit the “advance informed agreement” of an importing country prior to the release into the environment of “living modified organisms” (LMOs). The objective is to allow an importing country to assess potential adverse ecological or human health impacts of LMO releases. The protocol refers to “living” rather than to “genetically” modified organisms because of insistence by the United States that genetic manipulation did not pose risks different from other methods of transformation, such as traditional breeding. Although the language change sought to direct attention away from genetic engineering, the Protocol does in fact regulate only ‘genetically’ modified organisms.

The early history

During the half decade of the Cartagena Protocol’s negotiation, transgenic crop production has increased rapidly in agricultural exporting countries such as the United States, Argentina, Canada and Australia¹. At the same time, expanding public concern, especially in Europe, over ecological and food safety issues has led

to increased divergence in regulatory approaches, and an escalating trade conflict between the United States and the European Union in this area. A *de facto* moratorium has been in effect against entry of transgenic crops into Europe over the last two years, as the Community has debated amendments to its regional directives, and has halted new approvals until such amendments are in place. While protocol negotiations have been shaped by this growing intra-OECD conflict, a protocol on biosafety was originally demanded by developing countries, many of which lack domestic biosafety regulations. The desire for a protocol was the result of fear that developing countries might become the testing grounds for potentially novel and risky substances. An incident in Argentina in 1986, where a genetically altered rabies vaccine was field tested on an Argentinean farm by a United States research institute without the knowledge of the government, fueled such concerns and led to calls for an agreement which would mandate informed agreement prior to LMO transfers.

Main areas of controversy

Amongst many contentious elements, two issues have been the focus of sustained

conflict in Protocol negotiations. The first concerns agricultural commodities, i.e. transgenic varieties of bulk agricultural crops, such as maize or soybean, intended for direct consumption or processing. Fearing vast disruption of the bulk agricultural commodity trade, major agricultural exporting countries (organized into a six country coalition called the Miami Group, consisting of Argentina, Australia, Canada, Chile, the United States and Uruguay) refused to have “advance informed agreement” prior to trade in commodities, even as developing countries made this their central demand. The Protocol’s final obligations on commodities call for information sharing through a largely internet-based Clearing House Mechanism housed within the Protocol Secretariat. Importing countries can access this information in order to make decisions about whether to restrict transgenic commodity imports. This procedure leaves the onus of responsibility on importing countries, and its effective functioning remains dependent on whether countries have the institutional wherewithal to use information provided to the clearing house. The Protocol does, however, require documentation accompanying transgenic commodity shipments

butterflies stood behind a wall symbolizing the obstruction and held a banner demanding, “U.S. and Canada stop blocking Biosafety!”. The butterflies, portraying the unintended victims of GE crops urged the delegates to ignore the demands of the U.S. and Canadian-led ‘Miami group’ and take the decision millions of citizens world-wide expect them to take.

“The 50 environment ministers starting the meeting today need to break the barrier erected by the U.S. and Canada and get the job done,” said Benedikt Haerlin of Greenpeace.

According to Greenpeace, a failure in Montreal could not only threaten the environment but also the world’s food security. “The lack of international regulation on GMOs would result in a plethora of national legislation inconsistent with each other, possibly including protectionist and

retaliatory measures,” added Haerlin. “Not even U.S. and Canadian trade and industry interests would gain from it.”

The ‘Miami group’ still insists that genetically engineered food crops, which represent over 95 per cent of all GMOs traded world-wide, be excluded from the Protocol. The group also insists that World Trade Organization rules should supersede the Protocol’s regulations and it continues to block adequate measures on labelling and traceability of GMOs. Furthermore, the group rejects the use of the precautionary principle, which has become a standard in international environmental law.

“The Biosafety discussions have so far taken more than two years without any consensus between the six rogue nations of the Miami Group and the rest of the world,” said Haerlin. “In all democratic

processes there is a time for discussion, but there is also a time for decision making. We have talked long enough. Now is the time to make these decisions and finalize the Protocol, even without the Miami group if necessary.”

Cartagena Protocol on Biosafety to the Convention on Biological Diversity, January 29, 2000 ⁴

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as “the Convention”,

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,

Aarti Gupta

Research Fellow, Kennedy School of Government, Harvard

to state that they “may contain” LMOs. This flags, at a minimum, the entry into a country of transgenic commodities, even though it does not require either the advance consent of the country or segregation of transgenic from non-transgenic commodities.

In addition to disputes over agricultural commodities, a second contentious issue has been the intra-OECD conflict over whether decisions on LMO imports are to be based on “sound science” (desired by the Miami Group) or whether recourse to the precautionary principle is allowed (of primary importance to the European Union). While the United States was wary that “precaution” would be used to justify arbitrary restrictions on trade, the European Union wanted to ensure that its enshrinement of the precautionary principle in community-wide environmental directives would be mirrored in the Protocol. The final outcome calls for decisions to be based on a “scientifically-sound” risk assessment but also allows for precautionary decisions in the face of scientific uncertainty. This has been hailed as the first operationalization of the precautionary principle in an environmental agreement, and a significant advance for global environmental governance. While seen as a

victory for the European Union, the Protocol’s language on precaution remains open to multiple interpretations, and ensures that the bilateral conflict on this issue will continue. Related to this, the Protocol’s relationship to the multilateral trade regime (which favors sound science based decision-making) is also characterized by ambiguity in the final outcome/2.

Future issues

The Cartagena Protocol on Biosafety was opened for signature in May 2000. It has since been signed by 79 countries, and will come into force after 50 countries have ratified it. Its effective implementation hinges partly on whether the major LMO exporting countries of the Miami Group sign the agreement. To date, only two members of this group, Argentina and Chile, have signed. The United States, the leading LMO exporter, cannot be a party to the Protocol in the foreseeable future since it has not yet ratified the parent Convention on Biological Diversity. Key issues in implementation of the Protocol include, first and foremost, the setting up of the Clearing House Mechanism, which is at the heart of the Protocol’s information sharing obligations. Also on the agenda is a liability and compensation clause, to give enforcement teeth to an agreement which

currently lacks it. Any such provision will remain extremely contentious. Documentation requirements to accompany transgenic commodities and possible segregation of such commodities is also a continuing agenda-item. More broadly, however, it remains to be seen whether an agreement emphasizing information sharing as a risk mitigation strategy can be adequate in this realm of extreme scientific uncertainties and value conflicts.

- 1 In 1998, 27.8 million hectares were planted with transgenic crops worldwide, of which the United States contributed 74%, Argentina 15%, Canada 10% and Australia 1%. Data from C. James, Global Review of Commercialized Transgenic Crops: 1998. ISAAA Briefs, no. 8 (Ithaca, New York).
2. For more detailed analysis, see Gupta, A. “Governing Trade in Genetically Modified Organisms: the Cartagena Protocol on Biosafety” in Environment (Vol. 42, No. 4: 23-33, May 2000); and ‘Framing Biosafety in an International Context’ Discussion Paper E-99-10 (Cambridge: Harvard University, October 1999. Available at <http://environment.harvard.edu/gea>).

Recalling also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,

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

Recognizing also the crucial importance to humankind of centers of origin and centers of genetic diversity,

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,

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,

Have agreed as follows:

Article 1: Objective

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, 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.

CHRONOLOGY

1994

November. First meeting of the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) in the Bahamas; sets up a Biosafety Experts Group open to all governments, and a 15-member experts panel to prepare a background paper for the Group.

1995

May. 15 government-appointed experts panel meets in Cairo.

July. Biosafety Experts Group meets in Madrid to work out terms of reference, with active participation from NGOs and independent scientists; controversy over the scope and elements of a biosafety protocol.

November. Second meeting of the COP in Jakarta sets up a Working Group on Biosafety to negotiate a biosafety protocol, after intense debates on the scope and elements.

1996-1998

From July 1996 until February 1999 Working Group on Biosafety chaired by Denmark's Dr Veit Koester meets six times; fails to reach agreement on all key issues, based on the Chairman's draft; Group dissolves on 22 February.

1999

February 22-24. First Extraordinary Meeting of the COP convenes under chairmanship of Colombian Minister of Environment Juan Mayr Maldonado; negotiations fail and the meeting is suspended.

July 1. Informal consultation with delegates at a CBD meeting in Montreal to confirm political will to proceed.

September. Informal consultations in Vienna to build goodwill and explore areas of possible agreement on three core issues (general scope, Advance Informed Agreement (AIA) scope, relationship of protocol with WTO agreements).

2000

January. Extraordinary meeting of the COP resumes in Montreal; Cartagena Protocol on Biosafety concluded and adopted.

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Article 2: General Provisions

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.

2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

Article 3: Use of Terms

For the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

(c) "Export" means intentional transboundary movement from one Party to another Party;

(d) "Exporter" means any legal or natur-

al person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

(e) "Import" means intentional transboundary movement into one Party from another Party;

(f) "Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) "Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

(j) "Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

Article 4: Scope

This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

GLOSSARY

APHIS (Animal and Plant Health Inspection Service). An agency of the U.S. Department of Agriculture responsible for regulating the field testing of genetically engineered plants and certain microorganisms.

