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BIOSAFETY REGULATIONS IN BIOTECHNOLOGY

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BIOSAFETY REGULATIONS
IN BIOTECHNOLOGY

Introduction: The exploding population, especially in the developing countries needs to have quantum jumps in production in food and other agricultural products. Productivity has to be increased from both sources that are well bestowed and otherwise under conditions of environmental stress, both biotic and abiotic. The phenomenal increase in food, fodder, fiber, fuel and other materials needed for both human being and animal has to be achieved in an affordable, employment generating, environmentally sustainable and ecologically sound manner. The new technologies and products needed for this purpose have to be safe (acceptable risks) to both human well being and to the entire ecosystem. Further, it should be seen and accepted by public at large as being so. (Fig. 1)

Fig. 1

BIOTECHNOLOGY DIRECTIONS

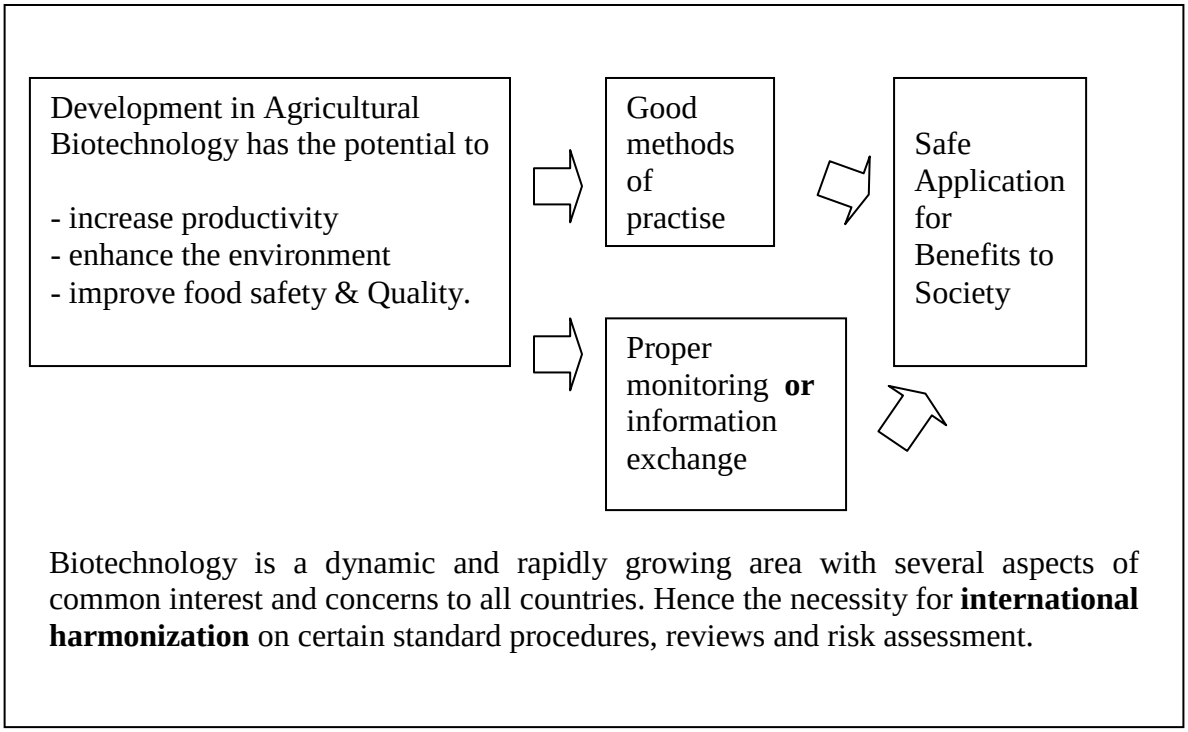
AGRICULTURE
- Improved Pesticides
- integrated Pest Management
- Stress Tolerant Plants (Herbicides, Salt, Drought)
- Disease Resistant Plants/Animals
- Animal Vaccines
- Improved Nutritional Quality
- Improved Keeping Quality
- Improved Growth Characteristics

