

## THE IMPACT OF INTERNATIONAL HARMONISATION ON ADOPTION OF BIOSAFETY REGULATIONS

I. VIRGIN and R.J. FREDERICK  
Biotechnology Advisory Commission  
Stockholm Environment Institute  
Box 2142, 10314 Stockholm, Sweden

### ABSTRACT

Modern biotechnology will provide important tools for developing countries seeking to gain benefits from their genetic resources in a sustainable way, but concerns about the safety of the technology have been raised. Consequently, a key component of national biotechnology development strategies is the establishment of an effective biosafety regulatory oversight infrastructure. Today, less than 10% of developing countries have adopted biosafety regulations and guidelines. International efforts towards biosafety harmonisation include training, information exchange, the creation of technical guideline frameworks, and stimulating open debate in public forums. The results of these efforts can facilitate the processes for creating, adopting and implementing national biosafety regulatory procedures.

**Key Words:** Biotechnology, biosafety, genetic resources

### RÉSUMÉ

La biotechnologie moderne fournira des outils importants aux pays en voie de développement cherchant à profiter des bénéfices de leurs ressources génétiques d'une façon viable, mais les inquiétudes concernant la sécurité de la technologie ont été soulevées. Par conséquent, un élément clé des stratégies nationales de développement de la biotechnologie est la création d'une infrastructure régulatrice de supervision de la biosécurité. Aujourd'hui, moins de dix pour cent des pays en voie de développement ont adopté des directives et réglementations sur la biotechnologie. Les efforts internationaux visant à harmoniser la biosécurité comprennent notamment la formation, l'échange d'information, la création des cadres de directives techniques, et la stimulation de débats ouverts dans des forum publics. Les résultats de ces efforts peuvent faciliter les processus de création, d'adoption et d'application des procédures nationales de réglementations de la biosécurité.

**Mots Clés:** Biotechnologie, biosécurité, ressources génétiques

### INTRODUCTION

Developing countries contain at least 80% of global biodiversity, together with more than three quarters of the world's population. Yet developing countries are today home to only about 6% of the world's scientists (Raven, 1994). For developing

countries to gain benefits from their genetic resources in an environmentally sound and sustainable manner, biotechnologies will have to be incorporated appropriately into their development strategies.

The diversity of techniques that constitute modern biotechnology offers much to serve the

pressing needs for sustainable development in agricultural, environmental and energy programmes. In the last decade these techniques have been integrated into developing countries' research and developmental programmes, especially in the field of agricultural research. As with any new technology, the rate of transfer and the level of success are dependent not only upon the capacity to train, educate, and create a supporting infrastructure but also on an accepting environment in which to introduce and use it. Technology transfer is a complicated affair and requires intricate interactions of many parties with no guarantees for success (Brenner and Komen, 1994). A key component in the formulation of a biotechnology accepting environment is the establishment of a biosafety regulatory oversight infrastructure (Persley *et al.*, 1992; Komen and Persley, 1993).

While much of the focus has been on bottom-up approaches at the national level, more and more attention is being paid to international efforts that may afford top-down assistance. This paper discusses the status of national guidelines and regulations, efforts by international organisations towards harmonisation, and thoughts on how these may benefit the safe application of biotechnology.

## ACQUISITION OF TECHNOLOGY

The acquisition and use of innovative technologies requires effective interaction between various national sectors, including private research organisations and academic institutions, governmental ministries or agencies, and the public (Fig. 1). In the sector of private research and academia, institutional and human capacity building is vital. The influence of the public sector in establishing consumer patterns and defining national and local needs should not be underestimated (Walsh, 1993). To the government falls responsibilities for developmental strategies and priorities, allocating resources for capacity building, and the creation and execution of a regulatory oversight framework. For biotechnology this includes biosafety regulations, property rights and trade issues, and the creation of a favourable environment for technology advancement. While different sectors may work

independently, they do not work in isolation. Communication and cooperation will strongly influence inculcation of new technologies.

## CURRENT STATUS OF REGULATIONS

The Convention on Biological Diversity (hereafter the Convention) calls explicitly for information exchange and technology transfer from the North to the South. The Convention also calls for the safe handling of biotechnology and encourages harmonisation of biosafety regulations across countries (Krattiger and Lesser, 1994). To share fully the benefits of the biotechnology while minimising the risks, biosafety regulations must be effective and based on the best scientific principles (Persley *et al.*, 1992).

