Implementing the Cartagena Biosafety Protocol through national biosafety regulatory systems: an analysis of key unresolved issues

Gregory Jaffe
Center for Science in the Public Interest, USA

- The Cartagena Biosafety Protocol is the primary driving force behind countries establishing national biosafety regulatory systems for genetically engineered crops and animals. That international agreement attempts to set forth the scientific and legal boundaries for those systems, and establish a minimum set of rules and procedures. This paper analyzes whether the Protocol will achieve a degree of legal certainty in the field of biosafety regulations and some level of global harmonization. The paper concludes that, while the Protocol is a good model for certain portions of a national biosafety regulatory system, it provides little guidance on several issues key to biosafety regulation. The Protocol gives discretion to individual countries to decide on what the applicable safety standard should be, how to incorporate socioeconomic considerations, how to address food safety and how to incorporate public participation. The resolution of these four issues by each country could have a far greater influence than the Protocol itself on the nature of their national biosafety regulatory system.

Copyright © 2005 John Wiley & Sons, Ltd.

Introduction

Although genetically engineered (GE) crops were planted on 200 million acres in 17 countries in 2004 (James, 2004), agricultural biotechnology is still in its infancy. GE has the potential to benefit countries around the globe with crops that are environmentally friendly, more nutritious and that produce beneficial compounds, such as pharmaceuticals. At the same time, some GE applications may pose risks to humans or the environment, such as producing an allergen or harming wildlife.

When a new technology has both potential benefits and risks, governments usually step in to ensure that products using that technology are safe. In countries where scientists and businesses are at the forefront of agricultural biotechnology (such as the USA and the EU), biosafety regulatory systems have been established to govern GE crops. At the same time, governments from around the world came...
together in the late 1990s to negotiate the Cartagena Biosafety Protocol ("Protocol"), a legally binding international treaty setting forth legal requirements for the transboundary movement of living modified organisms (LMOs).  

Today, both developed and developing countries are establishing national biosafety regulatory systems to regulate the introduction of GE organisms into the environment and the food supply, regardless of whether those GE organisms are imported or produced domestically. The Protocol, which became effective on 11 September 2003, currently is the primary driving force behind the establishment of these systems. It both empowers countries to establish biosafety procedures and provides the scientific and legal boundaries under which such systems should operate. The Protocol has the potential to effectuate a common set of processes and procedures for biosafety that will safeguard the environment and the public, while allowing for international commerce and product innovation.

Does the Protocol provide a clear set of rules to govern whether an LMO is safe? Will compliance with the Protocol by countries result in transparent, predictable, efficient and effective national regulatory systems? Will the Protocol result in national regulatory systems that are generally harmonious with one another? Will the Protocol facilitate or hinder international trade with GE products? Does the Protocol answer the key questions surrounding national biosafety regulation?

This paper will look critically at the Protocol and the questions identified above, to determine whether the balance struck between international rules and national sovereignty in the Protocol gives countries sufficient guidance on how to establish national biosafety regulatory systems.  

Background

The Protocol is a binding international agreement related to its parent treaty, the Convention on Biological Diversity. It was negotiated to result in a common and coordinated approach among countries to address potential risks of LMOs. (Mackenzie et al., 2003a). As stated by an authoritative guide on the Protocol:

"The Protocol offers to its Parties significant benefits in that it provides a potentially globally accepted set of rules on LMOs. … The overall goal … is to provide a degree of legal certainty in the field of biosafety regulation (Mackenzie et al., 2003a)."

While the Protocol seeks some level of global harmonization, it also balances a number of different issues which are often competing or contradictory with one another. First, the Protocol attempts to resolve the tensions between environmental protection, international trade and the potential benefits from GE. The Protocol:

...provides an international regulatory framework to reconcile the respective needs of trade and environment protection with respect to a rapidly growing global industry, the biotechnology industry. The Protocol thus creates an enabling environment for the environmentally sound application of biotechnology, making it possible to

---

1Living modified organisms' is a term defined in the Biosafety Protocol. It includes GE organisms. For the purposes of this paper, LMO will be used when directly referring to the Biosafety Protocol. In other instances, the term 'GE organisms' and 'agricultural biotechnology' will be used interchangeably to include organisms produced using recombinant DNA technology to insert genes.