ENVIRONMENT
- Bioremediation
- Biofilters (Air Purification)
- **N**atural Plastics
- New Composite Materials
- Biosorption Processing
- Biosensors

ENERGY
- Cleaner Fuel (Alternatives/ Additives)
- Desulfurization Processing
- Enhanced Oil Recovery

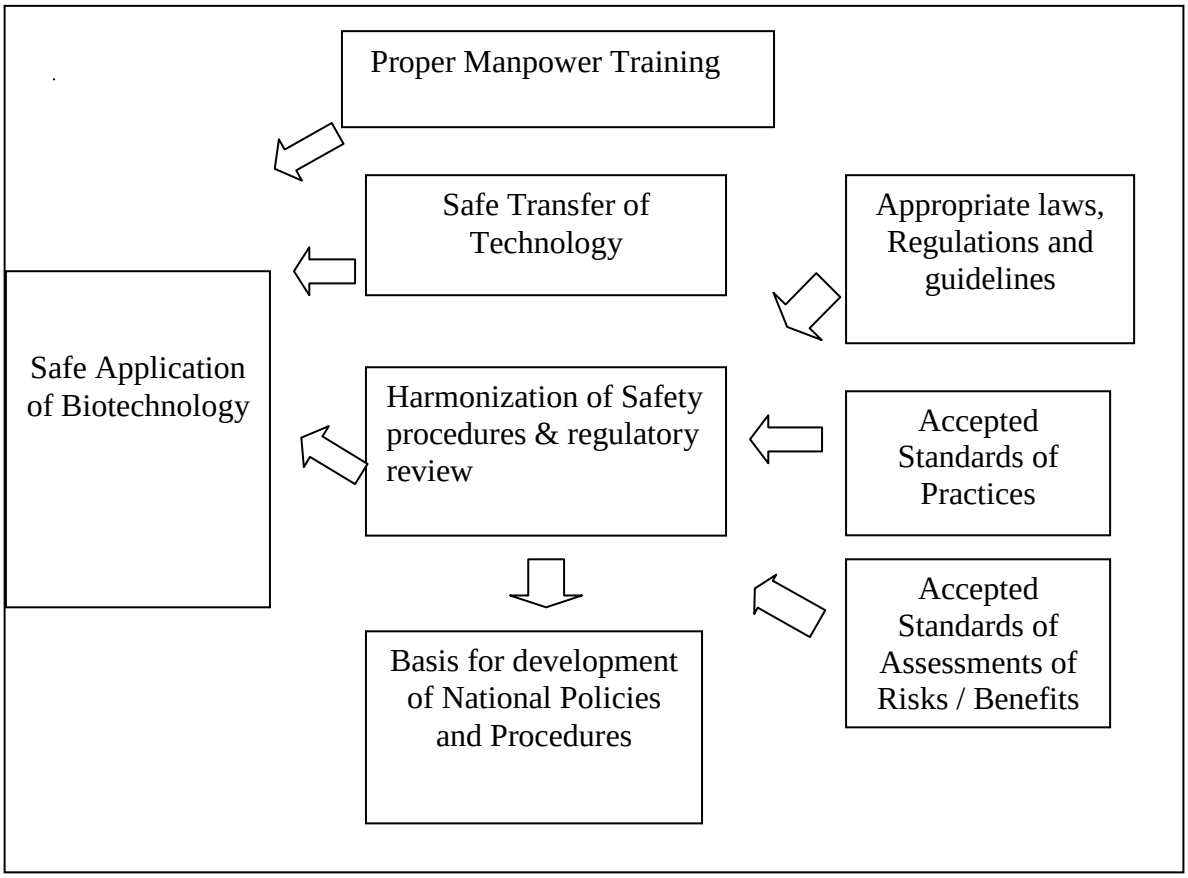
It has been amply demonstrated that the developments in modern biology and biotechnology during the past few decades, in conjunction with various types of conventional and well established techniques offer unique opportunities to solve many of these problems and increase productivity and production in the near future. In the last decade these technologies have been integrated into developing count**ries** R&D programs, especially in the field of agricultural research. As with any new technology the rate of integration and the level of success are dependent on the capacity to transfer technique and expertise from innovators to the users. The transfer of techniques is a complicated affair and requires intricate interactions of many parties with no guarantees for success. The key factor is the technical capacity available to receive and implements. (Fig. 2)

