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Biosafety Protocol for Genetically Modified Organisms: Overview

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name redacted
Agricultural Policy Analyst
Resources, Science, and Industry Division

name redacted
Senior Analyst in International Environmental Policy
Resources, Science, and Industry Division

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Summary

The Biosafety Protocol to the 1992 Convention on Biological Diversity (CBD) was adopted in January 2000, by the 176 nations that are parties to the CBD. Not having ratified the CBD, the United States participated in the negotiations as an observer, but nevertheless was an active participant in the discussions. The Protocol addresses a major area of concern that was not resolved by the parent CBD in 1992 — the safe handling, transfer and trade of biological organisms. In recent years, this issue has gained new prominence — and controversy — as genetically modified organisms (GMOs) have become widely used as agricultural crops, and have become the focus of concern by U.S. trading partners and citizens around the world. While GMOs are widely used in U.S. crops, citizens and governments in many countries, particularly in Europe, have questioned the environmental and health safety of such products, and have rejected them in the marketplace.

The Biosafety Protocol sets forth a number of procedures and rules concerning trade in biological products, including agricultural commodities. These rules are therefore of key importance to U.S. economic interests, including those who develop biotechnology. The Protocol applies to the transboundary movement, transit, handling and use of most GMOs. It incorporates a number of principles that are still under development and in the process of being defined. These include some controversial concepts such as the precautionary approach (popularly known as the "precautionary principle"), which is generally understood to mean that if definitive scientific certainty is lacking, it is valid to err on the side of caution. This approach is a source of concern for critics, who worry about the erection of trade restrictions justified by using this concept. The Protocol also calls for "Advance Informed Agreements" between exporting and importing countries regarding first shipments of a GMO and labeling of subsequent shipments; and the establishment of a Biosafety Clearinghouse as a means to share scientific, technical, environmental, and legal information on GMOs. Issues relating to these provisions are discussed in this report, including concerns about trade restrictions that might ensue from the protocol, the possibility of burdensome information responsibilities, and others.

Given the importance of the Protocol to U.S. interests, the United States is likely to remain an active participant in refining the elements set forth in it. A related issue is whether the United States is hampered in this participation by the fact that it has not ratified the parent Convention on Biological Diversity. Consequently, the United States cannot sign the Protocol and attends the related negotiations as an "observer." In general, the issues related to GMOs and how the Biosafety Protocol may affect U.S. interests related to them are likely to be of continuing interest to Congress in terms of possible economic impacts and trade considerations.

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Introduction

In general, "biosafety" refers to efforts to ensure safety in using, transporting, transferring, handling, releasing and disposing of biological organisms–including genetically modified organisms (GMOs)--when they are considered potentially capable of harming human, animal or plant health, or the environment. Currently, most developed countries have laws and regulations that ensure the biosafety of potentially hazardous organisms in domestic use and in trade.[1] However most developing countries lack similar legal biosafety safeguards.

The Cartagena Biosafety Protocol,[2] completed in January 2000, is the international agreement that addresses safety concerns related to trade in genetically modified organisms.[3] The Protocol applies to the transboundary movement, handling and use of those GMOs that may have impacts on human health, the environment, or biological diversity. The Protocol is viewed by many as the main mechanism for dealing with biosafety concerns when GMOs cross international borders.[4] This Biosafety agreement is a protocol to the 1992 Convention for Biological Diversity (CBD–also popularly known as the Biodiversity Convention), a global agreement that addresses major aspects of biological diversity, including species conservation, genetic resources, and ecosystem protection, with a general goal of reducing species extinctions. The CBD entered into force in 1993, and at present, 179 nations are parties to this treaty. [5] The United States is not a party to the CBD (the Senate has declined to approve the treaty, as discussed below), and thus could not participate directly in the official proceedings that drafted the biosafety Protocol. However, U.S. observer delegations have attended all CBD meetings since 1992, and have played an

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[1] In the U.S., biotechnology is regulated jointly by the Department of Agriculture, the Environmental Protection Agency, and the Food and Drug Administration. For a thorough discussion of biotech regulation in the U.S. see CRS Report RL30198, *Food Biotechnology in the United States: Science, Regulation and Issues*, by Donna Vogt & Mickey Parish.