Biosafety Protocol. A treaty being negotiated under the Convention on Biological Diversity to set up a process for the safe movement across countries' boundaries of living genetically engineered organisms.

Biotechnology. Broadly defined, the use of biological processes of microbes and of plants or animal cells for the benefit of humans. When used in conjunction with genetic engineering, it is the genetic modification of an organism's DNA such that the transformed individuals have new traits that enhance survival or modify quality. The actual use of biotechnological methods began centuries ago, when plants and animals were selectively bred and microorganisms were used in the production of beer, wine, cheese, and bread. In addition to genetic engineering, biotechnology is concerned with such areas as plant tissue culture, gene splicing, enzyme systems, plant breeding, animal cell culture, immunology, molecular biology, and fermentation. Modern biotechnology is being used in medicine, fuel production, agriculture and food production, and criminal science, as well as in environmental activities.

Bovine Somatotropin (BST/BGH). Known both as BST and BGH (for bovine growth hormone), a naturally occurring protein that has been genetically engineered as a synthetic compound to stimulate milk production in cows.

Bt Crops. Crops that are genetically engineered to carry the gene from the soil bacterium *Bacillus thuringiensis*. The bacterium produces a protein that is toxic when ingested by individual species of insects, thereby providing protection throughout the entire plant.

Bt Cotton Cotton that is genetically engineered to control tobacco budworms, bollworms, and pink bollworms.

Bt Corn (Maize). Corn that is genetically engineered to provide protection against the European Corn Borer.

CGIAR (Consultative Group on

International Agricultural Research).

An informal association of 58 public and private sector members supporting 16 international agricultural research centers. The centers develop advanced breeding material for adoption and use by national agricultural research systems in developing countries.

Clone. A group of genetically identical cells or organisms asexually descended from a common ancestor.

Codex Alimentarius. A World Health Organization body that develops standards for food safety and international food trade.

Convention on Biological Diversity (CBD). An international conference on biodiversity issues. Its objectives are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. This convention is the first comprehensive global agreement to address all aspects of biological diversity. Currently, there are 168 signatories to the convention and 175 members of the Conference of Parties.

DNA (Deoxyribonucleic Acid). The molecule that encodes genetic information. It is constructed of a double helix held together by weak bonds between base pairs of four nucleotides adenine, guanine, cytosine, and thymine.

EPA (Environmental Protection Agency). A U.S. government agency that issues permits for large-scale testing of herbicides and biotechnology-derived plants containing new pesticidal substances.

FDA (Food and Drug Administration). A U.S. government agency responsible for ensuring that foods derived from new plant varieties are safe to eat. FDA also has legal authority for food labeling.

Genetically Modified Organism (GMO). An organism produced from genetic engineering techniques that allow the transfer of inherited characteristics from one organism to another. Bacteria, fungi, viruses, plants, insects, fish, and mammals are some examples of genetic material that have been artificially changed or altered in order to change some physical property or capability. Liv-

ing modified organisms (LMOs), genetically engineered (GE) foods, and transgenic crops are other terms often used in place of GMOs.

Genetic Engineering. Very broadly, a technique used to alter or move genetic material (genes) of living cells. In the United States, under guidelines issued by Department of Agriculture's Animal and Plant Health Inspection Service, genetic engineering is defined as the genetic modification of organisms by recombinant DNA techniques. Definitions used in Europe tend to be broader.

Gene Stacking. Combining traits (e.g., herbicide tolerance and insect resistance) in seed.

Genome. The sum of the genetic material in the chromosomes of a particular organism.

Herbicide-tolerant Crops. Crops developed to survive certain herbicides. These crops previously would have been destroyed along with targeted weeds, but now can be used by farmers as an effective weed control. The most common herbicide-tolerant crops (cotton, corn, soybeans, and canola) are marketed under such names as Roundup Ready (RR), resistant to glyphosate, a herbicide effective on many species of grasses, broadleaf weeds, and sedges; Liberty Link (LL) corn, resistant to glufosinate-ammonium; and BXN cotton, resistant to bromoxynil.

Plant Breeding. The technique of crossing plants to produce varieties with particular characteristics (traits) that are carried in their genes and passed on to future generations.

Recombinant DNA (rDNA). DNA produced using genetic engineering techniques. Such techniques involve transferring a DNA segment from one organism and inserting it into the DNA of another, possibly unrelated, organism.

Transgenic Plants. Plants that result from the insertion of genetic material from another organism, generally through recombinant DNA techniques, to make the plant exhibit a desired trait.

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Article 5: Pharmaceuticals

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations.

Article 6: Transit and Contained Use

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

Article 7: Application of the Advance Informed Agreement Procedure

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as

food or feed, or for processing.

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 8: Notification

1. 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.

2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

Article 9: Acknowledgement of Receipt of Notification

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.

2. The acknowledgement shall state:

(a) The date of receipt of the notification;

(b) Whether the notification, *prima facie*, contains the information referred to in Article 8;

(c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.

3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.

4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

Article 10: Decision Procedure

1. Decisions Taken by the Party of Import Shall Be in Accordance with Article 15.

2. The Party of import shall, within the period of time referred to in Article 9,

inform the notifier, in writing, whether the intentional transboundary movement may proceed:

(a) Only after the Party of import has given its written consent; or

(b) After no less than ninety days without a subsequent written consent.

3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:

(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;

(b) Prohibiting the import;

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.

4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.

5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

6. 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 the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

Article 11: Procedure for Living Modified Organisms Intended for Direct Use as Food or Feed, or for Processing

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

(a) A risk assessment undertaken in accordance with Annex III; and

(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

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.

9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

Article 12: Review of Decisions

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

(a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or

(b) Additional relevant scientific or technical information has become available.

3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its deci-

sion.

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

Article 13: Simplified Procedure

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:

(a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and

(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

Article 14: Bilateral, Regional and Multilateral Agreements and Arrangements

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.

3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its

decision.

Article 15: Risk Assessment

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.

Article 16: Risk Management

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. 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.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavor to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its

life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article 17: Unintentional Transboundary Movements and Emergency Measures

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

Article 18: Handling, Transport, Packaging and Identification

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly

identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

Article 19: Competent National Authorities and National Focal Points

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

Article 20: Information Sharing and the Biosafety Clearing-house

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centers of origin and centers of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of living modified organisms; and

(e) Reports submitted by it pursuant to Article 33, including those on implemen-

tation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 21: Confidential Information

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favorable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

(a) The name and address of the notifier;

(b) A general description of the living

modified organism or organisms;

(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(d) Any methods and plans for emergency response.

Article 22: Capacity-Building

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

Article 23: Public Awareness and Participation

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) Endeavor 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 endeavor to inform its public about the means of public access to the Biosafety Clearing-House.

Article 24: Non-Parties

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.

2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

Article 25: Illegal Transboundary Movements

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.

2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

3. Each Party shall make available to the Biosafety Clearing-House information

concerning cases of illegal transboundary movements pertaining to it.

Article 26: Socio-economic Considerations

1. 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.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Article 27: Liability and Redress

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 the ongoing processes in international law on these matters, and shall endeavor to complete this process within four years.

Article 28: Financial Mechanism and Resources

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particu-

lar the least developed and the small island developing States among them.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multi-lateral channels.

Article 29: Conference of the Parties Serving as the Meeting of the Parties to this Protocol

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions

assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within

six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article 30: Subsidiary Bodies

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

Article 31: Secretariat

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article 32: Relationship with the Convention

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

Article 33: Monitoring and Reporting

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

Article 34: Compliance

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

Article 35: Assessment and Review

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

Article 36: Signature

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

Article 37: Entry into Force

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 38: Reservations

No reservations may be made to this Protocol.

Article 39: Withdrawal

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article 40: Authentic Texts

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

DONE at Montreal on this twenty-ninth day of January, two thousand.

ANNEX I: INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLES 8, 10 AND 13

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centers of origin and centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(j) Quantity or volume of the living modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with Annex III.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(o) A declaration that the above-mentioned information is factually correct.

ANNEX II: INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING UNDER ARTICLE 11

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the living modified organism.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

(e) Any unique identification of the living modified organism.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(g) Centers of origin and centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(i) Approved uses of the living modified organism.

(j) A risk assessment report consistent with Annex III.

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

ding, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

ANNEX III: RISK ASSESSMENT

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, *inter alia*, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. 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.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which

may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realized;

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centers of origin and centers of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) Vector. Characteristics of the vector,

including its identity, if any, and its source or origin, and its host range;

(d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centers of origin of the likely potential receiving environment.

Statement by Undersecretary of State Loy, January 29, 2000 ⁵

During this negotiation the United States worked hard for an agreement it could support—one that protects the earth's biological diversity without disrupting world food trade.

The final text is a major improvement over the draft agreement prepared almost a year ago in Cartagena. We are gratified that an agreement emerged.

Make no mistake. This agreement is not perfect. The key to its success will lie in its implementation.

The agreement will contribute to the protection of biological diversity.