2Although the context behind the Protocol is important, it is not discussed in this paper. Instead, the paper looks at the Protocol as an international legal instrument, and will analyse and interpret it similarly to other legal documents, based on the text agreed to by the countries, not the context which led to its adoption. For more information about the negotiations on the Protocol and the issues that led up to its adoption, see 'Cartagena Protocol on Biosafety: From Negotiation to Implementation' (CBD, 2003).
derive maximum benefits from the potential that biotechnology has to offer, while minimizing the possible risks to the environment and human health. (Secretariat of the Convention on Biological Diversity, 2000)

Secondly, the Protocol tries to balance the need of individual countries to retain their national sovereignty in an area that countries have decided needs collective actions on a global scale. Thirdly, the Protocol acknowledges that it is not meant to alter or change other international agreements previously agreed to. Thus, the Protocol balances several competing goals, while attempting to address issues surrounding LMOs and biodiversity.

What the Protocol establishes

The scope of the Protocol is the "transboundary movement, transfer, handling, and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health" (Article 4). Under the Protocol, LMOs are organisms (such as seeds, trees or fish) that contain novel genetic material introduced through in vitro techniques (e.g. recombinant DNA) or cell fusion (Article 5). Although the Protocol covers all LMOs, it primarily addresses two particular uses of LMOs: (1) those that will be intentionally introduced into the environment; and (2) those used for food, feed or processing (FFP). For LMOs used for other purposes, such as LMOs used in the laboratory, the Protocol leaves any regulation to the discretion of the individual country. The Protocol also does not cover products derived from LMOs, such as processed foods that have ingredients that came from LMOs.

To ensure the safe transfer, handling and use of LMOs, the Protocol sets up two separate procedures. The first time that an LMO will be intentionally introduced into the environment, the Protocol sets up an 'Advanced Informed Agreement' (AIA) procedure (Article 7). This procedure requires that an exporter of an LMO provide a notice with detailed information about the LMO to the importing country (Article 8). The importing country then reviews the information, conducts a risk assessment and decides, based on the risk assessment results, whether to approve or reject the LMO (Articles 10 and 15). In deciding whether to accept the LMO, the importing country can invoke risk management measures to address issues that arise from the risk assessment (Article 16). The importing country also can err on the side of precaution and not approve an LMO if there is insufficient information to adequately assess its particular potential risks (Article 10(5)).

The second procedure setup by the Protocol is for LMOs for FFP (such as corn, soybean, wheat or other grains that will be fed to humans or animals). For these LMOs, the AIA procedure is not required (Article 11). Instead, the Protocol establishes a simpler system which reflects the decreased likelihood that these LMOs will affect the biodiversity of the exporting country. Before the LMO can be exported to another country, the safety decision in the exporting country is communicated to other countries through the Biosafety Clearinghouse. A country may require prior consent; however, under its domestic regulatory framework, is as long as that requirement has been posted on the Biosafety Clearinghouse (Article 11).

The Protocol also contains numerous other provisions that complement the review procedures for LMOs discussed above and address issues important to a uniform and comprehensive biosafety regulatory process. There are provisions on reviewing decisions for new information (Article 12), simplified procedures for certain LMOs that do not present risks (Article 13) and emergency procedures for unintentional releases of LMOs (Article 17). The Protocol also addresses issues such as public awareness and participation (Article 25), and what to do about confidential information (Article 21). Thus, the Protocol attempts to establish a complete and comprehensive set of procedures and legal obligations to assess and manage the potential risks of LMOs on...
biological diversity, also taking into account risks to human health.

The Protocol is not self-executing. Countries which have agreed to be bound by it must establish national biosafety laws and regulations that implement its substantive provisions. In many cases, these countries establish legal systems that are broader than the minimum requirements of the Protocol. For example, they can cover not just imported LMOs but also domestically produced LMOs. These regulatory systems, however, must be consistent with the country's other international legal obligations, such as the General Agreement on Tariffs and Trade (GATT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The Protocol acknowledges that it does not change the rights or obligations of a Party 'under existing international agreements' (Protocol preamble). It also specifically states in several Articles that a Party's actions need to be in accordance with 'other obligations under international law' (see e.g. Article 2(4) and Article 26(1)).

