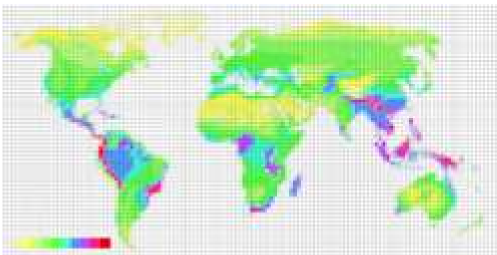
GENEWATCH

http://www.councilforresponsiblegenetics.org/GeneWatch/GeneWatchPage.aspx?pageId=422

May 12, 2012

A PRIMER ON GMOS AND INTERNATIONAL LAW
By Phil Bereano



Introduction

Two international instruments changed the playing field in the past decade regarding the international regulation of genetically engineered organisms. One is the Cartagena Protocol on Biosafety, which is intended to regulate the international transfer of "living modified organisms" (LMOs). The second is a set of guidelines, the Risk Analysis Principles for Foods Derived from Biotechnology, established by a little-known United Nations body called the Codex Alimentarius Commission.

These two instruments signal attempts by the world community to establish rules governing the production, trade and use of genetically modified foodstuffs. Both agreements emphasize the rights of consumers and farmers, and the protection of ecosystems. However, it is still not completely clear how their provisions will work alongside the free-trade rules of the World Trade Organization (WTO).

The Cartagena Protocol: a greener way

By joining the WTO, countries agree to limit their freedom to impose restrictions on foreign trade. The Cartagena Protocol, however, stresses that trade considerations need not always be given precedence over other national objectives. It recognizes that the need to protect biodiversity, the environment and human health are valid priorities in decision-making. As of today, some 163 countries (minus several of the most important agricultural exporters, including the United States, Canada, Argentina and Australia) have ratified the Protocol, which came into force on 11 September 2003.

The Protocol establishes a procedure called Advanced Informed Agreement. Under an AIA, those planning to export LMOs for introduction into the environment must notify the country to which they are being sent. That country is then entitled to authorize or refuse permission for the shipment, based on a risk assessment. Furthermore, the Protocol allows the recipient nation to invoke precautionary regulation if, in its judgment, there is not enough scientific information to make a proper assessment:

"Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism..."

The Protocol does not specify how to resolve any conflict between its own rules allowing an importing country to control trade in LMOs and that country's obligations not to impede trade if it is also a member of the WTO.

The state of international law regarding LMOs is intentionally fuzzy in some respects; diplomatic concerns for the WTO resulted in having a Protocol Preamble containing three intentionally conflicting provisions: that trade and the environment should be "mutually supportive"; that the agreement does not change any Party's international rights and obligations; and that the Protocol should not be interpreted as being "subordinate" to any other treaty. In particular, the Protocol's adoption of the precautionary principle—the idea that an action should not be carried out if the consequences of it are unknown but highly likely to be negative—is claimed by trade interests to run counter to the WTO mandate.

Those involved in drafting the Protocol, along with other observers, also acknowledge that there are a number of outstanding issues relating to the oversight of genetic manipulation technologies even after adoption of the Protocol text. These include:

- "Living modified organisms" (LMOs) is a more restricted category than "genetically modified organisms" (GMOs), since it excludes those no longer alive, and their products.
- "Intentional introduction into the environment" may not address situations where the exporter knows that some shipped modified grain, for instance, will be planted within the importing country, but does not necessarily "intend" this to happen.
- Many important countries are not members of the Protocol, including the largest growers and exporters of LMOs: the United States, Canada, Argentina and Australia.
- The Protocol's provisions on trade in LMOs between a party and a non-party state does not require that its procedures be followed.
- The Protocol says nothing about any regulatory oversight within a country.

In the fall of 2010, a Supplemental Protocol on issues of liability and redress for damages caused by LMOs was adopted after 7 years of intense negotiations, and is in the process of being ratified by the requisite 40 countries.

The Codex Alimentarius: focus on food safety

Two months before the Protocol entered into force, a separate breakthrough took place. In July 2003, with the backing of all its 168 member nations, the Codex Alimentarius Commission produced the first set of international guidelines for assessing and managing any health risks posed by GM foods.

A relatively obscure United Nations agency, the Commission is charged with the key global task of setting international guidelines for food quality and safety. It was established in 1963 by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), and given the mandate of "protecting the health of the consumers and ensuring fair practices in the food trade". The Commission draws up voluntary international food guidelines through negotiations in approximately 30 committees and task forces.

The most significant element of the 2003 guidelines is that they call for safety assessments of all GM foods prior to their approval for commercial sale. This has important implications for WTO members. In

1995, the WTO had agreed that Codex norms should be the reference point for evaluating the legitimacy of food regulatory measures that are challenged as restrictions on trade. Thus, although the Codex guidelines are strictly voluntary, they have legal significance for WTO members as a defense to charges of "unfair trade." Also significant is that all of the major countries growing GMOs—the US, Canada, Argentina, and Australia—are Codex members and agreed to these risk assessment guidelines.