Fig. 2



As most of these traits transferred through r-DNA technologies are of relevance to and met the needs of the developing countries, the pressure on these countries is increasing, both from within and outside to introduce these GMOs and realize the benefits there from even as these products are under development in their respective countries of origin. To facilitate the introduction, assessment and transfer of technology, the receiving country, international agencies and the industry developing the products, all realize the importance of having in place, both in the country of development and that of the recipient, compatible guidelines and/or regulations that would ensure that appropriate risk/benefit analysis have been done and suitable risk management measures are being instituted. In fact, there is a high level of public awareness in this regard in many countries (Fig.3)

Fig. 3



The various international and national meetings, especially those held in the recent past in Latin America, Africa, Asia and other places show that a large number of guidelines exist. However, harmonization of these in order to help their adoption by others who do not have any in place and then building into it specific criteria in order to meet the country/product requirement is yet to take place. Efforts, therefore, are needed for :

1. Development of harmonized guidelines based on common elements;

2. Regional and national capacity building in both technology and training ;

3. Setting up of and providing access to global information networks to facilitate free exchange of information on existing experiences on introductions, HRD sources and the state of the art of technologies and products that are needed.

Capacity and product development : The last two or three years have seen a spectacular increase in the applications for large scale field testing of transgenic crop plants with new traits of economic importance. In 1994 in the US along, 583 field releases were approved (69 permits and 514 notifications) in 1803 different field sites. This involved 17 different crops, by 21 different parties, involving a large number of traits. Perhaps another 30 per cent can be added to these figures on an all world basis.

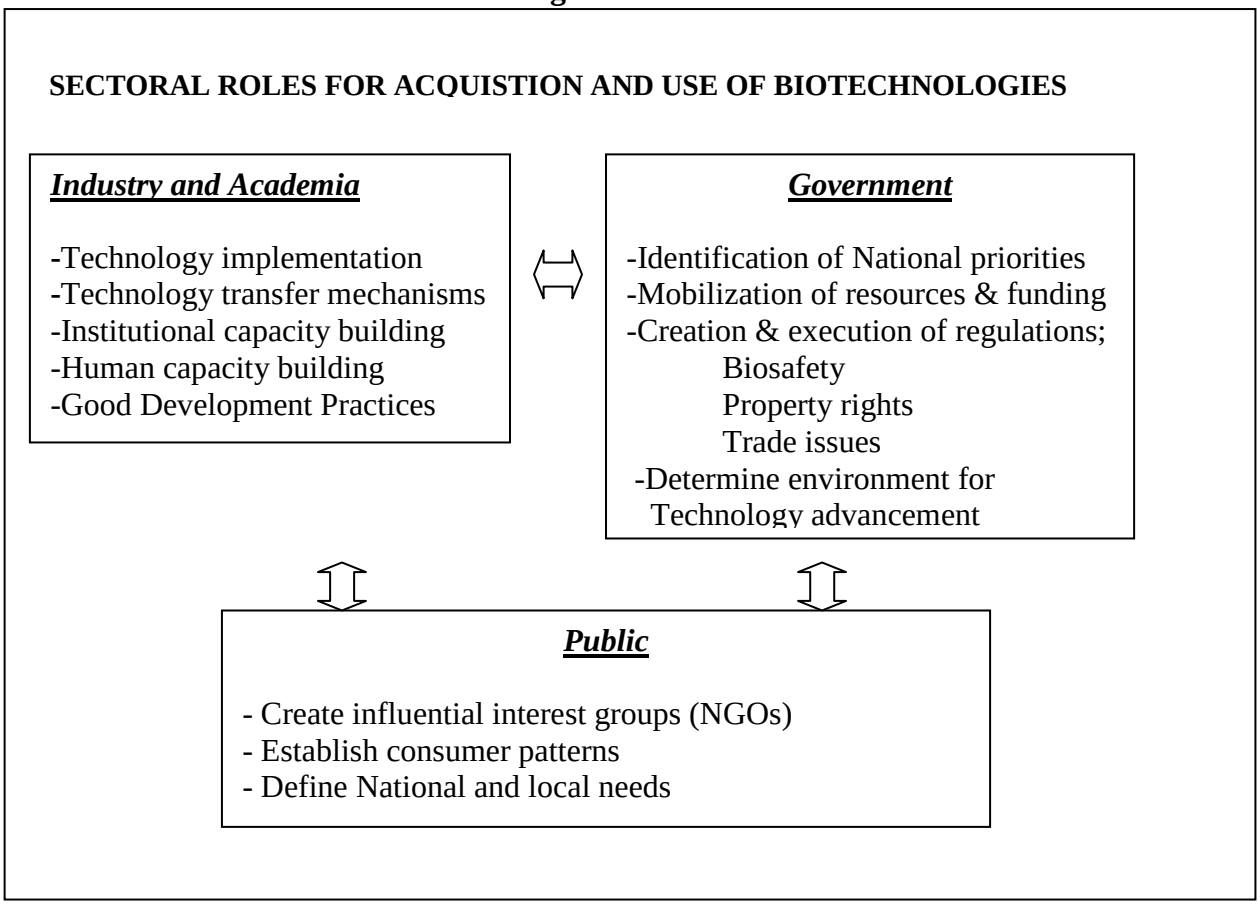
Thus in the near future the shopping list would be very attractive and the choice would be met through a cafeteria approach.

