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Cartagena Protocol on Biosafety: A Report on Policy Analysis, Program Design and Implementation

FINAL REPORT
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EXECUTIVE SUMMARY

Adopted in 2000 by the United Nations *Convention on Biological Diversity* (CBD), the *Cartagena Protocol on Biodiversity* is one of the most significant international treaties in recent years. In accordance with the CBD, the Cartagena Protocol's objective is to ensure an adequate level of protection from the potential risks posed by living modified organisms (LMOs), which is a term used for organisms that have been genetically modified through modern biotechnology.

Parties to the CBD recognized that modern biotechnology has the potential for significant improvements in human well-being, but agreed that it must be developed and used safely. Modern biotechnology, better known as genetic engineering, differs significantly from traditional animal and plant breeding techniques. In modern biotechnology, researchers can now take a single gene from a plant or animal and insert it into another plant or animal to give it a desired characteristic. Genetically engineered products promise advances such as higher crop yields, increased nutritional content of food, new medical treatments and vaccines, decreased pressure on land use, and improved fibres and fuels. However, the extent to which LMOs pose significant risks on the environment or human health remains contentious and uncertain. For example, genetically modified corn pollen has been shown to be harmful to monarch butterflies and other beneficial insects. Many scientists believe that more efficient, genetically engineered crops may out-compete native crops, posing a major threat to endemic and endangered species. Bioengineering may also allow plants to grow in otherwise unsuitable areas such as arid land, further pressuring habitat loss and disrupting soil systems. The Cartagena Protocol establishes efforts to reduce and ultimately eliminate the potential risks posed by modern biotechnology and its resulting LMOs, by addressing the safe transit, handling, and use of LMOs across nations.

The Protocol's founding parties grouped themselves around their support of the inclusion or exclusion of the "precautionary approach" as a guiding principle for regulating LMOs. This approach, first contained in Principle 15 of the *Rio Declaration on Environment and Development*, states that "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Agricultural commodity exporting countries, such as the United States and Argentina, formed the so-called Miami Group with the common interest of excluding the precautionary approach arguing that the potential benefits of LMOs outweighed any potential risks. On the opposite end of the political spectrum sat the Like-Minded Group consisting of mainly developing countries, which argued for the inclusion of the precautionary approach, the right to refuse imports and collectively believed the risks posed by LMOs outweighed the potential benefits. The resulting Protocol is a highly negotiated policy instrument, reflecting a balance between these competing interests.

The *Cartagena Protocol on Biosafety* was finally agreed upon in January 2000, with no clear winner or loser. The Miami Group won the full exclusion of products derived from LMOs, such as cereals and pharmaceuticals. The developing countries retained the right to refuse LMO imports, with elements of the precautionary approach reflected in the final Protocol provisions. Parties to the Protocol must ensure that LMOs are produced, packaged, and transported under safe conditions and must be accompanied by appropriate documentation classifying the identity and destination of the LMOs

contained within each package. In addition, non-parties such as the United States must adhere to Protocol requirements when exporting to countries that are signatories.

Under the Cartagena Protocol, a country of export must complete a comprehensive risk assessment prior to transport. Risk assessments are scientific evaluations of a product, based on laboratory and field testing, which guarantees that it does not pose any harm to biological diversity. Reports documenting the procedures and results of each risk assessment are submitted to the *Biosafety Clearing House* (BCH), an international database. Importing countries can then view these risk assessment studies and determine whether the product can be deemed "safe" for import. Under the *Advanced Informed Agreement* (AIA), exporting parties must provide notification of the intentional introduction of an LMO prior to export. The importing country then acknowledges receipt of the notification, assesses the risks associated with the LMO, and agrees or refuses to import. The Protocol encourages developed countries to assist with capacity-building in developing countries through financial assistance, technology transfer, and international training.

Implementing the Cartagena Protocol within the United States poses a number of political challenges. Given the lack of well-defined public support for the regulation of LMOs and the current economic mood, this issue may take a backseat to more pressing public concerns. Further regulation of LMOs in the United States is strongly opposed by entrenched economic interests. Finally, strong traditions of trade secrecy and intellectual property rights within the United States will likely interfere with both the disclosure and the technology sharing provisions of the Protocol. Given these political challenges, implementing the Cartagena Protocol within the United States is best addressed by a Public-Private Sector partnership. The public sector is charged with producing the regulations necessary for implementation, prosecuting violations, reporting to the Conference of the Parties, and ensuring the overall fulfillment of the Protocol obligations. Performance of comprehensive risk assessments, the most time and cost intensive activity, will be carried out by private-sector laboratories.

The Environmental Protection Agency (EPA) possesses the technical expertise and enforcement capability to ensure a high level of compliance with the Protocol's provisions in the public sector, and is the focus of this report. The EPA will be responsible for setting risk assessment guidelines, certifying private laboratories, auditing private-sector risk assessments, submitting data to the BCH, and evaluating the risk of LMO imports. Actual inspections of import/exports will continue to be carried out by the *United States Department of Agriculture* (USDA) with capacity-building efforts including public education and outreach coordinated through existing *U.S. Agency for International Development* (USAID) programs.

Given the current political and economic environment, the feasibility of this option is high because the financial burden of implementation is split between the private and public sectors. This division of activities closely resembles that used in the regulation of pharmaceutical safety in the U.S. over the past 100 years, offering the highest potential for successful implementation.

INTRODUCTION

The *Convention on Biological Diversity* (CBD) was signed by 150 government leaders at the 1992 Rio Earth Summit as a testament to the global recognition of the risk human actions pose on biodiversity. "The Convention recognizes that biological diversity is about more than plants, animals and micro organisms and their ecosystems – it is about people and our need for food security, medicines, fresh air and water, shelter, and a clean and healthy environment in which to live."[1] Over the last decade, modern biotechnology has progressed to the genetic modification of organisms. This burgeoning field attempts to engineer organisms that have enhanced qualities, like nutrition and increased yield, to meet better the demands of a growing population. Modern biotechnology is a relatively new science, however, and many of both the potential benefits and risks are yet unknown. In response to growing concern about the potential risks of modern biotechnology to biological diversity, the CBD created the *Cartagena Protocol on Biosafety*. The *Cartagena Protocol on Biosafety*, hereafter to be referred to as the Protocol, addresses these crucial issues of genetically modified organisms, or living modified organisms (LMOs) as stated in the Protocol, and attempts to protect biodiversity and human health.

In this report, we will discuss the scientific issues surrounding the Protocol, the historical and political background of the Protocol, the prospect of implementation of the Protocol in the U.S., and the design for a U.S. program that would implement the provisions of the Protocol. Our discussion of the scientific issues affecting the Protocol includes a brief description of modern biotechnology and genetic engineering, and the development of living modified organisms that are covered by the Protocol. This section then proceeds through an analysis of the potential benefits and risks of modern biotechnology.

The second section in the report focuses on the background of the Protocol and its provisions. This section includes a history of the Protocol describing both the rise and proliferation of genetically engineered crops and the development of the international agreement addressing this science. We then go on to discuss the positions of the various stakeholders in the development of the Protocol provisions and what their policy objectives were in this debate. This is followed by a summary of the key provisions and primary mechanisms that came out of the compromises of the stakeholders and make up the current Protocol. This section is concluded with a discussion of the policy issues and implications of the Protocol, investigating what makes this agreement so important.

In the next section of the report, we explore the potential for implementing a program in the U.S. that would meet the provisions of the Protocol. This includes a discussion of the political implications of the Protocol in the U.S. giving special attention to the opposition to implementation both in private industry and in government. Given this opposition, we provide descriptions of several program design options that we developed, public implementation, public-private implementation, private implementation.

Section four of this report provides a detailed account of the program design option that we found to be the most politically viable and economically feasible, the public-private implementation. This section

[1] The Convention on Biological Diversity, "About the CBD". Retrieved 11/25/2004. http://www.biodiv.org/default.shtml

includes a description of the design and organizational plan under this program option, the staffing and budget plans, the performance management plan, and an outline of the master calendar for the first year of implementation of this program.

The issues of biotechnology and biosafety are complex and far-reaching. Through this discussion of the various mechanisms and regulations that make up the Cartagena Protocol and the proposed U.S. implementation program it is clear that many of those complexities can be addressed while minimizing the threats to biological diversity.

I. SCIENTIFIC ISSUES

MECHANISMS OF GENETIC ENGINEERING

Generally, "biotechnology" refers to the use of technology to generate products or processes from biological systems, living organisms, and their derivatives. Living modified organisms (LMOs) is a term used in the Protocol to describe organisms that have been genetically modified through modern biotechnology. 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. 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 offspring incapable of further reproduction, typically limit these traditional methods. Genetic modification dramatically reduces these barriers, making it possible to intermix characteristics of unrelated species, phyla, and kingdom such as combining the genes of plants and animals.

Molecules of deoxyribonucleic acid (DNA)—made up of cross-linked 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 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 vectors – an artificial DNA construct derived from a virus that has RNA as its genetic material -which leads to the formation of more, identical viruses used to insert sequences into an organism's chromosomes - that transfer genetic material to their host organisms as a normal part of their lifecycle (Borem, Santos & Bowen, 2003). While such methods allow very efficient

transfer of genetic material, they suffer from a lack of specificity. As a result, it is possible that the retroviral vector, if it were released from the laboratory or persisted in the target organism after its introduction into the environment, could impart the modified genetic material to non-target organisms, with unknown consequences. (Borem, Santos & Bowen, 2003).

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 altered 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 hybrids that with increased yield and higher performance, and more economical to produce these seeds. Sterility also helps ease concerns that genetically modified crops will spread their enhanced genetic characteristics, such as herbicide resistance, to wild plants. Finally, an organism's genes may be suppressed to avoid the occurrence of undesirable traits, like the production of propanthial S-oxide, the chemical in onions that causes crying. (Borem, Santos & Bowen, 2003)

POTENTIAL BENEFITS OF GENETIC ENGINEERING

Genetic engineering offers considerable benefits for medicine and agriculture including new medical treatments and vaccines, new industrial products, and improved fibers and fuels. Proponents argue that biotechnology has the potential to lead to increases in food security, decreased pressure on land use, increased crop yields 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.

