

Staff Paper

The Economics of Biosafety: Implications for Biotechnology in Developing Countries

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Abstract

There is a growing body of literature on the safe use of biotechnology and the need for an international biosafety protocol and national regulations to facilitate the safe development and transfer of biotechnology. Most of these studies, however, address the issue of biosafety from a scientific, legal, environmental and organizational perspective. The purpose of this paper is to add to this discussion by providing an economic perspective on regulating products of agricultural biotechnology, with special emphasis on implications for developing countries who are under increasing pressure to put a biosafety framework in place. The paper provides a brief discussion on the economic rationale for biosafety regulations, explains the economic benefits and costs of biosafety, and discusses the appropriate form of biosafety policy and the effects of regulation on resource allocation.

The benefits of biosafety discussed include - the reduction of possible human and environmental risks of biotechnology products and "accident" costs to the society; increased predictability for a research organization of the expected time and money to get a new product on the market; making the products of biotechnology accessible to a country; and the provision of certainty and stability to the social framework, necessary for the development of biotechnology research and development activities. Developing countries should balance these potential benefits with the tangible costs of biosafety regulation to the biotechnology organizations and the society. To a biotechnology organization, biosafety will increase the research lag, production costs, transaction costs and marketing costs. Given the scarcity of human and physical resources, setting up a biosafety system also poses opportunity costs to the society.

The following issues need careful examination in designing a biosafety policy in a developing country: the goal of biosafety policy; the appropriate means of controlling risk; the impact of biosafety on scientific development and private investments; the impact of biosafety on the international transfer of technology and international trade; the incidence of biosafety costs; and the size of biosafety system.

Keywords: Biosafety, economic aspects, developing countries, agriculture, biotechnology, research

15 pages.

1. Introduction

In many developing countries traditional agriculture and plant breeding programs are now being supplemented by genetic engineering techniques. These include tissue culture techniques to produce disease free seedlings, new formulations for animal vaccines and growth hormones, and more recently the development of transgenic plants. Biosafety, which is used here to encompass the policies and procedures adopted by a government to ensure the safe application of modern biotechnology, is a topic which has generated a wide public interest in recent years as more and more countries field test transgenic crops developed by their own national laboratories or international public and private research organizations¹ (De Kathen, 1997).

While a majority of industrialized countries have biosafety regulatory procedures in place, the situation in developing countries is quite different. Virgin (1997) points out the results of a 1995 Biotechnology Advisory Center survey, which indicates that only about ten percent of the developing countries have any established biosafety regulations. In the absence of a clear biosafety regulations and guidelines, countries may not be able to take advantage of the international transfer of modern biotechnologies.

The role of regulatory issues in the discussion of biotechnology reflects the increasing awareness of the influence of law on technology, technology on society, and the increasing pressure for policies that anticipate rather than react to new technology. There is a growing body of literature on the safe use of biotechnology and the need for an international biosafety protocol and national regulations to facilitate the safe development and transfer of biotechnology. Most of these studies, however, address the issue of biosafety from a scientific, legal, environmental and organizational perspective (Lesser and Maloney, 1993; Persley et al., 1992; OECD, 1992; Persley, 1990; OTA, 1988). The purpose of this paper is to add to this discussion by providing an economic perspective on biosafety regulation of products of agricultural biotechnology.

¹ Research organizations as used in this paper refers to all firms, corporations, laboratories, institutes and centers, whether publicly supported or private, national, international or multinational, that are involved in some aspects of agricultural biotechnology research and development.

Societies are comprised of a number of regulatory systems. Regulation involves choices between alternate rules of the game and between alternate assignments of rights that are prior to economic analysis. Thus, a caveat to note is that economics can no more tell us what biosafety rules and rights structures should be than whether and what agricultural biotechnologies should exist. For an economist to aver the substance of biosafety regulations is equivalent to asserting the rules and rights structures and to reach beyond economic analysis. The purpose of this paper, therefore, is to address several economic issues rather than conduct an economic assessment of biosafety. In addition to providing a brief discussion on the economic rationale for biosafety regulations, the three objectives of this paper are to explain the economic benefits and costs of biosafety, appropriate form of biosafety policy, and the effects of regulation upon the allocation of resources. The implications of these issues discussed in this paper are specially geared towards developing countries who have been lagging behind in building a biosafety regulatory capacity but are under increasing pressure to put a biosafety framework in place. For example, the Convention on Biological Diversity has recently set-up an international biosafety protocol to facilitate and ensure the establishment of a biosafety regulatory framework in developing countries (Virgin, 1997).

