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**As the politics around genetically modified (GM) food and crops intensifies, the regulatory scene is also becoming more complicated. One of the instruments that could play a significant role in the future is the UN's Codex Alimentarius. The authors outline Codex's relationship to other relevant treaties, and argue for strong lobbying from civil society to help give Codex the teeth it needs to be an effective instrument for the regulation of GM foods.**


# To Eat ... or Not to Eat?

## An obscure UN agency tries to provide an answer

PHIL BEREANO AND ELIOTT PEACOCK



Concern over genetically engineered foods is now being expressed in farmers' fields, supermarket aisles, commodity exchanges, legislative halls, scientific circles and at dinner tables. The fate of such crops and foods is being determined in many and varied meetings and institutions, some well known and others less so. While many people have learned about the World Trade Organisation's relevance to food, two lesser-known international instruments have recently changed the playing field regarding genetically engineered organisms: the Cartagena Biosafety Protocol and the Codex Alimentarius Commission's Risk Analysis Principles for Foods Derived from Biotechnology. These instruments signal a growing interest among the world community to address the pitfalls of establishing rules and regulations based on trade considerations alone, and the alarming potential consequences for humans and ecosystems of tampering with genes at the molecular level.

These progressive international instruments emphasise the rights of consumers and farmers, and protecting ecosystems. But reaping the benefits offered by these new agreements is contingent upon governments actually implementing them. In attempting to do so, they are bound to meet strong opposition from industry and exporter governments. For this reason, advocacy and lobbying efforts by civil society organisations will be an integral part of making governments use these instruments.

### The Cartagena Biosafety Protocol

In September 2003, a new international agreement, the Cartagena Biosafety Protocol, came into force to regulate the international transfer of *"living modified organisms"* (LMOs). Although every sovereign nation has an absolute right to control its borders and bar what it wishes, most have bargained away this aspect of sovereignty by adhering to the World

Trade Organisation and its limitations on any trade restrictions. The Protocol may prove to be useful in order to re-establish that trade considerations need not always be accorded primacy in balancing out national objectives. Under the Cartagena Protocol and its parent agreement, the Convention on Biological Diversity, protecting biodiversity, the environment, and human health are recognised as valid decision-making criteria.

The Protocol establishes a procedure whereby would-be exporters of LMOs intended to be introduced into the environment must notify the country into which they are being sent. The latter may require an Advanced Informed Agreement governing the shipment, based on a risk assessment. The Protocol clearly allows the latter nation to invoke the Precautionary Principle if, in its judgment, sufficient scientific information is lacking to do a proper assessment.

The 82 countries that have joined the Protocol had their first meeting in Kuala Lumpur, Malaysia, in February 2004. Although many of those activists involved in the process of drafting the Protocol are pleased at much of its language, they recognise that this agreement does not itself resolve many of the existing concerns about creating proper oversight for genetic engineering:

- *"Living modified organisms"* is a more restricted category than *"genetically modified organisms"* since it excludes those no longer alive, and the products thereof.
- "*Intentional introduction into the environment"* may not address situations where the exporter knows, but does not necessarily 'intend' that some of the shipped grain will be planted within the country of import.
- Many of the world's most influential countries are *not* members of the Protocol, including the largest growers and exporters of LMOs: the US, Canada, Argentina, and Australia.
- The Protocol's provisions regarding trade in LMOs between a party and a non-party does not require that its procedures actually be followed;
- The Protocol says nothing about any regulatory oversight *within* a country;
- The Protocol is ambiguous about how to resolve any conflict that arises between the regulation of LMOs by an importing country and the obligations it may have not to impede trade if it is also a party to the World Trade Organisation (WTO). In particular, the Protocol's adoption of the Precautionary Principle is claimed by trade interests to run counter to the WTO mandate. The Protocol text reflects the controversial negotiations on this point by including three somewhat inconsistent provisions in its Preamble.
- A system for identifying and tracing LMOs in international trade remains to be developed. What such a system might look like will be the subject of negotiations among the parties until September, 2005.
- The parties still have to produce a system of *"liability and redress"* in order to deal with any damages LMOs cause, such as the genetic contamination of other farmers' fields.