[2] This Protocol is named after the city of Cartagena, Colombia, where the 1st Extraordinary Meeting of Conference of Parties (ExCOP) drafted significant portions of this key accord on February 14-22, 1999.

[3] GMOs are organisms altered by using recombinant DNA and RNA techniques.

[4] The Biosafety Protocol refers to GMOs alternatively as "Living Modified Organisms" or LMOs.

[5] Countries become parties after signing and ratifying the CBD. Currently, 12 nations have not ratified the CBD: Afghanistan, Andorra, Bosnia-Herzegovina, Brunei, Iraq, Kuwait, Libya, Malta, Saudi Arabia, Somalia, Thailand, and the United States.

active role in making its positions known and influencing treaty deliberations. Drafting of the Biosafety Protocol started in 1996, and in January 2000, the parties to the CBD agreed upon a final draft Protocol in Montreal, Canada.

Many, especially within the Clinton Administration, thought that U.S. actions were key in shaping the draft Protocol to protect U.S. interests, yet they acknowledged the U.S. capacity to influence CBD's deliberative bodies was affected by its non-party status. Other analysts think that the Protocol will change international trade rules for biotechnology in ways contrary to U.S. interests. They have argued that provisions in the Protocol are mostly based on controversial concepts, such as the precautionary approach (popularly known as the "precautionary principle"; see page 6), which they see as veiled threats to fair trade.

Other potentially controversial Protocol provisions, still subject to further negotiation, will require mandatory labeling of bulk commodities or could call for environmental studies, and may establish compulsory product information and disclosure procedures. In general, provisions in the Biosafety Protocol are likely to shape market rules and impact U.S. interests in biotechnology trade.

Background –The Convention on Biological Diversity

As noted above, the Biosafety Protocol is an outgrowth of the Convention on Biological Diversity. Only parties to the parent treaty, the CBD, are part of the official negotiations on protocols, which are effectively adjunct treaties on specific issues that the parties believe require elaboration or treatment. The United States played an active role in the negotiations that produced the CBD, even though the Congress has declined to approve its ratification. Similarly, because of the importance of the Biosafety Protocol to U.S. agricultural and biotechnology interests, the United States has remained actively involved, sending observer delegations, to the negotiations on it. These delegations actively participated in substantive discussions and formulation of positions that were made part of the official proceedings of the protocol negotiations. Because the United States is not a party to the CBD, it is not in a position to sign the Protocol, and thus the history and status of the Biodiversity Convention is a key element in considering the U.S. role in the Biosafety Protocol.

The Convention on Biological Diversity (CBD) dates back to intensive negotiations in the early 1990s. In 1992, world leaders came together in Rio de Janeiro, Brazil, to attend the world's largest summit –the United Nations Conference on Environment and Development (UNCED–popularly known as the "Earth Summit") to take up the wide array of issues relating to environmentally and economically sustainable use of the world's resources. One major area of concern was biological diversity – the concern that rapid loss of species around the world is occurring and international cooperation was needed to address the problem. The CBD was one of two major treaties opened for signature at UNCED (the other was on climate change).

In 1992, President Bush declined to sign the CBD treaty, citing concerns including the lack of sufficient protection for intellectual property. In 1993, President Clinton signed the CBD and sent it to the Senate for its advice and consent for ratification. The Administration accompanied the proposed treaty with a statement

of interpretation in order to allay concerns raised by detractors (see CRS report 95-598 ENR, *Biological Diversity: Issues Related to the Convention on Biological Diversity*). In 1994, the Senate Foreign Relations Committee reported favorably on ratification, but the full Senate did not act on the treaty before the end of the 103rd Congress. Since 1995, consideration of the treaty has received little or no attention from the U.S. Senate. Currently, the treaty remains pending in the Senate Committee on Foreign Relations. The CBD treaty contains few binding obligations, relying instead on largely voluntary measures. Also, the United States is in compliance with the treaty on the basis of current U.S. law, so no changes in U.S. law would be needed if it should become a party.