In a survey of the global status of adoption of biosafety guidelines and regulations, we chose to focus on the signatories of the Convention. This seemed a reasonable starting point since the Convention deals specifically with biosafety (Article 8[g] and 19.3) and, because of the considerable debate it has generated in its call for an international protocol.

For our purpose here, "adopted regulations" or "procedures" include laws, rules, executive decrees or *ad hoc* guidelines. We recognise that there are significant differences in regulatory authority associated with the different oversight mechanisms, but accept the generalisation for simplicity. As an indication of the adoption of the technology, we used summary data on field trials for genetically modified organisms (GMOs) and for practical reasons we concentrated on the release of transgenic crops (Krattiger, 1994; Ahl Goy and Duesing, 1995). This is of primary concern for many developing countries and where the greatest activity has occurred. Finally, we have also subcategorised countries based on economic income level as described by the World Bank (1993). This allows a useful comparison based on relative wealth of countries.

Of the 154 signatories to the Convention only 36 have some form of biosafety regulations in place. In the last eight years most of the industrialised countries passed laws or enacted regulations specifically addressing the deliberate release of genetically modified organisms.

Consequently, today 24 countries with High to Upper-middle income economies (57%) have laws or regulations in place (Table 1). Some, for example, the United States, have adapted an existing regulatory framework by adjusting it to the specific concerns linked with new recombinant techniques. Others, for example member states of the European Union (EU), have instituted new laws that, because they are based on EU directives, are similar in scope, requirements, and impacts.

In developing countries, the situation is dramatically different and fewer than 10% have any established biosafety regulations. This is not to say there has not been any progress taking place. Today, at least 12 developing countries have regulatory procedures in place. Geographically, starting with Africa, South Africa and Egypt have formal regulations in place. In Nigeria, guidelines have been signed by the Minister of Agriculture but additional approval is necessary before they are fully instituted. In the near future, Zimbabwe will follow and it is believed that Kenya will pass biosafety regulations for deliberate releases soon. In Latin America, Argentina, Brazil, Mexico, Chile, Costa Rica and

Cuba have regulatory biosafety procedures in place. In Eastern Europe, Hungary has an *ad hoc* review process and Russia has submitted a biosafety law. Of the developing countries in Asia, only China, India, Thailand and the Philippines have guidelines. Malaysia is preparing new legislation and Indonesia is in the process of drafting guidelines. Interestingly, there is a difference in the type of regulations between the developing and industrialised countries. For example, many countries in Latin America lack legislative instruments. Instead, ministerial decrees authorise the formation of national biosafety committees with responsibility for preparing guidelines, formulating application procedures and reviewing proposals. In some cases the National Biosafety Committees are *ad hoc* advisory groups with no regulatory authority. Also noteworthy, several of these *ad hoc* committees are limited to agricultural biotechnology and little or no attention is paid to other uses, such as environmental uses of microorganisms.

The rate of adoption of guidelines for countries categorised by income level is shown in Figure 2.