### The Codex Alimentarius

Just two months prior to the Protocol's entry into force, a breakthrough regarding the oversight of risks related to genetically modified organisms (GMOs) occurred under the auspices of a little-known United Nations agency charged with setting international guidelines for food regulations, the Codex Alimentarius Commission. The Food and Agricultural Organisation and the World Health Organisation established Codex in 1963 with the mandate of *"protecting the health of the consumers and ensuring fair practices in the food trade"*. Codex drafts voluntary international food guidelines via negotiations that take place in approximately 30 committees and task forces. A handful of civil society organisations and more than 100 industry groups periodically participate as observers with the right to speak at meetings and distribute documents. Most committees are focused on a particular subject (such as fisheries, oils, or food additives) and several are cross-cutting in their agendas (such as labelling, analytic methods, or General Principles).

**"Codex has moved from obscurity to playing a potentially significant role in GMO regulation, though few people recognise it"**

In July 2003, with the consensus of its 168 member nations, Codex produced the first set of international guidelines for assessing and managing the health risks posed by GM foods. They were prepared by an Ad Hoc Task Force on Foods Derived from Modern Biotechnology that met for 4 years in Japan. Most notably, these risk analysis guidelines call for safety assessments to be conducted for all GM foods prior to market approval. While this may seem like common sense to most people, it has not been the policy in countries such as the US – the largest grower of GM crops and home to the world's largest biotechnology firm, Monsanto.

Codex thus has moved from obscurity to playing a potentially significant regulatory role in defining internationally acceptable modalities for GMO

regulations, although relatively few civil society activists are aware of it. This new importance is due to the status of Codex guidelines in trade disputes. In 1995, the WTO established that Codex norms would be the reference point in evaluating the legitimacy of food regulatory measures that are challenged as restrictions on trade, under the WTO agreements known as Sanitary and Phytosanitary Standards and Technical Barriers to Trade (TBT). This linkage means that Codex guidelines now have legal significance for WTO members.

Codex guidelines are merely recommendations to governments, which may voluntarily adopt them, but are under no obligation to do so. But since the guidelines are shielded from WTO attack, they may have an impact on what governments might require of firms and farmers producing GM foods, and consequently, on the level of risk to which consumers of foods are exposed. These guidelines may be called on in the case the US has taken to the WTO against the EU for its GM food regulations; the US claims that the EU has prevented many GM foods from the US from being sold in Europe without any legitimate basis for the restrictions. In its defence, the EU is likely to cite the new Codex risk analysis guidelines to show that it has been acting in accord with evolving international norms for GM foods.

**"Codex guidelines may be called on in the case the US has taken to the WTO against the EU for its GM food regulations"**

Although the risk assessment guidelines Codex has adopted for GM foods contain a great deal of language about carrying out a *"scientific"* evaluation of the actual hazards presented by the new foods, they also allow a certain amount of subjective judgment as well. For example, one provision says that *"Risk managers should take into account the uncertainties identified in the risk assessment and implement appropriate measures to manage these uncertainties"* which appears to recognise the validity of a precautionary regulatory regime similar to that provided for international shipments under the Cartagena Protocol. Other provisions call for a "*transparent*" safety assessment, communicated to "*all interested parties*" that have opportunities to participate in "*interactive*" and "*responsive consultative processes*" where their views are "*sought*" by the regulators. Codex also recognises that there are Other Legitimate Factors – non-scientific in nature – that can be valid contexts/bases for regulations. These non-scientific aspects are consistent with the second prong of the Codex mandate, to deter deceptive practices, which might include, for example, selling or distributing GM foods to consumers without labelling these foods as such, even though this information has been shown to be important to consumers on all surveys that have been conducted.

The US, as a top world food exporter, has lobbied other governments and advocated vigorously that only the objective scientific health claims should be the basis for regulation of GM foods, arguing strongly for de-emphasising the second Codex mandate, the Other Legitimate Factors, and precautionary regulations of any kind.

Few citizens know about the Codex, and fewer still are in touch with their country's Codex Contact Point to lobby for positions which would balance the views of industry. But all will be affected by their government's decisions under this international regime.