Developing countries contain at least eighty per cent of the global biodiversity together with more than three quarters of the world's population. Yet, developing countries are today home to only about 6 per cent 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 strategy. A vital part of such a strategy is the establishment of a biosafety regulatory oversight infrastructure. While much of the focus has been on national development of guidelines, more and more attention is being paid to the international efforts that may afford top-down assistance. This paper discusses the current status of national guidelines and regulations, efforts by international organizations towards harmonization and thoughts on how these may benefit the safe application of biotechnology.

ACQUISTION OF TECHNOLOGY

The acquisition and use of innovative technologies requires effective interaction between various national sectors, including private research organizations and academic institutions, governmental ministries or agencies, and the public (Figure 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 need should not be underestimated (Walsh,1993). To the government lines 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 issued, and creating a favorable 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. (Fig. 4)

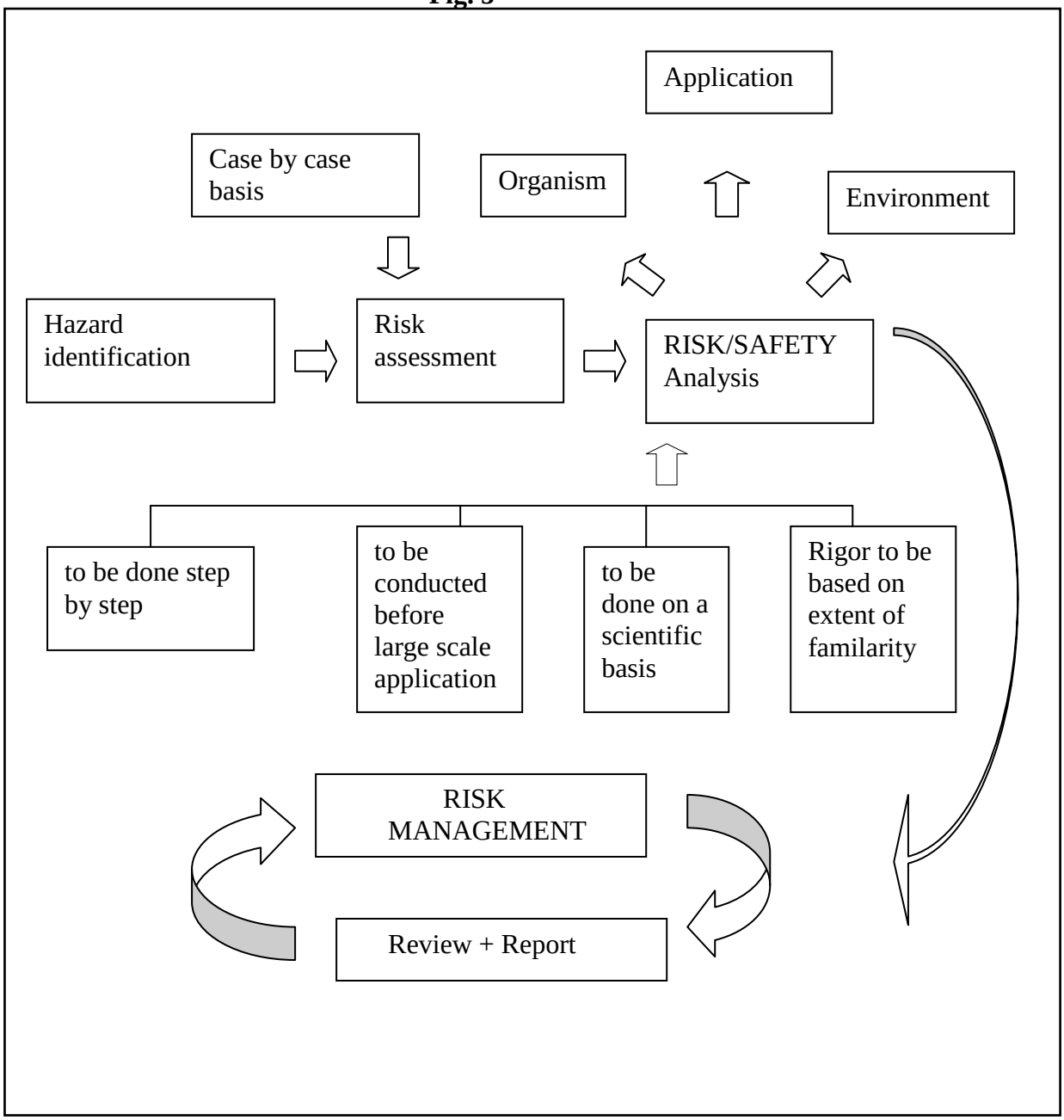
Fig.4



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 harmonization of biosafety regulations across countries (Krattigr and Lesser, 1993). To share fully the benefits of the biotechnology while minimizing the risks, biosafety regulations must be effective and based on the best scientific principles (Persley et al. 1992). (Fig. 5)

Fig. 5



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 the considerable debate it has generated in its call for an international protocol. See discussion below).

