16. BIOSAFETY

I. Introduction

1. Biotechnology which is the use of biological processes to develop products, has a long history and refers to a range of techniques, including selective breeding, cross-fertilization and fermentation. Generally, biotechnology has brought about many economic and human health benefits. For example, the selection and breeding of grains has produced better quality and higher yielding varieties and has expanded the use of diverse crop species well beyond their centres of origin.

2. Over the past four decades, science has evolved rapidly beyond conventional methods of biotechnology. Scientific research into the genetic properties of living organisms has revealed how several biological functions are determined through information encoded in the organisms' genes. Science has made it possible to isolate a gene and transfer genetic code, Deoxyribonucleic Acid ("DNA"), between organisms. Thus, techniques in modern biotechnology now include genetic engineering.

3. Animals, plants, and micro organisms, in which one or more foreign genes are introduced, are called "transgenic organisms". These Genetically Modified Organisms ("GMOs") [in some instances, reference is made to Living Modified Organisms ("LMOs") have combinations of genes or genetic materials that have been altered in a way that does not occur naturally through mating or recombination.

4. GMOs have potential benefits. Modern biotechnology, makes it possible to mass produce therapeutically useful compounds, vaccines, new drugs, diagnostic aids, novel or improved industrial enzymes, and crops with improved agronomic or consumer benefits. Genetic manipulation can improve the quality and quantity of agricultural production and allows the development of plants and animals that are disease- and pest-resistant. Agricultural output better sustains climatic hazards and incorporates additional vitamins and nutrients that can enhance their consumers' health. The environment also benefits from farmers' reduced dependence on fertilizers and herbicides, which, in turn, reduces pollution and allows farmers to reinvest their savings on increasing production. This leads to increased food security for the world's increasing population. Finally, efficiencies made possible by GMOs could reduce the area of land dedicated to agriculture, leaving more habitats and ecosystems undisturbed and preserving biodiversity.

5. GMOs, however, also pose serious risks. Genetic engineering raises issues of misuse, new health risks and the unintended creation of organisms or genetic traits that may irreversibly affect the world's complex ecological cycle. GMOs may also threaten human health by giving rise to new food allergies and unintended immune response to existing antibiotics and medicines.

6. With regard to the environment, use of GMOs raises concerns about the possible transfer of modified genes to naturally occurring plant and animal species. The effects of such transfers are unknown and uncontrollable. Of particular concern is the effect GMOs could have on genetic diversity in plants and animals. Large-scale farming is another potential problem resulting from society's dependence on GMOs. Mass production of identical plants and animals can lead to a loss of indigenous species. Further, as agricultural output is homogenized, it becomes more susceptible to disease and pests. This increased vulnerability could rapidly outweigh the benefits of increased food security.

7. The production of "super crops" in higher-technology countries could have deleterious effect on the agricultural markets in countries relying on more traditionally cultivated food. Small scale farmers could be disadvantaged as modified varieties displace traditional crops.

8. Large seed companies that develop transgenic crop varieties have a strong interest in preventing farmers from harvesting seed for use in the next planting season. In fact, some companies are actively considering the development of GMO technology that would genetically "switch-off" the ability of a plant to re-germinate. Supporters of Genetic Use Restriction Technology ("GURT") view this as a way of preventing growers from pirating the GMO technology, while avoiding the risk of unintended gene flow and potential contamination. Detractors of GURT, however, view it as an unnecessary and potentially exploitative business scheme aimed at forcing farmers to buy a new supply of seeds each year, an expense that many farmers, and particularly the small scale farmers, in the developing world cannot bear. Thus, the GURT issue pits farmers' traditional rights and methods against corporations' new technologies and intellectual property rights.

II. International Framework

The Development of an International Framework on Biosafety

9. Biosafety has been a matter of concern in the international community since the first GMO field trials took place in the 1980s. The use and release of GMOs into the environment, particularly transgenic plants, has provoked debate around the world.

