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Cartagena Protocol on Biosafety: A Report on the Investigation into the Scientific Issues, Protocol Mechanisms and Proposals.

FINAL REPORT
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Gabriela Alarcon
Mark Aranha
Amanda Bergqvist (Manager)
Alexander M'Closkey
Amy M'Guire
Julie M'Laughlin
Joanna Pajkowska
Devika Pant (Deputy Manager)
Yonathan Perl
Reis Lopez Rello
Jacob Winiecki

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Introduction

At the 1992 Earth Summit in Rio de Janeiro, world leaders agreed on a comprehensive strategy for "sustainable development" - meeting the world's present needs without compromising the ability of future generations to meet theirs. The Convention on Biological Diversity (CBD) emerged as a means to address some of the concerns outlined by the Earth Summit. The Convention, signed on January 29 2000, establishes three main goals: the conservation of biological diversity, the sustainable use of its components, and fair and equitable sharing of the benefits from the use of genetic resources. In response to growing concern about the potential risks of organisms modified through biotechnology, the CBD created the Cartagena Protocol on Biosafety to ensure the protection of biodiversity and human health. The burgeoning field of biotechnology attempts to engineer organisms that have enhanced qualities, like nutrition, to better meet the demands of a growing population. Although biotechnology holds the promise of improving the quality of human, neither the benefits not the risks of this nascent science have been proven.

The current field of biotechnology has evolved over a relatively short time. The publishing of the structure of DNA in 1953 laid the foundation for the manipulation of genes to produce desirable traits. The 1970s witnessed the first cloning, and the founding of Genetech, the first genetic engineering company. By 1984, the genetically engineered plants were being tested, followed by the marketing of consumer food products in the 1990s. The first successfully commercialized genetically modified organisms were brought to market only eleven years after their development, compared to the decades it can take pharmaceutical products to receive approval. At present, six countries dominate the commercialization of biotechnology: the United States, Brazil, South Africa, Argentina, Canada, and China; these countries account for ninety-nine percent of genetically engineered crop acreage worldwide.

The rise and proliferation of genetically engineered crops has led to fierce opposition from environmental advocacy groups for several important reasons. First, the novelty of genetically engineered food poses many unanswered questions and potential risks. Second, food and agriculture, by nature, engender strong emotions in cultures throughout the world. Third, the lack of extensive and reliable scientific tests to prove the safety of genetically modified crops on biodiversity and human health results in societal distrust and controversy.

The Cartagena Protocol on Biosafety, hereafter to be referred to as the Protocol, addresses these crucial issues of genetically modified organisms and attempts to protect biodiversity and human health. The Protocol outlines provisions that govern the transboundary movement of Living Modified Organisms (LMO) (from one country to another). A LMO is defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology,"1 including, but not limited to, genetically engineered (modified) organisms.

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[1] *"Living organism"*: any biological entity capable of transferring or replicating genetic material; including sterile organisms, viruses and viroids (Article 3).
"*Modern biotechnology"*: the application of 'In vitro' nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) that are not techniques used in traditional breeding and selection. (Article 3)

The Protocol is a unique international agreement with mechanisms for regulating transboundary movements of LMOs, facilitating information sharing between signatories (also described as member parties), and promoting scientific advancement in the understanding of LMOs behavior in the natural environment. The Protocol was ratified by the 50th country in July 2003 and came into force in September 2003. Currently, the Protocol has been ratified by 101 countries; prominent agricultural powers that are not party to this Protocol include the United States, Canada, and Argentina. The implications for these countries, and specifically the U.S.A., are complicated, and will be discussed further.

Scientific Issues Associated with the Protocol

Generally, "biotechnology" refers to the use of technology to generate products or processes from biological systems, living organisms, and their derivatives. "Modern biotechnology," as used in the Protocol, is a deliberately broad term, chosen to maintain the Protocol's flexibility in the face of rapidly changing scientific knowledge and laboratory techniques. For present purposes, "modern biotechnology" may be taken as synonymous with techniques of genetic modification, although the successful commercialization of techniques like cloning may alter this operational definition; for the moment, however, discussion of LMOs may be safely restricted to the consideration of genetically modified organisms, or GMOs. Genetically modified products are those that have been altered through the artificial insertion of genes, making them distinct from organisms created through traditional techniques like crossbreeding and grafting. Significant natural barriers, such as those that limit crossbreeding between unrelated species, and often render viable progeny incapable of further propagation, typically limit these traditional methods. Genetic modification dramatically reduces these barriers, making it possible to intermix characteristics not only of unrelated species, but also of unrelated phyla and kingdoms, with resultant self-propagating offspring.