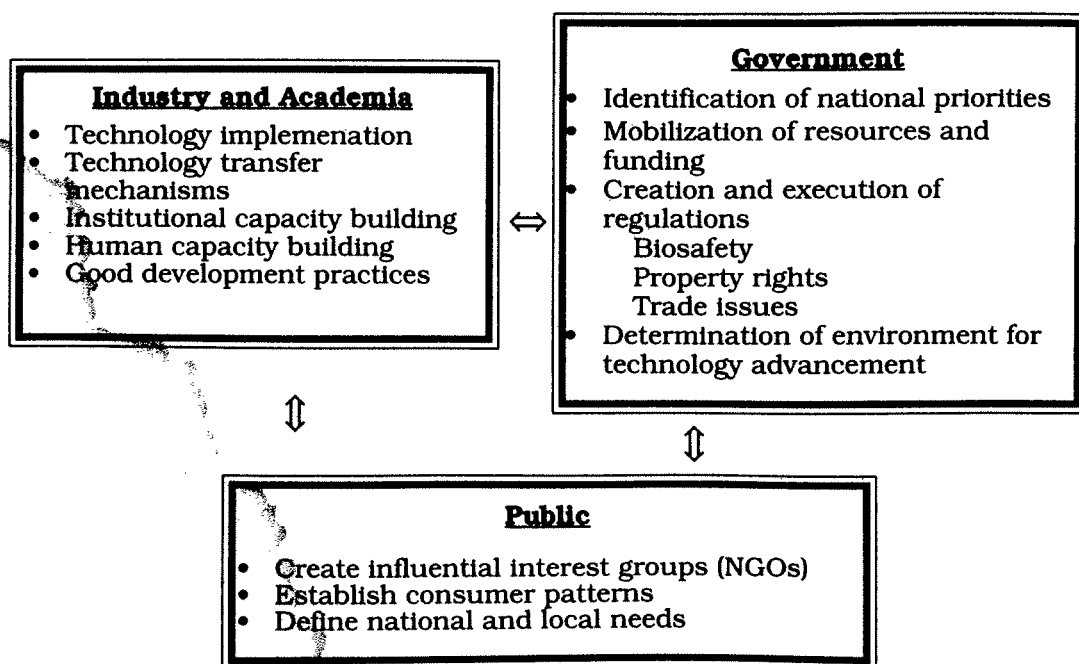


Figure 1. Interaction between different government sectors and the public in technology

In the High to Upper-middle income economies the large majority of countries have regulatory procedures in place. We project that in two years the figure will reach around 67%. In comparison, less than 10% of Lower-middle to Low income countries currently have regulations. Given the number of countries in the process of drafting regulations the situation will not change dramatically in the near future. Whether this is a reflection of limited financial and institutional capacities in developing countries or disinterest is not known. However, based on these figures, it is reasonable to predict that, without increased international support, less than 30 % of the Lower-middle to Low income countries will have biosafety procedures within 10 years. Even with support, it is unlikely that the rate will reach that obtained by High to Upper-middle income countries between 1991-1994. Irrespective of the actual rate, however, international efforts towards biosafety harmonisation could facilitate the

adoption process and subsequently provide additional benefits to biotechnology development.

### IMPACT OF REGULATIONS

Not surprisingly, field trials have been conducted in 47% of the High to Upper-middle income countries and, in all known cases, within the framework of existing regulations (Krattiger, 1994; Ahl Goy and Duesing, 1995). No field trials have been performed in 43% percent of those countries where biosafety regulations are yet to be adopted (Table 2). The remaining 10% of the countries have regulations but no field trials have been performed. In contrast, the picture for Lower-middle to Low income countries is more complex. Overall, 92% lack biosafety regulations. Field trials have been performed in 9% of these countries but in over half these cases field trials were carried out before regulations were in place. Moreover, in China, Argentina and Chile where a majority of field trials in the developing world have occurred, biosafety evaluations are done by *ad hoc* committees. Finally, 4% of the Lower-middle to Low income countries having regulations have had no field trials. While some may argue that absence of established biosafety procedures is a major constraint to the development of biotechnology in the developing countries (Brenner and Komen, 1994), to date it has not been prohibitive. The data are too few to form any conclusions regarding the level of impact of not having regulations. However, heightened attention to this issue as a result of the Convention will seem to discourage biotechnology applications in countries without regulation.

In overview, it is clear that there is a regulatory imbalance between developing and industrialised countries. It has been argued that companies in the North may try to "take advantage" of the situation and concentrate their actions in countries where regulations are less strict or non-existent. Again looking at Latin America, a large majority of field trials have been initiated by Northern private companies not only for crop evaluation, but for counter crop season evaluation or seed production as well. Field trials by companies in countries with no biosafety legislation were conducted primarily between 1991-1992, with no trials in 1994 (Krattiger, 1994; Ahl Goy and Duesing,

TABLE 1. Biosafety regulations in countries from the 154 signatories to the Convention on Biological Diversity as of February 1995

Regulations/guidelines adopted		Currently Drafting Regulations
Industrialized Countries	Developing Countries	
Australia	Argentina	Hungary
Austria	Brazil	Indonesia*
Belgium	Chile*	Kenya
Canada	China*	Malaysia*
Denmark	Costa Rica*	Russia
Finland	Cuba*	Zimbabwe*
France	Egypt*	
Germany	India*	
Greece	Mexico	
Ireland	Nigeria*	
Israel	Philippines*	
Italy	Thailand*	
Japan		
Luxembourg		
New Zealand		
Norway		
Portugal		
South Africa		
Spain		
Sweden		
Switzerland		
The Netherlands		
United Kingdom		
United States		

\*Lower-Middle to Low income economies

1995). A majority of field trials have been conducted in countries such as Chile, Argentina and Mexico that have biosafety regulatory procedures in place. In Asia the majority of field trials have been performed by the public rather than the private sector (Ahl Goy and Duesing, 1995).