10. The Organization for Economic Development and Cooperation ("OECD"). In 1986, published a book on Recombinant DNA Safety Considerations ("Blue Book"), which provided guidelines on scientific principles that could be applied in the assessment and management of risks associated with the development and use of GMOs. In the wake of the Blue Book, an increasing number of social groups and governments began to express their views in favour of adopting binding regulations to ensure biosafety.

11. In 1990, the European Council undertook a major step in ensuring biosafety by adopting the first international instruments regulating biotechnology. The Council issued Directive 90/219, on the contained use of genetically modified micro organisms, and Directive 90/220, on the deliberate release into the environment of GMOs ("1990 Directives"). Both of these Directives were issued to underscore the European Council's dual goals of protecting the environment from the potential threats of GMOs, while ensuring the furtherance of biotechnology. Later, Directive 90/220 was repealed and replaced by Directive 2001/18/EC.

12. The United Nations first addressed biosafety in 1991, when the United Nations Industrial Development Organization issued the "Voluntary Code of Conduct for the Release of Organisms into the Environment" ("UNIDO Code"). The UNIDO Code was developed in conjunction with the United Nations Environment Programme ("UNEP"), the World Health Organization and the United Nations Food and Agriculture Organization. The purpose of the UNIDO Code is to provide a framework for member countries in establishing an international network committed to biosafety and facilitating information exchange on the topic.

13. At the United Nations Conference on Environment and Development in Rio de Janeiro. In 1992, United Nations member countries emphasized the importance of international cooperation on biosafety, Chapter 16 of Agenda 21 specifically stresses the need to ensure safety in the development, application, exchange, and transfer of biotechnology while, at the same time, recognizing the potential of GMOs to contribute to sustainable development.

14. The issue of safety in biotechnology found also its way into the 1992 Convention on Biological Diversity ("CBD"). The Convention is, in fact, the first international legal instrument after the EC directives to provide for rules on biotechnology as regards its safe handling. The Convention also deals with the question of access to benefits arising from biotechnology. Specifically its articles 16 and 19 stipulate the importance of biotechnology in achieving the objectives of the Convention and highlight how the results and benefits of biotechnology should be distributed. Article 19 requires parties to consider the need for a protocol on biosafety. It also requires each contracting party to provide information on the potential adverse impact of living modified organisms that cross borders and on any available safety requirements.

15. In May 1992, in Resolution 2 of the Nairobi Final Act in which the Convention was approved, UNEP was invited to prioritize issues arising from the Convention, including Article 19. As a result, UNEP established a small group of experts to consider the need for and modalities of a protocol on biosafety. The experts were generally of the view that international cooperation in the fields of biotechnology and biosafety would be best served by adopting a legally binding instrument.

16. Upon entering into force in December 1993, the question of biosafety was included in the agenda of the first meeting of the Conference of the Parties to the Convention ("COP") of 1994. The first meeting of the COP established an open-ended ad hoc group of experts, nominated by governments, to meet period prior to its second meeting to consider the need for and modalities of a protocol as envisaged under paragraph 3 of article 19 of the Convention. This particular paragraph of the Convention marked both a conclusion and a beginning of international negotiations on biosafety. It reflected the final compromise that the Convention negotiators managed to make then, and provided the basis for the commencement of fresh negotiations by calling upon parties to the Convention to:

> "consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advanced informed agreement, in the field of the safe transfer, handling and use of any living

modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."

17. The second meeting of the COP was held in 1995, and in Decision II/5 the parties established an open-ended ad hoc working group ("BSWG") with the task of negotiating a biosafety protocol.

18. The BSWG began negotiations in July 1996 and the final text of the biosafety protocol, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, was adopted on 29 January 2000 ("Protocol" or "Biosafety Protocol"). The Protocol entered into force on 11 September 2003, having been ratified or acceded to by fifty parties to the Biodiversity Convention. It has currently (October 2005) 127 Parties. The first meeting of the Parties to the Protocol took place in February 2004 in Kuala Lumpur, and the second one in May-June 2005 in Montreal, Canada.