Genetic engineering may even 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 assess adequately the desirability of modified organisms. Despite this lack of evidence, both the creation of new organisms and the wholesale adoption of them, especially in agriculture, continue at a rapid pace.

POTENTIAL RISKS 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 such as environmental and consumer advocacy groups 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 and genetic pollution. Genetic pollution is the uncontrolled spread of genes from modified to previously unmodified organisms. Such unintended transfer of genetic material could occur through a variety of mechanisms, for example through the retroviral 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 surrounding ecosystem 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 maize plants engineered to produce BT have shown that the compound 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 effect 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 itself. Genetic engineering is, at best, 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 (Crawley, Brown, Hails & Rees, 2001). Researchers have modified a variety of soybeans using Brazil nut genes in order to improve the nutritional content of the crop (Dixon, 2001). 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 effects.

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 alleged; none have been documented or proven. However, the risks are real, including virus creation due to the use of retroviral vectors, 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.

The *Cartagena Protocol on Biosafety* addresses these scientific issues surrounding 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). In the Protocol text, a LMO is defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology," including, but not limited to, genetically engineered (modified) organisms.

II. POLITICAL BACKGROUND

PROTOCOL HISTORY

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:

- Conservation of biological diversity,
- 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 meet better the demands of a growing population. Although biotechnology holds the possibility of improving the quality of human life, neither the benefits not the risks of this growing 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, 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 consumer and 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 Biodiversity* is an 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 LMO 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 103 ratifying parties; 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., are complicated, and will be discussed further.

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*. Explain briefly. 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 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 *World Trade Organization* (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. These economic and ideological differences prompted countries to form alliances in order to address their concerns, which reflect the diverse interests and priorities of the main players.

KEY STAKEHOLDERS

Following the ratification of the *Convention on Biodiversity* (CBD), several parties initiated informal biosafety negotiations in 1995, leading up to the first formal Protocol meeting in 1996. Inevitable differences of opinion regarding the provisions of the eventual Protocol resulted in the formation of several major working groups, each of which endorsed their own vision of what the Protocol should become. The parties formed during the Protocol negotiations are represented in the following table, including their main arguments for or against certain proposed additions to the agreement.

Miami Group	Agriculture commodity-LMO exporting countries	Argued that LMOs presented no scientifically proven threats to biodiversity, exclusion of processed foods containing LMO ingredients.

		Potential benefits outweigh any potential risks
Like-Minded Group	Developing –LMO importing countries	Argued for the right to refuse imports – concerned with mere existence of risks to biodiversity. Demanded capacity building and technology transfer. **Potential risks outweigh any potential benefits**
Compromise Group	Japan, Mexico, Norway, Singapore, South Korea, Switzerland, New Zealand	Bridged the gap between the Miami and Like-Minded groups by explicating compromise positions. Urged parties to accept potential risks and benefits, consider socioeconomic conditions and capacity when assessing risk.
European Union	EU countries	Faced strong public pressure, promoted clear labeling and identification of LMO products.

The formulation of international agreements is ultimately a process of compromise and negotiation, with no party wanting to take a position so extreme as to be excluded from the ultimate product. Thus, elements of all the above positions are founded in the final Protocol text. For example, the *Miami Group* received its desired exemption for processed foods, but lost to the *Like-Minded Group* the inclusion of risk assessments based on the *Precautionary Principle.*

POLICY OBJECTIVES

The framework for upholding the objectives of the Protocol stems from the adoption of the *Precautionary Principle*, mentioned above. This principle states "parties may err on the side of caution when there is a lack of scientific certainty about the impacts of LMOs and until there is evidence to demonstrate adequate safety." (See Appendix 1, Article 1). The Protocol takes into consideration risks to both the environment and human health, but only applies to LMOs intended for cultivation. Goods specifically excluded from consideration include pharmaceuticals, processed foods, food additives and food derivatives containing LMOs. Furthermore, the Protocol specifically focuses on the transboundary movement of these organisms, and aims to protect the sovereignty of member-States and their right to take more protective action for the conservation and sustainable use of biological diversity.

KEY PROVISIONS AND PRIMARY MECHANISMS

While the framework for the Protocol is established with the Precautionary Principle, the primary mechanisms for achieving the Protocol objectives are:

(1) Mandated risk assessments
(2) Participation in the *Biosafety Clearing-House* (BCH)
(3) The completion of the *Advanced Informed Agreement* (AIA)

Under Article 15, a thorough risk assessment –a scientific evaluation of a product's safety through laboratory and field testing –of the LMOs intended for transboundary movement must be undertaken

before acceptance into the importing country. The objective of this assessment is to identify and evaluate potential adverse effects of LMOs prior to movement. These assessments should take into consideration the risks posed to unmodified counterparts or parental organisms.

Once a risk assessment study is completed, the Protocol mandates that it be submitted to the BCH, an information-sharing database established to facilitate the exchange of scientific, technical, environmental and legal information on and experience with LMOs. The country of import, through the BCH, then has access to all information regarding the said LMO prior to transfer. The *Advanced Informed Agreement* (AIA) procedure, states that the country of import is given the right to then approve or reject the LMO based on their evaluation of the risk assessment results. The three main mechanisms for accomplishing the Protocol's objectives – described below- include ensuring the safe transfer, handling and use of LMOs.

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. An environmental risk assessment requires the identification of three fundamental components:

(1) Presence of a potentially harmful agent at levels sufficient to be dangerous;

(2) Existence of a receptive (and thus at-risk) population; and

(3) Exposure pathway between the harmful agent and the receptive population.

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) recommended that the BCH start with a pilot phase, which is now operational. The BCH facilitates the exchange of scientific, technical, environmental and legal information regarding LMOs. 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.

Advanced Informed Agreement

The *Advanced 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:

(1) Notification by the Party of export (the exporter),

(2) Acknowledgment of receipt of notification by the Party of import,

(3) 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:

(1) approving the import,

(2) prohibiting the import,

(3) requesting additional relevant information

(4) or 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.

Several other key provisions of the Protocol include obligatory non-member Party compliance, "capacity building" mechanisms and legal measures for resolving conflicts. Non-member parties wishing to trade with member parties are required to perform risk analysis studies and adhere to the transboundary movement procedure described above.

The Protocol also draws special attention to developing countries, calling for "capacity building" to strengthen their abilities to comply with and participate in the Protocol through financial support, technology training and transfer, and expert training. However, the Protocol does not mandate guidelines for providing this capacity building. Finally, the Protocol states that the *Conference of the Parties* will "adopt a legal process for the appropriate elaboration of the international rules and procedures regarding liability and redress for damage resulting from transboundary movements of LMOs" (Article 27). However, such a legal framework has not yet been established.

Non-member parties believe that the Protocol faces major obstacles to implementation and have shown concern on some key issues, which prevent them from becoming signatories. The main concern issues that are under consideration are the elaboration of regimes for compliance, and the liability and redress mechanisms.

As of November 2004, the United States has signed but not ratified the Cartagena Protocol and is not a ratifying member of the CBD. However, according to representatives the U.S. Department of State, the possibility of seeking ratification is currently being reviewed. This increased interest in the Protocol may be due to its potentially serious implications for global agricultural trade and the delivery of food in times of crisis. In order to ratify, it is critical that the United States develop an implementation plan that does not create unnecessarily strict regulatory barriers. The United States government believes that it should be implemented in a manner that both accomplishes the goal of biodiversity protection and provides for uninterrupted trade in agricultural commodities.

III. PROGRAM IMPLEMENTATION

U.S. POLITICAL AND TECHNICAL CONSIDERATIONS

Implementation of the Protocol in the U.S. poses a number of political and technical challenges. First, it will require both statutory authority and the promulgation of new regulations, each of which bear their own challenges in the face of entrenched political and commercial interests. The U.S.'s strong traditions of protecting intellectual property rights and trade secrecy will likely interfere with both the disclosure and the technology sharing provisions of the Protocol. Another issue is that current scientific consensus on the risks of LMOs is not favorable to additional regulation, and there is no strong public mandate for such measures. Finally, implementing the Protocol may require significant expenditure, either by private companies or by the federal government, which will also likely prove unpopular in the current fiscal climate. These factors combined strongly suggest that both the legislative authority and regulatory development needed to implement the Protocol may be extremely difficult to obtain.

The trade regulation and intellectual property issues in the U.S. business and political context are difficult to resolve from an implementation perspective, since they arise from fundamental tensions between the Protocol and entrenched business interests. Nonetheless, adequately addressing these concerns will be key to achieving the buy-in necessary to implement any of the foregoing options. In the case of trade concerns, a representative of the U.S. government would have to contest aggressively the exclusion of goods in Protocol compliance as a *non-tariff barrier* (NTB) under the WTO framework. This would help avoid situations where a shipment would be rejected under the Cartagena Protocol and would qualify for a NTB discrimination case under the WTO. This commitment will be necessary for companies to justify and absorb the varying degrees of expense and nuisance they will undertake under any of the following three program design options.

In the case of intellectual property, the Protocol's commitments to confidentiality lack the rigor necessary to lessen industry fears of expropriation of trade secrets of LMOs. Thus, the U.S. government must further commit itself to the aggressive pursuit of actions in violation of U.S. and international intellectual property laws, working through both Justice Investigation and enforcement divisions and within the parameters of the WTO TRIPS (*trade-related aspects of intellectual property rights*) framework. Adequate appropriations for and coordination of these functions must be included within any eventual implementation program.

Below, we present three program options that could be implemented in the U.S. if the necessary conditions for becoming a Party of the Protocol were met. The difference between these options refers to whether the main responsibilities or activities should rely on the public or private sector.