The Codex risk assessment guidelines contain much language about the need for a "scientific" evaluation of the actual hazards presented by the new foods. But they also recommend that "risk managers should take into account the uncertainties identified in the risk assessment and implement appropriate measures to manage these uncertainties". This wording appears to acknowledge the validity of a precautionary regulatory regime, similar to that allowed for international shipments under the Cartagena Protocol.

The Codex also recognizes that "Other Legitimate Factors"—non-scientific in nature—can form a valid basis for regulations, such as using halal or kosher standards. Other provisions within the guidelines call for a "transparent" safety assessment, that should be communicated to "all interested parties" that have opportunities to participate in "interactive" and "responsive consultative processes" where their views are "sought" by the regulators.

These non-scientific aspects are consistent with the second prong of the Codex mandate, namely its role in deterring deceptive practices. Such practices might, for example, include selling or distributing GM foods to consumers without labeling them as such. As a top world food exporter, the United States has vigorously advocated that only "objective" and "scientific" health claims be used as the basis for regulating GM foods, but consumer groups have vigorously contested this position. In the summer of 2011, after 18 years of struggle, Codex finally adopted a guidance document recognizing that countries can adopt laws and regulations covering the labeling of GE foods, including mandatory labeling.

Too rich a mix?

It is not obvious how the Protocol, the Codex guidelines and WTO rules mesh together. Seeking a simple answer to this question assumes that the negotiation of these agreements was guided by a logical process. In fact, they were produced at different times, by delegations from different national ministries with various missions (trade, environment, food, agriculture, health, etc), and without any reference to the bigger picture. These agreements also reflect the different configurations of industry and public interest groups that helped shape them.

Environmentalists argue that the new Codex guidelines on GM foods simply underscore how easy it has been for industry to bring GM foods to market without regulatory supervision, for example in the US. This practice has been criticized by many activist organizations and a growing number of scientists, as well as several international authorities on food safety matters.

Many of these critics point out that there is virtually no peer-reviewed, published scientific research on the risks or benefits of GM food that would allow for safety claims to be tested. They argue that the lack of evidence of risk is not the same as evidence of no risk. Many civil society organizations have insisted that precautionary steps should be taken to avert potential risks. Even the WTO Appellate Body, which settles its disputes, has recognized that divergent scientific views may be considered in making assessments, such as those evaluating food risks.

Using the precautionary principle to manage risks also puts the burden of proof on those seeking to introduce the new technology. The United States and other exporters of GM foods have blocked efforts to incorporate the principle explicitly into the Codex guidelines. But some commentators and activists believe that, despite no actual mention of it in those guidelines, the precautionary principle is implicit in the document's suggestions for risk analysis because these call for the safety of a GM food to be analyzed before it is produced and sold.

The governments blocking the inclusion of the precautionary principle into the Codex guidelines have argued that if it were to be applied to regulating GM foods, it could be used to justify regulations intended primarily to protect domestic industries from foreign competitors — in violation of the WTO agreements. Others point out, however, that it is not the purpose of the Codex guidelines to stimulate trade, but rather, to protect consumers. The WTO is supposed to follow Codex norms, not vice versa.

Whither GMO politics?

The political storm raging round GM foods continues to grow in intensity, largely because the economic stakes rise steadily while scientific debate remains unresolved. Given the frameworks described above, what conclusion can one draw about the prospects for adequate regulatory supervision of the technology, and for proper protection of human health and the environment?

The four countries keen to export GM crops—the United States, Canada, Argentina and Australia—are all Codex members, but none of them are a party to the Cartagena Protocol. Therefore, one could argue that it would be inappropriate for such countries to object about others that choose to use the Codex risk assessments, since they all voted in Codex to adopt them.

On the other hand, as the countries that signed the Protocol meet to work out the details for carrying out risk assessments under its aegis, and to set rules on traceability and liability, none of these four nations will be legally able to block action taken under the Protocol. In reality, however, several nations which are Parties to the Protocol seem to be acting to protect the interests of these exporters.

As a result, the Protocol is likely to lead to rules that focus on protecting biodiversity and health more than any rules devised by the WTO. On that basis, there are grounds for believing that the future will see better environmental and health protection than exists at present.

A different situation, however, is likely to unfold behind the scenes as GM food exporters—particularly the United States—put pressure on countries, one by one, to waive their rights under international law. This already happened before the Protocol was enacted, where weak nations such as Croatia and Thailand had been subjected to pressure by the United States. And last year, Kenya—under enormous pressures from the US, Monsanto, the Gates Foundation and GE interests in South Africa—adopted a very weak "biosafety" law that will likely lead to the large-scale introduction of GE crops being grown in that country. Thus the responses of civil society will be crucial to ensure democratic and transparent oversight of this technology.

***Phil Bereano**, JD, is Professor of Technology and Public Policy at the University of Washington, Seattle. He is on the roster of experts for the Cartagena Protocol, co-founder of the Council for Responsible Genetics, and currently represents the Washington Biotechnology Action Council and the 49th Parallel Biotechnology Consortium at international meetings.*

An earlier version of this article appeared in the April 2004 issue of Seedling magazine, published by Genetic Resources Action International (GRAIN).