In our purpose here, "adopted regulations" or "procedures" include laws, rules, executive decrees or *ad hoc* guidelines, we recognize there are significant differences in regulatory authority associated with the different oversight mechanisms, but accept the generalization 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 greatest activity has occurred. Finally, we have also subcategorized 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 industrialized countries passed laws or enacted regulations specifically addressing the deliberate release of genetically modified organisms. Consequently, today 24 (80 per cent) of them 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 like, states of the European Union have instituted new laws. Because these laws are based on EU directives, they are, in practice similar in their scope, requirements and impact.

In developing countries, the situation is dramatically different and fewer than ten per cent have any established biosafety regulations. This is not to say there has been inaction. Today, at last 12 developing countries have regulatory procedures in place. Geographically, starting with Africa, South Africa, Zimbabwe have formal regulations in place. In Nigeria, guidelines have been signed by the Minister of Agriculture but additional approvals are necessary before it is fully instituted. In the near future Egypt will follow and it is believed that Kenya will pass their 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 industrialized countries. For example, many countries in Latin America lack legislative instruments. Instead, ministerial decrees authorize 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 is that several of these *ad hoc* committees are limited to agricultural biotechnology and little or no attention is paid to other uses e.g. environmental uses of microorganisms (Fig. 6)

Fig. 6

STATUS OF BIOSAFETY REGULATIONS
(FEBRUARY, 1995)

