

Biosafety Regulation in the North and South

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Abstract of Oral Presentation

Biosafety regulation is key to ensuring the environmental and human safety of genetically modified organisms (GMOs) and giving the public confidence in GMO products. It is essential to have a strong, but not stifling, regulatory system that independently reviews and approves each product for safety before it is released into the environment or commercialized.

Over the past several years, biosafety regulatory systems in many of the Northern, or developed countries, have been revised and updated. At the same time, Southern, or developing countries, have begun to establish their own regulatory systems for GMOs. In my talk, I will discuss key components of biosafety regulatory systems in the North and South and how those systems address different issues relevant to biosafety regulation. A summary of the key components and issues that I will focus on are set forth below.

Role of Biosafety Protocol

The Biosafety Protocol, which has been in effect for approximately one year, sets forth legal requirements for the transboundary movement of GMOs. As a binding international treaty specifically addressing biosafety, the Biosafety Protocol is very important and influential to the establishment of national biosafety regulatory systems in both developed and developing countries.

For countries without already established biosafety regulatory systems (including many countries from the South), the Biosafety Protocol is being used as a model or template for many of the key provisions of their biosafety legislation or regulations. For example, in many countries, the definitions, scope, and procedures from the Biosafety Protocol are incorporated into and form the basis for the national biosafety system. On the other hand, for countries that had a working biosafety regulatory system in place before ratifying the Biosafety Protocol, those countries are making slight modifications to their systems to ensure appropriate compliance with the Protocol. For many of those already existing systems, they are generally compliant with the Protocol, even if their scopes, definitions, procedures, and requirements are not identical to the Protocol. Thus, countries that are now establishing biosafety systems tend to look to the Biosafety Protocol as a template for their laws and regulations. Already established biosafety systems achieve the same result of compliance with the Biosafety Protocol, although sometimes they use procedures and definitions that are very different from the Protocol's language.

Comprehensiveness of System

A good regulatory system for GMOs needs to comprehensively address a number of different areas. First, it should address GMOs at the different stages of development from laboratory research and field trials to products that are commercially available and eaten by humans and/or animals. Second, it should address not just the environmental issues highlighted by the Biosafety Protocol but also food-safety issues. Finally, it should address not just engineered plants that will be used for food or feed, but plants engineered to produce non-food substances and transgenic animals.

For some developed countries, their regulatory systems have been in place for a number of years and those systems have been required to assess numerous GMOs at the various stages of development. Thus, the regulatory systems of the E.U., the US, Canada, and other developed countries tend to be comprehensive, covering environmental and food safety issues associated with genetically engineered plants and animals when they are in the laboratory, when they are tested outdoors, and when they become commercial products consumed by humans and/or animals.

For many developing countries, there has not yet been the need for a comprehensive biosafety regulatory system. Some countries may not have had any GMO field trials yet, so there is less concern for regulations addressing the commercialization of a GMO. Similarly, while releasing an engineered plant may be imminent, transgenic animals may be well off in the future.

Also, if a country is writing a law or regulation to specifically implement the Biosafety Protocol, it will focus on environmental issues and may not comprehensively address food-safety. Thus, the comprehensiveness of biosafety regulatory systems in developing countries varies tremendously.

Some countries only comprehensively address field trials, leaving until later the establishment of procedures for commercialized products when products are in that stage of development.

Similarly, many developing countries are focusing their biosafety systems on environmental issues surrounding release of GMOs into the environment and have not established clear pathways for the food-safety assessment and approval process surrounding GMOs.

Establishment of a Clear Safety Standard

Each regulatory system should have established safety standards for its food-safety and environmental approval processes. The safety standards should set forth what safety determination must be satisfied to approve an application. A safety standard is essential since determining safety usually involves establishing both a baseline to compare the new product against as well as determining the level of protection that is desired.

In general, developed country regulatory systems have articulated safety standards that are applied to GMOs. For example, EU regulations state that GMO foods must not “present a danger to the consumer.” Similarly, countries that use existing laws to regulate GMOs apply the established safety standards for the conventionally produced product to a similar GMO product. The US applies the “unreasonable adverse effects on the environment” standard for conventional pesticides to plants engineered to produce a pesticide.

Some developing countries writing new laws and regulations on biosafety always state that a GMO must be determined safe before it is approved. Those laws and regulations provide little explanation of the standard or criteria that will be used by the decision maker to determine whether the product should be approved. To have a biosafety regulatory system that is predictable, equitable, and fair, standards and criteria for approval need to be spelled out in advance so that all parties know when a product will be deemed safe.