PROGRAM DESIGN OPTIONS

The Protocol's language is suggestive of highly centralized implementation, like that undertaken by EU countries; one such model is presented below as *Option I (Public)*. Given, however, what we determine to be the limited political feasibility of this option and the challenges previously discussed, more innovative options are clearly needed; two such models are presented as *Option II (Public-*

Private) and *Option III (Private)*. We have compared the parties responsible for various implementation activities under each option based on Protocol objectives and evaluated each option along a number of different parameters, based on potential effects such as effectiveness and speed of implementation, and political and economic feasibility (See Appendix 2 for a detailed comparison of these Options).

All these factors have been taken into account to evaluate how viable it would be to implement the Protocol in that particular paradigm. The parameters are listed in Appendix 3 in order of importance to overall implementation feasibility, and one can see that any implementation option would require trade-offs between the aforementioned effects of effectiveness and speed of implementation, and political and economic feasibility. All three plans also possess a number of common elements necessary to their successful implementation. Some organization (EPA for I and II, SEC for III) must be charged with overseeing the particular regulations necessary for implementation, and the appropriate division within these organizations made responsible for prosecuting violations. Periodic reports to the Conference of the Parties must be made, likely by EPA or Commerce. Finally, an appropriate national agency must ensure the overall fulfillment of the treaty obligations contracted under the Protocol. Under all options, the federal government could further incentivize implementation by requiring all USAID food purchase to be Protocol-compliant.

Implementing the Cartagena Protocol within the U.S. poses significant political challenges best addressed by a Public-Private sector partnership. The Public-Private program design that follows splits the financial burden of implementation between the public and private sectors. The political viability of this option is high because the current political climate is favorable to neither the development of new bureaucratic institutions nor significant new expenditures.

IV. U.S. LMO PROGRAM: PUBLIC/PRIVATE PARTNERSHIP

The proposed U.S. LMO Program combines the high technical capacity and enforcement capability of existing government agencies with private sector flexibility and innovation. In this program, necessary compliance functions are carried out by government agencies, in most cases the Environmental Protection Agency (EPA), while risk assessments are administered by private laboratories (see Appendix 4). Additionally, the various implementation activities can in most cases be carried out by existing agencies within the government. Inspections of import/export products will continue to be carried out by the USDA *Animal & Plant Health Inspection Service* (APHIS). Capacity building will be administered through existing programs within the *U.S. Agency for International Development* (USAID).

Comprehensive risk assessments, a major component of Protocol implementation, will be carried out by private laboratories following EPA mandated standards and guidelines. These risk assessment studies are required for every LMO exported to Protocol member parties and is regulated under the *Advanced Informed Agreement (AIA).* Private laboratories must comply with all EPA laboratory certification standards, perform necessary laboratory and field testing, and submit risk assessment studies to the EPA.

KEY EPA FUNCTIONS

Designing a program for implementing the Protocol in the U.S. involves dividing a great deal of responsibilities among several agencies within the federal government as well as with the private sector. This analysis focuses on developing the full implementation strategy for only the EPA because this governmental agency faces the largest responsibility under the proposed program design. This program fosters an implementation of the Protocol's requirements that is both cost-effective and politically viable by taking advantage of the following existing EPA divisions (See Appendix 5 which shows how these divisions are organized within the EPA).

Office of Pollution, Prevention, and Toxic Substances (OPPT) – Risk Assessment Team
The *Risk Assessment Team* will begin the implementation process by establishing full risk assessment procedure standards within no less than 90 days of signing the Protocol and communicating these standards to the private sector. The Risk Assessment Team will also develop private laboratory certification standards, communicating each to the EPA's Office of Enforcement and Compliance Assurance.

Office of Enforcement and Compliance Assurance
The Agriculture Division's *Good Laboratory Practices Program* will certify private sector risk assessment labs and maintain records of each facility. Ongoing risk assessment studies are audited by the *Office of Compliance – Agriculture Division* staff and then sent to the OPPT Biotechnology Team. The Office of Enforcement and Compliance Assurance's *International Enforcement and Compliance Division* will be responsible for enforcing program regulations.

Office of Pollution, Prevention, and Toxic Substances (OPPT) – Biotechnology Team
Upon receipt of audited risk assessment studies, the *Biotechnology Team* will submit the appropriate Advanced Information Agreement materials and provide this data to the Biosafety Clearing House. This team is also responsible for attending all meetings of the Parties to the Protocol, maintaining open communications with the Protocol governing body, and communicating risk assessment results to other U.S. agencies involved.

ORGANIZATION AND STAFFING

The first step in designing a plan for implementing the Protocol in the U.S. involves creating an organization and staffing plan to accomplish the tasks listed above. It is essential to add staff to some the divisions within these offices for the U.S. LMO Program because of the unique risks and challenges involved with regulating these relatively young products. The first year's staffing plan employs the essential personnel in order to minimize costs in the program's early stages. A more extensive staff will be added incrementally as necessary following the first year of Program operation. Similarly, the first-year staffing plan will focus on personnel needed to develop the important risk assessment and laboratory certification standards. Once developed and communicated to the private sector, these standards allow U.S. biotechnology companies to perform risk assessment studies, through certified laboratories, that comply with the Protocol requirements and ultimately facilitate the continued export of U.S. produced LMOs.

Organizational Structure

As mentioned, the responsibilities of initial compliance with the Protocol will be with the EPA (Appendix 5). The most important department within the EPA involved in the LMO Program is the *Office of Prevention, Pesticides and Toxic Substances* (OPPTS), responsible for setting the risk assessment and laboratory certification standards, developing risk management standards, adopting laboratory certification standards and coordinating with the *Biosafety Clearing House*. The LMO Program Branch within OPPTS will also be responsible for publishing these standards and ensuring the full understanding and cooperation of the risk assessment and laboratory auditors within the EPA *Office of Enforcement and Compliance Assurance*. The OPPTS *Biotechnology Team* will be responsible primarily for coordinating with the Conference of the Parties to the Cartagena Protocol on Biosafety.

Once the *LMO Program Branch* has published their risk assessment standards it will be the responsibility of the *Office of Enforcement and Compliance Assurance* (OECA) to audit the private laboratories for compliance, audit risk assessment procedures. Finally, the enforcement of the regulations set out by the Protocol and the *LMO Program Branch* will be the responsibility of the *International Enforcement and Compliance Division* of the Office of Federal Activities.

The final department of the EPA involved in the U.S. LMO Program is the *Office of International Affairs* responsible for addressing international public relations related to Cartagena Protocol issues and coordinating U.S. participation in capacity building and technology transfer with less-developed countries. A full breakdown of staffing needs per EPA department is presented as Appendix 6. Finally, the U.S. LMO Program will not require any additional staff for carrying out the role of inspecting imports and exports through the USDA *APHIS* program.

BUDGET PLAN

The second step to implementing the U.S. LMO Program is developing a projected budget for the first year of operation. As a governmental program, the implementation of the U.S. LMO Program entails completing the congressional approbation process. This requires constructing and submitting a detailed budget plan with explicit ***budget line items***. This budget plan must then be approved by Congress via congressional committees and will be available only after Congress approves it and the Appropriations Committee allocates the money.

The projected budget for the U.S. LMO Program's first year of operation includes the costs of staffing 22 additional employees (both federal and contracted) in the EPA as well as the costs for the risk assessment laboratory, essential materials and travel (Appendix 7). These projected costs are based in part on existing government pay structures, based on the General Schedule (GS), to determine the salaries of each new staff member. The remaining portion of the budget, categorized as Other-than-Personnel, is estimated by comparing costs of the necessary resources identified in the program design like the laboratory and lab equipment. The highlights of the projected budget outlined here are attached as Appendix 7.

The U.S. LMO Program budget total is $US 4,432,834.68, with nearly half of the entire budget allocated to the Living Modified Organism (LMO) Assessment Branch. Two critical year-one tasks

included in the Program budget are $1,000,000.00 for the EPA risk assessment laboratory, and $245,000.00 for technical services essential to setting risk assessment standards.

Operating Expenses

There are several categories of expenses incurred throughout the first year of operation within OPPTS, totaling $2,820,000.00, also outlined in Appendix 7. Travel and Capacity Building expenses comprise the largest percentage of this amount, as EPA Auditors will be required to travel year-round in order to keep track of the certification process. In addition, the Capacity Building expenses will help to improve the institutional development of the Office of International Affairs, which deals with the imports of Living Modified Organisms (LMO).

It is important to note that the total LMO Program budget for 2005 would constitute merely 0.057% of EPA's 2005 budget projection. This would appear to be reasonable at a glance, compared to cost projections for other EPA programs and in terms of the economic implications of an increased market for United States Agricultural exports.

Fines and Fees
Fees have been scheduled for Laboratory Certification, Risk Assessment Auditing and AIA submissions. The fees assessed have been calculated to serve two purposes. First, as a barrier to entry so that frivolous applications are not entertained. The fees are also not so excessive as to deny a level playing field. The levels of the fines are commensurate with the likely impact of transgression. Note the high fine under 'Misappropriation of Intellectual Property', which reflects the commitment of the Federal Government to free enterprise.

As per accepted practice, fines are intended as a deterrent and not as a source of revenue, so they are not part of the projections. Projected estimations are based on grain export projections from the USDA. Note that the revenue is not intended to cover the costs for the protocol implementation, reflecting Congress' acknowledgement that entry into the Protocol is vital to the United States agricultural industry export efforts.

PERFORMANCE MANAGEMENT

Effectively coordinating the various functions explained above requires timely, accurate, and relevant measures of the EPA's performance. Such a system must serve to reinforce the mission of the Protocol (safe handling, transport, and use), but must also take into account other internal considerations such as personnel management and budgetary discretion. Since the Protocol has only modest political support, it is key that the organization be able to demonstrate that they are implementing it in a timely and cost-effective matter. Likewise, those responsible for carrying-out audits and inspections will be working closely with American businesses, which should ideally come to view these measures as extensions of their own internal Total Quality Management (TQM) systems. Regardless, the performance management system should also monitor the outcome and impact of regulatory interactions on business.