First, it creates an international framework for addressing the environmental impacts of bioengineered products. Information and expertise exchanged through this system will help governments assess the environmental risks and benefits of biotechnology in a more predictable and consistent manner.

Second, the agreement ensures that each

country will have an opportunity to get needed information before these products enter their market.

Third, the agreement reaffirms each country's right to regulate the import of bioengineered products, subject to existing international obligations.

The agreement seeks to address the special challenges faced by developing countries and creates a framework to help improve their capacity to protect biodiversity.

Lastly, the agreement should make it easier to harness the promise of this technology to feed the world's growing population using less land, water and pesticides.

Consumers, farmers, and industry can work with the agreement reached today.

We have worked hard with our Miami Group allies to ensure that the Biosafety Protocol does not subject agricultural commodities to onerous trade restrictions. As a consequence, consumers around the world will benefit from lower prices, and farmers and agricultural exporters will benefit from more predictable access to foreign markets.

The agreement establishes a process for developing appropriate documentation requirements for bulk agricultural products. I am particularly happy that the agreement managed to avoid the creation of costly and unworkable documentation requirements, and that the agreement emphasizes that regulatory decisions must be based on science.

More generally, by reaching agreement today we have taken an important step toward depolarizing the debate about biotechnology. Conversely, failure to reach agreement would have exacerbated tensions over this issue.

In sum, this agreement provides concrete benefits for the United States.

Let me say a few words about how these negotiations unfolded this week.

A spirit of cooperation and goodwill characterized the discussions among the various negotiating groups.

All of the negotiating groups set aside past rancor and pulled together the final text.

We are grateful to our partners in the Miami Group for their unflagging support. In addition, I wish to thank Canadian Environment Minister David Anderson, our host here in Montreal, for his gracious

hospitality.

Finally, let me emphasize that much of the credit for this successful outcome belongs to the Chairperson of this process, Colombian Environment Minister Juan Mayr. Without his tireless efforts and commitment to conclusion of what will be known as the Cartagena Protocol would have been almost impossible.

Global Industry Coalition Press Statement, January 29, 2000 ⁶

The Biosafety Protocol announced here today recognizes the importance of the biotechnology industry, creates a framework for continued development of the products and sets directions for rules to share social and economic benefits among the world's nations.

"The Protocol represents significant progress for biotechnology while protecting biodiversity," said Joyce Groote, chair of the Global Industry Coalition representing more than 2,200 companies in the biotechnology sector. "The Protocol provides an incentive for continued investment to develop innovative products. It is a very clear indicator that the biotechnology industry will continue to grow."

The agreement provides a framework for science-based rules and procedures. These will be developed as governments and companies determine how to implement the Protocol in the coming years. The Protocol will build on the base of domestic regulations that already exist in more than 60 nations—a majority of the multi-billion-dollar world market.

The Coalition praised the work of Juan Mayr Maldonado, the Colombian minister of the environment and chair of the negotiations. "Mr. Mayr's leadership was a key factor in achieving such significant progress on these complex issues. All the delegates displayed a very positive and constructive attitude."

The Coalition, representing companies that employ more than one million people in 130 countries, has provided constructive support for an effective Protocol that is consistent with existing international agreements.

Greenpeace Press Statement, January 29, 2000 ⁷

Greenpeace today congratulated the 50 environment ministers and approximately 130 government delegations for adopting an international Biosafety Protocol to control the trade of genetically engineered organisms (GMOs). "This is a historic step towards protecting the environment and consumers from the dangers of genetic engineering", said Benedikt Haerlin of Greenpeace. "The protocol adopted here today lays the foundation for a stronger future agreement which will eventually protect the environment from GMOs."

Greenpeace welcomes the fact that common sense is starting to prevail. "These minimum safety standards must be implemented immediately. We urge all countries to ratify this agreement so that it can enter into force at the latest by the tenth anniversary of the Rio Earth Summit in 2002," Haerlin said. "And until the protocol has come into force all exports of GMOs should be prohibited."

The Biosafety Protocol was finally adopted after a series of difficult negotiations complicated by the obstruction of a small minority of GMO-exporting countries, namely the USA, Canada, Argentina and their associates Australia, Chile and Uruguay. "We are happy that the U.S. and Canadian-led Miami Group failed in its efforts to force upon the world this untested and risky technology," said Haerlin.

In a last minute effort to hold hostage the adoption of the entire Protocol, the Miami Group succeeded in erasing mandatory labelling and information about the use of GMOs in food. "This is a cowardly attempt to deceive consumers and importing countries," Haerlin said. "We are confident that this smoke-screen strategy will fail." According to Greenpeace the future of GMOs will depend not only on international and national legislation, but upon consumers. "The market is falling for genetically engineered food. People are avoiding this food like they would mushrooms from Chernobyl, Haerlin explained, "We are confident that consumers will win this battle in the end."

World Wide Fund for Nature Position Paper, May, 2000 ⁸

WWF congratulates governments on the adoption of the Cartagena Protocol on Biosafety by the Extraordinary Conference of the Parties to the CBD in January this year. WWF welcomes the provisions of the Protocol, and in particular that it:

- Recognizes that LMOs are inherently different from non-LMOs, and gives countries the right to refuse entry to LMOs under the Advance Informed Agreement (AIA) procedures, which include comprehensive risk assessments; and that it also allows countries to attach conditions when approving entry of LMOs, for example, on where and how they are to be grown and used.

- Allows countries to take socio-economic considerations affecting the conservation and sustainable use of biodiversity into account in reaching decisions on approving or refusing entry of LMOs.

- Makes it clear that it is legitimate for States to apply the Precautionary Principle when deciding whether or not to allow the entry of LMOs into their territories.

- States, in its preamble, that the protocol is not subordinate to other international agreements.

- Places responsibilities on countries of export to check that exporters comply with the requirements of the Protocol, especially on documentation accompanying exports, before an export is shipped. No exports of LMOs may proceed without the Advance Informed Agreement (AIA) of the country of import.

- Requires all LMOs to be identified, and to be accompanied by documentation—LMOs for food, feed or processing mixed with non-LMOs, have to be identified as "may contain" specified LMOs.

WWF notes that the Cartagena Protocol was adopted by consensus, and therefore expects all countries, including the Miami Group countries (Argentina, Australia, Canada, Chile, and United States of America, Uruguay), to implement it since the consensus reached indicates that all countries agree with the provisions of the Protocol. WWF calls on all countries to start to implement the provisions of the Protocol immediately, in advance of its entry into force.

In particular, WWF encourages all governments to:

- Sign the Protocol at COP5, and to ratify it by 31 October 2001. The aim should be to ensure that the Protocol enters into force before COP6 to be held during 2002, and for the first Meeting of the Parties to the Protocol (MOP1) to take place in conjunction with COP6;

- Designate National Focal Points and establish Inter-Sectoral Committees to oversee biosafety regulatory activities at the national level;

- Establish national measures (including national biosafety legislation and guidelines);

- Declare a moratorium on use or release of genetically engineered organisms into the general environment until ecological interactions are fully researched and safeguards put in place;

- Cooperate with other countries to establish regional mechanisms to put the provisions of the Protocol into practice;

WWF's proposals concerning the ICCP's proposed work program;

WWF welcomes the establishment of the Intergovernmental Committee for the Cartagena Protocol (ICCP), and recommends that COP5 considers incorporating the following as priorities in the ICCP's work program:

1. LIABILITY AND REDRESS— ARTICLE 27

WWF views the development of effective provisions on liability and redress as a high priority for the Protocol. In addition to addressing costs of emergency action, compensation of victims of harm, and restoration of any damage to biodiversity and its sustainable use, provisions on liability and redress also provide an incentive for compliance with the Protocol.

WWF therefore urges governments to give strong support for establishment of a fair and equitable system of liability and redress in the event of harm to the environment, biodiversity, human or animal health or socio-economic welfare, arising as a consequence of LMOs (LMO-FFPs). Exporters should be strictly liable for any harm caused by such LMOs which they export and for providing compensation. This strict liability should extend to any failure of LMOs to perform and deliver anticipated benefits claimed by the exporter.

WWF advocates that provisions on liability and redress should:

- apply strict liability, which is already applied in other environmental agreements
- be based on civil liability, and channel liability to private parties. There is no justification for leaving states to assume liability concerning the activities of private parties which constitute the biotechnology and genetic engineering industry.

Recognizing the need for action to provide a clear regime in this area for Parties and for the private sector, as well as the complexity of the issues, WWF urges that MOP1 set a firm time limit for development and implementation of the liability and redress regime. WWF calls for an effective liability regime relating to biosafety, to be in operation within three years of MOP1. In addition, WWF calls on COP5 to request the ICCP to develop firm proposals on international rules and procedures on liability and redress for damage resulting from transboundary movements of living modified organisms, for presentation to MOP1.

As an interim measure, WWF also suggests that a fund be established for compensation for damage caused by deliberate or unintentional releases of LMOs.

2. COMPLIANCE—ARTICLE 34

WWF regards development of effective procedures for compliance and dispute resolution as a high priority for the Protocol—such procedures will contribute to its effectiveness, and will help to ensure that any disputes regarding the Protocol and its implementation are resolved within the framework of the Protocol rather than being transferred to other international fora. WWF therefore urges COP5 to include development of proposals for compliance and dispute resolution procedures in the ICCP's work program.

3. HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION—ARTICLE 18

The proposed work program for the ICCP includes development of the detailed requirements regarding documentation accompanying living modified organisms intended for direct use as food, or feed or for processing (LMO-FFPs).

WWF advocates that all LMOs, including for commodities intended for food, feed or processing that “may contain” LMOs, should be clearly labelled, as to

their contents, genetically engineered origin, name of patent owner(s), name of seed originator, name of exporter, and name of importer, and with a Statement that the Advance Informed Agreement of the competent authorities in the Party of Import has been obtained prior to export from the Party of Export; and that LMOs, including LMO-FFPs, should be segregated from non-LMOs in their handling, storage and transport.

The traceability of all LMOs, including LMO-FFPs, for example, through audit trails as part of product stewardship, enabling LMOs to be traced back to the original exporter, must also be ensured.

4. DECISION-MAKING PROCEDURES—ARTICLE 10

The basic elements to be developed by the ICCP for appropriate procedures and mechanisms to facilitate decision-making by Parties of import, should make it clear that States can impose limitations and ceilings on imports of LMOs, including LMO-FFPs, and to impose conditions on where and how they are to be grown and used, for example, to ensure that LMOs are kept away from centers of diversity or of organic production.

5. CAPACITY-BUILDING—ARTICLE 22

Capacity building is an essential part of the Protocol, and is necessary to assist all countries to develop the capacity to institute effective procedures that enable them to make full use of the provisions set out in the Protocol.

WWF recommends that as a first step to identifying the needs of signatories to the Protocol for capacity building, all signatories should be requested to review and report to the ICCP on their needs for capacity building in the field of biosafety, including the need to develop in-country expertise on the ecological effects and interactions, and risk assessment procedures for this. WWF suggests that the Secretariat be requested to draft guidelines for signatories on the preparation of such reports.

Care must be taken to ensure that capacity building encompasses all necessary expertise, including ecological and socioeconomic expertise; and to ensure that the credibility of capacity building in the field

of biosafety is maintained by ensuring that all organizations and individuals involved in capacity building activities adhere to appropriate guidelines which should be developed by the ICCP at its first meeting.

6. INFORMATION-SHARING AND THE BIOSAFETY CLEARING-HOUSE—ARTICLE 20

Establishment of the Biosafety Clearing House is an important priority to facilitate exchange of information between signatories. A prototype of the Biosafety Clearing House should be established as soon as possible, and in advance of entry into force of the Protocol for exchange of information between signatories on biosafety, including information on field trials and commercial releases of LMOs. As part of this, WWF urges signatories in conjunction with the ICCP to prepare comprehensive inventories and reviews of all field trials of genetically-engineered (GE) trees and GE fish.

1. Text from Greenpeace International [www.greenpeace.org].
2. Text from ResponsibilityInc [www.responsibility-inc.com].
3. Text from Greenpeace International.
4. Text from Convention on Biological Diversity [www.biodiv.org].
5. Department of State Press Release, January 29, 2000.
6. Text from ResponsibilityInc [www.responsibility-inc.com].
7. Text from Greenpeace International.
8. Text from the Worldwide Fund for Nature [panda.org].

Towards a common understanding of the precautionary principle?

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Summary

The precautionary principle has been a perpetual bone of contention in negotiations of international regulations and agreements that pertain to environmental protection and trade. Disagreements on this point played a role in both the failure of the Millennium Round of trade negotiations at Seattle and the failure of the negotiations on the Biosafety Protocol in Cartagena. There is no single internationally accepted definition, but common elements of most references to the precautionary principle include that precaution should govern action when indications of a potential hazard associated with a product, process or phenomenon cannot be described with sufficient scientific certainty. The main reason for the difficulties experienced in international negotiations on the subject of precaution is the fundamental divide between the United States and the European Union on this point. U.S. government representatives usually object to use of the term, mainly citing that it is not sufficiently well defined and hence lends itself to misuse as a basis for protectionist measures. Many Europeans argue that explicit reference to precaution in legal instruments will provide a legal basis for regulatory decision-making that takes into account scientific uncertainties and long-term considerations. In Europe a more formalised notion of precaution is spreading to other policy areas, most notably to the area of food safety. This trend also can be noted in the international arena, where it has recently been agreed to discuss the

precautionary principle under the auspices of the Codex Alimentarius Commission. The Codex Alimentarius Commission is the international body that determine food safety standards for reference by the World Trade Organisation (WTO). A more formal reference to the precautionary principle in Codex guidelines on risk analysis would not only contribute to the spread of the principle's relevance to policies beyond environmental policy in the international arena, but would also provide an additional entry point for discussion of the principle at WTO. The recent written contributions from the U.S. and EU delegations to discussions on the precautionary principle in the forum of Codex will be analysed in order to identify the main differences in the two official positions. The analysis will be the basis for recommendations on how to refine and frame the precautionary principle to allow a common understanding. A common language and understanding of the precautionary principle in the U.S. and the EU may provide a better basis for future negotiations of international regulations and agreements pertaining global trade and risk analysis in the face of uncertainty.

1. The Precautionary Principle as a bone of contention in international negotiations

Over the last two decades, the precautionary principle has repeatedly been a bone of contention between the European

Union (EU) and the United States (U.S.) in discussions on risk analysis and environmental protection in international fora. Recent events where differences on the precautionary principle were one contributing factor to failure of negotiations include the Millennium Round of the World Trade Organisation (WTO) in Seattle in January 2000 and the penultimate round of negotiations on the Biosafety Protocol in Cartagena, Columbia in February 1999.

One major reason for difficulties in international negotiations pertaining to risk analysis where the precautionary principle is mentioned is that there is no single internationally accepted definition. Over nineteen different definitions have been compared in detail; it has been established that these definitions differ in fundamental premises (Sandin, 1999). Common elements of most references to the precautionary principle include that precaution should govern action when there are indications of a potential hazard associated with a product, process or phenomenon if there is a lack of scientific certainty or of sufficient scientific evidence. Stronger interpretations of the principle call for absolute precaution when facing scientific uncertainty (Greenpeace, 2000). This may have significant repercussions on regulatory decision-making, as awareness of any uncertainty about a potential hazard could result in the ban of the respective product, process or phenomenon. This interpretation of the principle may jeopardise the commercialisation of new technologies, as predictions on future impacts of a technology which has no history of safe use and human exposure are usually associated with uncertainty (Miller and Conko, 2000).

Definitions of the precautionary principle can also have a 'weak form' with fewer regulatory implications, such as the definition given in the Wingspread conference "*When an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationship are not fully established scientifically.*" This represents a consensus definition of thirty-five representatives from academia, government and environmental groups (Raffensberger and Tickner, 1999). This definition is often equated to common sense. Some academics, which choose to

discuss the weaker definition, see no benefit in a legal reference to the term (Hammit, 2000). Others are in favour of a general principle, which is not seen as a 'command and control type regulatory standard', but needs secondary legislation at the national or international level to apply it to a particular procedure or discipline (Cameron, 1994). Several academics call for more detailed analysis on how the precautionary principle could be refined and implemented to improve public health and the environment (Graham, 2000a; Levidoff et al., 2000). It has also been argued that precaution embodied in legislation together with a systematic approach to risk assessment will allow a transition to more inclusive decision-making approaches on questions pertaining to safety and sustainability; this was seen as important in the context of public requests for more participation in decision-making, in particular in areas where decisions in one jurisdiction may have world-wide repercussions (Jasanoff, 2000). In the same vein, the institutionalisation of the precautionary principle is seen to provide more room for ethical and value-based concerns in risk debates and will therefore help in more general undertakings towards changing the social contract between science and society (Tait, 2000).

The inherent ambiguities of the precautionary principle in the absence of consensus definitions make discussions in the international arena particularly difficult. This is mainly because there is no common understanding of how the precautionary principle could be implemented and what the potential repercussions on decision-making dynamics would be. Questions on the legal definition, scope, trigger, and implementation prevail. Individuals involved in the negotiations are therefore likely to operate with different mental models of what is discussed and what is at stake.

A further and related problem in international negotiations is the fundamental divide between officials from the U.S. and the EU in approach to use of the precautionary principle in international regulation and agreements. Many European officials feel that explicit reference to precaution in legal instruments will provide a legal basis for the institutionalisation of more foresight in risk analysis and the adoption of measures allowing more sus-

tainable ways of development, even in the event that there is no certainty that potential present costs of such measures are justified. A large proportion of U.S. government representatives, however, argue that the precautionary approach has no place in the international arena, largely citing fear of misuse of the principle for protectionist measures.