2. Biosafety Regulations: The Perspective of Economic Theory

The economics literature contains frequent evaluative assertions to the effect that regulation *per se* produces inefficiency or distortions (Samuels, 1981). In fact, one can denigrate any law or legal change as inefficient (in the connotation of *pareto optimality*) because law is not voluntary adjustment and loss accrues to some former holders of rights. Hence, minimum government intervention and regulation have been advocated by political economists ever since the time of Adam Smith. Despite this long-held view from the discipline of economics, regulation, including biosafety, can be economically justified by its function of managing aspects of the indeterminacy, uncertainty and risk in the regulated industry.

Two alternative views about the regulation of an industry are widely held in the literature of economics of regulation. The first is that regulation is instituted primarily for the protection and benefit of the public at large or some large subclass of the public. The second

view is essentially that the political process defies rational explanation. In other words, they are guided by unpredictably shifting mixture of political forces (Stigler, 1971). The evidence of active participation by the scientists, biotech companies, consumer groups and policy makers in the debate about the extent of safety regulations needed for the new biotechnology products lends support to the view that biosafety regulations are for the protection of either the industry, consumers, research organizations or the public at large (Crawford, 1990; Schneider, 1993).

Although biotechnology is expected to produce valuable products that will increase crop yields, reduce chemical and pesticide use or increase the efficiency of agricultural inputs and outputs, questions have been raised about the possible side effects of biotechnologies in the form of migration of genetically engineered organisms (GEOs) to other environments and other deleterious ecological, property and human health effects (Betz et al., 1983). As a result, the possibility of harm from the generation of this new technology is an externality requiring public policies to transfer the costs imposed on the society to the externality generator.

Biosafety can be viewed as a mechanism for controlling these *possible* stochastic externalities generated from agricultural biotechnologies. Biosafety regulations induce the externality generator (biotechnology research organizations - public and private) to internalize the possible costs (discussed in later sections) to be involuntarily imposed on others. Since, most of the developing countries do not have a regulatory framework comprehensive enough to encompass the products of new biotechnologies, investments incurred by the government to develop a biosafety system can be similarly viewed as inducing the present generation to internalize the costs involuntarily imposed on future generations.

Thus, from an economic perspective, biosafety represents a mechanism of transferring the costs of possible "accidents" (externalities) to be incurred by agriculturists (in the form of increased pest problems, reduced yields), consumers (in the form of health hazards) and the society at large (in the form of environmental degradation, loss of biodiversity, etc.) to the research organizations and present generation citizens (whose tax money will be used to finance the biosafety system).

In the economics literature, an argument often made against regulation is that it will contribute to inflation. It is true that the immediate impact of biosafety regulations will be an increase in the production and regulatory costs. But because of biosafety, the costs borne by the agriculturists, the consumers and the society are likely to be lowered. With biosafety, the costs hitherto borne by a research organization will be imposed on another and passed on as costs of production to the consumer of the final product. Note however that the higher price will cover two products (the physical product and environmental safety) and will substitute for the price, which will be lower, hitherto borne by the society because of the unsafe biotechnology products. If the risks are correctly perceived and biosafety regulations are directed towards controlling these risks, then the regulation may not necessarily contribute to inflation. Biosafety regulation can act as a mode of registering and assigning the costs rather than their cause; It can be the mean by which interests in conflict is differentially protected.²

3. The Benefits and Costs of Biosafety

Developing countries in the process of establishing a national biosafety policy to promote the use of modern agri-biotechnology should be aware of the costs and benefits of establishing a regulatory framework. Economists define benefits as those outcome of an activity that adds to an objective and costs as those that lessen the objective. Hence, the discussion about costs and benefits of biosafety is meaningless without defining an objective function. Considering that the objectives of a research organization (private, public, national and international) will be different from those of the society as a whole, the costs and benefits of a research organization and the society are discussed separately.

² This assertion for biosafety regulation assumes that the perceived risks of biotechnology are real and correctly estimated. If, however, biosafety policies are based on overestimation of risks (i.e. it regulates everything and too much), then some of the costs incurred by the society may turn out to be redundant lending support to the inflationary argument.