Monitoring Framework

Appendix 8 presents a breakdown of some of the variables to be measured within the performance management system, providing the raw data to be used in making management decisions. These variables are broken down by program function (like auditing and import review, as well as the overall program), and into two broad classes –*output* and *outcome* measures. *Output* variables include measures of internal performance, like the time and cost to execute specific functions, the number of errors in work products, and compliance with Protocol timelines. *Outcome* variables measure external impacts of the program, like the number of certified products and their market penetration, and the economic value and job creation associated with the program, as well as measures of "customer" satisfaction.

The performance management system will be built upon seven components: management and organizational, personnel management, independent certification, internal auditing, regulatory assessment, TQM integration, and benchmarking assessment.

Management & Organizational

A successful organization requires a defined mission and clear goals to meet that mission. Thus, the first (and perhaps most critical) component of the U.S. LMO Program performance management system is such a mission-goals statement. Subsequent work plans and job descriptions may then be linked to these goals, making it possible to measure individual performance against specific organizational benchmarks.

Personnel Management

Equipped with well-crafted job descriptions linked to organizational priorities, it is possible to make a robust assessment of personnel performance. A 360-degree evaluation mechanism (incorporating feedback from supervisors, colleagues, subordinates, and customers) provides the best indication of overall performance. Such job evaluations may be tied to ongoing monitoring of personnel levels (especially since this program is beginning with a minimum of staff), and to updating job descriptions and performance benchmarks to reflect organizational priorities.

Independent Certification

The program includes within it a staff of seven scientists and a multi-million dollar laboratory. Because this staff and facility will serve as the benchmark for all LMO risk assessments carried out in the U.S., it is critical that their work products meet a correspondingly high standard. *The National Institute of Standards and Technology* (NIST) *National Voluntary Lab Accreditation Program* (NVLAP) certifies the nation's premier research laboratories, the standard against which our own should be measured. Periodic review of laboratory configuration and practices will help ensure output of consistent quality.

Internal Auditing

A dispersed organization may present challenges in financial management and overall accountability. Thus, it is necessary to provide for periodic financial and organizational audits. The EPA *Office of the Inspector General* (IG) will carry out periodic audits and reviews to ensure that program management meets the highest legal and professional standards.

Regulatory Assessment
The Protocol requires that Parties fully implement its provisions within 90 days of ratification. Given the nature of the U.S. regulatory process, this requirement is likely non-attainable, but it nonetheless provides an important interim benchmark. At 90 days, the existing (created in the past three months) implementation framework will be assessed, with a corresponding plan for attainment of unmet Protocol obligations by the EPA's *Biosafety Team*.

TQM Integration
The various performance monitoring systems previously discussed should be integrated along with the other data collected as part of the implementation process into a TQM-like system that has a goal of continual refinement and improvements in the quality of the "product delivered." However, in this case the "product" refers to inspections, auditing, technical assistance, etc. Additionally, outreach efforts to the biotechnology industry should focus on integrating the audit and inspection process into industry TQM programs, which will lessen resistance to the U.S. LMO Program and provide new sources of performance data and insight.

Benchmarking Assessment
The flagship of the first-year performance monitoring system, a comprehensive benchmarking assessment should be undertaken in the ninth month of the program (to be completed by the end of the first year). The goals of this effort will include comprehensive base lining of current performance, assessment of industry practices (including performance monitoring), development of a statement of best practices, and creation of a plan to implement appropriate best practices within the organization. Suggested benchmarking partners include FDA, USDA, IRS, GAO, Customs Service, UL, other EPA divisions, EU environmental programs, and other organizations with independent auditing and certification authority.

Implementation
Unless otherwise noted previously, the activities needed to implement this performance management system will be coordinated (and in some cases executed) by an appropriate staff member of the *Biotechnology Team* within OPPTS. Each division will be responsible for collecting and reporting relevant performance data, and for participating in the various activities required. Central to the performance management (and general organizational management) effort will be a monthly staff meeting that will include review of relevant performance metrics and their trends

YEAR ONE MASTER CALENDAR

Within 90 days of ratifying the Cartagena Protocol (projected for January 1st, 2005), the U.S. LMO Program aims to develop standards for private laboratory certification as well as for risk assessment procedures (both lab and field testing). This should be achieved by the simultaneous creation and adaptation of Program Strategic Vision and Goals, responsibility of the *Office of Prevention, Pesticides and Toxic Substances' (OPPTS)*

As we are anticipating shortage of personnel during the first quarter, new LMO Program staff will heavily rely on the existent EPA office structure until new personnel is on board. After the first quarter tasks are completed, issuance of certifications to the private laboratories wishing to test LMOs is possible, an ongoing function of the *Office of Enforcement and Compliance Assurance*. This EPA

Office will also perform audits of the Risk Assessment Procedures starting September 1st, 2005. Starting this same date, the *Biotechnology Team* will start submitting Risk Assessment reports and other relevant materials, submitted by private laboratories, to the Biosafety Clearing House.

The following important tasks will be carried out throughout the first year: coordination between internal EPA offices and external parties; international regulations enforcement, public education and outreach, and capacity building initiatives. The performance management functions in the U.S. LMO Program are mostly concentrated in the earlier mentioned *Biotechnology Team*. During the first year of operation, this group will develop a TQM Integration Plan, to be in place by the beginning of June 2005. Additionally, the *Biotechnology Team* is responsible for benchmark reporting from September 2005 on, and will produce and submit the required Annual Report to the Cartagena Protocol Secretariat. All three EPA offices engaged in the LMO Program implementation in are responsible for personnel performance through bi-annual review and monthly project status reporting. After initial staffing is completed (scheduled for the beginning of the second quarter of 2005), personnel needs and compliance with the Cartagena Protocol requirements will be re-evaluated, with necessary changes developed at that time to address any outstanding needs.

V. CONCLUSION

Through the various mechanisms and regulations discussed, the *Cartagena Protocol on Biosafety* 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. Finally, 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.

The U.S. has yet to ratify the *Convention on Biological Diversity* and therefore cannot ratify the Cartagena Protocol, as it is an agreement from within the Convention. The CBD has not been ratified principally because there has been no uniform industry stance on the issue and no one willing to champion the cause in Congress. Without this type of pressure, there is no impetus for Congress to move towards ratification. The result, however, is that U.S. interests and influence are marginalized in the international decision-making process with respect to both the Convention and the Protocol. Despite this marginalization, namely exclusion from the permanent record of comments, there is no consensus on what action should be taken. One view is that it is better for the U.S. to become a member party to be able to influence decision-making. On the other hand, many stakeholders believe that the course of the Convention and the Cartagena Protocol, in particular, have been set and in a manner that is unsatisfactory to them. Namely, the EU has engineered stricter guidelines that have been set in place by the ratification of over a hundred countries. Regardless, of individual stakeholder stances on the Protocol, due to the requirement for non-member parties to comply with the agreement

in order to trade with member parties, it seems appropriate for the U.S. to move toward ratification and implementation.

The U.S. LMO Program discussed in this report lays out the method for implementation of the provisions of this Protocol in the U.S. The Public-Private program design splits the financial burden of implementation between the public and private sectors. This design increases political viability given that the current political climate is favorable to neither the development of new bureaucratic institutions nor significant new expenditures. The proposed U.S. LMO Program combines the high technical capacity and enforcement capability of existing government agencies with private sector flexibility and innovation. Necessary compliance functions are carried out by government agencies, principally the Environmental Protection Agency (EPA), while comprehensive risk assessments, a major component of Protocol implementation, are administered by private laboratories (see Appendix 4). Additionally, the various implementation activities can in most cases be carried out by existing agencies within the government. Inspections of import/export products will continue to be carried out by the USDA *Animal & Plant Health Inspection Service* (APHIS). Capacity building will be administered through existing programs within the *U.S. Agency for International Development* (USAID).

The feasibility of the U.S. LMO Program is enhanced by its relatively small requirements for staffing and budget. Because the program uses existing government agencies to carry out the implementation it is estimated that only 13 additional full-time staff, spread across a number of offices and functions, will be required as the program moves into the future. Nine additional full-time contractors will be employed at the initiation of the program, but these people will only be needed to get the program started. Because the government only needs to hire a few additional staff people and because risk assessments will be carried out by private laboratories, the cost to the government is relatively small. In fact, the estimated budget for this program is $4.4 million, compared to the total budget for the EPA of almost $8 billion.[2]

Despite the development of a politically viable and economically feasible program design for implementation of the Protocol in the U.S., many obstacles must be addressed. As mentioned above, the U.S. must first ratify the Convention on Biological Diversity to be able to ratify the Protocol. This ratification is dependent on the ability of stakeholders in the U.S., namely the biotechnology industry and environmentalists, to come to consensus about the participation of the U.S. in these international agreements. Because the science of biotechnology is so nascent there is uncertainty surrounding the science in general, but primarily in the area of risk assessments. Once this issue is addressed, Congress must then be convinced that the proposed U.S. LMO Program will fulfill all the requirements of the Protocol efficiently and effectively. 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.

[2] EPA Budget FY2005. Retrieved 11/30/2004. http://www.epa.gov/ocfopage/budget/2005/2005bib.pdf

APPENDIX 1: SUMMARY OF ARTICLES

(Note – Referenced/key articles are underlined)

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 trans-boundary 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.

"Trans-boundary 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 trans-boundary movement, transit, handling and use of all LMOs that may have adverse effects.

Article 5 - Pharmaceuticals: This Protocol shall not apply to the trans-boundary 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 trans-boundary 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, for processing, or 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 trans-boundary 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 trans-boundary 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 trans-boundary 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 trans-boundary movements of LMOs consistent with the objective of this Protocol.

Article 15 - Risk Assessment: A thorough risk assessment of the LMOs intended for trans-boundary 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 trans-boundary 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 Trans-boundary Movements and Emergency Measures: In the case of an unintentional trans-boundary 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 trans-boundary 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 trans-boundary movement be 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 trans-boundary 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, expertise 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 Trans-boundary Movements: Each party shall implement appropriate domestic measures to prevent, and if necessary, penalize the illegal trans-boundary 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 trans-boundary 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 seek aid from the United Nations in case of need as this last specializes in International Atomic Energy.