### INTERNATIONAL HARMONISATION OF BIOSAFETY REGULATIONS

For the following discussion we have defined international harmonisation as the agreement in action, opinion, and feeling leading to a common

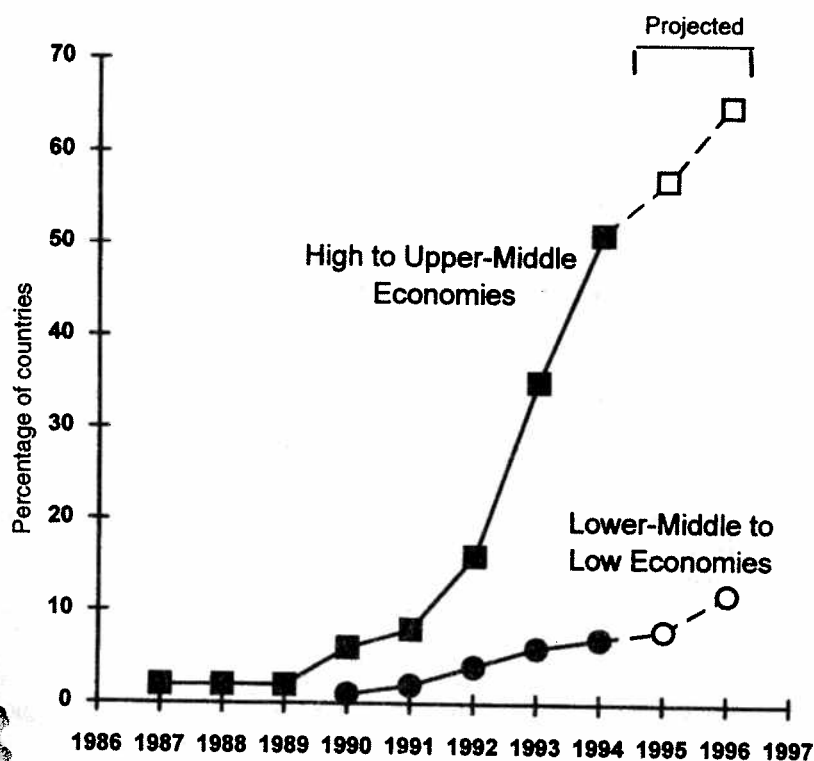


Figure 2. The rate of adoption of guidelines for countries categorized by income level.

TABLE 2. A comparison of biosafety regulations and field trials between economic categories of countries

Regulations/Field Trials	+/+	+/-	-/+	-/-
High to Upper-middle Income Economy	47%	10%	0%	43%
Lower-middle to Low Income Economy	4%	4%	5%	87%

set of biotechnology regulations at the regional or global level. The idea is not new. Ten years ago, Kuenzi *et al.* (1985) recommended that biosafety regulations and guidelines be harmonised. More recently United Nations Industrial Development Organisation (1990) and Lesser and Maloney (1993) have discussed harmonisation at some length. The following reasons for international harmonisation have been adapted in part from these authors.

International harmonisation may: (i) result in a higher level of security than national regulations alone. Genetically Modified Organisms (GMOs) do not respect political borders. Harmonised biosafety regulations provide a higher level of security (control) than possible solely through national legislation; (ii) moderate a tendency for national enthusiasm to acquire the technology from turning into a country versus country competition that supersedes biosafety considerations. With harmonisation, countries can feel free to develop rational regulation with less fear of creating unique barriers to biotechnology companies; (iii) facilitate the formulation, adoption and uniform interpretation of regulatory instruments. Using mutually agreed upon guidance principles will help developing countries create and implement national biosafety regulations. With multinational similarity, costly duplication of efforts in guidelines development can be avoided, a concept that may be especially valuable for countries with limited resources; (iv) encourage international data collection and information exchange. National biosafety experts will find information from applications and field tests in other countries easier to collect and use if common data sets and measurements are used; and (v) moderate industry burden and costs to satisfy requirements when multi-country testing is planned.

Clearly there are advantages to harmonisation. However, having a regulatory structure in place will not be enough in itself. If biotechnology is to be used safely and effectively, harmonisation at the international level must go beyond the biosafety component alone. Short and long term monitoring needs will have to be considered. Procedures for storage and exchange of genetic material need to be standardised. There is also a need to safeguard

the rights of diverse parties affected by the integration of biotechnology, including patent holders, farmers and indigenous peoples. To adequately address these issues, effective international harmonisation will require broad participation by countries from all developmental phases.