The remainder of this paper will focus on the establishment of those national biosafety laws and regulations at the country level, how helpful the Protocol is to that task, and where there are some conflicts with other international agreements.

**Strengths of the Protocol**

When countries look to the Protocol for guidance while establishing their own domestic regulatory systems, there are a number of areas where the Protocol provides an excellent model. A few of these areas are highlighted below:

Proportionate risk-based reviews

A good regulatory system looks at each application individually and assesses its potential risks to human health and the environment through a scientific risk-based analysis (Golchen, 2001). The system should have the flexibility to treat products differently, depending on the potential concerns raised. All products need to be reviewed and approved and they must meet the applicable safety standards, but the data requirements and the review procedures can be tailored to the potential product's risks.

The procedures set forth in the Protocol are a good example of a system which gives proportionate treatment to the LMO based on its proposed use. For LMOs intentionally released into the environment—an activity which poses, on a relative scale, greater potential risk to biodiversity—the Protocol establishes an informed consent process requiring a detailed risk assessment, risk management and consent by the importing country. For an LMO used for FIP—an activity in which the risk of harm to biodiversity is significantly lower—the Protocol does not require advanced informed consent but allows parties to make decisions based on the safety decision from the exporting country or conduct its own risk assessment. For the contained use of an LMO in a laboratory or greenhouse—an activity with less potential risk than a deliberate release—the Protocol has no required procedures. Thus, depending on the intended use of the LMO, the Protocol establishes different procedures corresponding to the relative risk of that activity.

The Protocol also provides for differential treatment of LMOs based on particular risk characteristics. Article 15 sets up a 'simplified procedure' which allows certain LMOs that would normally qualify for the AIA procedures to have a streamlined process or complete exemption from AIA if that LMO can be released safely. Similarly, Article 7 allows the Parties collectively to exempt certain LMOs from the AIA procedures if those LMOs are not likely to have adverse effects. Therefore, the Protocol acknowledges that LMOs deserve different treatments based on either their use or their particular risk characteristics.

Clear and understandable procedures

The Protocol sets forth clear and understandable procedures for LMOs that are directly released into the environment or used for FIP. For example, Articles 7–10 set forth the AIA procedures. These Articles explain what is
Implementing the Cartagena Biosafety Protocol

required of the exporter, what the importing country will do and how the importing country will make its decision. They provide specific deadlines for different actions and specify what acknowledgments and responses can be provided. They also specify legal obligations—such as ensuring the accuracy of the information (Article 8(2))—and require that any denial of consent specify the reasons (Article 10(4)). Article 12 also sets forth procedures and rights of relevant parties if a decision needs to be reviewed when new scientific information becomes available. A similar level of detail is provided for LMOs used for FFP (Article 11).

The details in the Protocol for these two different regulatory procedures can easily be copied into national biosafety systems. By providing detailed information on each step in the process and anticipating issues that might arise, the Protocol sets forth a transparent system where: (1) the exporter knows what is expected of them and what will happen with the information they provide; (2) the importing country understands their rights and obligations; and (3) the public understands how the decision maker will decide on the application.

Risk assessment information and analysis

The Protocol sets forth the information about an LMO that is needed before it is released into the environment or used for FFP. Annexes I and II contain detailed lists on the major categories of information needed to assess the potential risks of an LMO. They provide models which a national biosafety regulatory system can use as standard data requirements. Of course, individual countries may add to the list of required information, depending on particular environment issues within their country or if they choose to address other risk areas (such as food safety or socioeconomic concerns).

The Protocol also provides an excellent explanation of what a scientific risk assessment of an LMO should entail. Annex III sets forth the risk assessment's objective, what the risk assessment will be used for, and the general principles that the risk assessment must follow, the methodology of the risk assessment and particular points to consider when assessing the potential risks of an LMO. The Annex provides a clear explanation to interested parties about what is expected in the risk assessment, what will guide the risk assessment and how it will be used. Therefore, the Protocol's Annexes clearly provide sufficient information and details so that countries which adopt those provisions will establish harmonized and standardized procedures that will be transparent and understandable.