APPENDIX 2: PROGRAM DESIGN OPTIONS

EXHIBIT I: Assignment of Core Functions

	Option I *Public*	**Option II** *Public-Private*	**Option III** *Private*
Development of Risk Assessment Standards	**EPA**, Office of Prevention, Pesticides, & Toxic Substances, Office of Science Coordination & Policy, Biotechnology Team	**EPA**, Office of Prevention, Pesticides, & Toxic Substances, Office of Science Coordination & Policy, Biotechnology Team	**Underwriters' Laboratories**, with initial guidance from **EPA**
Risk Assessment	**EPA**, Office of Prevention, Pesticides, & Toxic Substances, Office of Pollution Prevention & Toxics, Risk Assessment Divisions	**Private Laboratories**	**Private Laboratories**
Auditing of Risk Assessments	**EPA**, Office of Enforcement & Compliance Assurance, Office of Regulatory Enforcement, Toxics & Pesticides Enforcement Division	**EPA**, Office of Enforcement & Compliance Assurance, Office of Regulatory Enforcement, Toxics & Pesticides Enforcement Division	**Underwriters' Laboratories**
Certification of Independent Laboratories	**N/A**	**EPA**, Office of Enforcement & Compliance Assurance, Office of Compliance, Agriculture Division, Good Laboratory Practices Program	**Underwriters' Laboratories**
Submission of AIA Materials	**EPA**, Office of International Affairs, Bureau of Environment & Trade	**EPA**, Office of International Affairs, Bureau of Environment & Trade	**Private**—direct to BCH
Approval of Imports	**EPA**, Office of Prevention, Pesticides, & Toxic Substances, Office of Pollution Prevention & Toxics, Risk Assessment Divisions; **USDA**,	**EPA**, Office of Prevention, Pesticides, & Toxic Substances, Office of Pollution Prevention & Toxics, Risk Assessment Divisions; **USDA**, Animal & Plant Health Inspection Service, Division of	***de facto***, mediated by **actuarial decisions** subject to appropriate technical oversight from

	Animal & Plant Health Inspection Service, Division of Biotechnology Regulatory Services, Office of Regulatory Programs, Risk Assessment Staff	Biotechnology Regulatory Services, Office of Regulatory Programs, Risk Assessment Staff	**Underwriters' Laboratories**
Inspection of Exports	**USDA**, Animal & Plant Health Inspection Service, Division of Biotechnology Regulatory Services	**Private Laboratories**	**Private Laboratories**
Inspection of Imports	**USDA**, Animal & Plant Health Inspection Service, Division of International Services, Trade Support Team	**Private Laboratories**	**Private Laboratories**
Certification of Import/Export Inspection Laboratories	**N/A**	**EPA**, Office of Enforcement & Compliance Assurance, Office of Compliance, Agriculture Division, Good Laboratory Practices Program	**Underwriters' Laboratories**
Capacity Building & Technology Transfer	**EPA**, Office of International Affairs, Division of Technical Assistance; **USAID**, Bureau for Economic Growth, Agriculture, & Trade	**EPA**, Office of International Affairs, Division of Technical Assistance; **USAID**, Bureau for Economic Growth, Agriculture, & Trade	**Federally chartered non-profit**, with tax incentives for donations from biotechnology & agricultural industries
Public Outreach & Education	**EPA**, Office of Environmental Information, Office of Planning, Resources, & Outreach, Outreach & Communications Staff	**EPA**, Office of Environmental Information, Office of Planning, Resources, & Outreach, Outreach & Communications Staff	**Federally chartered non-profit**, with tax incentives for donations from biotechnology & agricultural industries
Enforcement of Regulations	**EPA**, Office of Enforcement & Compliance Assurance, Office of	**EPA**, Office of Enforcement & Compliance Assurance, Office of Federal Activities, International Enforcement &	**SEC**, Office of Compliance Inspections & Examinations;

	Federal Activities, International Enforcement & Compliance Division	Compliance Division	Office of International Affairs
Prosecution of Violations	**DoJ**, Environment & Natural Resources Division, Environmental Enforcement Section	**DoJ**, Environment & Natural Resources Division, Environmental Enforcement Section	**DoJ**, Securities Division
Reporting & Data Collection	**DoC**, International Trade Administration, Department of Market Access & Compliance; **EPA**, Office of International Affairs, Division of Environment & Trade	**DoC**, International Trade Administration, Department of Market Access & Compliance; **EPA**, Office of International Affairs, Division of Environment & Trade	**DoC**, International Trade Administration, Department of Market Access & Compliance; **EPA**, Office of International Affairs, Division of Environment & Trade
Implementation Oversight	**DoS**, Undersecretary for Political Affairs, Bureau of International Organization Affairs	**DoS**, Undersecretary for Political Affairs, Bureau of International Organization Affairs	**DoS**, Undersecretary for Political Affairs, Bureau of International Organization Affairs

APPENDIX 3: DESIGN OPTION EVALUATION

Assessment of Options

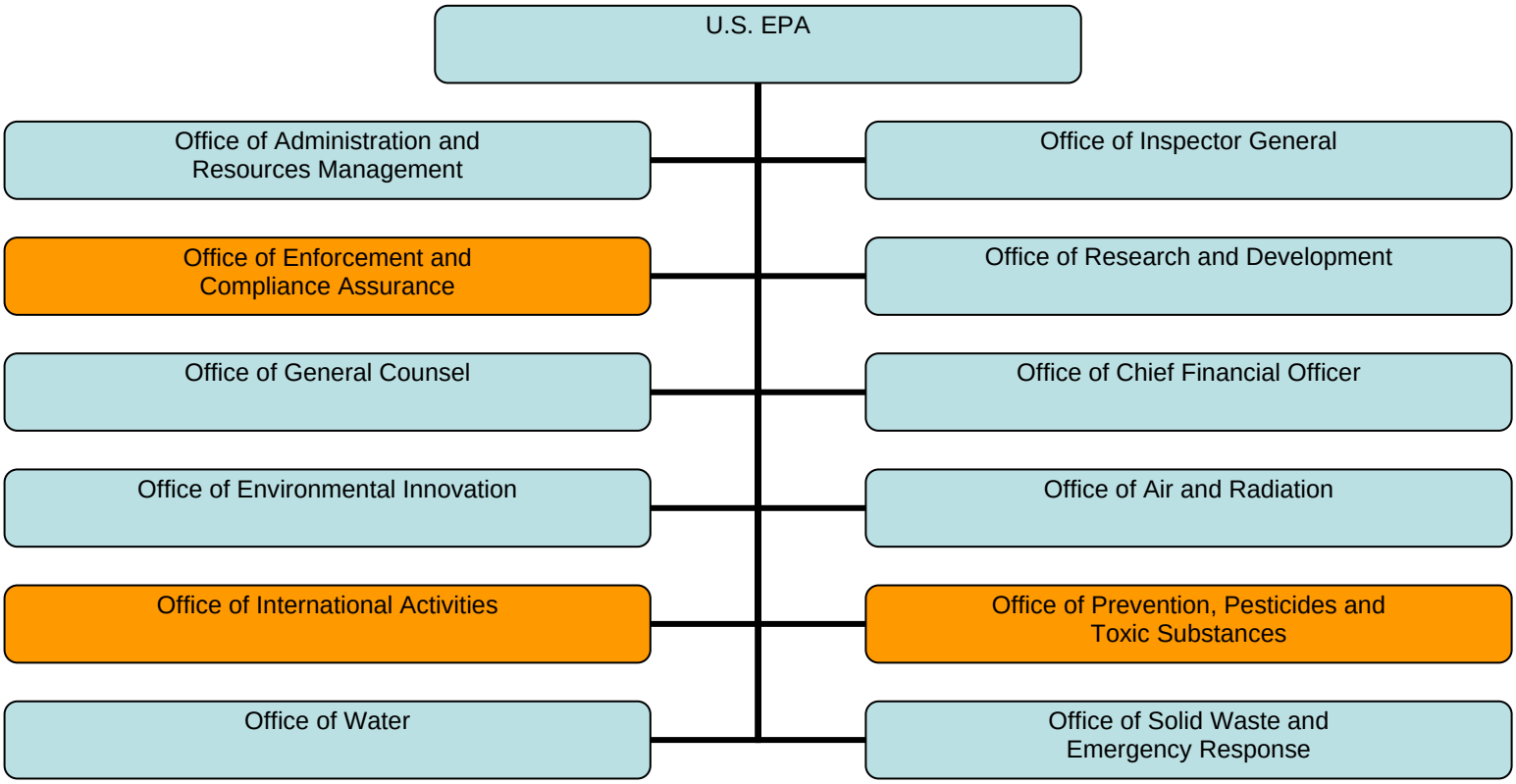
Parameter	**Effect**	**Option I** *Public*	**Option II** *Public-Private*	**Option III** *Private*
Cost Burden	Economic Feasibility	Public	50/50	Private
Stakeholder Involvement	Political Feasibility	Low	Moderate	**High**
Political Acceptance	Political Feasibility	Low	Moderate	**High**
Public Staffing	Economic Feasibility	High	Moderate	**Low**
Incentive for Innovation	Effectiveness of Implementation	Low	Moderate	**High**
Existing Capacity	Speed of Implementation	**Excellent**	Good	Fair-Good
Speed of Implementation	Speed of Implementation	Slow	Slow	**Moderate-Fast**
Initial Compliance	Speed of Implementation	**High**	**High**	Moderate
Private Accountability	Effectiveness of Implementation	**High**	**High**	Moderate
Distortion Effects	Effectiveness of Implementation	**Low**	High	High
Incidence of Liability	Economic Feasibility	Public	50/50	**Private***