The Cartagena Protocol on Biosafety

1. General

19. The Biosafety Protocol consists of forty articles and three annexes. The Preamble explains the genesis of the agreement and sets forth its status and relationship with existing trade agreements. The first six articles outline the Protocol's objective, general provisions, terms and scope; the last six articles stipulate standard final clauses, such as signatories and entry into force. The intervening articles outline specific requirements of the Protocol, including the procedure for advance informed agreement, the procedure for introducing LMOs into the food supply; risk assessment, risk management, documentation, information sharing and the creation of the Biosafety Clearing-House, ("BCH") characterization and treatment of confidential information, capacity-building, liability and redress, and compliance.

20. The objective of the Protocol is to contribute to ensuring an adequate level of safety in the transfer, handling, and use of LMOs. Generally, the Protocol applies to all LMOs, but excludes from the agreement certain transgenics or uses of transgenics, including LMOs used in pharmaceuticals for humans and addressed in other international agreements or by other international organizations.

21. The Protocol focuses on the obligation that requires exporters of LMOs that are intended for direct release into the environment to seek prior agreement from authorities of importing countries, unless the latter agree otherwise. Importing countries, in turn, are required to subject these LMOs to risk assessment before they make decisions regarding the approval or prohibition of imports.

22. The Protocol is only one part of a broader international regime on biosafety. There are a number of other international agreements and arrangements that address various aspects of biosafety. For example, the International Plant Protection Convention addresses plant pest risks and invasive species issues associated with LMOs. The activities of the Codex Alimentarius Commission include the development of standards and guidelines for genetically modified foods, including the labelling of foods derived from LMOs. The World Organization for Animal Health develops standards aimed at preventing the introduction of infectious agents and diseases through international trade in animals; it also sets standards for vaccines, including those that are genetically engineered.

2. Some of the Specific Requirements of the Cartagena Protocol on Biosafety

23. The very adoption of the Biosafety Protocol underscores the precautionary principle that runs throughout the agreement. In regulating the international movement of LMOs, the Protocol seeks to prevent or mitigate risk by requiring that exporters obtain the importing country's prior agreement before the transgenics are introduced into the importer's environment.

a) Advance Informed Agreement Procedure

24. Central to the Protocol is the Advance Informed Agreement ("AIA") procedure that is defined in articles 7, 8, 9, 10 and 12. While article 7 of the Protocol defines the scope of the AIA procedure, the actual procedural rules are described in articles 8 to 10 and 12 of the Protocol. According to these rules, the party of export or the exporter is obliged to notify in writing and to provide minimum information to the party of import, prior to the first shipment of any given type of LMO intended for introduction into the environment of the party of import. The party of import then has 90 days to acknowledge receipt of the notification. The party of import also has to inform the notifier, whether it intends to proceed with the Protocol's decision procedure, or according to its domestic regulatory framework.

25. The decision procedure works as follows: a risk assessment must be carried out for decisions made on the import of LMOs. The exporter has to carry out the risk assessment or bear its cost if the party of import so requires. Within 90 days of notification, the party of import must inform the notifier that either it will have to wait for written consent, or that it may proceed with the import without written consent. If the requirement is to wait for written consent, the party of import has 270 days from the date of receipt of notification to communicate, in writing, its decision. The decision could be either to:
    - Approve the import and add conditions as appropriate, including conditions for future imports of the same LMO;
    - Prohibit the import;
    - Request additional information; or
    - Extend the deadline for response by a defined period.

26. A party of import may, in light of new scientific information, review and change a decision at any time and also a party of export or a notifier (exporter) may request the party of import to review its decisions. The purpose of this procedure is to ensure that importing countries have the opportunity to assess risks associated with the LMO before agreeing to its import.

27. The importing country may also take into account socio-economic considerations as specified by the Protocol, when making its decision to import. Several developing countries consider this possibility to include socio-economic risks into decision taking process as important. They believe that the introduction of a certain LMO might result in considerable risks for local farmers, and national economies, which are based to a large extent on agriculture and biodiversity. The reference to socio-economic considerations also allows for the recognition of the value of biodiversity to indigenous and local communities and thus resonates with the strong link between biodiversity conservation and the recognition and protection of traditional knowledge, innovations and practices as provided for under article 8(j) of the Convention.