Questions left unresolved by the Protocol that need to be determined by national governments

Although the Protocol comprehensively covers many issues, it leaves unresolved critical issues that each country must address when establishing their biosafety regulatory regime. These issues are discussed below.

A legal standard for safety

A biosafety regulatory system should establish safety standards for its approval processes. These safety standards set forth what level of safety must be satisfied to approve an application and what factors a government will consider before making a decision. The safety standard provides the baseline that should be used to analyze new product safety and also determines the desired level of protection. While the Protocol provides essential details helpful to establishing a biosafety regulatory system, it is silent on the safety standard that should be applied.

For the first introduction of an LMO in the environment, the Protocol requires consent from the importing country and discusses the procedures to reach such a decision. There is no discussion, however, about what level of safety must be satisfied before an LMO is approved or what level of risk is unacceptable to justify withholding consent. Article 10(6) allows a party to use a precautionary approach...
when there is insufficient relevant scientific information to assess the potential adverse effects of an LMO, and Article 16 provides for risk management to mitigate or eliminate potential risks. The Protocol is silent, however, on what happens after a risk assessment is conducted and some potential risks are identified that cannot be eliminated by a restricted or conditional approval (as will invariably happen, since most activity has some potential risk).

The Protocol leaves it up to each individual country to decide on the safety standard that it believes must be satisfied before consenting to an LMO. Countries with existing biosafety regulatory systems currently apply different safety standards. In many countries, the safety standard for determining if a product is safe for human consumption is a fairly onerous standard which only looks at risks and does not factor potential benefits into the determination. For example, EU Regulation 258/97 states that the food-safety standard for genetically modified foods is that they must not ‘‘present a danger to the consumer” (European Parliament, 1997). Similarly, in the USA, if the US Food and Drug Administration approves a GE product that is a food additive, it must determine that the substance presents ‘‘a reasonable certainty of no harm” (US Food and Drug Administration, 1992). Although some biotech foods could be food additives, to date, biotech crops have been reviewed under a different standard, which ensures that the crops are ‘‘substantially equivalent” to their conventional counterparts (US Food and Drug Administration, 1992). This standard acknowledges that crops have some inherent food-safety risks, and one should ensure that biotech varieties neither add new risks nor increase existing risks.

The Protocol also does not state whether the scientific evaluation of an LMO need only address risks or can balance both benefits and risks. Many safety standards do in fact balance both risks and benefits, since agricultural systems (both new and existing) have positive and negative effects on the environment. In the USA, the Federal Insecticide, Fungicide, and Rodenticide Act states that a pesticide (including plants engineered to produce a pesticide) should not cause ‘‘unreasonable adverse effects on the environment” (US EPA, 1996). This standard has been interpreted to require a review of both benefits and risks during the risk assessment process. Similarly, the Hazardous Substance and New Organism (HSNO) Act in New Zealand states that an application can be denied in cases where the adverse effects outweigh positive effects, suggesting that benefits must be considered (New Zealand HSNO Act, 1996).

Without any specific Protocol requirement, countries have some autonomy to establish safety standards that conform to their country’s particular policies, practices and comforts with different potential risks. Their discretion to establish a safety standard and identify factors to consider in deciding if an LMO is safe, however, is bound by other international legal agreements. The SPS Agreement provides countries with the sovereign right to establish appropriate levels of sanitary and phytosanitary protection, but they must do so in a way that minimizes negative trade effects (Article 5.5). It also requires in Article 5.5 that countries ‘‘avoid arbitrary or unjustifiable distinctions in the level of protection they consider to be appropriate for different situations, if such distinctions result in discrimination or disguised restrictions on international trade” (Zorelli, 2005). The SPS Agreement may also limit how the precautionary approach language in the Biosafety Protocol (articles 10 and 11) can factor into a safety standard. The SPS Agreement does allow countries to adopt precautionary measures when relevant scientific evidence is insufficient (similar to the Protocol) but only allows that decision to remain for a reasonable period of time while additional scientific evidence is actively gathered.