Crop plants represent the predominant class of transgenic (genetically modified) organisms to enter both the environment and the human food chain to date. However, transgenic bacteria, fungi, animals, and fish are also being developed for use in food production and other commercial products. Initial productions of transgenic animals were mainly for biomedical research as drug-study models. Livestock breeders are working to produce transgenic cattle, sheep, pigs and chickens for human consumption, with faster growth rates, lower fat levels, and increased disease resistance.

Mechanisms of Genetic Engineering

Molecules of deoxyribonucleic acid (DNA)—made up of crosslinked chains of carbon, phosphorous, and nitrogen atoms—are the fundamental determinants of physiological characteristics and inheritance in all but the simplest organisms. Sequences of DNA are organized into discrete groups, called genes, which in turn are grouped into larger structures, called chromosomes, which mediate the transfer of genetic material from one generation to the next. Genes can be likened to a sequence of codes that specify the structure of proteins,

making them the smallest unit of DNA with discrete significance. Genes are transcribed into proteins that may, among other functions, catalyze biochemical reactions or form a structural unit of a cell, making them the fundamental building blocks for all biological activity in an organism.

The so-called 'central dogma' of genetic science is that DNA—in the form of genes—codes for a single protein, which in turn carries out a single function in an organism, for example determining eye color. This principle of 'one gene one function' is central to current applications of genetic engineering in the biotechnology industry. Reality is often more complicated than this simplified model would suggest, with single genes carrying out multiple functions and many genes needed to control a specific characteristic, considerably increasing the uncertainty of the outcome of a given genetic modification.

The actual process of engineering an organism varies considerably with the properties of a given species and the gene(s) being modified. New genetic material may be either created artificially or extracted from another organism whose traits are to be replicated. This genetic material must then in turn be introduced into the target organism, often the most difficult part of the process. Various techniques exist for injecting DNA directly into individual cells, but most commercialized methods rely upon the use of retroviral or bacterial vectors that transfer genetic material to their host organisms as a normal part of their lifecycle. While such methods allow very efficient transfer of genetic material, they suffer from a lack of specificity and increased risk that non-target organisms could be exposed to the microbiotic vectors and their genes also modified.

The physical changes that occur in a modified organism are usually biochemical in nature, and may not be observed in the physical characteristics of the organism. Altering genes that code for enzymes—the proteins that regulate chemical reactions—has the potential to alter an organism's metabolism, or its chemical response to its environment. For instance, a certain variety of genetically modified tomatoes are modified so as not to produce an enzyme that causes the tomato flesh to soften after it has been picked. The actual production and storage of a protein in an organism may also be altered, in order to control its nutritional value to humans. Soybeans, rice, and corn have all undergone various types of modification to increase their nutritional value, so that least-developed populations may have access to better opportunities for nutrition. The technique may also have application in promoting disease resistance, in cases where certain proteins may confer enhanced immunity to a particular pathogen. The reproductive mechanism of an organism may also be altered, usually by promoting sterility in male individuals. Male sterile plants do not produce pollen, making it easier to breed improved hybrids that yield and perform better, and to produce hybrid seed more economically Sterility also helps ease concerns that genetically modified crops will spread their enhanced genetic characteristics, such as herbicide resistance, to wild plants. Finally, genes endogenous to an organism may be suppressed. Partial or total suppression of gene expression can be used in order to avoid undesirable traits. By introducing a new gene with reverse orientation of nucleotides, undesired genetic function is effectively cancelled out.

Potential benefits of genetic engineering

Genetic engineering promises considerable benefits for medicine, agriculture, and other fields. These may include new medical treatments and vaccines, new industrial products, and improved fibers and fuels. Proponents of the technology argue that biotechnology has the potential to lead to increases in food security, decreased pressure on land use, sustainable yield increase in marginal lands or inhospitable environments, and reduced use of water and agrochemicals in agriculture. In the future, diseases may be prevented by determining subgroups of humans, plants, and animals genetically prone to a certain disease and using genetic engineering to "prepare" individuals for the inevitable. These infectious diseases may be treated by implanting modified genes coded for antigen-specific antiviral proteins. Animals and plants can be 'tailor-made' to display desirable characteristics, such as engineering trees to absorb more carbon dioxide, possibly reducing the threat of global warming.

Some believe that genetic engineering can increase biodiversity by producing more variant alleles. An allele is a form of a gene that codes for one possible outcome of a phenotype (an outward physical manifestation, for example eye color). These alleles can be crossed over and implanted into other species to increase biodiversity. Most of these outcomes, however, have yet to be achieved, or insufficient data exists to adequately assess the desirability of modified organisms. Despite this lack of evidence, however, both the creation of new organisms and the wholesale adoption of them, especially in agriculture, continue at a breakneck pace.