28. The Protocol's AIA procedure does not apply to:
    - Pharmaceuticals for humans that are addressed by other relevant international agreements or organizations;
    - LMOs in transit to a third party;
    - LMOs destined for contained use (in a laboratory or other containment facilities only);
    - LMOs intended for direct use as food, feed or for processing (LMO-FFP);
    - LMOs that have been declared safe by a meeting of the parties to the Protocol.

b) LMOs intended for Direct Use as Food, Feed or for Processing

29. LMOs intended for direct use as food, feed or for processing ("LMOs-FFP") represent a large category of agricultural commodities. They are not subject to the AIA procedure but are covered by a separate, less restrictive procedure outlined in article 11 of the Protocol.

30. A party making a decision approving an LMO that may be subject to transboundary movement for direct use as food or feed, or for processing, for a domestic use, including releasing it into the market, must inform others through the Biosafety Clearing-House, within 15 days of its decision. Other

Comparative Summary of the AIA and Article 11 procedures

Features	The AIA procedure	Article 11 Procedure
LMOs covered	Those destined for intentional introduction into the environment	Those intended for direct use as food, feed, or for processing
Trigger	Notification	Information
Actors	• Party of export • Exporter • Party of import	• A party making decision to release (for domestic use, including placing on the market) •A potential party of import
Obligations ***1. Provision of information;***	• Annex I	• Annex II
2. Observing time limits;	• Acknowledge receipt of notification (90 days). Communicate decision (270 days)	• No general requirement exists • Developing countries and countries with economies in transition (270 days)
3. Ensuring consistency	• Consistent with the Protocol	• Consistent with the objective of the Protocol • Any party can request for it • No detailed guidance exists • Does not imply consent or refusal

Additional information	The party of import can request for it	Any party can request for it
Types/content of decision	• Approving without conditions; • Approving with conditions; • Requesting for additional information; • Extending the time for decision taking by a defined period of time.	No detailed guidance exists
Consequence of silence	Does not imply consent	Does not imply consent or refusal
Basis for decision	• Domestic regulatory framework; • The Protocol procedure (article 10); • Risk assessment (article 15, Annex III); • Precautionary approach, • Socio-economic considerations	•Domestic regulatory framework; • Risk assessment (Annex III)-where there is no domestic regulatory framework • Precautionary approach; • Socio-economic considerations.
Review of decision	It is possible to review a decision	There is no explicit provision in this regard. But it should be possible
Simplified procedure	It may be applicable where there are adequate measures for safety in place	The procedure itself is meant to be simplified
Mode of transaction	Direct between the actors (bilateral)	Through the Biosafety Clearing-House (multilateral)

parties, which may be importing the LMO, could take their own decisions regarding whether and how to import such LMO. Decisions by parties of import could be taken under their domestic regulatory framework that is consistent with the objective of the Protocol. A developing country party or a party with an economy in transition may, in the absence of a domestic regulatory framework, declare through the Biosafety Clearing-House that its decisions on the first import of LMOs-FFP will be taken in accordance with risk assessment as set out in the Protocol. In case of insufficient relevant scientific information and knowledge, the party of import may use precaution in making its decision on the import of LMOs-FFP.

c) Risk Assessment and Risk Management

32. Prohibiting or restricting the import of LMOs is a trade measure. In order for a trade measure taken with a view to help protect human, animal or plant life within the importing country to be WTO compatible, it should conform to the 1995 WTO Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"). Any such measure, in order to be in conformity with the SPS Agreement, should adopt an internationally sanctioned standard or should be based on risk assessment. The first clause in the decision procedure of the Protocol regarding whether to import LMOs for introduction into the environment establishes that such decisions shall be taken in accordance with risk assessment, which seems to be in accord with the SPS Agreement. The Protocol describes how risk assessment should be carried out and further provides for its parameters.