Role of Non-Safety Concerns in Approval Decisions

It is universal among regulatory systems in both developed and developing countries that a GMO should not be approved for release into the environment or allowed into the food supply without a scientific determination that the GMO is safe based on a individual risk assessment with product-specific data. Whether a country addresses concerns raised by GMOs other than human and environmental safety in the regulatory process, however, is not consistent among both developed and developing countries.

The release of a GMO into the environment or its placement on the market as a food can raise social, economic, or ethical concerns for a country and its people. Some countries factor such issues and concerns into their safety approval processes while others leave it to the marketplace to resolve such issues. For example, the United States does not factor non-scientific safety issues in the GMO approval process but leaves those issues to be addressed by other governmental agencies after a product is approved or by the marketplace. In contrast, Argentina requires a market analysis as a formal part of its approval process and can deny approval of a safe GMO if it will have other adverse consequences for the country. Similarly, South Africa considers other societal concerns before deciding to approve the release of a GMO. Thus, a distinguishing feature among biosafety regulatory systems is their treatment of non-safety concerns raised by a particular GMO application.

Proportionate Risk-based Reviews

A good regulatory system has the flexibility to treat different products differently depending on the potential risks and concerns raised. Thus, the system prioritizes based on potential risk and gives the most scrutiny to products with the most risk while allocating less resources and time to products that raise less concerns. In developed country systems with experience regulating genetically engineered organisms, many of those countries tailor their risk assessments and regulatory processes to the risk of a particular product, allowing organisms with minimal risk a expedited review and approval process. For developing countries with less experience regulatory GMOs and less scientific expertise, the regulatory systems tend to have similar approval processes and risk assessments for all GMOs, independent of the riskiness of a particular application.

Scientific Expertise for Decision making

Deciding to approve a GMO usually involves conducting a risk assessment and assessing

scientific data on both environmental and human safety. For developed countries, much of that analysis is conducted within the government by scientists employed by that government. For developing countries, however, there is limited scientific and technical capacity within the government to conduct such analyses. To make up for the lack of personnel within the government with appropriate expertise, many of those countries look to experts outside the government to review, analyze and assess data on potential risks posed by a GMO application.

Thus, many biosafety regulatory systems, especially in developing countries, establish expert scientific advisory committees to review GMO applications and advise the government on their merits. The membership of those committees, their responsibilities and interactions with the government's regulatory body, and their conflict-of-interest rules are usually set forth in the biosafety laws or regulations. Developed country regulatory systems also rely on outside expert committees, although they tend to perform slightly different functions than in developing countries.

Transparency Trade-offs

An important component of a regulatory system is transparency. To have a transparent system, the government must provide the public and the regulated community with information about the regulatory process (who is involved, what are their responsibilities, and how will they carry them out), about the individual applications for releases into the environment, and about the approval decisions made by the government. With that information, the system can become understandable and an outsider can judge whether a GMO has been equitably and fairly assessed.

Although regulatory systems in both developed and developing countries strive for transparency, achieving a transparent system involves numerous trade-offs and the balancing of competing interests. Making information available to the public about both the regulatory system and specific applications is both expensive and time consuming. Thus, the government must assess the additional costs to the system from making more information available as well as the time added to the regulatory process from informing the public. Less transparent systems may reach their decisions quicker and at less expense but may not achieve the same public acceptance that might result from a more transparent process. Similarly, the regulatory system must balance the competing interests of the applicant, who may want to keep some information confidential for business purposes, with the public's right to know. Thus, while all biosafety systems strive to achieve some degree of transparency, differences among countries depend more on how they balance competing interests and less on whether they are from the North or South.

Challenges to Effective Public Participation

Public participation in the regulatory process is essential for consumer trust in that process. Public participation includes the opportunity to provide information and comment on regulations, guidance, and product applications. Government agencies should make a special effort to solicit information from stakeholders to ensure all points of view are heard before regulatory decisions are made. They should also respond to comments in decision-making documents to assure that

public concerns are seriously considered.

Many countries include in their biosafety regulatory systems the ability for the public to comment before a decision is made on a GMO application. Making sure that the public is aware of that opportunity and providing the public with the knowledge and tools to make their participation meaningful is much more difficult. In developed countries, the media, government publications, and the internet can inform the public about their participation rights. In developing countries, financial constraints, language barriers, and the lack of good communication vehicles makes implementing public participation requirements in a meaningful way much more difficult.

Conclusion

Although there are numerous differences that can be pointed out between biosafety regulation in the North and South, all the biosafety regulatory systems have the same goal – to ensure that only safe GMOs get released into the environment or approved as commercial products. While regulatory systems address issues differently and contain different components and characteristics, each one strives to provide that country with the legal tools to make its own determination whether a particular GMO product meets its safety standards.