Potential drawbacks of genetic engineering

The possible outcomes of interactions of modified organisms with the ecosystem remain largely unknown, and along with the potential benefits discussed above, various stakeholders have expressed concern about the potential adverse effects of genetic engineering on biological diversity and human health. Of especial concern are potential unintended changes in target and non-target species. Genetic pollution is the uncontrolled spread of modified genes from modified to previously unmodified organisms. Such unintended transfer of genetic material could occur through a variety of mechanisms, for example through the microbiotic vectors used to effect the initial modification. Natural processes such as pollination also have the potential to carry genetic material from modified to unmodified organisms, with unpredictable or undesirable results. For example, if genes for pesticide resistance were to leak from crops to weeds, pesticide-resistant "superweeds" could be produced, requiring increased, rather than decreased, use of agrochemicals. The potential risks of such genetic pollution have prompted many countries to take aggressive action against crops that appear to have been polluted with foreign genes, or to mitigate the potential risks by requiring buffer zones around fields of genetically modified crops.

In a related concern, the use of modified crops has the potential to alter the environment in unanticipated ways. The insect-killing toxin of the BT (Bacillus thuringiensis) bacteria has been used for years by organic farmers to spray crops. The toxin protects the plants against

moth larvae that burrow into plant stems. In its natural form, BT breaks down rapidly in sunlight, but studies on BT-enhanced GM maize plants have shown that BT persists in the soil for weeks, contrary to expectations (Saxena et al. 2002). Besides harming benign soil organisms, BT pollution through its persistence in the soil could lead to selection for pests resistant to it. This would negate the very premise for introducing the toxin into the maize.

It is also possible that unintended changes will occur in the target species. Genetic engineering is an imprecise science, often relying heavily on trial-and-error approaches, to say nothing of the difficulty of predicting outcomes in nature based on controlled laboratory data. For example, when engineers alter the sugar or starch composition of a plant, they often find unexpected changes in plant composition and behavior in the environment. Researchers modified a variety of soybeans using Brazil nut genes in order to improve the nutritional content of the crop. This effort was abandoned when it became apparent that commonly held allergic reactions to Brazil nuts were also evoked by the modified soybean. Such 'hidden' import of bad function with the good could undermine long held medical knowledge and food safety habits, with potentially deadly effect.

Changes in the competitiveness, virulence, or other characteristics of the target species could also lead to problems for non-target species that are in competition with the target species, affecting ecosystems both directly and indirectly. Intensification of agriculture tends to reduce biodiversity, with many formerly common agricultural varieties disappearing in favor of modified crops. Indirectly, biodiversity may also be threatened by rapid changes in water and land use patterns that often occur following the introduction of modified crops.

Direct threats to human health are mostly putative; none have been documented or proven. However, the risks are real, including virus creation or reactivation due to the use of viral promoters, increased pesticide residue on resistant crops, and superbugs created through selection for resistance. The State of Food and Agriculture 2003-04 report issued by the U.N. Food and Agricultural Organization states that "the international scientific community agrees that foods derived from the transgenic crops currently on the market are safe to eat and have been appropriately evaluated. However, new crops involving multiple transgenes may require additional food-safety risk-analysis measures." It should be noted that the long-term risks to health cannot be assessed at present, since the consumption of these foods began as recently as the early 1990s.

Protocol Framework and Implementation Mechanisms

The framework of the Protocol aims to mitigate any potential effects to biodiversity by employing the Precautionary Principle. The Principle states that "parties may err on the side of caution when there is lack of scientific certainty about the impacts of LMOs and until there is evidence to demonstrate adequate safety.'' The Protocol and Precautionary Principle applies to LMOs intended for cultivation and excludes pharmaceuticals, processed foods, food additives and food derivatives containing LMOs. Examples of LMOs addressed by the Protocol include agricultural crops genetically modified for increased productivity or for resistance to pests.

The manner in which the Cartagena Protocol seeks to ensure the safe transfer, handling and use of LMOs is through the following primary mechanisms: the Biosafety Clearing-House (BCH), Risk Assessments, and the Advanced Informed Agreement (AIA)

Biosafety Clearing-House

The Biosafety Clearing-House (BCH) is an information exchange mechanism established to assist Parties in implementing the provisions of the Protocol and to facilitate sharing of information on, and experience with LMOs. The Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP)2 recommended that the Biosafety Clearing-House start with a pilot phase, which is now fully operational. The BCH facilitates the exchange of scientific, technical, environmental and legal information regarding LMOs (Article 20). To ensure Protocol compliance, the BCH mandates the submission of a risk assessment study of the specific LMO, by the exporter, before its transboundary movement is executed. The BCH thus assists in implementing the Protocol and makes special reference to its function in assisting countries that otherwise lack the technical, legal and financial capacity for risk assessment on their own.