There are differences of opinion regarding U.S. ratification of the CBD. Some observers consider that the treaty is flawed and could be harmful to U.S. trade and national security interests. Some critics question the need for the United States to become a party to the CBD because, as the number one producer and exporter of biotechnology, the United States is already in a position of strength to set market rules. Some critics are concerned that other nations could use the Protocol provisions as disguised protectionism. Conversely, others feel that the CBD is needed to protect biological diversity, and that the United States is paying a growing price by its refusal to ratify. Backers of ratification cite a growing sense of isolation of the United States from some of its key trading partners, and they worry that the United States will have less leverage in future CBD decisions.

Framing the CBD Biosafety Protocol

The use of biotechnology has led to broad changes in medicine, industrial processes, engineering and agriculture. In agriculture, biotechnology is being used to improve crops' resistance to pests and environmental stresses and to enhance their nutritional content. Controversies have developed among various nations over whether certain types of GMOs constitute a potential hazard to human health or to the environment. GMOs have long been considered the subject of a number of biosafety concerns. Many genetically modified plants, for example, are produced with techniques that include the DNA sequences from common plant pathogens. Other biosafety concerns commonly cited are: the possibility of adverse impacts on non-target species or ecosystems; the potential for enhanced weediness of GM crops (i.e. a plant becomes invasive, or transfers resistance genes to its wild relatives); and the instability of inserted genes (i.e. the possibility that a gene will lose its effectiveness.)[6] To date, transfer of genes to weedy relatives has been observed, and a controversial laboratory study has shown potential damage to a non-target species

[6]The consensus among U.S. scientists is that no strict distinction exists between the health and environmental risks posed by GM plants and those modified by conventional breeding practices. Opponents counter that risks are potentially irreversible, untraceable and uncontrollable.

(the monarch butterfly).[7] Whether such effects prove to be widespread or manageable has not been fully established.

Biosafety Protocol Negotiations

The CBD's Biosafety Working Group (BSWG) negotiated the Biosafety Protocol in six meetings that took place between 1996 and January of 2000. After the Earth Summit in Rio, the BSWG became the principal forum for deliberations and negotiations for biosafety issues, regarded by parties to the CBD as an important area of "unfinished business."

According to observers, one difficulty in these negotiations was the fact that the United States, as the largest exporter and producer of GMOs, was not officially part of the proceedings. However, the United States actively participated as part of the "Miami group," a coalition of leading agricultural exporters that also included CBD parties: Argentina, Australia, Canada, Chile and Uruguay. This group developed proposals and positions during the drafting of the Protocol.[8]

According to the CBD Secretariat, the Protocol will enter into force by August 2000, having met the criterion in Article 37 of the Protocol at the closing of the 5th Meeting of the Conference of the Parties (COP5) in Nairobi, Kenya on May 26, 2000.[9] For many parties, signature to a protocol automatically confers ratification, since they have ratified the parent treaty; in others, like the United States, each protocol must be separately considered for ratification after signature. The Protocol is currently open for signatures by parties and will remain open at the United Nations Headquarters until June 5, 2001. Nations that wish to sign onto the Protocol after that date would have to do so by accession, which includes ratification.

Analysts agree that, while the Protocol is a substantially complete document, the pact delays final negotiations on a number of controversial issues for up to 4 years after its adoption. For example, the door has been left open for parties to revise or strengthen rules for 'contained use' GMOs (discussed below) that are not likely to propagate in the environment (i.e., bulk commodities.) The Miami group is expected to oppose any move to increase documentation and notification requirements for bulk commodities, arguing that the cost of segregation and identity preservation (i.e., tracing a GMO product from the farm to the consumer's table) could lead to irreparable harm to biotechnology trade.

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[7] Metz, et al. 1997. *The impact on biosafety of phosphinothricin-tolerance transgene in interspecific B. rapa x B. napus hybrids and their successive backcrosses*. Theor. Appl. Genet. 95:442-450. Springer-Verlag (weeds).; and Losey, J., et al., 1999. *Transgenic pollen harms monarch larvae*. Nature 399: 214.

[8] Other key interest groups that formed and were active during drafting of the Protocol were the European Union (EU), the "Like-minded" group of developing countries (the G-77/China, less the members of the Miami group), and the "Compromise group," (Japan, Mexico, Norway, the Republic of Korea and Switzerland.)