*Public when indemnification binds

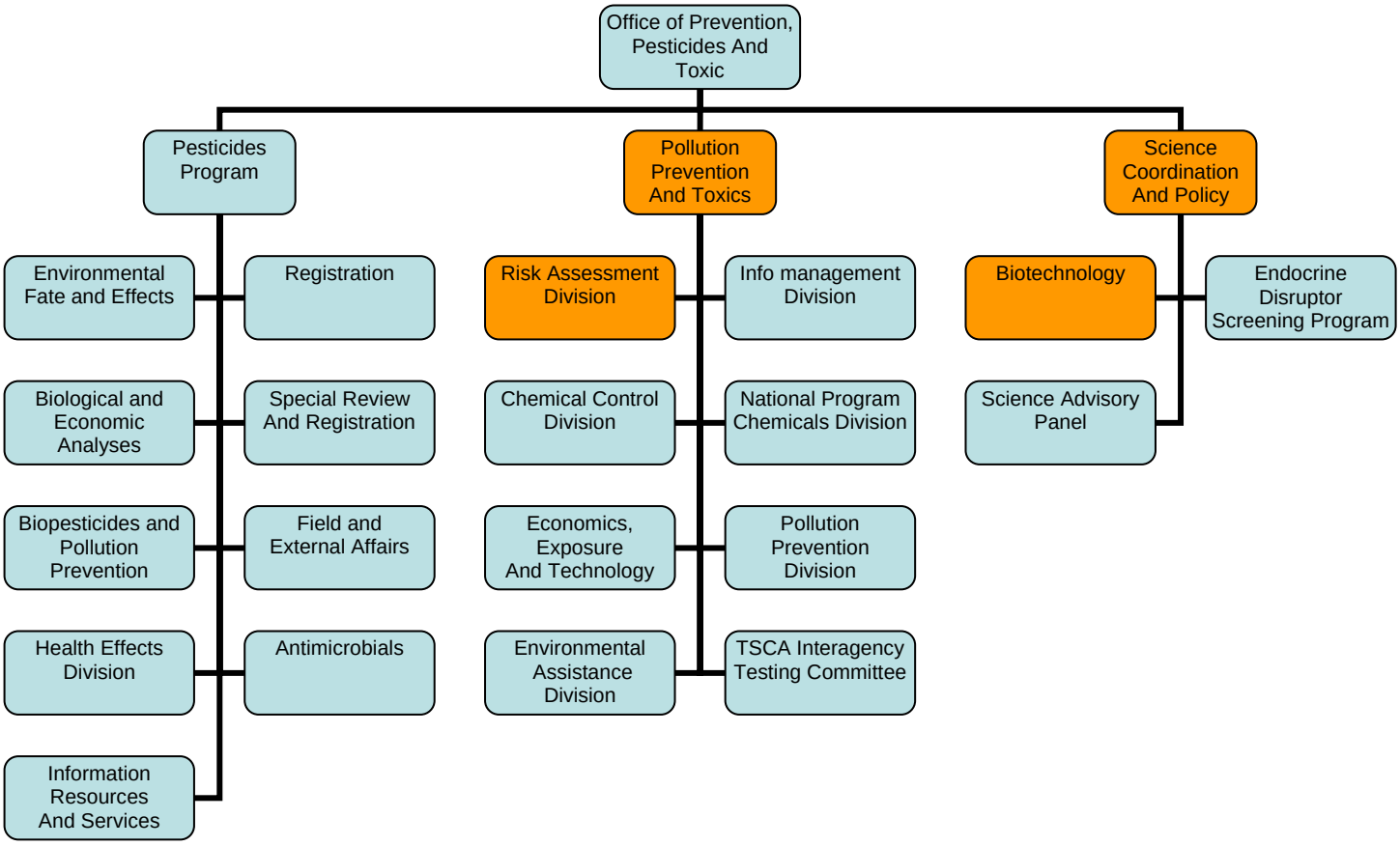
APPENDIX 4: ASSIGNMENT OF CORE FUNCTIONS

	Public-Private Partnership
Development of Risk Assessment Standards	**EPA**, Office of Prevention, Pesticides, & Toxic Substances, Office of Pollution Prevention & Toxics, Risk Assessment Division
Risk Assessment	**Private Laboratories**
Auditing of Risk Assessments	**EPA**, Office of Enforcement & Compliance Assurance, Office of Regulatory Enforcement, Toxics & Pesticides Enforcement Division
Certification of Independent Laboratories	**EPA**, Office of Enforcement & Compliance Assurance, Office of Compliance, Agriculture Division, Good Laboratory Practices Program
Submission of AIA Materials	**EPA**, Office of Prevention, Pesticides, & Toxic Substances, Office of Science Coordination and Policy, Biotechnology Team
Approval of Imports	**USDA**, Animal & Plant Health Inspection Service, Division of Biotechnology Regulatory Services, Office of Regulatory Programs, Risk Assessment Staff
Inspection of Exports	**USDA,** Animal & Plant Health Inspection Service, Division of Biotechnology Regulatory Services
Inspection of Imports	**USDA,** Animal & Plant Health Inspection Service, Division of International Services, Trade Support Team
Certification of Import/Export Inspection Laboratories	**EPA**, Office of Enforcement & Compliance Assurance, Office of Compliance, Agriculture Division, Good Laboratory Practices Program
Capacity Building & Technology Transfer	**USAID**, Bureau for Economic Growth, Agriculture, & Trade
Public Outreach & Education	**EPA**, Office of Environmental Information, Office of Planning, Resources, & Outreach, Outreach & Communications Staff
Enforcement of Regulations	**EPA**, Office of Enforcement & Compliance Assurance, Office of Federal Activities, International Enforcement & Compliance Division
Prosecution of Violations	**Department of Justice**, Environment & Natural Resources Division, Environmental Enforcement Section
Reporting & Data Collection	**Department of Commerce**, International Trade Administration, Department of Market Access & Compliance; **EPA**, Office of International Affairs, Division of Environment & Trade
Implementation Oversight	**Department of State**, Undersecretary for Political Affairs, Bureau of International Organization Affairs