Risk Assessment Procedure

Risk assessment is the Protocol's primary tool for ensuring the safety of LMOs in use and transit. The Protocol requires that the importing country review detailed risk assessment data prior to approving any import. Thus, the timely submission of accurate, complete risk assessment data on an LMO is critical to the functioning of the Protocol.

Article 15 of the Protocol requires that risk assessments be carried out in accordance with the following two principle components: "(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."

An environmental risk assessment requires the identification of three fundamental components: (1) the presence of a potentially harmful agent at levels sufficient to be dangerous; (2) the existence of a receptive (and thus at-risk) population; and (3) an exposure pathway between the harmful agent and the receptive population. Annex 3 Sec. 9 details additional information that may be useful in risk assessment, such as: (c) the vector by which the modification is effected; (d) information about the genetic insert or inserts and/or characteristics of modification; and (h) characteristics of the receiving environment. This

[2] The IPCC was created to prepare for the first meeting of the Parties to the Protocol, after which it ceased to exist exist.

information may be useful in establishing non-specific threats to the environment, such as those posed by genetic pollution.

Advance Informed Agreement

The "Advance Informed Agreement" (AIA) procedure ensures that importing countries have both the opportunity and the capacity to assess risks that may be associated with the LMO before agreeing to or accepting the import. The AIA has four components: notification by the Party of export (the exporter), acknowledgment of receipt of notification by the Party of import, decision procedure and review of decisions. Specifically, the exporter must notify the importer by providing a detailed, written description of the LMO in advance of the first shipment. The Party of import is to acknowledge receipt of this information within 90 days. Then, within 270 days of the date of receipt of notification, the Party of import must communicate its decision: (i) approving the import, (ii) prohibiting the import, (iii) requesting additional relevant information, or (iv) extending the 270 days by a defined period. Except the cases in which consent is unconditional, the Party of import must indicate the reasons on which its decisions are based. A Party of import may, at any time, in light of new scientific information, review and change a decision. An exporting Party may also request the Party of import to review its decision.

In short, the Protocol ensures that its objectives are achieved through this set of information-sharing and assessment mechanisms. Countries are obliged to submit and review risk assessments for LMOs intended for transport and use through the BCH. Importing countries then have the ability to grant or refuse entry of such LMOs into their borders via the AIA. In addition to the challenges faced in reaching its objectives, the Protocol faces major obstacles to implementation.

Obstacles to Protocol Implementation

Uncertainties in Risk Assessment

As previously mentioned, risk assessment study requires (1) the presence of a potentially harmful agent at levels sufficient to be dangerous; (2) the existence of a receptive (and thus at-risk) population; and (3) an exposure pathway between the harmful agent and the receptive population. In risk assessments pertaining to LMOs, identifying a potentially harmful agent and the existence of a receptive population is generally easy to determine. However, determining the exposure pathway is more complex, often relying on computer modeling (e.g. to track dispersal of modified pollen into surrounding fields). The models used at present to study pollen dispersion rely on various laboratory and computer modeling experiments to determine potential exposure pathways. The lack of calibration data and the uncertainties in these techniques may lead to results with low scientific credibility. Furthermore, while it may be possible to identify the three risk assessment components, the potential threat to biodiversity may not emerge until the LMO has been introduced into the natural environment. A famous

example of this lack of scientific consensus is the case of genetically modified (GM) maize pollen and its potential harm to Monarch butterflies. A study entitled 'Transgenic Pollen Harms Monarch Butterfly' (Losey et al. 1999) received substantial media coverage, which fixated on the title of the study and led to massive public opposition to Bt-maize. However, a follow-up study determined that the original study lacked credibility, as it was based on laboratory and in-field tests alone, therefore lacked environmental and behavioral investigations. Supplementing the original study with environmental and behavioral assessments showed that Bt-maize may be an "improvement" over current pest-management practices for non-target organism survival (Niller 1999).

While the Protocol tries to provide a standard framework for countries to assess the risks posed by LMOs, this controversy illustrates how difficult it is to establish the "safety" of LMOs. This is further complicated by the lack of standardization in terms of the risk assessment procedure across countries. For example, Monsanto, the leader in biotechnology in the U.S.A., performs only limited testing of their LMOs focused on adverse effects to human health and the extent to which they exhibit the bioengineered genetic desirability (i.e. drought, herbicide and insect resistance). Historically, European governments and consumers have exhibited distrust for similar risk assessment reports, citing their limited studies of potential risks. This aspect of the Protocol would disadvantage Monsanto and other biotechnology and agribusiness companies trading LMOs with Cartagena member parties, as some members would be inclined to reject such products.