What form will regulatory harmonisation take? Lesser and Maloney (1993) point out several levels of stringency for the goals of international harmonisation. The first is agreement on comparable scientific requirements concerning risk specification. This refers to normalisation of risk assessment procedures and data requirements. In this respect technical guidelines and general principles documents may play an important role. The second level of stringency would be that similar language used in regulations with mutually accepted definitions of terms. Regulations with common requirements will aid comparisons and information exchange. The highest level of stringency would be the formation of multinational treaties and binding protocols such as that called for in the Convention (Krattiger and Lesser, 1994).

## INTERNATIONAL EFFORTS

Participants in harmonisation efforts can take advantage of the many diverse activities currently ongoing at the regional and global level. To illustrate we discuss four general categories: projects by international organisations; collaborative training and information exchange; development of "general principles" documents; and the debate on the merits of an international biosafety protocol.

Many international organisations, including Biotechnology Advisory Commission (BAC), International Service for the Acquisition of Agri-biotech Applications (ISAAA), Organisation for Economic Cooperation & Development (OECD), ASEAN, International Service for National Agricultural Research (ISNAR), and United Nations Industrial Development Organisation (UNIDO), are directly or indirectly involved in harmonisation efforts. Their activities include providing independent advice, assisting information exchange, the creation and maintenance of data bases, organising meet-



and publishing on controversial issues. Expertise and experience are made available and documented for wide dispersal and entry into the public arena for debate and discussion.

Collaborative training and information exchange are effective means for shaping a common language and finding consensus on the use of technology. A considerable number of biosafety workshops have taken place over the past five years. Designed to illustrate regulatory infrastructure and the means for implementing guidelines, many have been offered at no cost to developing country scientists. A prime objective of these workshops has been to build institutional and individual capacity by sharing industrialised country experience in biosafety regulations and field releases of GMOs with scientists, policy makers and special interest group representatives. Regional meetings have been held to explore common frameworks that can be fleshed out to serve particular national needs.

General principles documents take the form of organisational position papers or consensus reports. Many come from meetings of scientists gathered to discuss particular issues within the context of biosafety procedures. These help to focus international discussions and provide a framework for biosafety regulation. The UNIDO/UNEP/WHO/FAO Code of Conduct is a good example. At the regional level there have been several conferences in Latin America that have produced general principles documents (e.g., Brasilia, June 1990; Cartagena, June 1994; Costa Rica, March 1995). In this context the European Union Directives (90/219 and 90/220) on the contained use and the deliberate release of GMOs into the environment should also be mentioned. At the global level, international technical guidelines for safety in biotechnology are being developed at the initiative of the UK Department of Environment and the Netherlands Ministry of Environment. In setting out the common elements of concern that might be addressed in formulating regulations and ensuring broad international participation in the effort, this initiative may facilitate the preparation of acceptable national procedures.

An international Biosafety Protocol will of

necessity be a global effort. The issue is explicitly addressed in Articles 8[g] and 19.3 of the Convention. The need for a binding protocol and possible modalities under the Convention are included. Such an international protocol is intended to obviate exploitation of countries lacking national regulations or guidelines. Not surprisingly, it is currently the subject of intense international discussion (Lesser and Maloney, 1993; Krattiger and Lesser, 1994). Views range from an "urgent need" (Meister, 1994) to "unnecessary" (Guarriaia, 1994) to "a bureaucratic time bomb" (Miller, 1995). There was considerable debate peripheral to the Conference of Parties meeting in Nassau in 1994. The issue was referred to a panel of experts on biosafety who will prepare a background document for development and consideration at a future Conference of the Parties meeting.

The full impact of these efforts is still to be realised. Through cooperation and continued international interest, harmonisation has the potential to be a positive force in the acquisition of biotechnology

## CONCLUSION

Biotechnology should be a welcome tool in the construction of sustainable development programmes. Yet concerns about the safety of biotechnology products and the inherent difficulties in successful transfer of the technology to developing countries portends a long and slow process. This view is supported by the analysis of the adoption of biosafety regulations in developing countries. While a majority of industrialised countries have regulations in place, more than 90% of developing countries do not. If the acquisition of biotechnology will be positively influenced by having regulations at the national or international level, efforts to harmonise take on increased importance. There are many activities ongoing that can be used to further the process and it is incumbent upon country representatives to take advantage of them. To be most helpful, perspectives should be broad enough to include not only biosafety evaluations, but also monitoring; information collection, storage and exchange, and the rights of parties (e.g., patent holders,

farmers, indigenous peoples). The challenge is great and will require participation by all stake holders.

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