
Regulatory and Economic Aspects of Accessing International Markets Workshop

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The group attending the Regulatory and Economic Aspects of Accessing International Markets Workshop was charged with exploring the consequences of agricultural biotechnology on marketing of agricultural products. The group considered a number of issues surrounding the international licensing, production and consumption of products arising from agricultural biotechnology programs. The group focused on several areas; international regulations, economic profitability, intellectual property rights, social and economic equity of producers and consumers, and access to biotechnology for research. Despite the diversity of people and perspectives, the group was able to weave a common set of recommendations on several priority issues.

PRIORITY ISSUES

The following issues were identified by workshop participants as the key issues affecting the movement of agricultural biotechnology into international markets. Other related issues were discussed, and where appropriate, these are incorporated into this report. Consideration of these issues through extensive discussion led to development of recommendations.

LACK OF UNIFORMITY IN INTERNATIONAL REGULATORY POLICY

Introduction of genetically modified organisms (GMO's) into many international markets is hindered by the varied regulatory requirements of different countries. Often, countries will not accept data generated in other countries, requiring costly repetition of testing. At times, regulatory decisions are based on information unrelated to the efficacy or safety of the product. Also, delays in acquiring regulatory approval can result in the inability to introduce a new product during its marketable life.

One major recommendation grew out of this discussion. We should strive for harmonization among international regulatory organizations by:

- *providing examples of the lack of harmonization to governments already participating in multilateral negotiations;*
- *emphasizing the importance of making science-based regulatory decisions, with the ultimate goal that decisions be product- rather than process-based;*
- *urging timely regulatory approval in order to: facilitate international trade, expedite access by farmers/consumers, and provide a level playing field for GMO's with traditional materials; and*
- *encouraging mutual recognition of appropriate regulatory decisions.*

ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

Introduction of new genetics into many international markets has been prevented or deterred by the lack of, or ineffective enforcement of, intellectual property rights laws. This is especially true in the developing countries where advanced technology could be beneficial. The expenses of product development and acquiring regulatory approval are too great to risk losing control of the material upon introduction into a new market.

Through whatever means available, governments in developing countries should be encouraged to enact laws and policies that effectively protect intellectual property. These laws and policies should:

- *emphasize the 'public good' aspect of intellectual property protection for addressing world hunger and poverty;*
- *encourage harmonization of patent policy for higher life forms; and*
- *foster research access to biotech materials while respecting intellectual property rights.*

UNDERSTANDING CONSUMER PERCEPTIONS

Consumer acceptance of GMO's is a concern. While much has been said about the problems associated with public opinion surveys, it is important to understand the underlying reasons for various perceptions in specific international markets. Consumer acceptance of non-traditional materials is often affected by social, cultural, or religious influences that may not be reflected in public opinion surveys. Furthermore, the benefits of adopting new technologies are often poorly understood by producers and consumers. Large industry developers/marketers are often seen as the sole beneficiary.

Support should be provided for research to elucidate the basis for consumer perceptions of GMO's in specific international markets through:

- *surveys that reflect social and cultural biases in consumer perceptions;*
and

- *educational programs to illustrate the sharing of benefits among the various stakeholders in technological advances.*

LACK OF COORDINATION IN RESEARCH AND DEVELOPMENT

Coordinated effort among the various players involved in agricultural biotechnology is viewed as essential in optimizing the benefits to be derived. Improved coordination is needed both within and between public, private and international contributors. A critical component of this coordination is the need to increase access to material for research purposes.

Efforts should be made to develop a systems approach to coordinate research and development programs. Disciplinary, organizational, and institutional barriers to improve coordination must be identified and eliminated.

MINOR USE CROPS/APPLICATIONS

The high cost and risk involved in biotechnology development has, by necessity, resulted in concentration of efforts on crops and traits that optimize potential returns on investment, i.e. the major crops. There is a need for application of biotechnology to the minor crops in the developed world. In many international markets, especially the developing countries, the needs for advanced technology involve minor crops and traits that may not be considered economically viable in more sophisticated markets. Furthermore, existing regulatory policies are often disincentives to efforts targeted for these markets.

In order to increase access to advanced technology, efforts to develop regulations and technology applications that are 'minor crop friendly' should be undertaken. A coordinated program similar to the IR 4 program for obtaining pesticide registrations for minor use crops, is needed to address this issue.

AVAILABILITY OF RISK CAPITAL

One of the primary barriers to technology and product development for agricultural uses is a shortage of investment capital. While many factors converge to this end, there needs to be recognition at both the public and private levels that such investment is essential for the common good in both domestic and international markets.

LABELING

There is substantial controversy regarding the labeling of products of agricultural biotechnology. Considerable confusion exists at many levels over the definitions of biotechnology and GMO's, often resulting in demand for labeling requirements that do not accurately reflect reality. For example, it would not seem appropriate to require special labeling for a product which has not been modified in any way simply because it was produced through a novel process. Equally as important as the public's right to know is the necessity to avoid misleading or misinforming the public with inappropriate labeling.

Every effort should be made to encourage international acceptance of reasonable, science-based labeling laws and policies that are product- rather than process-based.

OTHER IDENTIFIED ISSUES

Several other issues were discussed, but not fully developed, in the workshop. They were:

- There is no standardized definition of agricultural biotechnology that is accepted by all groups worldwide. As a result, processes or products may or may not be considered as agricultural biotechnology under varying regulations in different countries.
- The costs associated with complying with the varying regulatory and labeling requirements of different countries make it difficult for small and mid-size companies to get products registered, and therefore compete internationally.
- Regulations governing agricultural biotechnology within a country may fall under several different agencies.
- The increase in productivity through the use of agricultural biotechnology may further hasten the trend toward larger farms in the developed countries, and thus contribute to the decline of smaller, traditional family farms.

Finally, it is important to point out that encouraging a systems approach to dealing with agricultural biotechnology regulations, research and development programs, and consumer and producer issues of safety and acceptance is the responsibility of all participants in the system. Each group (producers, private industry, policy makers, researchers, and consumers) has its own unique role to play. This approach rests on the principle that we must endeavor to meet the needs of the present without compromising the ability of future generations to meet their own needs. Therefore, stewardship includes maintaining or enhancing the vital agricultural resource base for the long term, and consideration of social responsibilities such as consumer health and safety both in the present and the future.