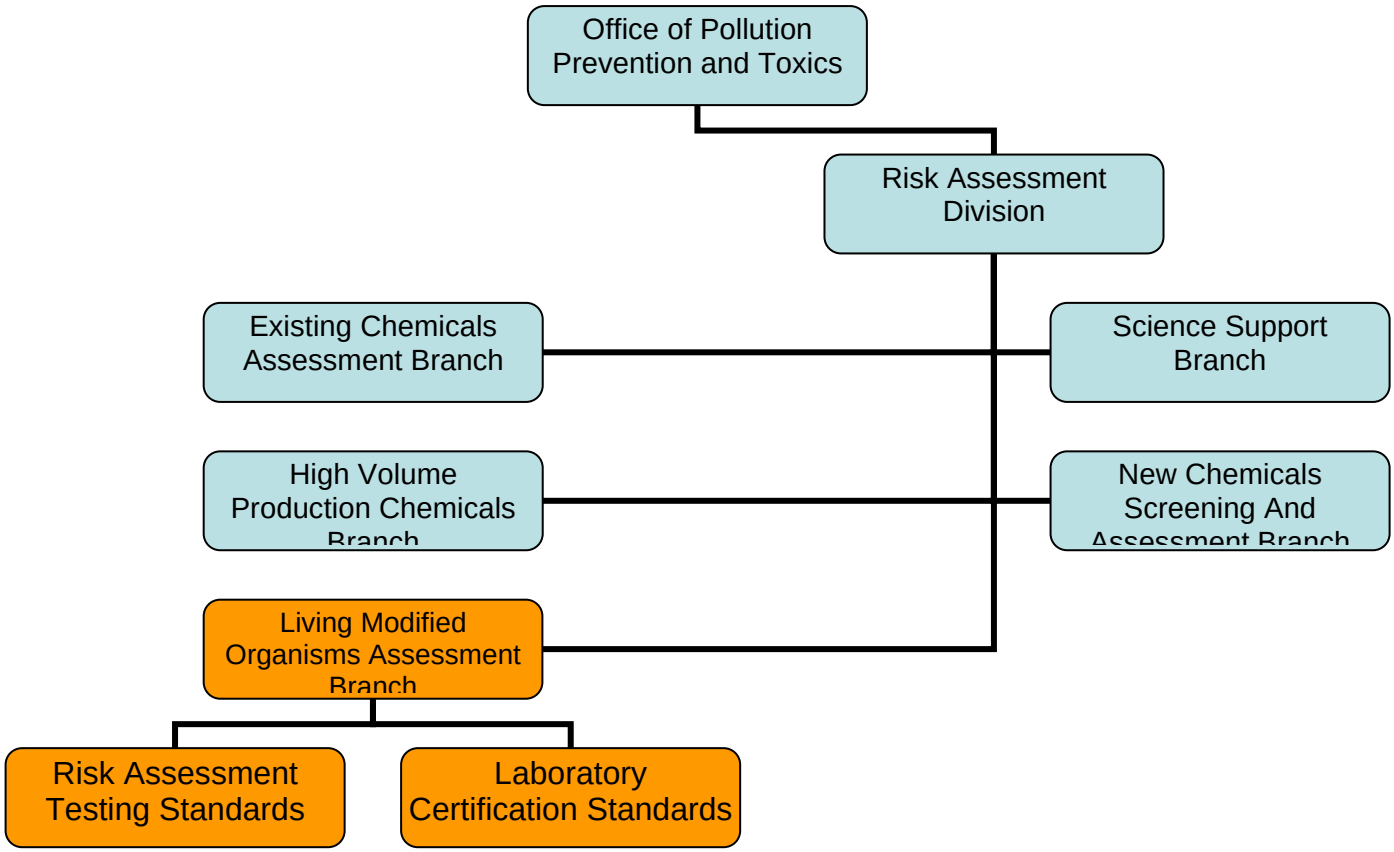
APPENDIX 5: EPA ORGANIZATIONAL CHARTS



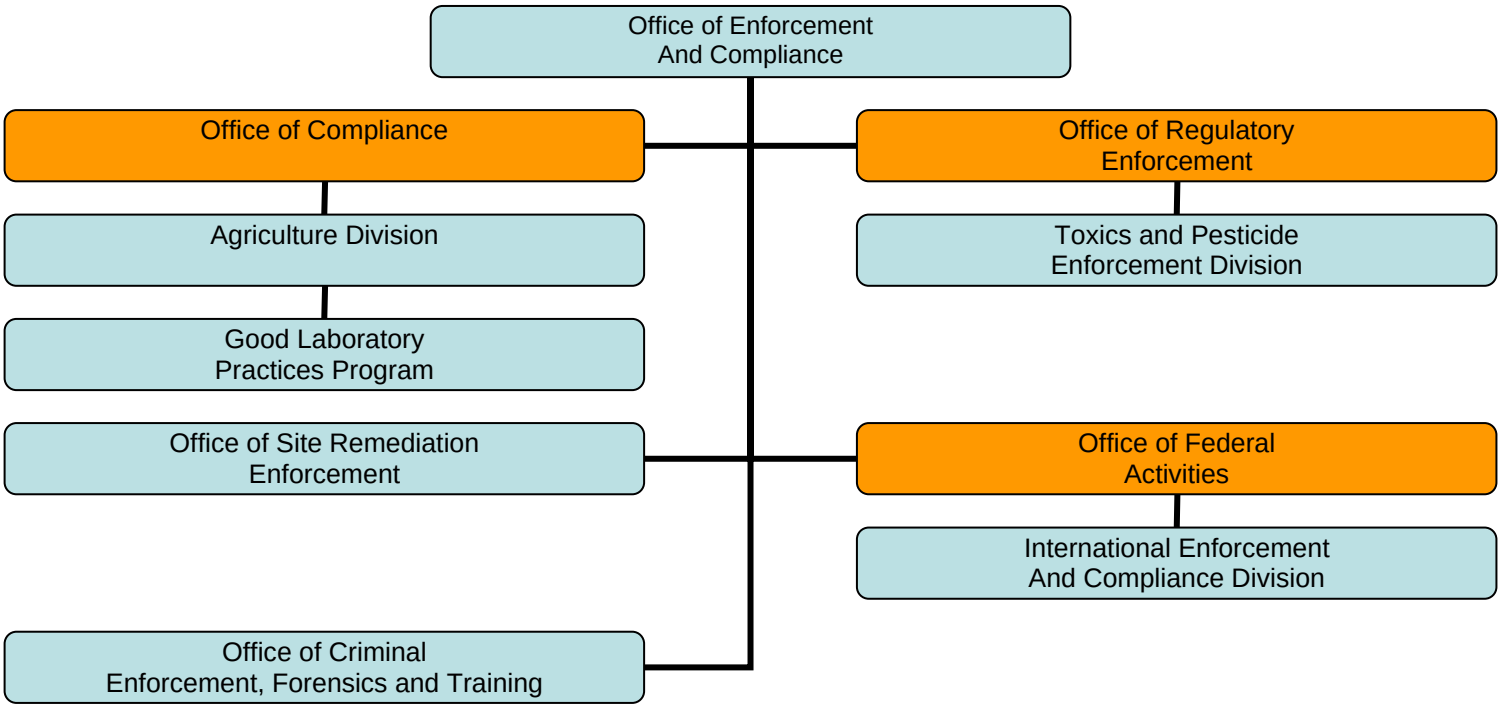
APPENDIX 5: ORGANIZATIONAL CHARTS (CONTINUED)



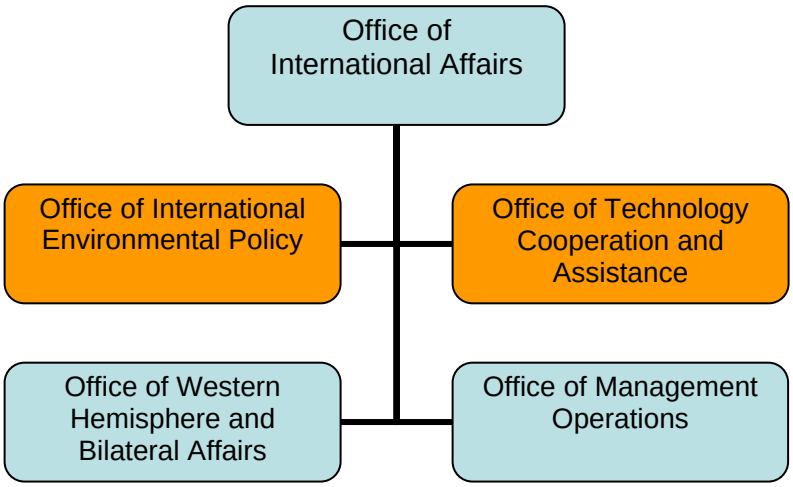
APPENDIX 5: ORGANIZATIONAL CHARTS (CONTINUED)



APPENDIX 5: ORGANIZATIONAL CHARTS (CONTINUED)



APPENDIX 5: ORGANIZATIONAL CHARTS (CONTINUED)



APPENDIX 6: ORGANIZATION AND STAFFING CHART

Office	Functions	# Staff	Title	GS
OPPTS	LMO Risk Assessment Branch Risk Assessment Standards Laboratory standards Biotechnology Team Risk Assessment Submission BCH Coordination	1 3 3 2 1 *6*	Chief of Branch Associate Chief of Branch and Scientific Staff Associate Chief of Branch and Scientific Staff International Cooperation Officer International Cooperation Officer *Contractors*	14 13 10 13 10 13 13
OECA	Laboratory Certification Risk Assessment Procedures Audit International Compliance	1 1	Environmental Protection Specialist	12 12
OIA	Public Education & Outreach Capacity building	.2 1 *3*	Public Affairs Specialist Technical Information Specialist *Contractors*	13 13 10
	Total	**22.2=(13.2+9)**		$1,612,834

APPENDIX 7: BUDGET AND REVENUE PROJECTIONS

Team	**Personnel**	**Other Than Personnel**	**Total**
Biotechnology Team	$281,226.00	$225,000.00	$506,226.00
LMO Risk Assessment Branch	$896,879.00	$1,650,000.00	$2,546,879.00
Office of Enforcement and Compliance Assurance	$157,652.00	$142,000.00	$299,652.00
Office Of International Affairs	$277,077.68	$803,000.00	$1,080,077.68
Total Program Budget	**$1,612,834.68**	**$2,820,000.00**	**$4,432,834.68**

APPENDIX 7: BUDGET AND REVENUE PROJECTIONS -PER EPA OFFICE

BIOTECHNOLOGY TEAM (SCIENCE COORDINATION & POLICY DIVISION--OPPTS)

Title	Number	Series	Grade	Salary	Total
International Cooperation Officer	1	GS-0136 (International Cooperation)	13	$ 93,742	$ 93,742.0
International Cooperation Officer	2	GS-0136 (International Cooperation)	13	$ 93,742	$ 187,484.0
TOTAL	3				**$ 281,226.0**

LMO ASSESSMENT BRANCH (RISK ASSESSMENT DIVISION--OPPTS)

Title	#	Series	Grade	Salary	Total
Chief of Branch	1	GS-0408 (Ecology)	14	$110,775	$ 110,775.0
Associate Chief of Branch, Field Testing Standards	1	GS-0430 (Botany)	13	$ 93,742	$ 93,742.0
Associate Chief of Branch, Laboratory Testing Standards	1	GS-0440 (Genetics)	13	$ 93,742	$ 93,742.0
Scientific Staff, Field Testing Standards	1	GS-0408 (Ecology)	10	$ 59,862	$ 59,862.0
Scientific Staff, Field Testing Standards	1	GS-0471 (Agronomy)	10	$ 59,862	$ 59,862.0
Scientific Staff, Laboratory Testing Standards	1	GS-0415 (Toxicology)	10	$ 59,862	$ 59,862.0
Scientific Staff, Laboratory Testing Standards	1	GS-0413 (Plant Physiology)	10	$ 59,862	$ 59,862.0
Contractors	6	GS-04xx	10	$ 59,862	$ 359,172.0
TOTAL	13				**$ 896,879.0**

OFFICE OF ENFORCEMENT AND COMPLIANCE ASSURANCE

Title	Number	Series	Grade	Salary	Total
Environmental Protection Specialist	1	GS-0028 (Environmental Protection Specialist Series)	12	$ 78,826	$ 78,826.0
Environmental Protection Specialist	1	GS-0028 (Environmental Protection Specialist Series)	12	$ 78,826	$ 78,826.0
TOTAL	2				**$ 157,652.0**

OFFICE OF INTERNATIONAL AFFAIRS

Title	Number	Series	Grade	Salary	Total
Technical Information Specialist	1	GS-1412 (Technical Information Services Series)	13	$ 93,742	$ 93,742.0
Public Affairs Specialist	0.2	GS-1035(Public Affairs)	13	$ 18,748	$ 3,749.7
Project Manager (Contract)	3	GS-1412 (Technical Information Services Series)	10	$ 59,862	$ 179,586.0
TOTAL	4.2				**$ 277,077.7**

APPENDIX 7: BUDGET AND REVENUE PROJECTIONS (CONT.) - OTHER THAN PERSONNEL COST ESTIMATES PER OFFICE

BIOTECHNOLOGY TEAM (SCIENCE COORDINATION & POLICY DIVISION--OPPTS)	
Description	**Cost**
Travel(Protocol Related)	$ 200,000
IT Equipment	$ 20,000
Office Supplies	$ 5,000
TOTAL	$ 225,000

LMO ASSESSMENT BRANCH (RISK ASSESSMENT DIVISION--OPPTS)	
Description	**Cost**
Travel	$ 100,000
Technical Services *	$ 200,000
IT Equipment	$ 250,000
Risk Assessment Laboratory – Setup *	$ 1,000,000
Risk Assessment Laboratory – Supplies	$ 100,000
TOTAL	$ 1,650,000