GATT also could affect a decision on the biosafety safety standard because it requires that ‘‘like products” be treated in the same manner, whether produced domestically or imported. Under GATT, it is unclear whether GE products can legitimately be distinguished...
Implementing the Cartagena Biosafety Protocol

solely by their process of production (Zanilli, 2005). Thus, while the Protocol leaves the safety standard as a rational sovereignty decision, individual countries will need to take other international obligations into account when establishing their national biosafety regulatory systems. These agreements may prevent an overly restrictive safety standard that is not justified by science or a standard that attempts to consider non-scientific factors.

Whatever safety standards are adopted by a country, if their biosafety regulatory system is to be efficient, effective and attain some of the Protocol's objectives, it is critical that the safety standards be clearly articulated. All interested parties must know and understand the safety standard and any government decisions must apply that standard in a uniform and fair manner. Then, if there are different safety standards in different countries, there may not be the uniformity that some stakeholders would like, but there will be transparency and predictability, which are two important goals of the Protocol.

Role of socioeconomic considerations in the approval process

Article 25 of the Protocol states that parties:

...may take into account, consistent with their international obligations, socioeconomic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

This provision, however, raises more questions than it answers, leaving each country to decide whether to factor socioeconomic considerations into its regulatory process and, if so, what to consider and how to do it.

The first question that arises is, what socioeconomic considerations can or should be considered in the decision-making process? A literal reading of Article 26 would not allow all socioeconomic considerations of LMOs to be considered but only those that arise directly from impacts on biological diversity (Mackenzie et al., 2003a). Many stakeholders believe, however, that the socioeconomic impacts of LMOs are much broader and could include concerns such as:

...impacts on farmers' incomes and welfare, cultural practices, community well-being, traditional crops and varieties, domestic science and technology, rural employment, trade and competition, the role of transnational corporations, indigenous peoples, food security, ethics and religion, consumer benefits, and ideas about agriculture, technology, and society (La Vina and Frease, 2004).

The Convention on Biological Diversity Secretariat recently wrote that LMO socio-economic concerns:

...could include the risk that imports of GE foods may replace traditional crops, undermine local cultures and traditions or reduce the value of biodiversity to indigenous communities (Secretariat of the Convention on Biological Diversity, 2003).

The Protocol has no definition of socioeconomic considerations, and leaves it to individual countries to define what they will consider in their regulatory process.

Any decision on the inclusion of socioeconomic considerations, however, must be consistent with that country’s other international obligations. In general, WTO rules emphasize procedures for decision making which primarily rely on scientific risk assessments and greatly limit the ability to make decisions based on non-safety concerns. Clearly, these rules could be interpreted to restrict greatly the role that socioeconomic considerations can play in LMO decision making and act as obstacles to countries which are concerned about the broad range of effects that could arise from imported LMOs. WTO rules sometimes do allow the narrow use of non-safety concerns. For example, the SPS Agreement does set forth a risk assessment
procedure that includes both scientific and socioeconomic considerations. (World Trade Organization, SPS Agreement, 1995) Some of the relevant economic factors under the SPS Agreement include:

...the potential damage in terms of loss of production or sales in the event of entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks (World Trade Organization, SPS Agreement, 1995).

That exception, however, is narrowly defined and primarily allows for a cost/benefit analysis to play a role in certain decisions. Therefore, to be consistent with WTO rules, countries that include socioeconomic considerations in their domestic regulatory systems probably need to tailor what they will consider solely to what is allowed by Article 26 (e.g. socioeconomic concerns directly linked to impacts on biodiversity). This could greatly hinder developing countries wanting to take into account a broader range of socioeconomic issues surrounding LMOs. Such broader socioeconomic considerations, however, might be addressed through other means, such as voluntary processes implemented by research institutions and companies or other laws and regulations (Fransen et al., 2005).