[9] Article 37 specifies that the Protocol will enter into force on the 90th day after the date of deposit of the fiftieth instrument of ratification. As of December 22, 2000, two countries (Bulgaria and Trinidad Tobago) have ratified the protocol and 79 others have signed it.

Several important aspects of current provisions have been left for future negotiations such as: (1) how to apply the "precautionary approach" to the Protocol; (2) how to develop rules to integrate the Protocol with other trade agreements, such as the WTO, into a "mutually supportive" framework; and (3) how to develop rules and procedures based on international law that would establish liability and redress for damages resulting from the movement of GMO (these are to be finalized within 4 years).

The Biosafety Protocol: Key Provisions and Related Issues

The Protocol addresses the major concerns that have arisen in connection with GMOs, and it bears directly on GMO trade. Most GMOs are covered by the Protocol except for those used to produce human pharmaceuticals. The key provisions, and the issues related to them, are briefly summarized below.

Advance Informed Agreements. The Protocol establishes the use of 'Advance Informed Agreements' (AIA) between the importing and exporting parties that cover the first transboundary movement of any GMO. The purpose of AIAs is to ensure that recipient countries have the opportunity to assess environmental risks associated with the importation of biotechnology products. The Biosafety Protocol creates the procedure by requiring exporters to seek consent from importers before *the first shipment* of a GMO is introduced into the environment (applies to seeds for planting, fish for field release, and microorganisms for environmental bioremediation). In addition, article 11 also requires that bulk shipments of GMO commodities to be used as food, feed, or for processing must be accompanied by declarations stating that such shipments "*May Contain*" GMOs and are "*Not intended for intentional introduction into the environment*."

Two categories of GMO are recognized according to their intended use: GMOs for 'contained' or 'direct' use (i.e., food, feed, or for processing) that require minimal biosafety precautions; and GMOs for 'intentional introduction' to the environment (i.e., agricultural seeds and other propagation materials, and live fish), which require more stringent biosafety procedures. GMOs unlikely to cause adverse effects on biological diversity, and those intended for contained use (i.e., feed, food, or processing) can be *exempted* from the application of AIA procedures. Confidential information received under Protocol procedures must be protected by importing and exporting parties. Further, parties are required to cooperate in developing and/or strengthening the biosafety capabilities of developing countries.

Key Issues. The rationale for Advance Informed Agreements (AIA), espoused in 1992 by article 19.3 of the CBD, is the perception that international trade in GMOs could adversely affect the environment and that trade should not proceed without the informed agreement of the recipient country. While support for some form of AIA is widespread, differing positions about their scope and breadth were among the principal issues under discussion. For example, as negotiations progressed it became clear that the GMO's intended use should determine the level of risk assessment and risk management needed to attain biosafety. Similarly, negotiators decided that the intended use of a GMO should determine the level of information disclosure needed from the exporting party. However, the issue of labeling and proper documentation

for bulk commodities will be revisited by the Conference of Parties (COP) within 2 years, thus opening the door for the introduction of additional restrictions and mandatory requirements.

Precautionary Approach. The Protocol reaffirms the importance of the precautionary approach in its preamble and in articles 10 and 11, which prescribe trading procedures for the importing parties. These articles, for instance, state that even in the case of a lack of scientific certainty (due to insufficient scientific data, analysis or information) importers could deny entry to undesired GMOs. At the same time, risk assessments and risk management are prominent features of the Protocol. The Protocol allows the importer to require that the exporter carry out and pay for risk assessments as well as any needed mitigation actions. In addition, the Protocol allows parties to use socioeconomic considerations in reaching a decision on importing GMOs.

The "precautionary approach" was established as a guiding tenet of the CBD, which directly referred to Principle 15 of the non-binding Rio Declaration. Principle 15 states that:

> "*In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation*."