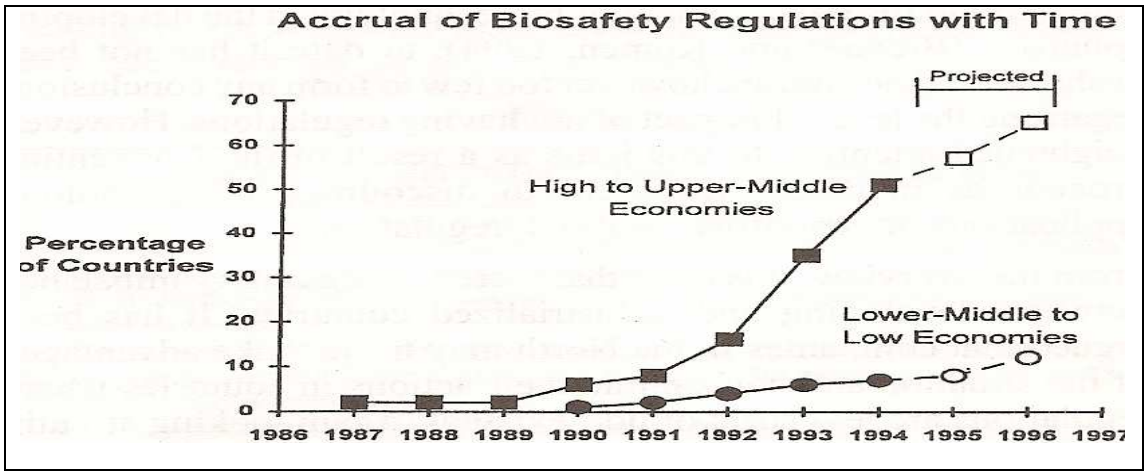
Regulations /Guidelines adopted_		Currently Drafting
Industrialized Countries	Developing Countries	Regulation
Australia	Argentina	Egypt**
Austria	Brazil	Hungary
Belgium	Chile**	Indonesia**
Canada	China**	Malaysia**
Denmark	Costa Rica**	Russia
Finland	Cuba**	
France	India**	
Germany	Mexico	
Greece	Nigeria**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

*(36/154 Signatories to the Convention on Biological Diversity)
** (Lower-Middle and Low Economies)

The rate of adoption of guidelines for countries categorized by income level is shown in Figure 2. In the "high-to-upper-middle" income economies, large majority of counties have regulatory procedures in place. We project that in two years the figure will reach around 67 per cent. In comparison, less than 10 per cent of "lower-middle-to-low" income countries currently have regulations. Given the number of countries 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 per cent 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 accrual rate, however, international efforts towards biosafety harmonization could facilitate the adoption process and subsequently provide additional benefits to biotechnology development. (Fig. 7)

Fig. 7



IMPACT OF REGULATIONS

Not surprisingly, field trials have been conducted in 47 per cent 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 per cent of these countries where biosafety regulations are yet to be adopted (Table 2). The remaining 10 per cent of the countries have regulations but no field trials have been performed. In contrast, the picture for "lower-middle-to-low" income countries is moiré complex. Overall 92 per cent lack biosafety regulations. Field trials have been performed in 9 per cent of these countries but in over half these cases filed trials were made 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 four "lower-middle-to-low" income countries have regulations, but there have been 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 however 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 procedures in place will seem to discourage biotechnology applications in countries without regulation.

From the overview, it is clear that there is a regulatory imbalance between developing and industrialized 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, however were

conducted primarily between 1991-1992, with no trials in 1994 (Krattiger 1994; Ahl Goy and Duesing, 1995). A clear majority of field trials have been conducted in countries such as Chile, Argentina and Mexico which 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 HARMONIZATION OF BIOSAFETY REGULATIONS

For the following discussion we have defined international harmonization as the agreement in action, opinion, and feeling leading to a common set of biotechnology regulations at the regional or global level (Persley et al, 1992). The concept is not new, ten years ago Kuenzi et al (1985), recommended that biosafety regulations and guidelines be harmonized. More recently **UNIDO (1990)** and Lesser and Maloney (1993) have discussed it at length. The following reasons for international harmonization have been adapted in part from these authors. (Fig. 8)

Fig. 8

REASONS FOR INTERNATIONAL HARMONIZATION

1. To achieve a higher level of security than national regulations alone.
2. To avoid having the desire for biotechnology development turning into a competition that supersedes biosafety considerations.
3. To facilitate the formulation, adoption and uniform interpretation of regulatory instruments.
4. To encourage international data collection and information exchange.
5. To reduce industry burden and costs to satisfy the requirements for multi-country applications.