33. Parties to the Biosafety Protocol are required to establish and maintain appropriate risk management mechanisms, measures and strategies taking into account article 8(g) of the Biodiversity Convention. They need to take measures to prevent unintentional transboundary movements of LMOs. Risk management measures should be based on risk assessment and imposed to the extent necessary to prevent adverse effects of LMOs on biological diversity and human health. In 2005, parties adopted the "Terms of Reference for the Ad Hoc Technical Expert Group on Risk Assessment."

d) Information Sharing

34. The Protocol relies heavily on the sharing of appropriate and timely information for its effective operation and implementation. In order to facilitate the exchange of information, the Protocol has established a BCH as part of the clearing-house mechanism of Convention. The BCH is a system of information sharing and a tool for implementation. Each Party is required to make available to the BCH information specified in several provisions of the Protocol. For instance, each party has to make available to the BCH:
    (a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required for the advance informed agreement procedure under the Protocol;
    (b) Any bilateral, regional and multilateral agreements and arrangements;
    (c) Summaries of risk assessments or environmental reviews of LMOs, including relevant information regarding processed products of LMO origin;
    (d) Final decisions regarding the importation or release of LMOs;
    (e) Reports submitted by it pursuant to the Protocol, including those on the implementation of the Advance Informed Agreement procedure.

At the second MOP, the Multi-Year Programmme of Work for the Operation of the Biosafety Clearing-House was adopted.

e) Unintentional Transboundary Movement of LMOs (article 17)

35. When a party knows of the occurrence of an unintentional transboundary movement of LMOs that is likely to have significant adverse effects on biodiversity and human health, it must notify affected or potentially affected states, the BCH and relevant international organizations and give information on the unintentional release. Parties must start immediate consultation with the affected or potentially affected states to enable them to determine response and emergency measures.

f) Identification of LMOs

36. The Biosafety Protocol provides for safe handling, transport, packaging and identification of LMOs. Each party is required, among other things, to take measures to identify LMOs as "LMOs" in documentation accompanying transboundary shipments. The specific documentation requirements are defined in the Protocol in accordance with the intended use of the LMO. In this regard, it is important to note that there are some existing documentation requirements under other regimes that are relevant to some types of LMOs. For example, the United Nations Model Regulations on the Transport of Dangerous Goods specify documentation requirements for certain categories of genetically modified micro-organisms. Depending on the existence of need and appropriate modalities, there is also a possibility of developing standards for identification, handling, packaging and transport practices involving LMOs, under the Protocol in the future, by the CoP serving as the meeting of the parties to the Protocol.

g) Confidential Information (article 21)

37. Each party is required to protect confidential information received under the Protocol and identified as such by the notifier. Each party has to put in place procedures to protect and treat such information in no less favourable manner than it treats confidential information in connection with domestically produced living modified organism. The party of import shall not use confidential information for commercial purposes without the written consent of the notifier. The Protocol does not allow the notifier to identify or withhold, as confidential, any information relating to: (a) the name and address of the notifier; (b) general description of the living modified organism; (c) summary of risk assessment; and (d) methods and plans for emergency response.

h) Capacity Building (article 22)

38. Capacity building is one of the subjects addressed by the Protocol. The preamble recognizes the fact that many countries, particularly developing countries have limited capabilities to cope with the nature and scale of known and potential risks associated with LMOs. In that regard, the Protocol requires the parties to promote international cooperation to help developing countries and countries with economies in transition to strengthen human resources and institutional structure in biosafety. Parties are encouraged to assist with scientific and technical training and to promote the transfer of technology, know-how and financial resources. Parties are also expected to promote private sector involvement in capacity building. The second MOP in 2005 adopted the "Terms of Reference for the Comprehensive Review and Possible Revision of the Action Plan for Building Capacities for the Effective Implementation of the Protocol".

i) Public Awareness and Participation (article 23)

39. The Protocol requires and encourages parties to inform and involve their public in matters relating to living modified organisms. More specifically, parties are required to promote and facilitate public awareness, education and participation, including access to information concerning the safe transfer, handling and use of LMOs. The public has to be consulted in the decision-making process and the results of such decisions should be made available in accordance with domestic legislation and with a respect to confidential information as provided for in the Protocol. The Protocol further requires parties to promote and facilitate public access to information on LMOs that may be imported, as well as access to the Biosafety Clearing-House.