3.1. Costs and benefits to a research organization

Assuming that the objective is to maximize the net returns to research, biosafety represents both time cost and opportunity cost to a research organization. Biosafety increases the research lag by postponing the commercial release of biotechnology products (Fleisher, 1989). Research organizations will have to shoulder the expense of providing needed data and test results and may delay large-scale testing and marketing of products; thus, reducing the (discounted) benefits to be generated from new biotechnologies. Biosafety will increase the production costs of the research organizations in the form of containment facilities, assembly of paperwork and laboratory results necessary to submit to the appropriate regulatory agency for approval of initial field test and other logistic costs. It may also increase the rejection rate of research products prior to their commercial release, if the products do not meet the safety standards. Thus, the production costs per released product will increase. Even the marketing costs (processing, packaging and labeling) of industries using GEOs as an input will increase depending on the regulatory requirements on product marketing. Biosafety will also increase the transaction costs for the research organization in the form of information costs, search costs and payment of fees, charges, etc.

A well established biosafety system will however, reduce uncertainty and increase the predictability of expected time and money to get a new product on the market. As a result it will encourage investments in biotechnology research by both public and private sector (Crawford, 1990). It will also reduce the possible liability costs which would be incurred if the products were to be released without regulatory approval. This is especially relevant to research organizations (both foreign and domestic) wanting to enter in the markets of developing countries.

3.2. Costs and benefits to the society

The goal of public policy is to maximize the welfare of all its citizens. Biosafety regulation helps to achieve this goal by reducing the unknown risks to human and animal health and the environment. Also, it provides the certainty and stability to the social framework, necessary for the development of biotechnology research and development activities, and then the introduction of products of biotechnology available in a given country.

However, these benefits to the society are not without costs. For example, setting up a biosafety system is a costly operation. It demands human and physical resources that are scarce in many developing countries. Also, the society has to incur risk assessment, other operational and bureaucratic costs of day to day operation of regulatory system. Thus, biosafety represents an opportunity cost to the society. Secondly, although the regulatory requirements are the same for all organizations producing similar products, the cost of meeting these requirements will have a proportionately larger claim on the resources of smaller organizations. Hence, biosafety may affect the market structure of biotechnology research industry by driving small organizations out of biotechnology research.

To economically justify a biosafety system, a country will need to assess the potential benefits and balance them against the costs of regulations. The arguments found in the literature for and against biosafety are mostly based on estimates of costs and benefits that are still hypothetical and speculative in nature.³ There is a need for more field research, risk assessment, and data collection and analysis to identify the real costs and benefits of biosafety. Moreover, developing countries need to assess these costs and benefits keeping in perspective the type and scope of biotechnology research to be undertaken and promoted in the country.

4. Forms of Biosafety Policy: Implications for Resource Allocation

4.1. Alternate means of controlling risks

The purpose of establishing a biosafety system is to control the possible risks associated with GEOs. However, given the uncertainty in the scientific community about risks of GEOs, public policy makers face a choice between alternative means of controlling risks. First of all, they face the choice of whether biosafety guidelines should be imposed as a “voluntary” or a “legally binding” code of conduct. If a legally binding system, what form should it take? *Ex ante* regulation of biotechnology products and processes (in the form of required permits, licenses, regulations, pre-manufacture notification submissions, or product

³ For example, Szybalske (1985) uses the following argument to unjustify biosafety: "(I) the known present and future benefits of genetic engineering are enormous; (ii) the hypothetical, inadvertent risks, if any, are balanced by the hypothetical inadvertent benefits; and, (iii) the overall cost of unnecessary regulation is high. Thus, the balance sheet clearly shows that regulations are not justified at present and are against the best interests of society." (Szybalski, 1985, p. 115).

approvals), a strict *ex post* liabilities (in the form of damage payments by the manufacturer) or a negligence rule (combination of *ex ante* regulation and *ex post* liabilities)? (Larson and Knudson, 1991). Each of these alternatives has different implications for the resource allocation decisions and sharing of benefits and burdens of biosafety.

Under an *ex ante* regulatory standard, a research organization must comply with the standard - spend a certain amount on "safety" - before conducting an activity. Thus, the burdens of biosafety are borne by the research organization and the government *a priori* of the occurrence of damages. The benefits of this approach is that it controls and minimizes the "accident costs." On the other hand, under strict liability for damages, the organization fully compensates injured parties if an accident occurs and if it can be shown that the organization's actions caused the damages. The benefit of this approach is that it minimizes the costs of biosafety but increases the "accident costs" to be borne by the research organization and the future generation citizens. Under a negligence rule, the research organization may not be held responsible for any damages if it follows stipulated standards or guidelines. This approach is a combination of *ex ante* regulation and *ex post* liability where by the organization managers decide on which approach they would like to adopt.