In spite of these differences between the world's two largest trading blocks, references to 'precaution', 'the precautionary principle', 'precautionary approaches', or 'precautionary measures' have been included in a range of international legal instruments, as described below. If one important landmark event had to be identified that helped the precautionary principle to gain a foothold in international environmental policy, a strong contender would be the reference to precaution in the 'Rio Declaration' resulting from the 1992 Conference on Environment and Development held in Rio de Janeiro. The conference helped to define a set of values and laid the foundation for a range of organisational arrangements, including Conventions, Agreements, Protocols and Regulations, that include the Framework Convention on Climate Change, the Convention on Biological Diversity and the Biosafety Protocol (O'Riordan and Cameron, 1994).

Lately, discussions on the precautionary principle have been transferred from the arena of environmental policy to food policy with relevance to trade agreements, since it is being discussed in the context of Working Principles for Risk Analysis of Foods under the auspices of Codex Alimentarius Commission. The Codex Alimentarius Commission provides international guidelines and standards for food products for use by WTO. An analysis of the transatlantic dialogue on the precautionary principle under the auspices of the Codex Alimentarius Commission will be used to illustrate fundamental differences in approach to the precautionary principle between the world's two major trading blocks. This in turn will be used as a basis to explore whether—and if so, how—the precautionary principle could be refined to provide a useful tool for risk analysis, related policy questions and trade dispute resolution.

2. The role of the precautionary principle in risk analysis

As the precautionary principle is mainly used in the context of risk analysis, the basic principles of risk analysis are explained below. Risk analysis comprises the activities of risk assessment, risk management and risk communication (FAO/WHO, 1995). The first step of a risk assessment is to identify a hazard, such as potential carcinogenicity of a substance, by establishing a cause-effect relationship between the hazard and the product or process. Subsequently the hazard is characterised by an analysis of dose-response relationship of harmful effects in the target organism and characterisation of the severity of the effect. Finally, exposure assessments are conducted, which determine the distribution and quantity of release of a potentially hazardous substance and the areas where contact of the target population with the substance can be expected. This information is used to determine the distribution of the risk, and the population groups that may be at risk. These are the elements that allow a probabilistic analysis to estimate the likelihood of occurrence of harm. The risk is determined as the product of the likelihood of the occurrence of harm and the magnitude or severity of the effect. The risk assessment is usually conducted by scientific expert advisory panels set up by government agencies.

The definition for risk management used in the Codex Alimentarius Commission is "the process of weighing policy alternatives in the light of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures" (FAO/WHO, 1997). Risk management strategies include authorisation, implementation of risk management measures to minimise the risk and banning of a product or process in question to prevent the risk. Examples of risk management measures for conditional approvals include labelling of products in order to inform the target group at risk as done for food products that contain major allergens, requirements for further research or post-market monitoring provisions to better characterise the risk, or implementation of measures to restrict use of the product or process, where tools include increased taxation or liability regimes for polluting products or process-

es. Decision-making on risk management is usually separated from risk assessment, and is mostly performed by government officials. Risk communication is defined as the exchange of information and opinion on risk between risk assessors, risk managers, other interested parties and the general public (FAO/WHO, 1995; FAO/WHO, 1997).

There are at least three types of risk management decisions in the face of uncertainty where the precautionary principle may be seen to be relevant. First, for every new product or process that is regulated, such as pesticides, pharmaceuticals and genetically modified organisms, decisions have to be made within the regulatory framework as to whether the product should or should not be approved, or whether it should subject to a conditional approval.

Secondly, circumstantial evidence may indicate immediate risks associated with products or processes that are already widely used, and where choices have to be made whether they should continue to be used, or whether use should be restricted or subjected to conditions. For instance, initially there was only circumstantial evidence as to whether, and if, how much of the blood supplies in France were contaminated with the AIDS virus, a policy choice of whether to use or not to use potentially contaminated blood supplies had to be made. The impact of the choice was immediate for both proposed risk management measures and hence would have immediate political repercussions either way. Similar decisions had to be taken by the UK government in the early days of circumstantial evidence of the potential of Bovine Spongiform Encephalitis (BSE) to be transferred across species.

Thirdly, new preliminary evidence may indicate that routine human practices or combinations of practices may result in long-term, low grade, cumulative potential future harm to human health and the environment. In these cases decisions have to take into account how human well-being will be affected by use or by restraint from a practice in the present, and the resulting risks or costs to a particular target population today may have to be compared to a different risk or cost to another target population tomorrow. Political repercussions of government policies

advocating restraint today may be more important than following a policy of 'laissez faire'. Examples of such considerations are environmental problems such as the effects of greenhouse gas emissions on climate change, acid rain, and the loss of biodiversity due to increasing habitat destruction and other threats.

A reference to precaution is seen by many to provide a moral and legal justification for decisions by administrations that embody a cost in a situation of uncertainty. These considerations were the basis for explicit reference to precaution in a series of international regulations and agreements.

3. Origin and use of precaution in international environmental law

The forerunner of the Precautionary Principle is seen by many to be the 'Vorsorgeprinzip', a term coined in Germany in conjunction with the German federal environmental legislation in the 1970's (von Moltke, 1988; Boehmer-Christiansen, 1994). The definition of the precautionary principle in German law is translated as follows: "*the Principle of precaution commands that the damages done to the natural world should be avoided in advance and in accordance with opportunity and possibility. Precaution further means the early detection of dangers to health and the environment by comprehensive, harmonised research; in particular about cause and effect relationships... it also means acting when conclusively ascertained understanding by science is not yet available. Precaution means to develop in all sectors of the economy technological processes that significantly reduce environmental burdens, especially those brought about by the introduction of harmful substances*" (BMI, 1984, 53; as cited in Boehmer-Christiansen, 1994).

The then ruling social democrats first embodied the concept of foresight and precaution in new legislation on clean air, in order to address legal constraints from immediate economic feasibility and cost benefit analyses and to provide a conceptual and legal basis for more proactive longer-term environmental policy prescriptions in the constitution. The 'Vorsorgeprinzip' is seen as a moral legitimation and legal justification for greater state involvement. It is also seen to help to shift

the power from the Courts to the bureaucracy and therefore to help in the transition from greater consideration of the concerns of individuals to more collective approaches to planning. Germany's success in the implementation of the clean air act, which led to a reduction of emissions of sulphur dioxide to one sixth and of nitrogen oxides to a quarter of the original values over a ten year period was in part attributed to the legal basis of precaution for the costly retrofitting programme of large combustion plants in Germany in that period (Boehmer-Christiansen, 1994).

Since the mid-1980's, explicit references to precaution can be found in international legal instruments pertaining to the protection and sustainable use of resources of the sea, the air and the earth (for an overview see Cameron, 1994; Sand, 2000). The first explicit reference to a precautionary approach was made in relation to protection of the resources of the sea at the Ministerial declarations of the second conference on the protection of the North Sea in London in 1984 and 1987; the subsequent New Ministerial Declaration of 1990 calls for the application of the precautionary principle. Precaution has since then also been referred to in the 1992 UN/ECE Convention on the Protection and Use of Transboundary Watercourses and International Lakes, and in a series of conventions and protocols relating to the protection of marine environments, including the Baltic sea, the North East Atlantic and the Mediterranean, and the 1995 Agreement relating to Straddling Fish Stocks and Highly Migratory Fish Stocks.

Since then precaution has been embodied in other multilateral agreements. The 1992 Framework Convention for Climate Change, which states in article 3 (3) that parties should "*take precautionary measures to anticipate, prevent, or minimize the causes of climate change and mitigate its adverse effects*", it also rejects "*lack of full scientific certainty*" as a reason for postponing preventive measures. An entry point for the precautionary principle in international agreements and regulation on matters of the earth was provided for in Principle 15 of the Declaration of the 1992 Rio 'Earth Summit' which states that: "*In order to protect the environment the precautionary approach shall be widely applied by states according to their*

capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". The 1992 Convention on Biological Diversity and the resulting Biosafety Protocol also make reference to precaution. In the Biosafety Protocol Article 8.7 states that "lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of a adverse effects [...] in the Party of imports shall not prevent that Party from taking a decision, as appropriate with regard to the import of the living modified organism [...] in order to avoid or minimise such potential adverse effects".

It is generally accepted that the above are examples of explicit references to precaution in instruments of international environmental law. It has been more contested whether legal provisions relating to the functioning of the WTO, such as the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) refer to precaution.

As agreed in the Uruguay Round of Trade Negotiations, rules for the protection of consumer health and the environment for WTO Members are set out in the SPS Agreement. The Overall objective of the SPS Agreement is to permit countries to take legitimate measures to protect life and health of their consumers while prohibiting them from using those measures in a way that unjustifiably restricts trade. In the SPS Agreement Article 2 (2) states that "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human and animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence except for as provided in paragraph 7 of article 5." Article 5(7) states that "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 relevant international organisations 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 phytosani-

tary measure accordingly within a reasonable period of time." The SPS Agreement does not explicitly use the term precautionary principle in Article 5.7. It is pointed out by proponents of wider application of the precautionary principle that the report of the Appellate Body in the case on EC measures concerning meat and meat products (hormones), 16 January 1998 # 16 stated that "there is no need to assume that Article 5.7 exhausts the relevance of the precautionary principle".

There is, however, no agreement on the issue, as yet. This was illustrated by the unsuccessful attempt of the EU to include precaution on the agenda of the Millennium round of WTO negotiations in Seattle.