If a country does include socioeconomic considerations into the decision making process, it must set forth when and how these factors will be analysed (Fransen et al., 2005). Countries must decide whether this will occur during the risk assessment, in the risk management plan, or in a separate assessment process occurring after the risk assessment has been completed, but before an approval is granted. They also must spell out which socioeconomic considerations should be analysed, what information should be used for the analysis, how that analysis should be performed and by whom. Annex III of the Protocol, which sets forth the general risk assessment process and information needed for that process, does not mention any methods, principles or information needs to address socioeconomic considerations. The Executive Secretary of the Convention on Biological Diversity and others (e.g. Fransen et al., 2005) have presented examples of how socioeconomic considerations might be assessed (Executive Secretary of the Convention on Biological Diversity, 2005). There are numerous practical questions requiring answers if a domestic regulatory system is to include socioeconomic considerations.

When looking at different biosafety regulatory systems around the world, countries have addressed socioeconomic considerations in different ways. The USA and Canada do not factor non-scientific issues in their approval processes (World Bank, 2003). By contrast, Argentina requires a market analysis as the third part of its formal approval process (parts one and two involve environmental and food-safety risk assessments), and can deny approval of a safe LMO if it will have adverse economic consequences for the country (Buachik and Traynor, 2002). In South Africa, there is a provision which states that when deciding to approve a release, the Council may consider socioeconomic impacts on "...a community living in the vicinity of such introduction" (Republic of South Africa Department of Agriculture, 1997). There is little discussion in the regulations, however, about how broad or narrow that language should be read, what socioeconomic impacts can be considered and when an impact should affect an approval decision.

Socioeconomic considerations could have no place in the biosafety system, a minor role in the approval process or constitute a major factor in the process, becoming more important than the scientific risk assessment. Countries will need to decide which path to take alone, since the Protocol and other international agreements provide only some guidance on this important issue.

Addressing food-safety concerns

The Protocol primarily addresses environmental issues, with emphasis on impact to biological diversity. The public, however, is most
Implementing the Cartagena Biosafety Protocol

They are concerned about whether LMOs or products made from LMOs are safe to eat. While the Protocol provides detailed legal and scientific procedures to ensure that LMOs do not adversely affect biological diversity, it does not substantively address food-safety concerns surrounding LMOs.

The potential human health hazards from GE foods are generally recognized by the scientific and regulatory communities (US Food and Drug Administration, 1992; Kuiper et al., 2001; National Research Council, 2001; The Royal Society of Canada, 2001; GM Science Review, 2003). The potential food-safety risks of GE foods are:

...the possibility of introducing new allergens or toxins into food plant varieties, the possibility of introducing new allergens into pollen, or the possibility that previously unknown protein combinations now being produced in food plants will have unforeseen secondary or pleiotropic effects (National Research Council, 2000).

Scientists have found engineered crops that contain allergens (Nordlee et al., 1996) and crops with unintended effects (Kuiper et al., 2001; Haselberger, 2003). Although the likelihood that a particular GE food will have a harmful health effect may be small, governments should regulate the products to make sure that any food with harmful characteristics is not commercialized.

The Protocol does mention "risks to human health". Article 4 states that:

This protocol shall apply to ... [LMOs] that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (emphasis added).

The placement of the phrase "taking into account risks to human health", however, leads to two possible interpretations: (1) ... that human health concerns are addressed only if they result from the potential adverse effects of the same LMO on biological diversity (Mackenzie et al., 2003a) or (2) that they can be addressed independently or separately from effects on biological diversity. Elsewhere in the Protocol, there is no elaboration on how to interpret "risks to human health". Other Articles in the Protocol do not discuss food safety or the need for consent before a GE food is marketed to consumers for consumption. In fact, Annex I and II make no mention of information about the potential allergenicity or toxicity of the engineered protein, and the risk assessment discussion in Annex III makes no mention of assessing potential food-safety risks.

Whether or not the Protocol's legal processes and procedures require or allow for a food-safety evaluation and advanced informed consent before a GE food is marketed, there is no substantive discussion about food-safety risks and how to evaluate them. Thus, countries must establish their own procedures to address this important issue if they wish to achieve a comprehensive regulatory regime for all known risks associated with LMOs. However, they do not need to start from scratch. The Codex Alimentarius Commission has already set forth a number of guidelines on how to conduct food-safety assessments of GMOs and their products (Codex Alimentarius Commission, 2005a, 2005b).