Key Issues. In general, most interpretations agree that the precautionary approach urges policymakers to err on the side of caution in the face of scientific uncertainty.[10] Environmentalists, particularly in Europe, consider this approach to be a valid policy option in the face of incomplete or inadequate scientific knowledge about health or environment impacts. Defenders of the application of this approach maintain that it is only "a temporary mechanism" that gives time for scientific inquiry. Policymakers in Europe recognize, as do those in the United States, the need for an assessment of risks based on accepted scientific facts.[11] However, critics worry that elevating the precautionary approach to the level of a 'political principle' may create false public expectations for absolute safety and the demand for zero environmental risks. At worst, some critics maintain, the precautionary approach can easily be used as a form of disguised protectionism.

Current language in the Protocol leaves the development of procedures for trade and/or entry decisions subject to further refinement by the CBD's Conference of Parties. Presently, few countries agree on just what the precautionary approach is. Analysts believe that future refinements may be affected by this lack of accepted

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[10] For a discussion on the precautionary approach see CRS Report RS20310, *Science behind the regulation of food safety: risk assessment and the precautionary principle* by Mickey Parish.

[11] Internal political disagreements exist within the EU over the use of the precautionary approach. E.g, France is at odds with the EU over France's use of precautionary approach for not admitting British beef into the country after the "mad cow" disease.

disciplines to guide the uniform application of the precautionary approach. The current situation has enticed international bodies, like the EU, the Codex Alimentarius Commission, and the Organization for Economic Cooperation and Development (OECD), to offer comprehensive views on the subject in hopes of setting a world's standard for the application of the principle in GMO trade.[12]

Biosafety Clearinghouse. The Protocol establishes the Biosafety Clearing-House (BCH), which will be used as the mechanism to share scientific, environmental, and legal information on GMOs.

As currently envisioned, the BCH will be a centralized source for information on national laws, guidelines and regulations for the implementation of the Protocol, as well as on other agreements on biotechnology. The need for a centralized information source on scientific and technical data about GMO trade was also envisioned in 1992 by the CBD (Articles 18.3 and 19.) To accomplish this, Article 20 of the Protocol establishes an internet-based "Biosafety Clearing-House" to help countries exchange information about GMOs. Currently, the BCH is housed at the CBD's Executive Secretariat in Montreal, Canada.

The Protocol requires that transboundary movements of GMOs between parties and non-parties be consistent with the Protocol and encourages non-parties to contribute information through the BCH. Parties are required to notify the BCH of unintended or illegal movements of GMOs, and must adopt measures to prevent and penalize illegal transboundary movements.

Key Issues. Two critical issues were foremost in the minds of negotiators in establishing the BCH: (1) how to adequately balance the rights of parties to access and use relevant information about traded GMOs; and (2) how to protect the intellectual property rights of owners of biotechnology products. Article 20(3) and Article 21 address the protection of confidential and proprietary information by making both trading parties responsible for protecting confidential information received under the Protocol under AIA requirements. However, some controversy exists because the Protocol does not prescribe explicit liabilities for failures to protect intellectual property. Some critics would like to see clear-cut mechanisms in the Protocol to sanction failures to protect confidential information. Recent proposals by by Canada to establish a pilot implementation phase and to have each country apply its domestic laws and requirements to information sharing seem to be favored by other Miami group members.[13] Formal procedures and measures of intellectual property protection are to be developed by the Conference of Parties within 2 years.

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[12]OECD deliberations on the precautionary approach can be found at http://www.oecd.org/subject/biotech/edinburgh.htm . The European Union's position is presented in "*Communications from the Commission on the precautionary principle*" February 2, 2000. Brussels. (see http://europa.eu.int/comm/trade/whats_new/dpp_en.htm.); Codex Alimentarius position found in "*Report of the First Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology*", April 2000, in http://www.fao.org/waicent/faoinfo/ECONOMIC/esn/codex/default.htm.

[13]First Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) December 11-15, 2000 . Montpellier, France.

Relationship of The Protocol with Other Agreements: The Savings Clause. One of the most contentious issues faced by negotiators was to establish how the Protocol's measures would relate to other bilateral or international trade agreements, notably those under the World Trade Organization (WTO). The issue became important after the 1997 Biosafety Working Group meeting in Montreal, where the Miami group insisted on the need for consistency between the Protocol and WTO agreements such as the Sanitary Phytosanitary-Standards (SPS) accord.[14] The key question revolved around how to reconcile differing perspectives in environmental protection philosophies between advocates of the precautionary approach (e.g., the EU), and countries where environmental protection systems stress the use of the best available scientific evidence and risk assessment (i.e., the Miami Group and the United States).