The failure of the negotiations on the Biosafety protocol in Cartagena, Columbia in February 1999 was partly attributed to disagreements by the U.S. and the EU on whether countries had the right to precautionary decision-making, that is, to restrict imports of Living Modified Organisms in the absence of scientific certainty of harm (Gupta, 2000). The question was linked to the highly contentious issue of the relationship to WTO obligations, such as the provisions of the SPS Agreement. In the final protocol that was agreed in Montreal over a year later, Article 8.7 spells out the right of parties to take import-restrictive actions and is said to be the first time the precautionary principle is explicitly linked to a strong risk management measure in an environmental agreement. In response, the U.S., backed by five other countries, requested a 'savings clause', stating that the Protocol could not exempt countries from obligations under other international agreements. This was not accepted by the EU or negotiators from the developing world in the main text of the Protocol, but was in the end included in the preamble. Immediately adjacent points in the text of the preamble, that were inserted on request by the EU then clarified further that the Protocol is mutually supportive with trade and other environmental agreements and not subordinate to other agreements (Gupta, 2000). Some feel that 'protectionism-minded regulators' are unlikely to feel constrained by the rights and obligations under the SPS Agreement of WTO to refuse international shipments with genetically modified crops without a valid scientific demonstration of a true risk (Miller and Conko, 2000).

Over the last five years there have been several requests in the international arena to extend references to precaution from environmental law and policy to other areas such as food law. Discussions on this question are currently taking place under the auspices of the Codex Alimentarius Commission, the international body to determine food standards for reference by the WTO. A more formal reference to the precautionary approach under Codex would both, contribute to the spread of the concept's relevance beyond environmental policy in the international arena, and provide an entry point into WTO in addition to ongoing discussions on precaution in the context of the SPS Agreement. This will be analysed in more detail in section 6 of this paper.

4. The use of the precautionary principle in the U.S.

Explicit references to the precautionary principle or to a precautionary approach have not been found in U.S. legal instruments or U.S. environmental policy documents in the cited studies (Bodansky, 1994; Raffenberger and Tickner, 1999; Appelgate, 2000).

This was confirmed in a document submitted to the Codex Committee on General Principles, in which the U.S. government states that precaution has been an inherent part of the U.S. food safety system at federal, state and local level in the executive, legislative and judicial branches of government (CAC, 2000a). Federal agencies involved in determination of food safety such as the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (U.S.DA) exercise precaution during risk assessment and management processes by identifying hazards, analysing risk and deciding on the most appropriate protective measures. Statutory requirements demand regulations to be developed in a transparent and interactive process with the public to ensure that actual and perceived concerns of food safety are taken into account. Furthermore, precaution is also embedded in the legal requirement to provide only safe foods of producers, distributors and importers; this can be enforced by injunction, product seizure, criminal punishment of producer and other penalties. Private liability laws are said to reinforce these

requirements (CAC, 2000a).

Opinions of American academics on the role of the precautionary principle in U.S. environmental policy diverge, mainly depending on the definition they chose to adopt. In an analysis of the Toxic Substances Control Act the author argued that more precaution could be asserted in the implementation of the regulation, and that a legislative change is required to correct this state of affairs (Wagner, 2000). Appelgate suggests that any risk assessment is an action based on precaution: in particular the use of 'worst case scenarios' and frequently applied 'margins for safety' are often used as a basis for risk assessments. Yet, Appelgate suggests that while implicit in some practices, precaution is not as rigorously instituted as it could be, and is often subject to challenge and overruling by other kinds of concerns (Appelgate, 2000).

In another American example Bodansky asserts that U.S. environmental regulation illuminates the difficulties in implementing a precautionary approach (Bodansky, 1994). Bodansky cites the 1970 Clean Air Act that regulates emissions of hazardous air pollutants if necessary by setting zero emission standards, as an example of a law where an excess of precaution has hampered its implementation. According to Bodansky the fact that EPA identified only seven substances for standard setting, was evidence for an intentional delay by EPA. It was suggested that in consequence, U.S. environmental policy "risk assessment and cost-benefit analysis has been increasingly stressed, both of which unlike the precautionary principle, presume we have sufficient knowledge to measure risks and calculate appropriate responses".

The analysis and conclusions of Bodansky can be challenged on several grounds. First, a distinction should be drawn between setting a standard, adopting a measure and the taking into account the underlying principle of precaution. Secondly, the Act should be judged by the effectiveness in the reduction of harmful pollutants, not by the number of molecules that are regulated. Furthermore, delays in the setting of meaningful standards could stem from scientific problems likely to be encountered in any standard setting exercise.

Finally, it is possible that there are other

reasons for the alleged failure of U.S. EPA to implement more effective measures for the management of the risk of air pollution than just a reference to excessive precaution. In 2000 the EPA Office of Air Quality Planning and standards (OAQPS) set National Ambient Air Quality Standards for six principal pollutants (EPA, 1999). Based on the ruling of a district court, one standard defined for a specific particulate matter was vacated. Furthermore, it was decided that the EPA did not have the authority to implement the revised ozone standards on the basis that "the Clean Air Act is unconstitutional as an improper delegation of legislative authority to the Environmental Protection Agency" (American Trucking Association v. EPA, 1999). The EPA has asked the Supreme Court to reconsider this decision (EPA, 1999), and the Supreme Court has decided to hear this case. The case in point supports the idea that EPA's difficulty in recommending and implementing measures towards cleaner air are more due to the larger proportionate impact of the courts and the legal profession on environmental policy definition and implementation than even the impact of federal agencies. In a comparison of German and U.S. environmental policy Boehmer-Christiansen also suggests that in the U.S. the central role of the courts leaves less room for agencies to make complex decisions than in Germany (Boehmer-Christiansen, 1994).

It could be argued that a clearer and more explicit reference to the precautionary principle in environmental law, along with explicit guidelines on the choice of risk management measures in the face of uncertainty, might have provided a more sound legal basis for EPA to set and implement safety standards. This might have helped to win the court case on the implementation of ozone standards. Similar suggestions are made based on an analysis of the Toxic Substances Control Act (Wagner, 2000). It would be interesting to verify the tractability of this argument in the context of a detailed legal analysis of the exact nature of the statutory mandates that were given to U.S. EPA and the delegation doctrine, which states that Congress, the elected representative of the American public, is the repository of all federal legislative power.

In spite of a broader delegation of sub-

stantive authority to administrative agencies becoming the rule, the Supreme Court has not invoked the delegation doctrine to invalidate a statute since 1936 (Ashford and Caldart, 1994). Some case law has contributed towards consolidation of the legal base for precautionary action (Appelgate, 2000), a particularly explicit example can be seen in the case of Ethyl Corporation v. EPA: "Where a statute is precautionary in nature and the evidence difficult to come by, uncertain of conflicting because it is on the frontier of scientific knowledge, the regulations designed to protect public health and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of effect and cause. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served." (Ethyl Cor. v. EPA, 1976).

The significance of legal action for policy making in the U.S. may also explain the reluctance of U.S. government officials to accept the use of the precautionary principle that is at present not well defined as a concept for decision-making. It could, however, be considered whether a better defined precautionary principle, together with clearer guidelines on its application and the definition of risk management measures could be acceptable and provide a more sound legal basis for proactive and longer-term considerations in environmental decision-making by governmental agencies.

5. The use of the precautionary principle in the European Union

The precautionary principle was first introduced into European Community law in 1992 in the Maastricht Treaty in Article 130R(2) on environmental policy. The subsequent Treaty of Amsterdam, effective since 1 May 1999, explicitly refers to the Precautionary Principle in Article 174 on Environmental Policy (Official Journal of the European Communities, 1997). A broad interpretation of the Treaty would support that the precautionary principle is relevant to all community policies, as Article 2 states that sustainable development is one of the key objectives of the European Union, and Article 6 states that integration of environmental concerns [based on Article 174] into all EU activities and policies is the best way to achieve sustainable development. Article 95 (3) con-

tributes to implicitly extending the notion of precaution to other policy domains such as health, safety, and consumer protection (Dratwa, 2000).

The European Court of Justice clarified the definition of the precautionary principle in case law. For example, in the case of British Beef the Court stated: “*Where there is uncertainty as to the existence or the extent of risks to human health, the institutions may take protective measures without having to wait until reality and seriousness of those risks become fully apparent*” (ground 63) “*That approach is borne out by Article 130r(1) of the EC Treaty, according to which Community Policy on the environment is to pursue inter alia the objective of protecting human health. Article 130(2) provides that policy is to aim at a high level of protection and is to be based in particular on the principle that preventive action should be taken and that environmental protection requirements must be integrated into the definition and implementation of other Community policies.*” (ground 64). (Case C-157/9 National Farmers Union, 1998). Other cases in which reference was made to precaution include cases on the implementation of Directive 90/220/EEC on the deliberate release and placing on the market of genetically modified organisms, cases on phthalates, and cases on beef hormones.