Public Participation in the Regulatory Process

Public participation is essential for consumer trust in the regulatory system. With the current international debate over LMOs, the public should have the opportunity to participate and provide information that will inform the decision maker. The Protocol acknowledges the importance of public participation when Article 25 states:

The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms...

Public participation is important both in the overall development of the national biosafety system (the laws, regulations and guidance...
documents) and in the specific decision making on individual applications (Lin and Ling, 2003).

The Protocol provides little guidance on how to conduct public consultations or how to factor the results of consultations into the decision-making process. Public participation can take several different forms, including the opportunity to provide information and comments on regulations, guidance and product applications, as well as the opportunity to provide oral and/or written testimony at public hearings (McLean et al., 2002). In some countries, such as the USA and Australia, the public is informed by government publications when a policy or product application is available for review and is given a specific amount of time to send the decision maker the relevant comments. (World Bank, 2003) A similar process occurs in the EU, whereby EU Directive 2001/18 specifies that all applications are made publicly available and the public has 30 days to comment (European Parliament, 2001). These processes work, however, only if the public is provided with both enough information about the application or policy to comprehend the issues and enough time to provide the government with thoughtful and relevant information. Thus, public participation needs a transparent system, whereby the government makes information publicly available before the decision is made, and reaches out to different stakeholders who may have opinions about the issues, especially small farmer groups, and provides them with the knowledge and tools actively to participate (Lin and Ling, 2003).

Once the public is involved, the regulatory system must decide how the information provided by the public is factored into the decision. For facts and evidence directly relevant to the risk assessment of a particular product, it is clear that any publicly provided information should help to determine whether the product meets the legal safety standard for approval. For other information, such as general opinions that GE foods are harmful or bad, however, it is not clear that such information has any relevance under the Protocol's decision-making processes or any scientific risk-based system. Countries such as Tanzania have suggested that public opinion "... must be taken into account in the decision" (United Republic of Tanzania, 2004) but it remains to be seen how such a system will be implemented and whether it would satisfy international obligations that limit decision making to scientific evidence and the results of risk assessments.

Public participation can also be used by governments to obtain expert scientific advice about a product application or government policy. Many regulatory agencies use outside experts on science advisory committees to supplement inhouse expertise when novel scientific questions arise. The advice that these committees provide to the government is helpful in making good decisions, but it is important that they only provide advice and not force the government to take it.

In conclusion, incorporating public participation into the biosafety regulatory process is extremely complicated and it is difficult to make it effective and meaningful. The Protocol establishes public participation as a key component of its processes, but provides little guidance on how to implement it. Thus, individual countries are left to grapple with how to engage the public, what information to provide them with, and what to do with the information they receive from the public. The likely result will be that countries will establish very different processes and procedures for public participation.

Other issues not adequately addressed by the Protocol

There are other issues that are not addressed by the Protocol. Article 18(2) states that the Parties need to address the details of the documentation requirements for LMOs that are intended for direct use as FFP. Article 27 states that the Parties need to decide on the appropriate rules for liability and redress that might arise from the transboundary movement of LMOs. Article 34 states that the Parties need to decide on institutional mechanisms to "... promote compliance with the..."
Implementing the Cartagena Biosafety Protocol

provisions of this Protocol and to address cases of non-compliance. Each of these issues could affect the domestic biosafety regulatory systems that countries put in place but have been left unresolved, in part, because the negotiators could not reach agreement (Mackenzie et al., 2005). Thus, the decisions taken on those issues in the future (or the absence of decisions) will directly affect the types of regulatory systems that countries put in place. In the interim, however, if a country cannot wait, it must decide on these issues on its own.

Summary and conclusion

Millions of farmers are currently benefiting from GE crops, and the technology offers additional potential benefits for the future. While most applications of genetic engineering will be found to be safe, a few applications may pose risks that need management. Countries are currently establishing national biosafety regulatory systems to assess and manage any potential risks and are being guided in their actions by the Protocol.