j) Compliance Procedures and Mechanisms (article 34)

40. The Biosafety Protocol anticipates the adoption of procedures and institutional mechanisms to promote compliance and to deal with cases of non-compliance by the Conference of the Parties serving as the meeting of the Parties to the Protocol. The procedures are already determined to be cooperative ones (as opposed to confrontational) that shall include provisions to offer advice or assistance for those parties that may be faced with difficulties to comply with the obligations of the Protocol. The compliance procedures are required to be separate from, and without prejudice to, the dispute-settlement procedures and mechanisms established by the Convention. These procedures

have been adopted by the first meeting of the parties to the Protocol. A Compliance Committee has also been established by a decision of the same meeting to implement or oversee the procedures. The second meeting adopted the "Rules of Procedure for the Meetings of the Compliance Committee under the Cartagena Protocol on Biosafety."

k) Liability and Redress (article 27)

41. The Biosafety Protocol commits the first meeting of the parties to put in place a process to elaborate rules and procedures on liability and redress for damage resulting from the transboundary movements of LMOs. It sets a desirable period of four years for completion of this task. The provision reflects the compromise that was possible at the end of the negotiations of the Protocol between the opposing views of some who sought to have detailed rules of liability and redress in the Protocol on the one hand, and those who wanted to see no provision at all concerning liability and redress, on the other. The parties to the Protocol agreed, at their first meeting, on the nature and timetable of the process envisaged in the Protocol. An open-ended ad-hoc working group of legal and technical experts is established to carry out the process in accordance with its terms of reference provided in Decision BS-I/8.

l) Transboundary Movement of LMOs with Non-Parties

42. The Protocol addresses the obligations of the parties in relation to transboundary movements of LMOs to and from non-parties to the Protocol. Movements between parties and non-Parties must be carried out in a manner that is consistent with the objective of the Protocol. Parties are required to encourage non-parties to adhere to the Protocol and to give relevant information to the BCH.

m) Administration of the Biosafety Protocol

43. The governing body of the Protocol is the COP to the Convention serving as the meeting of the parties to the Protocol ("COP-MOP"). Its main function is to review the status of implementation of the Protocol and to make decisions necessary to promote its effective operation. Only parties can take decisions under the Protocol. Parties to the Conventions that are not parties to the Protocol may only participate as observers in the proceedings of meetings of the COP-MOP. The COP-MOP may decide to use any subsidiary body established by or under the Convention, or establish its own subsidiary bodies as deemed necessary for facilitating the implementation of the Protocol. The Secretariat of the Convention serves also as the Secretariat to the Protocol.

44. At the national level, each party needs to designate a national focal point to be responsible for exchange with the Secretariat. The functions will include, for example, receiving notifications of meetings relating to the Protocol from the Secretariat and invitations to submit views on matters under discussion. Each party also has to designate at least one competent national authority to perform the administrative functions as required by the Protocol. It shall be authorized to act on the Party's behalf with respect to those functions, which may be dependent on the type of LMO(s), for which the authority is responsible. A party may decide to combine the functions of both focal point and competent national authority in one institution. A list of focal points and competent national authorities is maintained by the Secretariat and is available in the BCH.

3. Relationship of the Cartagena Protocol on Biosafety with other Agreements

45. The relationship between environmental treaties, which prohibit trade in certain goods or allow parties to ban certain goods on environmental grounds, on the one hand, and the trade regime, which seeks to restrict non-tariff barriers to trade, on the other, is increasingly becoming important. The World Trade Organization agreements such as the General Agreement on Tariffs and Trade ("GATT"), Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS") and the Agreement on Technical Barriers to Trade ("TBT"), contain provisions relevant to the Cartagena Protocol. The final text of the Protocol has not settled, in a definitive way, the question of how it relates to the WTO and other international agreements. However, in its preamble, the Protocol states that parties:
    - Recognize that trade and environment agreements should be mutually supportive;
    - Emphasize that the Protocol is not interpreted as implying a change in the rights and obligations under any existing agreements and
    - Understand that the above recital is not intended to subordinate the Protocol to other international agreements.