In the last legislative period from 1994 to 1999 the European Parliament has referred to the precautionary principle in over twenty seven resolutions applicable to a wide range of sectors, including fisheries, environment, and feed and food safety (Dratwa, 2000). It was, for instance, mentioned the context of the European Community biodiversity strategy, the use of antibiotics in animal feed, public exposure to electromagnetic fields, the amendment of Directive 90/220/EEC on the Deliberate Release and Placing on the Market of Genetically Modified Organisms and the Regulation EC No. 258/97 on Novel Foods and Food Ingredients.

Several fundamental elements of the Parliamentary position are outlined in the resolution from 10 March 1998 on the Green Paper of the European Commission on Food Safety. It is pointed out that food law policy should be based on scientifically backed risk analysis, supplemented where necessary by precautionary risk

management measures. The Parliament also urged the Commission that the precautionary principle and scientific understanding alone are not sufficient a basis for policy, but that consumer concerns also need to be taken into account. The Parliament also reaffirmed the overriding need for precaution in decisions on marketing genetically modified organisms in the EU (Dratwa, 2000).

The European Commission has published more detailed guidelines in the “Communication on the Precautionary Principle” (European Commission, 2000a). The aim of the Communication is four fold: first, it outlines an approach to using the precautionary principle, secondly, it establishes guidelines for application, thirdly, it is intended as a first step towards building a common understanding in the international arena of how to assess, appraise, manage and communicate risks which can not be fully evaluated by science in that instance, and fourthly, a main stated aim of the Communication is to avoid unwarranted recourse to the precautionary principle as a disguised form of protectionism.

In order to clarify *the scope* of the precautionary principle, the Commission defines that the principle applies to all areas where there are “reasonable grounds for concern of potentially dangerous effects on the environment, human, animal or plant health”. It is also specified that in a general framework of risk analysis that encompasses risk assessment, risk management and risk communication the term relates to risk management; it presents a tool for decision-makers to identify the most appropriate risk management measure when facing uncertainty.

To address the *legal trigger*, it is clarified by the European Commission that recourse to the precautionary principle presupposes that “potentially dangerous effects from a phenomenon, product or process have been identified on the basis of a detailed scientific assessment, that includes a description of areas of scientific uncertainty, and that asserts that scientific evaluation does not allow the risk to be determined with sufficient certainty.” Moreover, the selection of risk management measures should be based on the precautionary principle only where scientific evidence is insufficient, inconclusive or uncertain and where available scientific

information points to unacceptable possible risks to health.

Guidelines on the application of the principle specify that risk management measures should be proportional to the chosen level of protection, non-discriminatory in their application and consistent with similar measures already taken in equivalent areas where there was no uncertainty. Furthermore, in order to choose appropriate risk management measures a broad range of available options ranging from a research project or a recommendation to a legally binding measure should be assessed; the decision should be based on a general cost/benefit analysis of action or lack of action, including, where appropriate and feasible, consideration of economic concerns. Decision-makers have to assign responsibility for producing new scientific evidence necessary for a more comprehensive risk assessment. The application of precaution-based measures has to be subject to review in the light of new scientific data. The determination of an acceptable risk is inherently political and will be partly be based on the risk assessment and the definition of risk management measures but also needs to take into account public and political concerns.

More general comments on the decision-making process include that the process should be transparent and should “involve all interested parties as early as possible and to the extent reasonably possible” (European Commission, 2000a).

The Communication was intended to reflect the current thoughts of the European Commission on the Precautionary Principle and to serve as a basis for an international dialogue to refine the principle. Other governments and institutions in Europe and internationally were invited to provide comments on the Communication. The European Parliament (European Parliament, 2000) and the Council Presidency welcomed the initiative and endorsed the goals of the Communication. The Member States of the European Union proposed key points for guidelines of application for the principle that are fully in line with suggestions in the Communication and proposed the following definition: “*When a preliminary risk assessment indicates the likelihood of unacceptable effects on human health from hazards present in food, lack of full scientific information shall not be used as a reason to postpone*

the introduction of appropriate, proportionate measures which are intended to prevent such effects.”(CAC, 2000b). This document and the European Commission’s Communication were provided as a basis for further discussion under the auspices of the Codex Alimentarius.

6. The precautionary principle under the auspices of Codex Alimentarius

The stated objective of the Codex Alimentarius Commission is to ensure consumer protection and to facilitate international trade. Towards this aim the Committees within the Codex Alimentarius System develop standards, guidelines and other recommendations for food safety. These are considered by WTO to reflect international consensus regarding requirements for protecting human health from food borne risks. Furthermore, food safety measures of WTO Members that are based on the Codex standards and related texts are judged to be in line with the provisions of the SPS agreement (FAO/WHO, 1997).

At a conference on ‘International Trade in Food Beyond 2000’ hosted by the United Nations Food and Agricultural Organisation in Australia in October 1999 it was recognised that “precaution has been and should remain an essential element of risk analysis in the formulation of national and international standards” and it was recommended that the Codex Alimentarius Commission was the appropriate forum to further discuss this issue.

The Codex Alimentarius Commission requested the Committee on General Principles to address the question of the precautionary principle. It is now being explored whether to refer to the principle in a document on ‘Working Principles for Risk Analysis’. This document may be considered as a possible basis for international guidelines on risk analysis (CAC, 2000c). A reference to the precautionary principle in such guidelines would represent a recommendation to Governments worldwide to refer to it in food safety policy.

So far, no consensus could be reached as to whether the document section on risk management should contain a reference to precaution. Governments and international organisations were invited to comment on this question in writing. The European Commission submitted the

‘Communication on the Precautionary Principle’. This was the basis for a written exchange between the U.S. government (CAC, 2000a), the Codex Secretariat (CAC, 2000c) and the European Commission (European Commission, 2000b). This written exchange illustrates the fundamental transatlantic differences on precaution and lends itself to an analysis of how the principle would need to be refined for potential recognition by all parties as a useful tool for risk analysis and regulatory guidelines.

The U.S. welcomed the Communication as a ‘noteworthy effort to seek clarification of the EU’s complex concept’ and consented that precaution can be an integral component of decision-making, but also emphasised that decisions usually need to be made in the face of uncertainty. Further points of agreement were that decision-making procedures should be transparent and involve all interested parties, and that the authorisation of products that appear safe but ultimately are shown to be harmful should be prevented. The U.S. stressed, however, several times that the precautionary principle “can under no circumstances be used to justify the adoption of arbitrary decisions”. Moreover, no advantages to making explicit reference to the precautionary principle were recognised that could offset these potential risks.

In order to probe as to whether the precautionary principle can be applied at the international level, the U.S. government asked Codex to delineate between what aspects of risk management lie within the jurisdiction of Member Countries and what is appropriate for Codex to consider at the international level. The request was followed by a reference to the Codex Alimentarius Commissions stated principle that it’s standards and related texts have to be based on “sound scientific analysis and evidence”.

In reply, the Codex Secretariat specified that the role of Codex is two-fold, first to provide advice, recommendations, and guidelines for national governments for the harmonisation of processes for risk analysis, and secondly, to provide advice to governments on specific risk management decisions by developing standards on the basis of available scientific evidence. The current approach in Codex requires that prescriptive risk management

measures for particular products, such as standards, should not be taken when the risk assessment is not sufficient. In this respect a distinction should be made between questions on the application of precaution for decision-making at the national level and for standard setting for particular products at the international level. The latter is not acceptable. Codex asserted that the applicability of the relevant sections of the document on ‘Working Principles for Risk Analysis’ will need to be clarified in the next meeting before discussions on content, including on references to precaution, can be continued.

Several questions of the U.S. government to the European Commission pertained to the *definition and the scope* of the precautionary principle. The U.S. feared that without a clearer definition and guidelines for practical application the principle could be used to mask protectionist measures. Examples of more specific questions include: Where does the precautionary principle differ from “general principles of risk management”? How can one principle apply to the broad areas of food safety, environmental safety, human, animal and plant health?

The European Commission referred to the definition of the principle provided by the Member States (see section 5 above). It explained that the precautionary principle can apply to areas of human-, animal- and plant health and environmental protection, as it “is nothing else than a risk management policy decision that provides that lack of full scientific evidence does not prevent the decision-maker from acting.” Therefore, an explicit reference to the precautionary principle, given that it is appropriately defined, provides a basis for “taking an action” to define provisional risk management measures in a situation of uncertainty, without having to wait until more comprehensive scientific information becomes available. Furthermore, it was argued that an appropriately conducted risk assessment that points out areas of uncertainty does not necessarily give an adequate justification to define risk management measures. Discussions on the precautionary principle also provide an opportunity to define guidelines for the definition of risk management measures. These should be based on the general principles for risk management, including proportionality, consistency and non-dis-

crimination.

With respect to the proposed *legal trigger* for the application of the principle, the U.S. requested definitions of the terms “incomplete risk assessment”, “uncertainty”, and “inconclusive”. Other questions related to the legal trigger included: Given the diversity of socio-economic conditions among nations, are there aspects of precaution that while appropriate at the national level or community level would not be appropriate at an international level? How would the Commission establish preventive measures to mitigate potential risks without a scientific basis? Are political and consumer concerns placed on the same level as scientific information? How do you define an acceptable risk?