### How the treaties relate

It may seem confusing to understand how these various international agreements – the Protocol, the Codex, and the WTO – mesh together. But that question supposes that some rational, logical process guided the negotiation of these agreements. It didn't. These compacts were produced at different historical times, by delegations from different national ministries with different missions (trade, environment, food, agriculture, health), and without any grand plan, and different configurations of industry and public interest groups. Despite the existence of some language in their texts about *"harmonisation"*, they exist separately, and it is only through their applications that countries will be forced to try to work out some accommodations. For example, the US challenge in the WTO to the EU regulation of GM crops is expected to be defended by Europe by claiming that its approach is justified by either or both the Protocol and the Codex. However, the decision on whether to accept such a defence will be made by a WTO dispute panel. Political power will, of course, be a major determining factor – the power of different governments, their will to pursue certain goals, and the power of civil society organisations to influence governments by building up constituent pressures and gradually altering the consciousness of decision-makers.

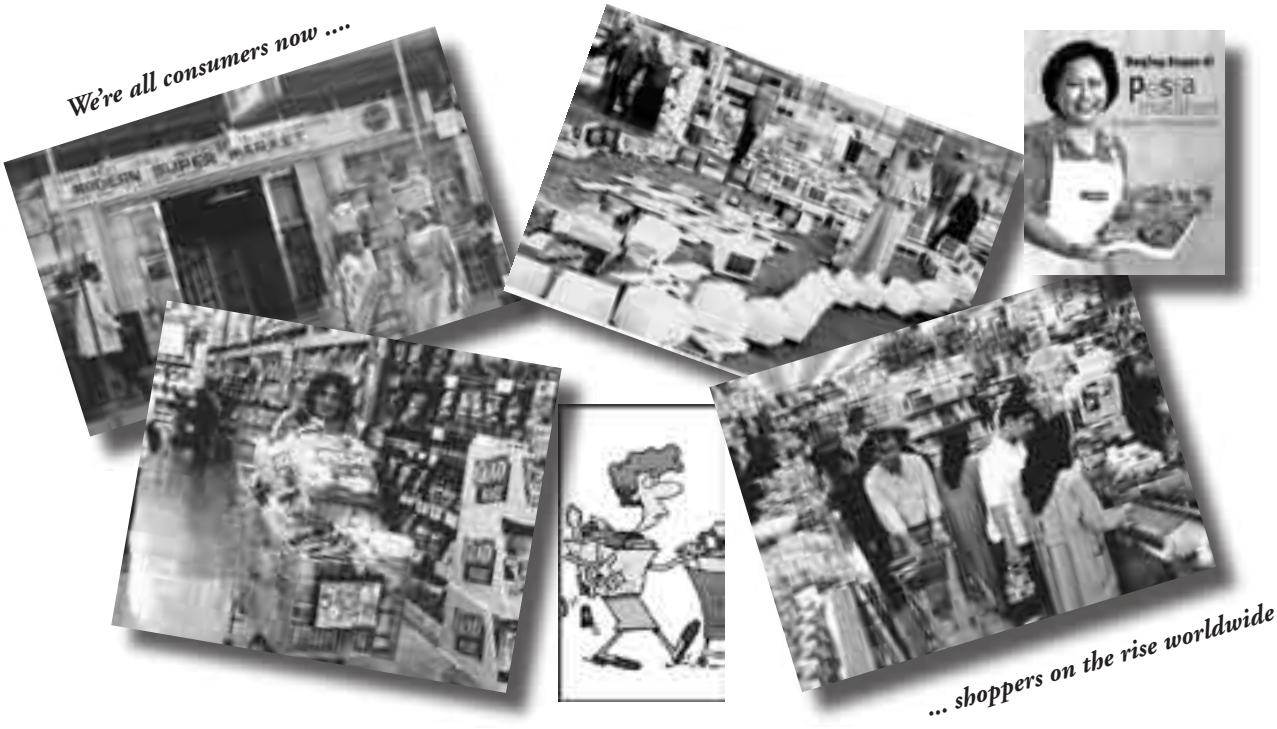
The new Codex international norms for regulating GM foods underscore the deficiencies in practices that allow industry to bring GM foods to market without regulatory oversight, as has happened in the US. This practice has been the object of criticism by many activist organisations, a growing number of scientists, much of the rest of the world, and international authorities on food safety matters. As former US government agriculture policy expert Charles Benbrook has observed: *"The*

[1] Charles Benbrook (2003), *GMOs, Pesticide Use, and Alternatives Lessons from the US Experience.* Paper presented at the Conference on GMOs and Agriculture, Paris, France, June 20, 2003. www.biotech-info.net/lessons_learned.pdf