Contentious position of Developing Nations

Another important concept of the Protocol is that it grants equal rights to all member parties. This provision allows all member parties to participate in the decision-making process equally. To facilitate this, special considerations are made for less developed countries in order to assist in the import decision-making process. In this regard, the Protocol acknowledges the need for funding, technology and training. However, the source of funding and donors of essential biotechnology have not been specified and remains a significant uncertainty in the Protocol.

Furthermore, by adopting the Precautionary Principle, developing nations reserve the right to refuse scheduled LMO imports. Not surprisingly, most of the current international controversies regarding the Protocol stem from this right. The leaders in biotechnology (U.S.A., Canada and Argentina) feel that the benefits of LMO crops, such as drought-survival and the possibility of ameliorating malnourishment in impoverished populations far outweigh the potential, and unproven, risks. These ideological differences create situations that require legal intervention insufficiently addressed in the Protocol.

Lack of a Regulatory Mechanism

Under the Protocol, it is unclear what governing body will address the legal liability and redress described in Article 27 as it applies to international transactions. The Protocol fails to provide a solution to the conflict between international trade rules and environmental regulations, outlining the relationship as "mutually supportive." While the Protocol clearly recognizes a country's right to use the Precautionary Principle in decision-making, it does not provide a solution to situations where environmental protection may take precedence over a country's legal obligations under international trade. Moreover, doubt exists in the ability of least developed countries to prosecute illegal transboundary movements (as suggested) under defunct and corrupt legal systems. This conflict will undoubtedly continue as the Protocol continues to be implemented and applied across the globe.

Political and Trade Implications

The Protocol contains a complex and highly negotiated text that addresses the relationship between trade rules and environmental agreements with an underlying philosophy of the Precautionary Principle. With regard to trade and present international treaties, the Protocol does not mandate a change in the rights and obligations of any country, but also does not intend to subordinate the Protocol to other international agreements. Many stakeholders view these provisions as contradictory. Further, this lack of clarity has led to disputes that question the hierarchy of the Protocol with respect to other international agreements.

A number of agreements under the WTO, such as the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), the Agreement on Technical Barriers to Trade (TBT), and the Agreement on Trade-Related Intellectual Property (TRIPs) contain provisions that are relevant to the Cartagena Protocol. However, while the SPS measure assigns the burden of scientific proof to the nation imposing trade restrictions, the Cartagena Protocol assigns that burden to the originator of the produce; the mechanism for this proof being the results of the risk assessments study. In accordance with the Protocol, member parties have the right to reject scheduled LMO imports based on the risk assessment studies. This ability to refuse imports based on risk-assessment studies has led to a polarization within the member countries that reflects the competing interests at stake. Because of these economic and ideological differences, during the Protocol meetings, countries formed alliances to address their concerns. The following three alliances reflect the diverse interests and priorities of some of the key member countries:

1. The Miami Group – consisting of the U.S.A., Canada, Argentina, and other agricultural exporters, argued that the scope of the Protocol should not include products derived from LMOs (final food products), and highlighted the lack of "actual" threats to biodiversity. The Miami Group insisted that import decision-making should be based on 'sound-science' as outlined in WTO requirements. This group further insisted that the Precautionary Principle need not be added to the Protocol, as no actual threats to biodiversity or human health have been proven, and identified the Protocol itself as a precautionary measure.

2. The Like-Minded Group - consisting mainly of agriculture-importing developing countries demanded the right to refuse LMO imports, and requested the inclusion of products derived from LMOs.

3. The Compromise Group and the European Union - positioned between the above two groups, requesting a labeling system, and adoption of the Precautionary Principle.

This spectrum of interests has manifested in disputes that arise from the ability of importing countries to restrict import based solely on the Precautionary Principle. In one such current case (May 2003), U.S.A., Canada and Argentina (the Miami Group) asked the WTO to invalidate the current EU moratorium on GM crops, claiming that the moratorium was harming the livelihoods of their farmers and food. This WTO decision is due at the end of 2004, and will be a milestone in determining the importance and existence of the Cartagena Protocol in the current political and economic scenario.

Implications of the Protocol for the United States

Currently, the U.S.A. has not ratified the Cartagena Protocol. While the decision making process for the ratification is underway, an important aspect of the Protocol to consider is the provision that member Parties are permitted to engage in transboundary movements of LMOs under "bilateral, regional and multilateral" trade agreements only if they do not "result in a lower level of protection than that provided for by the Protocol." Hence, according to the Protocol, the U.S.A. must abide by their provisions in order to access member Parties' LMO markets regardless of whether the U.S.A. decides to ratify.