(Adapted from Lesser and Maloney, 1993**)**

International harmonization may :

1. result in a higher level of security than national regulations along-GMOs do not respect political borders. Harmonized biosafety regulations provide a higher level of security (control) than possible solely through national legislation.

2. moderate a tendency for national enthusiasm to acquire the technology from turning into a country vs country competition that supersedes biosafety considerations. With harmonization; countries can feel free to develop rational regulation with less fear of creating unique barriers to biotechnology companies.

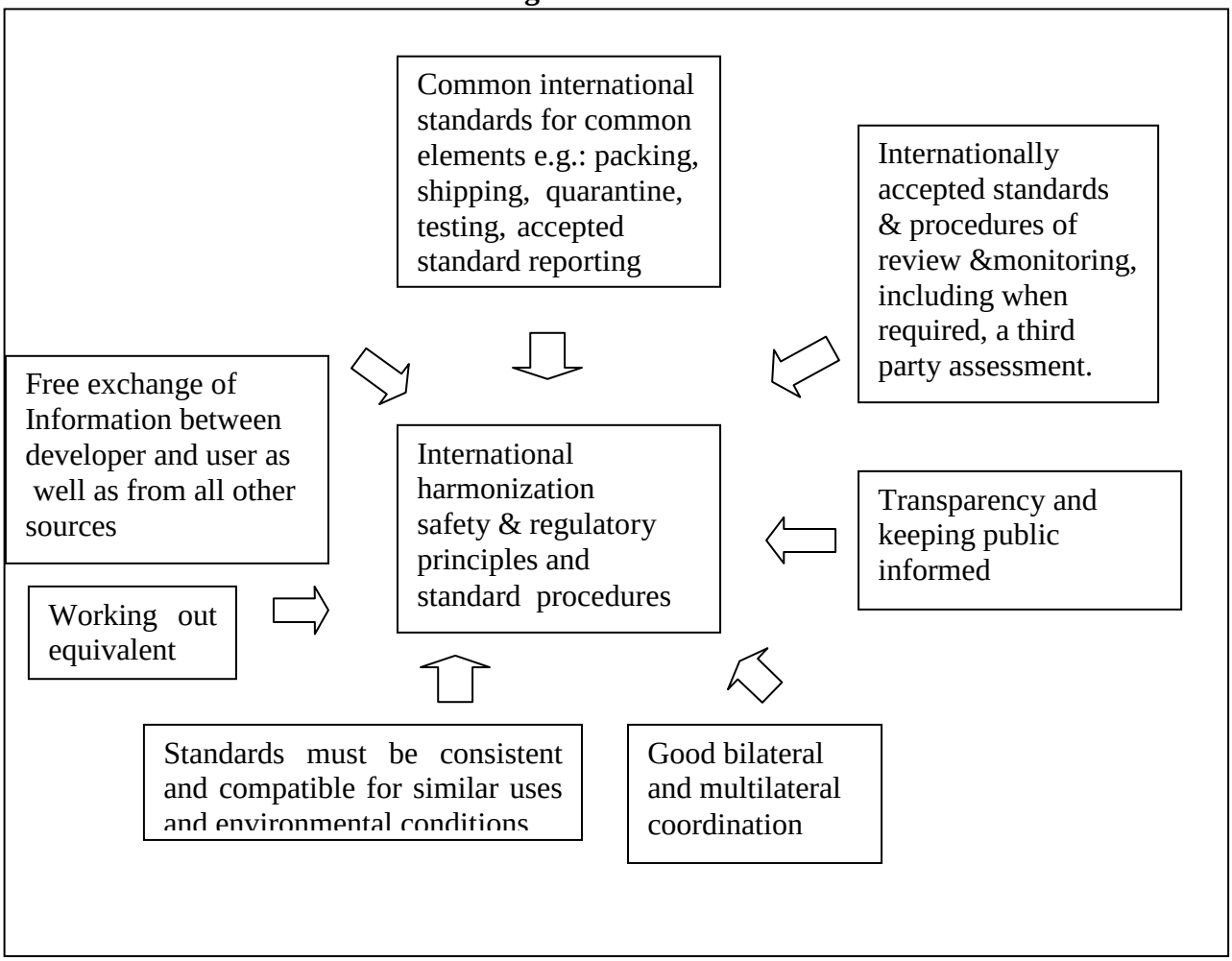
3. facilitate the formulation, adoption and uniform interpretation of regulatory instruments. Using mutually agreed upon guidance principles will help developing countries create and implement national biosafety regulations. With multinational similarity costly duplication of efforts in guidelines development can be avoided, a concept which may be especially valuable for countries with limited resources.