*US agricultural biotechnology regulatory system and policy framework is…difficult to defend as thorough and rigorous relative to contemporary scientific understanding and international food safety norms and testing recommendations."*[1] Even international civil servants recognise that while products assessed prior to marketing by the US Food and Drug Administration (FDA) *may* be safe, the FDA has not conducted safety assessments of the foods produced from the roughly 50 genetically modified crops grown in the US. Despite this, the FDA claims that such foods are *"safe"* for human consumption on the basis of a logical construct, the principle of analogy. Under this approach, the FDA assumes that since GM foods are like their parent counterparts in many ways, they must be *"substantially equivalent"* to these conventional foods in other aspects as well, such as safety and nutrition. On this basis, the US government has allowed for GM crops in the US to become common ingredients in 70% to 75% of all processed foods sold in local supermarkets. (Whether this action by the US government might amount to a *"deceptive trade practice"* under the Codex mandate is perhaps an interesting open legal question.) The FDA apparently has no plans to change its policies by adopting the mandatory pre-market safety assessments called for in the Codex guidelines.

A growing number of critics of such non-regulation have called attention to the virtual absence of any peer-reviewed, published scientific research on GM food risks that would allow for safety claims to be tested. As Benbrook has noted, *"I am near certain that no independent scientist or laboratory has received the funding, information, and technical cooperation required to carry out what any team of experts would consider a thorough and independent assessment of GM food safety claims."* Yet no evidence of risk is *not* the same as evidence of no risk, although the industry and compliant governments often try to confuse the two. Apparently, neither the industry nor the governments promoting this technology have any interest in finding out if hazards really might exist. Work by independent scientists, such as Arpad Putzai and Ignacio Chapela has been ridiculed and ignored, and the researchers themselves vilified by colleagues who often are financially beholden to the biotech industry. Nonetheless, even the WTO Appellate Body has recognised that divergent scientific views can be considered in making assessments, such as those evaluating food risks.

Since there are so many concerns raised about the high degree of scientific uncertainty regarding the health and environmental impacts of GM foods, many civil society organisations have insisted that precautionary steps should be taken to avert potential risks. 'Look before you leap,' the folk expression of what has become known as the Precautionary Principle, is the basis for EU biotech regulations and, as previously noted, is enshrined in the new Cartagena Biosafety Protocol. (Although the US now shuns the Precautionary Principle, it is embedded in some 40-odd US laws from the mid 20th century, when the US government saw its role more in protecting consumers rather than stimulating industry profits.)



Using a precautionary approach to assessing and managing risks means taking preventative measures when it is reasonable to believe that potential hazards may become evident (even when no scientific evidence of such hazards may exist). It also puts the burden of proof on the industry that wants to introduce the new technology. The US and other exporters of GM foods have stymied efforts to incorporate the Precautionary Principle into Codex guidelines *explicitly*. But some commentators and activists believe the Precautionary Principle is *implicit* in the risk analysis guidelines established by Codex, despite the absence of the term, since these guidelines call for a safety analysis before there is any commercialisation of a GM food. The governments blocking the inclusion of the Precautionary Principle in Codex have argued that applying it to regulating GM foods could be used to justify protectionist regulations that might be a strategy for insulating domestic industries from foreign competitors (in violation of the WTO agreements). However, it is not the purpose of Codex to stimulate trade, but to protect consumers; the WTO is supposed to follow Codex norms, not vice-versa.

**"Some people believe that the Precautionary Principle is implicit in Codex, since it calls for a safety analysis before any commercialisation of a GM food"**

### Tracking the risks

Another concept under negotiation in Codex and Article 18 of the Protocol is *"traceability"*. The idea behind traceability is to keep track of information about the origins, transformation and fate of foods on their journey to the market. There are several reasons touted in favour of traceability. By keeping clear records and creating a transparent communication system, regulators would be able to respond quickly and effectively in the event of any consequent food-borne health hazards. This would also enable consumers to hold industry liable for any wrongdoing. Another argument for traceability is that if foods are going to be labelled, traceability provides support for the information presented to the consumer and would facilitate the exercise of free choice in the marketplace. Just as some households may want to avoid buying goods made in some particular countries which abuse human rights or have poor labour conditions, they may wish – for reasons scientific or political – to avoid GM foods.