The Cartagena Protocol makes special considerations to less developed countries and aims to cooperate with "financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention." Such transfer of technologies and money could be seen as a burden on the wealthier, LMO-producing countries like the U.S.A. However, the benefits of Protocol ratification have the potential to outweigh these costs. Since 101 countries have ratified the Protocol to date, U.S.A. ratification will enable better access to their markets. Another consideration for ratification would be that in the absence of U.S.A. ratification and participation, the Cartagena Protocol's procedures and provisions will most likely be implemented in ways that are not favorable to U.S. interests.

In the end, taking measures to make U.S.A.-produced LMOs acceptable by Cartagena member Parties is necessary. Hence, to prepare for complying with the agenda set forth by the Protocol, the U.S.A. would need to assess its present position and plan for its future needs. This would require the U.S.A. to broaden its scope of LMO risk assessment studies and establish a comprehensive risk assessment methodology, following both the model of risk assessment already practiced by LMO-producing companies, and complying with the requirements of the Protocol.

Future Direction

Since the Protocol came into effect, in February of this year, it has taken several important steps towards developing essential scientific and regulatory procedures. Recently, the Conference of the Parties established a Compliance Enforcement Committee and an Open-ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress. The creation of these Groups will help establish a framework for mandating Protocol compliance, therefore making the Protocol more effective. However, the Protocol still necessitates greater global participation and further development of its regulatory components. The current trade dispute under the WTO threatens to derail the Protocol's functionality. The Miami Group, who filed the dispute, argues that WTO rules prohibit discrimination against agricultural products based on their development (breeding, hybridization, or bioengineering). If the WTO rules in its favor, the Protocol will have the legitimacy necessary to regulate the international trade of LMOs. In this case, the Protocol has the potential to protect biodiversity and facilitate the advancement of LMO science and understanding.

The current science behind assessing the risks of LMOs is not able to predict the exact effects of global release of LMOs on the environment and human health over long periods. The Protocol is, however, likely to raise risk assessment study standards. With time, the scientific risk assessments mandated by the Protocol are thus expected to become increasingly more sophisticated and reliable, generating more conclusive and reliable results about the behavior and effects of LMOs in the natural environment. This trend can be further advanced by increased information sharing through the BCH.

Furthermore, models such as spatially explicit simulation will be able to provide more precise estimates of risks posed by LMOs. These models take into account the life cycles of the particular LMO as well as those of key insects (i.e. moths or monarch butterflies), potential locations of crops, natural areas and weather conditions. By using actual datasets for all relevant variables, spatial models can estimate the worse case scenario for each potential cultivation region. While they are not a substitute for scientific field and lab studies, these models can be used in conjunction with current tests to more accurately assess LMO risks and thus help increase public confidence.

To ensure that the Protocol achieves its objectives, a monitoring strategy is needed to evaluate implementation success. This requires a set of indicators that try to objectively measure a set of selected variables over time to determine success. As of now, the Protocol does not outline indicators for success measurement. Article 7 of the Protocol and the decision made during the Expert Meeting on Indicators of Biological Diversity (February 2003) invite the Parties to develop a set of indicators based on their own priorities.

An effective set of indicators that could be used on a national level, should address issues such as: (a) the level of implementation of the Protocol; (b) the economic benefits derived from the ratification of the Protocol; and (c) the effects of biotechnology on biodiversity. A set of ten key indicators have been proposed for this purpose (see Appendix 3). This information may provide credibility with other Parties already providing this information to the BCH, and begin to track the economic benefits of ratification.

From a U.S.A. perspective, the data needed for these indicators would be relatively easy to obtain, from departments such as the Environmental Protection Agency, the United States Department of Agriculture and United States Department of Commerce.

Conclusion

Through the various mechanisms and regulations discussed, the Cartagena Protocol attempts to address the potential risks to biological diversity associated with the transboundary movement of Living Modified Organisms (LMOs). On one hand, potential LMO benefits promise to feed the world's growing population by overcoming the natural limitations of agricultural crops. On the other, potential risks threaten indigenous biological diversity, environmental and human health. The Cartagena Protocol is a milestone in international agreements for several reasons. It addresses the inchoate issues surrounding genetic engineering, which are a result of the accelerating pace of technological growth, by employing the Precautionary Principle. It creates a framework for addressing ethical and cultural issues, as well as scientific controversies regarding LMOs at an international level. Lastly, it has the potential to generate important advancements in scientific risk assessment, which will provide more accurate cost benefit scenarios of using LMOs as viable solutions to natural agricultural challenges.