A compromise position was reached through the inclusion of a "savings clause" in the Protocol's preamble that states: "*...nothing in the Protocol implies a change in the rights and obligations of governments under the WTO or other existing international agreements.*" However, the preamble further clarifies that the Biosafety Protocol will not be subordinated to other international agreements, and that they should be mutually supportive.

Key Issues. The Clinton Administration and industry analysts interpret the 'savings clause' to mean that trade disputes originating from Protocol implementation could be handled through existing mechanisms, such as the WTO dispute settlement agreements and its appellate review bodies. Others, especially EU policymakers, are inclined to stress that the Protocol is not subordinated to any agreement, and do not necessarily extend the 'savings clause' to future agreements or to existing ones, which do not adhere to the Protocol.

Notification/Labeling. The Protocol establishes mandatory entry notifications by exporting countries to the competent national authority in importing countries about trade of non-exempted GMOs. A key feature of the Protocol is the requirement for bulk shipments of GMO commodities to be accompanied by documentation stating that such shipments "*May Contain*" GMOs, and that they are "*Not intended for intentional introduction into the environment*," in lieu of a formal AIA. This applies only to GMOs intended for food, feed, or processing (e.g., corn or soybeans).

Other provisions. Finally, parties are allowed to enter into bilateral, regional or multilateral agreements provided that such agreements and arrangements do not result in a lower level of protection than that provided by the Protocol. Also, in the case of unintended or illegal movements, the Protocol also allows the affected party to request the party of origin to dispose of the GMO in question at the expense of the latter. In addition, the Protocol calls for the elaboration and adoption of a liability and redress process for damages resulting from transboundary movements of GMOs.

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[14] This accord establishes disciplines on the use of sanitary and phytosanitary measures in restricting trade. For a complete discussion on SPS see CRS Report 98-254 ENR. *Agricultural Negotiations in the World Trade Organization* by (name redacted).

Impacts on Trade

Analysts agree that the future impact of the Protocol on trade is difficult to gauge because so many key aspects are still to be decided. Also, the current climate of controversy surrounding trade in agricultural GMOs in many countries, especially in Europe, further complicates assessments of trade implications. The Clinton Administration and the U.S. biotechnology industry have stated that the new rules will make it easier to harness the promise of biotechnology without unduly disrupting world food trade.[15] Others, especially critics in Congress, have viewed the accord with skepticism, and have charged that many of its provisions will harm biotechnology trade by opening a potential "flood gate" to restrictive and costly labeling and documentation requirements for U.S. goods.

Conclusion

The United States has pioneered the use of biotechnology and is the world's leading producer of GMO crops. While most U.S. analysts consider that the current Protocol language is a victory for GMO trade, others point to likely future battles and continued friction between the United States and Protocol parties over unresolved areas. Some, particularly in Congress, felt that the Clinton Administration had gone too far in giving concessions for the inclusion of the precautionary approach, and criticize U.S. negotiators for placing the future of GMO trade on a slippery slope by allowing even a modicum of labeling requirements in bulk commodities. Others within that Administration defended their efforts for keeping human health issues out of the Protocol; for lobbying to protect existing trade obligations by introducing the 'savings clause'; and for insisting upon increased intellectual property protection guarantees. They saw these efforts as victories fought and won under the handicap of U.S. non-party status within the CBD. Differences in viewpoints on ratification persist, with some who feel that ratification of the CBD would give the United States a seat at the table and the power to make its full weight be felt, and others who feel that the United States can continue to have adequate influence on the process without being party to a treaty that they consider to be flawed.

These issues related to GMOs and how the Biosafety Protocol may affect U.S. interests related to them are likely to be of continuing interest to Congress in terms of possible economic impacts and trade considerations.

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[15] The United States, through the Miami Group, was a key lobbyist for the "savings clause" and for securing minimal AIA procedures for bulk shipments of GMO foods and feed. The savings clause establishes the relationship between the Protocol and other international trade agreements.