The US has been the major government opposing traceability of GM foods. In the US, traceability measures for food have historically been limited to known hazards (e.g., marking tin cans with a numeric code to make it possible to trace a botulism outbreak), not hazards that are merely plausible but unknown. This latter situation is now being debated within Codex. It is also debating whether all relevant information about a food item will be accessible at a single point or, instead, if only partial information will be available at various points throughout the food system. Interestingly, the new US regulation on protection from *"bioterrorism"*, by requiring the monitoring of imported foods, is at variance with the position of the US in these negotiations, by being both precautionary (there has never been a documented case of food bioterrorism in the US) and using subjective terms (since it addresses *"credible threats of serious adverse health consequences or death")*.

The tail end of a traceability system would be the labelling of foods for consumers. Codex can adopt labelling guidelines that are objective or scientific in nature (like how much acid is the maximum allowable for an olive oil to still be called *"virgin"*) or social (like the definitions of halal or kosher).The question of whether those shopping at the market should be able to identify GM foods has been under negotiation in Codex for ten years. The debate has been about which criteria, if any, should trigger labelling. Consumer organisations, along with the EU, Japan, Brazil and some other governments, are calling for mandatory labelling of GM foods. In these negotiations the US delegation has argued that labels would suggest to purchasers that there is a difference between GM and non-GM foods and that this would be *"misleading."* But most civil society organisations believe that there is a difference and, indeed, the industry itself makes such an argument when it applies for a patent on the GM food. The US government acquiesced in voluntary labelling after the FDA actively tried to discourage it.

At present, two labelling options are being battled out within the Codex Committee on Food Labelling. One calls for labelling to identify all GM foods, while the other (supported by the GM food-exporting countries) proposes labelling GM foods only where the food's nutritional content, composition or intended use are no longer *"substantially equivalent"* to non-GM foods. The strong push from the exporting delegations is indicative of the high degree of industry penetration into government; in contrast, the EU's system of proportional representation has empowered activists working through Green parties to effectively champion consumer demands for labelling. But without Codex labelling guidelines, it is possible that any labelling regulations the EU introduces could be challenged under the WTO agreement. Even if such a challenge were successful, it is likely that the EU would pay financial penalties rather than change its regulations. But the US could

use such a win to terrorise weaker countries into abandoning GM food labelling.

The costs of segregating GMO crops and foods, doing risk assessments, and tracing the products need to be borne by the GMO producers and exporters, not consumers, since they are the ones altering existing practices for their own benefit. The attempts by these industry parties to stimulate concerns – claiming that unreasonable environmental NGOs will be imposing a financial burden on developing countries and poor consumers in the North who are unable to pay – must be resisted.

### Where are GMO politics going?

The politics around GMOs is increasingly intense, as the economic stakes become more extreme and scientific debate continues. Within the past year, several new instruments have come into play – the Cartagena Protocol, the guidelines of the Codex Alimentarius, and the WTO challenge by the US to the EU's regulatory approach to GMOs. Is it possible to make any sense out of these configurations, to suggest whether the prospects for safe oversight of the technology exist, whether human health and the environment are likely to be adequately protected?

The four countries that want to export GMOs – the US, Canada, Argentina, and Australia – are all members of Codex, and none of them is (or is soon likely to be, with the possible exception of Argentina) a party to the Biosafety Protocol. Thus, one can argue, they cannot object to countries that use the Codex risk assessments. On the other hand, when the Protocol parties meet to work out the details for risk assessments under that compact and to set rules for tracing and for liability, none of these four nations will be legally able to block action. Because of this, the Protocol is likely to evolve rules that are more protective for biodiversity and health. So it seems that higher levels of environmental and health protection are feasible in the future.

But the actual scenario is also likely to unfold behind the scenes, as the exporters (particularly the US) pressure countries, one by one, to waive the exercise of rights they have under international law. We have seen this happen with the new International Criminal Court, for example. And it has happened in the past regarding GMO regulation, where small nations, such as Croatia and Thailand, have been squeezed by the US. The role of civil society in blunting such attempts will be crucial. Concerned citizens need to figure out ways that the Cartagena Protocol and the new Codex rules can help achieve their valued ends of protecting biodiversity, the environment, and human health.

### Going further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