Currently, although the legality of the Protocol is being questioned by a WTO dispute committee, the significance of the Protocol in addressing global concerns is not mitigated. The 101 signatories to the Protocol are reflective of its global importance. The increasing land area of LMOs being cultivated further suggests that the controversies and threats encompassed by their production require global collaborative action. Although there is scope in the Protocol for further enhancement and clarity, the Protocol has the potential to fulfill this role of a global facilitator.

Appendix 1: Summary of Articles

Article 1 - Objective: The objective of 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.

Article 2 - General Provisions: The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that upholds the objective of this Protocol. This Protocol shall not affect in any way the sovereignty of States over their territorial rights and their jurisdiction or restrict the right of a Party to take a more protective action for the conservation and sustainable use of biological diversity.

Article 3 - Use of Selected Terms in the Protocol:

"Contained use": any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms controlled by specific measures that effectively limit their contact and impact on the external environment.

"Living modified organism" (LMO): any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

"Living organism": any biological entity capable of transferring or replicating genetic material; including sterile organisms, viruses and viroids.

"*Modern biotechnology*": the application of 'In vitro' nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) that are not techniques used in traditional breeding and selection.

"Transboundary movement": the geographic movement of a living modified organism from one Party to another Party, or to non-Parties.

Article 4 - Scope: The Scope of this Protocol applies to the transboundary movement, transit, handling and use of all LMOs that may have adverse effects.

Article 5 - Pharmaceuticals: This Protocol shall not apply to the transboundary movement of pharmaceuticals for humans that are addressed by other relevant international agreements or organizations.

Article 7 - Application of the Advance Informed Agreement Procedure: The advance informed agreement procedure shall apply prior to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import. It does not refer to living modified organisms intended for direct use as food or feed, or for processing, nor to the LMOs identified as being not likely to have adverse effects on the conservation and sustainable use of biological diversity.

Article 8 - Notification: 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 LMOs. The notification shall contain, at a minimum, the information specified in Annex I.

Article 9 - Acknowledgement of Receipt of Notification: The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.

Article 10 - Decision Procedure: The Party of import (within two hundred and seventy days) shall inform the notifier and the Biosafety Clearing-House, in writing of: Approving the import; Prohibiting the import; Requesting additional relevant information; or Informing that the period specified in this paragraph is extended by a defined period of time.

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a LMO shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question..

Article 11 - Procedure for Living Modified Organisms Intended for Direct Use as Food or Feed, or for Processing: A Party that makes a final decision regarding domestic use of a LMO that may be subject to transboundary movement for direct use as food or feed shall inform the Parties within fifteen days through the Biosafety Clearing-House. It should contain the information specified in Annex II. A developing country or a Party with an economy in transition may and in the absence of the domestic regulatory framework declare through the Biosafety Clearing-House that its decision (prior to the first import of a LMO) will be taken according to a risk assessment undertaken in accordance with Annex III, or/and a decision made within a predictable timeframe. Such Party will have to indicate its needs for financial and technical assistance and capacity-building with respect to LMOs intended for direct use as food or feed, or for processing.

Article 12 - Review of Decisions: A Party of import may, at any time (under specific circumstances) 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 LMO referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

Article 14 - Bilateral, Regional and Multilateral Agreements and Arrangements: Parties may enter into bilateral, regional and multilateral agreements regarding intentional transboundary movements of LMOs consistent with the objective of this Protocol.

Article 15 - Risk Assessment: A thorough risk assessment of the LMOs intended for transoundary movement must be undertaken before the acceptance of LMOs by importer parties. These risk assessments shall be carried out in a scientifically sound manner in accordance with Annex III.

Article 16 - Risk Management: The member parties of the convention shall establish, manage and control risks identified in the risk assessment relevant to the use, handling and transboundary movement of LMOs. Any LMO that has been imported or developed locally must be observed for a period appropriate to its life-cycle or generation time before it is put to intended use by member parties.

Article 17 - Unintentional Transboundary Movements and Emergency Measures: In the case of an unintentional transboundary movement of or an emergency caused by a LMO, each party is responsible to notify affected or potentially affected states, the Biosafety Clearing-House and relevant international organizations.

Article 18 - Handling, Transport, Packaging and Identification: LMOs that are subject to transboundary movement must be used, handled, packaged and transported under conditions of safety in order to avoid possible adverse effect on the conservation and sustainable use of biological diversity and human health. This Protocol also requires that LMOs intended for transboundary movement are identified for their relevant traits and characteristics.

Article 19 - Competent National Authorities and National Focal Points: At their date of entry into the Protocol, each party shall designate a focal point responsible for liaison with the Protocol Secretariat.