In summary, the Commission replied that the trigger depends first, on the identification of a potentially adverse effect, secondly, on the impossibility of assessing the risk with sufficient certainty, and thirdly, on the chosen level of protection within a jurisdiction. It was explained that scientific information is a prerequisite for the application of the precautionary principle. The lack of scientific certainty may stem from lack of sufficient data, their inconclusive or imprecise nature, or from divergent scientific opinions. It was ascertained that concepts of science, scientific uncertainty and risk are objective concepts of general and potentially universal application. If the evaluation shows that non-action may have undesirable health or environmental consequences, the question of adopting an appropriate protective measure arises. Consumer and political concerns then may trigger the decision to act before more scientific evidence becomes available. The decision must be deemed necessary to achieve the chosen level of protection. The countries chosen level of health or environmental protection, which is applied at national- or community-level may depend on socio-economic factors. Socio-economic factors may therefore play a role in defining the trigger of the precautionary principle. The decision to exercise precaution by the responsible regulatory authority is a political decision, because the definition of an acceptable risk that is “imposed on a society as a whole is essentially a political or societal value judgement.”

Questions by the U.S. pertaining to the

guidelines for application included: How will the precautionary principle be applied in practice and what measures would be implemented by applying it? How can one principle apply internationally, given the diversity of socio-economic conditions among nations? What considerations other than public health could come into play when selecting a particular measure? What boundaries, if any, would the Commission seek to prevent adoption of arbitrary measures or abuse? How would a cost-benefit analysis be used together with the precautionary principle? What is the distinction between the proposed precautionary principle and the SPS Agreements concept of “appropriate level of protection”?

The European Commission replied that the suggestion to establish guidelines for the definition of risk management aims precisely at avoiding unwarranted and arbitrary risk management decisions. Furthermore, it emphasised the need to clarify the precautionary principle in the WTO in order to dispel fears of its use in an arbitrary or unjustified way. It was confirmed that there is no difference in the approach to establishment of the appropriate level of protection outlined in the Communication and the relevant provisions of the SPS Agreement. Guidelines for the application of the precautionary principle would be required to confirm that risk management measures should conform to basic trade law principles such as non-discrimination, selection of the least trade restrictive measure, technical and economic feasibility and transparency. A cost/benefit analysis of all risk management measures was recognised as a necessary basis for decisions. The Commission suggested exploring whether more precise guidelines for the actual application of the precautionary principle could be developed, and proposed that this could take place under the auspices of Codex Alimentarius.

Questions from the U.S. relating to the broader context of regulatory *decision-making processes* included: What practical guidelines will exist to achieve a transparent decision-making process that involves as early as possible the views of all interested parties? Would this include opening scientific advisory meetings to the public? What is the role of governments to address higher levels of risk perception in the general public due to misinformation

spread by the media?

The Commission confirmed that guidelines to achieve more transparency, more risk communication and more active participation by the public will be part of the ongoing process to develop European risk analysis guidelines, as indicated in the European Commission White Paper on Food Safety.

7. Analysis

It is often suggested that the lack of the *definition of the precautionary principle* that provides it rallying power, both to provide the public with reassurance on general intentions to manage risk responsibly, and to use the flexibility of the term to mask a range of motives in international negotiations. In the assumption that the present situation of divergent courses in negotiations is not a tenable state of affairs, and that therefore refinement of the term in the international arena is desirable and might build on the definition provided by the European Union Member States to Codex Alimentarius, additional thoughts are presented below that might be useful in future efforts to establish guidelines for the application of the precautionary principle.

In discussions on the *legal trigger*, it might be helpful to systematically address the multiplicity of concepts that can be encompassed by the term uncertainty. Criteria for types of uncertainties that can act as trigger for recourse to the precautionary principle could be elaborated. Uncertainty may arise, both, from incomplete information, or from of disagreement of information sources. Incomplete information may arise from shortage of budget and/or time to complete the experiments. Alternatively, limits of predictive tools can be experienced that would require experiments to be set up at a larger scale or to run for longer time than technically feasible before any information can be gained that is statistically meaningful. Even where complete information exists in principle, uncertainty may persist because of simplifications and approximations introduced to make analysis of the information more tractable. There can also be uncertainty about the degree of uncertainty. Some types of uncertainties can be more easily defined and assessed than others. A more detailed assessment of uncertainty in risk analysis is provided by Morgan and Hen-

tion (1990). Furthermore, for cases in which uncertainty results from divergent scientific opinions, reference to general internationally accepted criteria might help to establish whether specific scientific information (and its source) is a legitimate base for decision-making.

Further to the points raised in the written exchange between the U.S. and the EU on *guidelines on the application of the precautionary principle* it is recommended to map out different options of risk management measures in more detail. At least four types of risk management measures have been described in documents sent to Codex Alimentarius: authorisation or non-authorisation, restriction of use, further research before or after approval, and monitoring. It might be helpful to explore whether general criteria can be defined that guide the selection of the most appropriate type of risk management measure for the different types of risks or uncertainties. With regard to the comparison and evaluation of different risk management options it could be explored whether the comparison of different options of risk management measures is sufficient, or whether decision-makers should routinely consider risks, costs and benefits of alternative products or processes in a broader risk trade-off analysis. Further, it might be discussed whether general guidelines for the weighting of risk trade-offs that may include comparisons of different types of risks to different target groups at different points in time can be established.

Approaches to risk trade-off analyses, as pertains to a wide range of applications, are described by Graham and Wiener (1995). General guidelines may also address questions on how to ensure legitimacy and maximise credibility of additional information by appropriate assignment of the burden of proof.

It would also be of interest to include more detailed guidelines on the definition of acceptable timelines for decision-making, and for the criteria that determine the need for a periodic review of the risk management strategy. It is essential to consider the institutional systems for the review process and to consider the resulting and administrative burden for administrators and applicants. In particular, where risk management measures are applicable to individual products or processes and need to be sustained over long periods of

time it should be kept in mind at all times that requirements for all present and future individual products will represent cumulative administrative burdens.

In general, comparative studies of different institutional systems for risk analysis in different jurisdictions may help to test whether the extent to which inherent institutional differences lead to diverse decision-making and is comparable to the potential effect of making legal reference to the precautionary principle. Looking at comparisons of the role of courts and the role of regulatory agencies in deciding on economic and/or social considerations pertaining to proposed risk management measures in different jurisdictions might also be of interest in the context of discussions on the precautionary principle. Such comparative analyses also provide a basis for more general discussions on harmonisation activities, and for discussions on how to manage at the international level national disparities in decision-making stemming from socio-economic and cultural differences.

8. Conclusion

Factors that differ widely between countries and affect decisions on risk management, apart from elements in the risk assessment that pertain to specific local conditions, include the institutional infrastructure for decision-making processes, the socio-economic situation, and cultural factors. These factors will contribute to shaping decisions by determining the framing of questions on risk and by influencing to what degree environmental concerns will be given primacy over economic concerns.

The written exchange on the precautionary principle under Codex Alimentarius illustrates the fundamental differences between the EU and the U.S. on the benefits or risks in relation to these factors, that are cited to be derived from referring to the precautionary principle. The two opposing positions, as distilled from the analysis of the written exchange under Codex, are described in more general terms below.

On one hand it is assumed that the definition of an acceptable risk that is imposed on a society as a whole is essentially a political or societal value judgement. Therefore, any regulatory decision will be influenced by the institutional

structure, socio-economic considerations and cultural factors. It is believed that by acknowledging this and by providing general guidelines on how to take these factors into account, decision-making processes, timelines and conclusions will be harmonised to a greater extent than if these factors are denied. Furthermore, such guidelines will make decision-making processes more transparent, allowing protectionist measures to become more apparent.

On the other hand, questions have arisen as to whether the application of the precautionary principle may exasperate the risk that regulatory authorities in different countries will come to different conclusions on what risk management measures should be proposed, even in cases where they start from the identical scientific information in risk assessments. The precautionary principle is seen to increase the risk of differential decision-making, first, because it is ill defined and can therefore easily serve as a guise for protectionist measures. Secondly, the explicit consideration of socio-economic factors in decision-making is seen to lead to different conclusions in countries that are at different levels of development. Thirdly, more inclusive approaches to decision-making give more weight to consumer concerns and political considerations that embody human values, which are likely to result in different framing of problems in diverse cultures. The resulting differences in decisions and decision-making timelines may have potential repercussions on international trade. No benefit is perceived from making reference to the precautionary principle.

These concerns will need to be explicitly addressed in order to facilitate upcoming international negotiations on the precautionary principle. The written exchange on such questions may help to provide a common language and understanding of the precautionary principle that may in turn facilitate, both, the next meeting under the auspices of Codex Alimentarius and the next round of discussions at WTO. The implementation of the Biosafety protocol may represent a first system to assess of the extent to which the precautionary principle can be misused to mask protectionist measures, and, if internationally accepted guidelines on the application of the precautionary principle

were to be elaborated, it could also be used as a first testing system for the effectiveness of such a tool.

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