



PROGRAM FOR BIOSAFETY SYSTEMS

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ESTABLISHING NATIONAL BIOSAFETY REGULATORY SYSTEMS

KEY OUTSTANDING ISSUES UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY

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Countries around the world are in the process of establishing national biosafety regulatory systems to address issues surrounding living modified organisms (LMOs). The Cartagena Protocol on Biosafety (“the Protocol”) is a major driving force behind countries establishing those systems. This international agreement attempts to set forth both the scientific and legal boundaries for those systems, as well as a minimum set of rules and procedures. While the Protocol is a good model for certain portions of a national biosafety regulatory system, it provides little guidance on several issues essential to biosafety regulation. Addressing the biosafety issues that are not answered by the Protocol will help countries establish comprehensive and workable biosafety regulatory systems that both minimize risk and allow safe products to be marketed.

Ensuring LMOs are Safe to Eat

One substantive safety area covered by many biosafety regulatory systems throughout the world is the food safety of LMOs. To date, many LMOs are foodcrops meant to be eaten by humans and animals, and the public has wanted confirmation from regulators that those products are safe to consume. The Protocol, however, primarily addresses environmental issues, with an emphasis on impact to biological diversity. 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.

Including a food safety review process as a component of the national biosafety regulatory system (although not necessarily in the same government agency), would mean that food safety risk assessments could be conducted on LMOs that are ready to be commercialized, allowing food safety issues and environmental issues to be addressed simultaneously. Food safety is also an important issue when LMOs are imported solely for food and feed purposes, such as grain shipments or food aid. Thus far, countries have been left to establish their own procedures to address this important issue if they wish to achieve a comprehensive regulatory regime for potential risk issues associated with LMOs.

A Legal Standard for Safety

A national biosafety regulatory system usually establishes a decision standard, such as whether the LMO is “as safe as” a similar non-engineered organism, which determines when an activity will be approved. Because no activity is risk free and safety is relative, the decision standard sets forth what level of protection must be satisfied to authorize the activity and what factors the government will consider before making the decision, including the baseline for any risk analysis. The standard also identifies whether the benefits from the LMO or the opportunity costs of not introducing the organism will be considered.

The Biosafety Protocol does not provide a standard upon which to judge applications for releasing LMOs into the environment, but instead leaves it up to individual countries to set their own standard. This may be because the concept of safety is relative and may vary greatly from country to country, due to different societal values and notions of risk. In any case, it is essential that a national biosafety regulatory system clearly articulate a safety standard in its laws and regulations.

In a functional, transparent, and protective system, all interested parties know and understand the standard beforehand and government decisions apply that standard in a uniform and fair manner.

The Role of Socioeconomic Considerations in the Biosafety Regulatory Process

Another concern that may arise with LMOs is the socioeconomic impact of their commercial release. Article 26 of the Protocol allows countries to take this into account—under certain conditions. First, it limits the socioeconomic considerations to those effects that arise “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.” The plain language used in Article 26 does not allow all socioeconomic considerations of LMOs to be considered, but only those that directly arise from impacts on biological diversity. Second, the Protocol states that inclusion of socioeconomic considerations must be done in a manner that is consistent with other international obligations. In general, World Trade Organization rules emphasize procedures for decisionmaking that primarily rely on scientific risk assessments and limit the consideration of nonsafety concerns to specific situations where cost/benefit analysis is appropriate.

National biosafety regulatory systems must decide if they are going to take into account socioeconomic considerations when making decisions on individual LMOs. If a country is going to include such considerations, it must define “socioeconomic considerations” since the Protocol has no definition. Countries should consider tailoring what they will consider to only what is allowed by Article 26 (for example, socioeconomic concerns directly linked to an impact on biodiversity). The biosafety regulatory system also should set forth when and how socioeconomic factors will be analyzed: 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. The system should spell out what information should be used for the analysis, how that analysis should be performed, and by whom. While it is possible for a country to include socioeconomic considerations in its national biosafety regulatory system, it will require a significant amount of work to specify all the details in its laws and regulations that are needed to make the analysis of those considerations consistent with international obligations as well as fair and transparent to biosafety stakeholders.

Public Participation in the Biosafety Regulatory Process

Public participation in the regulatory process is essential for consumer trust in the process. The Protocol acknowledges the importance of public participation in Article 23, which states “The Parties shall ... consult the public in the decision-making process regarding living modified organisms.” The Protocol, however, provides little guidance on how to conduct public consultations or how to factor the results of consultations into the decisionmaking process. Such public participation might include the opportunity to present written comments to the decisionmaker, to participate in a hearing about the LMO, or take part in interviews with government officials. In most countries around the world, public participation informs the decisionmaking process, but the ultimate decision remains with the regulatory agency and its designated leaders.

Incorporating public participation into the biosafety regulatory process can be extremely complicated, and making it effective and meaningful may be difficult. Biotechnology and biosafety are complex areas and many citizens may not have the educational background to understand the issues. Also, many countries use several languages, and so the language of choice for official meetings may pose a language barrier and may hinder some citizens from participating. Thus, while the Protocol establishes public participation as a key component of biosafety regulation, individual countries are left to grapple with how to engage the public, what information to offer them, and what to do with the evidence and opinions they receive in return. It is clear, however, that a country should strive to provide the public with information about biosafety issues and allow individuals the opportunity to provide comments on the issues before the government makes a decision.

Conclusion

While the Protocol establishes worldwide practices and procedures surrounding risk issues involving LMOs, it does not answer all the questions that countries will encounter when they set up a comprehensive and fair national biosafety regulatory system. As countries build their national biosafety regulatory systems, the issues identified above should be considered. By addressing those issues, the national biosafety regulatory system can ensure the safety of LMOs and conform to international obligations.

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