OFFICE OF ENFORCEMENT AND COMPLIANCE ASSURANCE	
Description	**Cost**
Travel (certification)	$ 100,000
Inspection Materials	$ 5,000
Technical Services (certification and auditing)	$ 20,000
IT Equipment	$ 15,000
Office Supplies	$ 2,000
TOTAL	$ 142,000

OFFICE OF INTERNATIONAL AFFAIRS	
Description	**Cost**
Travel (certification)	$ 100,000
Outreach & Education Grant	$ 100,000
Capacity Building Seed Money	$ 600,000
Office Supplies	$ 3,000
TOTAL	$ 803,000

APPENDIX 17: BUDGET AND REVENUE PROJECTIONS (CONT.) - RISK ASSESSMENT FEES, FINES AND REVENUE PROJECTION

Fee Schedule

Description	**Fee**
Laboratory Certification – Initial	$40,000.00
Laboratory Certification – Biennial Recertification	$20,000.00
Laboratory Certification – Appeal	$5,000.00
Risk Assessment Audit - New LMO	$25,000.00
Risk Assessment Audit – Reevaluation	$15,000.00
Risk Assessment Audit – Appeal	$10,000.00
Submission - AIA Request – Initial	$10,000.00
Submission - AIA Request - Amendment/Clarification	$5,000.00

Fine Schedule

Description	**Fine**
Unapproved LMO Import - First Violation	$250,000.00
Unapproved LMO Import - Subsequent Violation	$500,000.00
Unapproved LMO Export - First Violation	$100,000.00
Unapproved LMO Export - Subsequent Violation	$250,000.00
Deliberate Misrepresentation - Risk Assessment	$100,000.00
Deliberate Misrepresentation – Laboratory Certification	$250,000.00
Withholding Information – AIA Submission	$100,000.00
Withholding Information – Risk Assessment	$100,000.00
Misappropriation of Intellectual Property	$1,000,000.00

Revenue Projections

Description	**Number**	**Fee**	**Total**
Laboratory Certification – Initial	10	$40,000.00	$400,000.00
Laboratory Certification – Appeal	2	$5,000.00	$10,000.00
Risk Assessment Audit - New LMO	25	$25,000.00	$625,000.00
Risk Assessment Audit – Appeal	5	$10,000.00	$50,000.00
Submission - AIA Request – Initial	20	$10,000.00	$200,000.00

APPENDIX 7: BUDGET AND REVENUE PROJECTIONS (CONT.)
LABORATORY SETUP FOR LMO RISK ASSESSMENT

Description	**Cost**
GC-MS	$ 15,000.00
Electrospray MS-MS	$ 150,000.00
MALDI-TOF MS	$ 250,000.00
GC-FID/EIC	$ 10,000.00
PCR	$ 10,000.00
Refrigerated Centrifuge	$ 10,000.00
Glassware	$ 50,000.00
Imaging and Visualization	$ 25,000.00
UV/VIS	$ 10,000.00
Ventilation Hoods	$ 100,000.00
Water Filtration/Purification	$ 15,000.00
Plant Pathology/Dissection	$ 25,000.00
Confocal Microscope	$ 30,000.00
Coplanar Microscope	$ 25,000.00
Computer Workstations	$ 100,000.00
Supplies	$ 75,000.00
Reagents	$ 100,000.00
TOTAL	**$1,000,000.00**

APPENDIX 7: BUDGET AND REVENUE PROJECTIONS (CONT.) TECHNICAL SERVICES BREAKDOWN FOR LMO RISK ASSESSMENT OFFICE

Description	**Cost**
Electron Microscopy	$ 75,000.00
Sample Preparation	$ 10,000.00
Sample Transport	$ 10,000.00
Elemental Analysis	$ 75,000.00
NMR Spectroscopy	$ 75,000.00
Other Lab Work	$ 55,000.00
TOTAL	$ 245,000.00

APPENDIX 8: PERFORMANCE MANAGEMENT OUTPUTS & OUTCOMES

Risk Assessment Auditing

Output Measures	Outcome Measures
1 Average time of audit	1 Customer satisfaction rating
2 Average total cost of audit	2 Percentage of program participants by sector
3 Appeals rate	3 Value of patents of LMO SAFE products
4 Average number of errors	
5 Rate of initial acceptance	
6 Rate of acceptance with revisions	
7 Cost and time to establish initial audit	
8 Baseline cost overruns	

Laboratory Certification

Output Measures	Outcome Measures
1 Average time to certification	1 Customer satisfaction rating
2 Average total cost of certification	
3 Appeals rate	
4 Rate of initial certification	
5 Rate of certification with modifications	
6 Average numbers of discrepancies	
7 Baseline cost overruns	

BCH and AIA Submissions - Export

Output Measures	Outcome Measures
1 Average processing time	1 Customer satisfaction rating
2 Average processing cost	2 Percentage of LMO SAFE exports
3 Rate of requests for clarification	3 Individual market penetration of US LMO SAFE products

AIA Submission Review - Import

Output Measures	Outcome Measures
1 Average review time	1 Customer satisfaction rating
2 Average review cost	2 Percentage of LMO SAFE imports
3 Rate of requests for clarification	3 Market penetration of LMO SAFE imports
4 Rate of initial approval	
5 Rate of approval with revisions	
6 Rate of 90-day receipt notification	
7 Rate of 270-day decision notification	

Overall Process

Output Measures	Outcome Measures
1 Rate of unintended LMO release in US	1 Customer satisfaction ratings
2 Rate of unintended LMO release in trade partners	2 External ratings/rankings
3 Rate of compliance with Article 8(2)	3 Metrics of biodiversity
4 Rate of final notification within 270 days	4 Value of LMO trade before and after
5 Jobs created or retained in industry	
6 Benefit/Cost ratios net of subsidies and certification costs	
7 Percentage change in unlabeled LMO products in domestic markets	

APPENDIX 9: YEAR ONE CRITICAL TASKS (MASTER CALENDAR)

I) Office of Prevention, Pesticides and Toxic Substances (OPPTS)

a) Risk Assessment Division (of OPPTS)

Laboratory Certification Standards (completed by February)
- Set Lab Certification Standards based on NIST requirements
- Laboratory Review

Risk Assessment Standards (completed by April)
- Develop Lab and Field Testing Standards
- Promotion of Risk Reduction and related public communication

b) Biotechnology Team (of OPPTS)

Coordination (year-long activity)
- Provide leadership, peer review and science & policy synthesis within OPPTS
- Focal coordination point of biotechnology issues within all federal agencies
- Coordination with other EPA offices and Protocol Secretariat

c) Risk Assessment Submission
- Submit Risk Assessments and AIA Materials to BCH (completed by December)

d) Performance Management
- Monthly Performance Reports for the OPPTS (year-long activity)
- Program Performance Management (completed by May)
  - Strategic Vision & Goals
  - Staffing Plan & Standards
  - Regulatory Assessment
  - NVLAP Accreditation
- Personnel Review and Staffing Assessment (completed by August)
  - Initial Personnel Review & Staffing Assessment
  - Personnel Review
- Inspector General's Audit (completed by December)
  - Initial Inspector General's Audit
  - Inspector General's Audit
  - TQM Integration Plan
  - Benchmarking Report
  - Annual Report to CoP

II) Office of Enforcement and Compliance Assurance (OECA)

a) Auditing Risk Assessment Procedures (completed by December)
- Perform a Demo Assessment
- Issue Risk Assessment Audit Report
- Create Risk Assessment Procedure Manual
- Establish Risk Assessment Regulations

b) Issuing Laboratory Certification (year-long activity)
- Inspection of Laboratory's Processes and Equipment
- Issuance of Certification if Standards are met

c) Enforcement of International Regulations (year-long activity)
- Create divisional manual with Int'l Regulations directives

Monitor the compliance with Protocol requirements by auditing
Practices set by EPA standards enforceable by the Government

d) Performance Management for the OECA (year-long activity)
Monthly performance Reports

III) Office of International Activities (OIA)

a) Public Education and Outreach (year-long activity)
Develop Educational Kits and Posters
Provide state, direct and grants channeled through NGOs
Work with external agency to develop awareness materials

b) Capacity Building (year-long activity)
Biosafety training for Project managers
Preparation to Capacity Building Projects
Coordinate Capacity Building Projects
National Biosafety Frameworks
Human-resources development

c) Performance Management for the OIA (year-long activity)
Monthly performance Reports

APPENDIX 10: REFERENCES

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1. **Cartagena Protocol on Biosafety: Text of the Protocol**
http://www.biodiv.org/biosafety/protocol.asp

LAWS AND REGULATIONS:

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2. **Bilateral, Regional & Multilateral Agreements:**
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3. **Decision making under the Cartagena Protocol on Biosafety;** Jank, Bernhard and Gaugitsch, Helmut; Trends in Biotechnology; May 2001 Vol. 19, Issue 5, pp. 194-197.

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http://www.sipa.columbia.edu /RESEARCH /Paper/99-9.pdf

CAPACITY BUILDING AND RISK ASSESSMENT:

9. **Capacity Building Projects**
http://bch.biodiv.org/database/record.aspx?searchid=123514&recordid=97#Outco

10. **Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety**; Annex I to decision BS-I/5; Extracted from document UNEP/CBD/BS/COP-MOP/1/15.
http://bch.biodiv.org/doc/ACTION%20PLAN-CPB-EN.pdf

11. **European Commission Health & Consumer Protection;** Directorate General; Guidance document for the risk assessment of genetically modified plants and derived food and feed, Brussels; 2003.

12. **MATRA project: Implementation of Biosafety Frameworks in Pre-Accession Countries of Central and Eastern Europe**; Capacity Building Project.
http://bch.biodiv.org/database/record.aspx?searchid=123562&record id=108#Outcomes

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2. **Biotechnology: Transgenic crops in natural habitats**; Crawley, M.J., Brown,S.L., Hails, R.S., & Rees, M., Nature Magazine # 409, p. 682-683, 2001

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