4. 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 measures are used.

5. moderate industry burden and costs to satisfy the requirements for multi-country applications. Companies could use similar applications and perform field trials in several countries at the same time.

If biotechnology is to be used safely and effectively, harmonization at the international level must go beyond the biosafety component alone. Short and long term monitoring needs to be considered. Storage and exchange of genetic material needs to be harmonized. There is also a need to safeguard the rights of diverse parties, including patent holders, farmers and indigenous people. To adequately address these issues, effective international harmonization will require broad participating by countries from all developmental phases. (Fig. 9)

Fig. 9



Lesser and Maloney, (1993) also point out several levels of stringency for the goals of international harmonization. The first is agreement on comparable scientific requirements concerning risk specification. This refers to normalization 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 similar language used in regulations with mutually accepted definitions of terms. Regulations with common requirement 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, 1993). (Fig. 10)

Fig. 10

HOW TO ACHIEVE INTERNATIONAL BIOSAFETY HARMONIZATION
POSSIBLE LEVELS OF STRINGENCY

1. Comparable scientific requirements concerning risk specification
2. Similar/identical language with mutually accepted international standards
3. The formation of multinational treaties and binding protocols

(Adapted from Lesser and Maloney, 1993)

INTERNATIONAL EFFORTS

Participants in harmonization 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 organization; collaborative training and information exchange; development of "general principles" documents; and the debate on the merits of an international biosafety protocol.

'Many international organizations e.g. Biotechnology Advisory Commission (BAC), OECD, ASEAN, ISNAR and UNIDO are directly or indirectly involved in harmonization efforts. Their activities include providing independent advice, assisting in information exchange, the creation and maintenance of data bases, organizing meetings, 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 industrialized 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 organizational position papers or consensus reports. Many come from meetings of scientists gathered to discuss particular issues within the context to 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 which produced general principles documents. (e.g., Brazilia, June 1990; Cartagena, June, 1994; Costa Rica, March, 1995). In this context the European Community 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. (Fig. 11)

Fig. 11

INTERNATIONAL EFFORTS TOWARD HARMONIZATION

1. International Organization Projects :
   Publications/Data Bases/ Advice
2. Collaborative Training/Information Exchange:
   Biosafety Wkshps/Regional Mtgs/Special Programs
3. General Principles Documents:
   Regional/Global
4. Debate for international Protocol

An international Biosafety Protocol will of necessity be a global effort. The issue is explicitly addressed in article 8(g) and 19.3 of the Convention on Biological Diversity. The need for a binding protocol and possible modalities under the Convention are included. Such an international protocol in 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” (Guarraia, 1994) to “a bureaucratic bomb” (Miller, 1995). There was considerable debate peripheral to the conference of Parties meeting in Nassau last year. 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 Parties meeting.

The full impact of these efforts is till to be realized. Through cooperation and continued international interest, harmonization 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 programs. 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 industrialized countries have regulations in place, more than 90 per cent 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 harmonize 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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FIGURE LEGENDS

Figure 1. Sectoral roles for acquisition and use of biotechnology.

Figure 2. Accrual of biosafety regulations by signatories of the Convention on Biological Diversity. High to Upper-Middle and Lower-Middle to Low economies refers to countries in different income categories according to World Bank (1994) classification. The open symbols represent projected levels based on the number of countries in the process of drafting biosafety regulations at the present time.