Article 20 - Information Sharing and the Biosafety Clearing-House: In concordance with article 18, a Biosafety Clearing-House is hereby established to facilitate the exchange of scientific, technical, environmental and legal information on and experience with LMOs. The Clearing-House will as assist parties to implement the Protocol, as well as make information available regarding existing law, regulations, and guidelines; any bilateral, regional and multilateral agreements and arrangements; summaries of risk assessments or environmental reviews of LMOs; its final decisions regarding the importation or release of living modified organisms.

Article 21-Confidenial Information: The importing and exporting parties have the right to submit a written request that information regarding the risk assessment and transboundary movement of the LMO in question remain confidential.

Article 22-Capacity Building: The Protocol favors the expansion and development of human resources & institutional capacity regarding Biosafety and biotechnology for the purpose for the effective implementation of this Protocol. Special attention shall also be given to developing countries to strengthen their capacity with financial support, know-how and training as to reach favorable level for the institutionalization of biodiversity research, including the private sector level.

Article 23 - Public Awareness and Participation: Mandates development of public awareness and education concerning the safe transfer, handling and use of biological diversity. The parties shall endeavor to ensure public access to information on LMOs in accordance with the Protocol and consult the public in the decision making process.

Article 24-Non-Parties: The Parties in the Protocol should promote movements of modified organisms between Parties and non-Parties, by adhering with the objectives of the Protocol.

Article 25 - Illegal Transboundary Movements: Each party shall implement appropriate domestic measures to prevent, and if necessary, penalize the illegal transboundary movement of LMOs carried out in contravention of this Protocol.

Article 26 - Socio-Economic Considerations: Parties may take into account socio-economic considerations of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities, when reaching a decision on import under this Protocol.

Article 27 - Liability and Redress: The conference of the parties shall adopt a process for the appropriate elaboration of international rules and procedures regarding liability and redress for damage resulting from transboundary movements of LMOs.

Article 28 - Financial Mechanism and Resources: Finances shall be managed by the Protocol and that special consideration will be given to developing countries.

Article 29 - Conference of the Parties Serving as the Meeting of the Parties to this Protocol: The conference shall serve as the meeting of the parties during which they will be the authorities and will administer the Protocol compliance. Non-parties will be only allowed to observe the proceeding but not to participate. These bodies will have the power to make recommendations for the Protocol, as well as create subsidiaries, call for external help of organizations in case of need, decide the course of escalation of the subject within their authority, and take other actions that may be required for the implementation of the Protocol. The Conference will have a secretariat and will also seek aid from the United Nations in case of need as this last specializes in International Atomic Energy.

Appendix 2: Mechanisms of transboundary LMO regulation

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) Centres of origin and centres 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.

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) Centres of origin and centres 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, labeling, documentation, disposal and contingency procedures, where appropriate.

RISK ASSESSMENT:

To fulfill 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.

Appendix 3: Proposed Indicators

PROPOSED INDICATORS OF PROTOCOL SUCCESS

Within the U.S.A. and between the U.S.A. and its trade partners
Compliance with Article 34 regarding substantive progress toward the goal of protecting biodiversity: 1. *Differences in Shannon's biodiversity index levels between similar areas exposed to LMOs and unexposed ones.*
Comparison between the number of notifications of unintended releases of LMOs inside the U.S.A. and the number of notifications for deliberate transfer and use of LMOs into the U.S.A.: 2. *Percentage of unintended releases of LMOs inside the U.S.A.*
Comparison between the number of notifications of unintended releases of LMOs inside U.S.A.-trade partners and the number of notifications for deliberate transfer and use of LMOs into those countries: 3. *Percentage of unintended releases of U.S.A.-produced LMOs in other countries*
Comparison between the value of U.S.A. LMO-trade before ratifying the Protocol and the value of LMO-trade after ratifying it: 4. *Increase in trade value, from ratification of the Protocol ($)*
Global Protocol implementation
Relative involvement of the international community 5. *Number of countries that have ratified the Cartagena Protocol, compared to the total number of countries that have ratified other major environmental treaties: Rio Declaration, Montreal Protocol, and Kyoto Protocol.*
Compliance with Article 8(2), regarding notification requirements provided by the exporter: 6. *Number of countries who have established legal requirements for the accuracy of the Annex I notifications.*
Compliance with Articles 9(1) and 10(3), provisions for receipt of notification and communication of final decision: 7a. *Number of importing countries who provide written receipt of Annex I notifications within 90 days of receipt* 7b. *Number of importing countries who provide their written final decisions within 270 days.*
Development of Article 17 emergency response procedures: 8. *Mean response time for controlling unintended LMO transfers.*
Condition of Article 25 legal provisions in the country: 9. *Existence and enforcement of legal provisions regarding illegal movements of LMOs.*
Status of Article 27 redress mechanisms: 10. *Existence of provisions to assign liability for damages resulting from transboundary movements of LMOs.*

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