Due to the pressure of consumer groups and environmentalists, the biosafety policy developed in most industrialized countries emphasize the *ex ante* regulation approach (Persley et al., 1992; Lesser and Maloney, 1993). The major advantage of this approach is that it provides information to both the producers and consumers of biotechnologies. For example, if a research organization produces new products according to the regulations, it is less likely to be fined *ex post*. Thus, regulation and product standards reduce risk (arising from the lack of predictability concerning how the legal system will respond) and thereby allow the market to work more smoothly as the participants are more informed about the rules of the game (Wittman, 1977). However, if the risks of biotechnologies are overstated, as claimed by Brill (1985), Davis (1987), Miller (1991) and others, then *ex ante* regulations pose unnecessary costs to the society.

Since all types of biotechnology products do not face the same risk profile, it is often socially advantageous to employ the two means of controlling risks (*negligence rule*) - i.e. require research organizations to satisfy a regulatory standard and also to face possible liability

(Segerson, 1986). In this case, research organizations producing relatively high risk products are led to do more than to satisfy the regulatory standard, for their potential liability makes that worth their while. In effect, a reduction of the regulatory standard can be afforded because liability is present to take up some of the "slack" associated with the less stringent standard. In theory, this approach will minimize both the "accident" costs and "accident prevention" costs to the society.

In practice, the emphasis given to different approaches in developing a biosafety policy will depend on several factors including, the nature of risks (probability and consequence) of biotechnologies (which in turn will depend on the type of biotechnology product/process being promoted in the country -- e.g., GEOs versus tissue culture), goal of public policy (whether the goal is to minimize the "accident costs" or the sum of "accident" costs and "accident prevention" costs), institutional and judicial framework, and the involvement of private sector in biotechnology research. Simply translating the biosafety regulations of industrialized countries will not work in developing countries where the existing legal framework may not be comprehensive enough and the judicial system not strong in enforcing laws. In some cases, the establishment of a biosafety framework may entail the establishment of new legislation and building up of an administrative and law enforcement network.

4.2. Economic issues in designing a national biosafety policy

Although, the costs of biosafety will be ultimately borne by all the sectors of the society, its immediate cost will be imposed on research organizations. It is, therefore, important that biosafety policy makers in developing countries give particular attention to the impacts on research organizations in designing a biosafety policy.

In countries that have a federal and state government system, such as the United States and India, a national rather than state-level biosafety policy would be more conducive to biotechnology research organizations. Disparate regulations can lead to unseemly and possibly dangerous competition among states to stage experimental releases on a fee basis (Lesser and Maloney, 1993). Harmonization is also important at regional and international

levels to promote the international transfer of technologies.⁴ Disparate, excessive or no regulations can act as a non-tariff barrier inhibiting trade.

An expanded policy of strict standards and bans would have a negative impact on technological change and product innovation (Miller, 1991).⁵ Although one of the benefits of biosafety is that it will promote private research and development, too much regulation may discourage private investments. One way to speed up adoption, interpretation process and reduce the uncertainty of investment in biotechnology would be to use, where possible, the existing legislation rather than develop an entirely new system of rules and laws.

An issue that needs to be addressed in designing biosafety policy is the incidence of risk assessment and other costs. Clearly, one of the immediate implications of biosafety is that it will be a cost increasing policy for both the government and research organizations. Given the stringent budgets, governments in developing countries may decide to pass on some of the burdens (viz. risk assessment) on to the research organization. This will add to the increasing costs of biotechnology research programs. Policy makers should make sure that additional costs of biosafety, particularly of risk assessment should not adversely affect the productivity of biotechnology research.

⁴ Transfer of crop varieties across political boundaries can be potentially inhibited by two factors - the genotype by environment interactions and the social, economic, legal and political framework. Both direct and indirect transfer of technology has been an important phenomenon in conventional plant breeding research not only because of common agro-climatic environment but also due to minimum and harmonized legal framework (Maredia et al., 1996). Such international transfers are mutually beneficial to all the countries and particularly the small countries who do not have the critical mass to engage in a full-fledged crop improvement program. Given the high costs of biotechnology research, harmonization of biosafety regulations is particularly important if these countries want to benefit from biotechnologies developed in other countries.

⁵ The inability for a country to internationally compete in agricultural commodities and feed the increasing population are frequently cited as the projected consequences of overregulation of biotechnology. In the U.S., lobbyists have often used the combination of national self-interest and global altruism in justifying biotechnology. For example, Monsanto's Senior Vice President for Research and Development, Howard Schneiderman writes: "Genetic engineering and other new agronomic methods should enable the American farmer to continue to lead the world in agricultural productivity in the next century and to feed a significant number of these nine billion people... However unless we keep genetic engineering on a fast track with research funding, and unless federal regulations permit the controlled field testing of new crop varieties and beneficial soil microorganisms, America will lose out." (Schneiderman 1985, p.11).