The Protocol is a first step at establishing worldwide practices and procedures surrounding LMOs. The Agreement requires countries to establish domestic biosafety regulatory systems that allow the safe introduction of LMOs into the environment or the food supply. The Protocol contains very detailed procedures for reviewing and approving LMOs and provides the legal and scientific framework for the risk assessment, risk management, and decision-making surrounding LMOs.

However, the Protocol may fall short of achieving one of its primary objectives—the establishment of harmonious regulatory systems, with standardized rules around the globe, which safeguard the environment and effective international trade. It fails to address critical questions that a country must resolve when it establishes its domestic biosafety regulatory system. The Protocol does not set forth the safety standard that will determine if an LMO should be approved, nor does it state the role that non-scientific factors such as socioeconomic considerations can play in the decision-making process. It also does not address the food safety issues surrounding LMOs, which are more important to the world’s population than are biodiversity risks. Finally, the Protocol does not provide sufficient guidance on involving the public in regulatory processes.

By leaving the resolution of key issues up to individual countries, it is likely that national biosafety regulatory systems will look and operate very differently. While the individual country systems may apply similar processes and procedures, substantive differences in safety standards, or in how one system factors in socioeconomic considerations, could negate the benefits of any harmonious procedures. These systems could also conflict with other international agreements, such as the SPS Agreement and GATT, which imposes any unjustified restrictions on biosafety regulatory systems.

Given the current polarized international debate over both genetic engineering and the Protocol, it is unlikely that countries will come to a consensus in future Protocol meetings on the issues identified in this paper. There are actions, however, that can be taken both at the national and international level to help national governments to address those unresolved issues. Some potential actions are set forth below:

- When establishing safety standards, national governments should not start from scratch. Countries should look to other environmental and/or food approval processes that they manage and see if the safety standards might be adaptable to biosafety concerns. Countries can also copy the safety standards for biosafety used in other countries. If they meet their needs. By using existing standards from comparable systems, there will be familiarity and understanding among stakeholders concerning the way in which the system will operate.

- Regulation of the food safety issues surrounding LMOs should be based on the documents that are produced by the Codex Alimentarius Commission. Codex, not the Protocol, is the proper forum for establishing

Copyright © 2005 John Wiley & Sons, Ltd.
procedures, guidelines and standards to assess and approve GE foods.

- Countries should attempt to reach some sort of consensus (either in Protocol meetings or other international fora) on which socio-economic considerations are appropriate for analysis and how their analysis should be factored into the approval process. Without an international legal consensus on definitions and procedures, systems put in place by national governments could easily violate other international agreements and obligations. In the interim, biosafety regulatory systems that include socioeconomic considerations should ensure that these provisions are extremely clear, transparent and well defined, so that all parties can easily understand them.

- Different types of public participation processes have been tried in both developed and developing countries over the past few years. Compilation of the procedures used and their success would help national governments to learn about the range of ways to engage the public to meaningful participation. Although collecting this information would not answer all of the questions raised, it would begin to provide national governments with possible solutions to a very difficult issue.

Every time countries attempt to establish international laws and agreements, there is a need to balance individual sovereignty with the advantages of an international regime. Although the Protocol may have done a good job at balancing these two competing interests, the resulting document raises many issues when it is implemented at the national level. Thus, in the immediate future, rather than international harmony, one should expect significant differences among the biosafety regulatory systems established by different countries who are trying to meet their international obligations.

Biographical note

Gregory Jaffe is the Director of the Project on Biotechnology for the Center for Science in the Public Interest (CSPI) in Washington, DC. Mr. Jaffe is a recognized expert on the regulation of agricultural biotechnology. He has published numerous articles and has spoken at a multitude of conferences addressing agricultural biotechnology issues, both in the USA and abroad. Mr. Jaffe earned his BA with high honours in Biology and Government from Wesleyan University, and received his law degree from Harvard Law School.

References


Implementing the Cartagena Biosafety Protocol

into Biosafety decisions: The Role of Public Participation. World Resources Institute: Washington, DC.