46. Conflict may well arise over how parties implement the provisions of the Protocol. For instance, WTO rules impose strict limitations on the use of precautionary trade measures. However, a party to the Protocol might decide, based on a small amount of scientific evidence, to ban imports

of, say genetically modified tomatoes, arguing that it is allowed to do so under paragraph 8 of article 11. In the first place this raises a question of jurisdiction. It may lead to the question of where such disputes should be dealt with or adjudicated. The WTO's Committee on Trade and Environment has expressed its preference for disputes arising from a Multilateral Environmental Agreement ("MEA"), to be handled within the proper framework of the latter. However, if the claimant in the example above asserts that the basis of the dispute is not a violation of the rules of the Protocol but that of WTO, then it is likely that the dispute might be handled under the WTO Dispute Settlement Procedure.

47. The last paragraph of the Protocol, which states that the Protocol is not intended to be subordinate to other international agreements, is very important. This language appears to be relatively strong as compared to a similar one used in another MEA adopted prior to the Protocol. Thus, in case a dispute over the implementation of the Protocol is brought to the WTO, it would be very difficult for the dispute panel to ignore the Protocol's wording even if the same preamble simultaneously states that the Protocol will not be interpreted as changing the rights and obligations of a party under any existing agreements. In any event, like any other agreement, reasonable interpretation of the Protocol depends on the understanding of its context, which includes the text, the preamble and its annexes.

III. National Implementation

48. As a party to the Protocol, a country is expected to put in place domestic implementing legislation that will allow it to adhere to the terms of the international agreement. This section presents the programmes of Indonesia, Australia, and Cuba, as examples of national biosafety frameworks. See under chapter 2 above as well of which this part is a reinforcement.

49. The number of countries that have ratified or acceded to the Protocol is growing. Each country joining the Protocol, as a party, is required to take necessary legal and administrative measures to implement its obligations under the Protocol. As implied in the previous section, the design and implementation of biosafety frameworks at national level should take into account not only the Protocol, but also a range of issues and concerns addressed by other regimes that have relevance to biosafety.

Some Examples of National Experiences in the Development and Implementation of Biosafety Frameworks

1. Indonesia

50. As one of the centres of mega biodiversity, Indonesia seeks to utilize its immense biological resources in a sustainable manner as well as to develop biotechnology. Indonesia has placed a high priority on the development of biotechnology since 1985 in order to address the need for sufficient food production in a more sustainable and performing agricultural system. It ratified the Cartagena Protocol in December 2004.

51. Indonesia established a national committee for biotechnology in 1993 at the State Ministry for Science and Technology. The purpose of the committee is to formulate policies and programmes relating to biotechnology which are overseen through a system of four national centres for excellence in agriculture and industrial and medical biotechnology. As a result of this initiative, Indonesia now has plant transformation programmes carried out at public and private research institutes, a public university, and an industrial laboratory.

52. Indonesia's biotechnology efforts are focused on a long-term strategy that involves drug discovery, genomics, conservation of germ plasma, genetic improvement of agricultural output, and marine and environmental biotechnology.

53. In 1993 the State Ministry on Research and Technology released guidelines for genetic engineering research, which control research of GMOs/LMOs. The guidelines include specific provisions that cover plants, cattle, fish and microbes.

54. Further it adopted biosafety regulations in 1997, through the Decree for Genetically Engineered Agricultural Biotechnology Products (the "Biosafety Decree"). The Biosafety Decree established Indonesia's Biosafety Commission, which advises the government on the safe release of GMOs/LMOs. The Biosafety Decree also created an expert technical team to assist the Biosafety Commission in the evaluation and implementation of procedures around the release of GMOs/LMOs.

55. Based on the early experience of the Biosafety Commission, the Ministries of Agriculture, Estate Crop and Forestry, Food, and Health issued, in