Another important issue in designing a biosafety system is its size (number of employees and total investments). Biosafety is an emerging policy area in developing countries, and in developing appropriate policies and procedures for the regulation of biotechnology, a country will have to establish various committees, sub-committees and regulatory agencies (Persley et al., 1992). Naturally, these countries will look towards industrialized countries, which are advanced in biotechnology research, for biosafety guidelines and system design. However, for economic justification, the size of a biosafety system should be congruent with the stage of economic development of the country and the biotechnology research industry (which is likely to be at initial stages in many developing countries). Thus, developing countries should make sure that they do not duplicate the size of the biosafety system from industrialized countries such as the U.S. but the basic concepts of the biosafety system.

5. Conclusions and Implications for Developing Countries

Rapid development in agricultural biotechnology has stimulated both industrial and developing country governments to develop national programs and policies aimed at realizing its potential benefits. An efficient biosafety system is one of the prerequisite for realizing the potential benefits of biotechnology research. Thus, in recent years, many international and national organizations in industrialized countries, such as the OECD, WHO, FAO, UNEP, USAID, USDA, GTZ, and UNIDO have been involved in assisting developing countries in developing biosafety guidelines. In this paper, I discussed the economic aspects of regulations and outlined various economic issues that developing countries and the various organizations assisting these countries need to keep in mind while designing an efficient biosafety policy.

From an economic perspective, biosafety can be viewed as a mechanism for controlling externalities and transferring costs to be incurred by the consumers, farmers and society to the research organizations and present generation citizens. The benefits of biosafety include - the reduction of possible human and environmental risks of biotechnology products and "accident" costs to the society; increased predictability for a research organization of the expected time and money to get a new product on the market; making the products of biotechnology accessible to a country; and the provision of certainty and stability to the social

framework, necessary for the development of biotechnology research and development activities.

Installing a biosafety system to avail these benefits is, however, not an easy task. It entails establishing national committees, working groups and advisory panels, developing rules and regulations, getting legislative approval, developing technical manuals, handbooks and guidelines for research organizations, hiring inspectors, conducting risk assessment tests, carrying out the day-to-day administration of applications, approvals and complaints, enforcing biosafety laws, and so on. A functional legal and administrative infrastructure is therefore an absolute necessity for establishing a biosafety system in a developing country.

In developing the biosafety guidelines, developing countries should balance the potential benefits with the tangible costs of biosafety to the research organization and the society. To a research organization, biosafety represents both a time and opportunity cost. It will increase the research lag, production costs, transaction costs and marketing costs of biotechnology research organizations. Moreover, the increased costs of biosafety may drive out small biotechnology research organizations from the market. Also, given the scarcity of human and physical resources, setting up a biosafety system also poses opportunity costs to the society.

As more and more countries come under the increasing pressure for developing a biosafety framework, the following issues need careful examination in designing a biosafety policy.

- a. The goal of biosafety policy (whether it should be the minimization of only "accident" costs or the sum of "accident" costs and "accident" prevention costs?).
- b. The appropriate means of controlling risk (*ex ante* regulation, *ex post* liability or a combination of both).
- c. The type and functionality of the legal and judicial system in the country.
- d. The impact of biosafety on scientific development and private investments.
- e. The impact of biosafety on the international transfer of technology and international trade.

- f. The incidence of biosafety costs (who is going to pay for the creation and maintainance of a biosafety regulatory system?)
- g. The size of biosafety system.

Of course, there are no “blanket recommendations” for developing countries on many of these issues. Each country will need to develop a biosafety system based on the development status of its biotechnology industry (which varies widely across countries in Asia, Africa and Latin America), types of biotechnology products to be developed or traded (which can range from simple tools and products of tissue culture and micropropagation to genetically engineered crops and plants) and, the overall legal and administrative infrastructure in which the economy operates.

In conclusion, in designing a biosafety policy, developing countries should emphasize the safe use of biotechnology rather than imposing unnecessary restrictions on the pretext of safety in biotechnology. The latter will only lead to more bureaucracy and less efficiency, especially, in today’s climate of shrinking resources for agricultural research. The growing pressure for developing biosafety regulations should not lead to the elephantiasis of biosafety system and atrophy of biotechnology research.

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