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BIOSAFETY CONCERNS IN BIOLOGICAL RESOURCE MANAGEMENT*

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The development of transgenies and their release into both contained and open environments have raised concerns relating to their direct or indirect impacts on management of biological resources and human health. Following UNCED (1992), the non- legally binding International Technical Guidelines for Safety in Biotechnology were finalized in 1995 under the aegis of UNEP. In the meanwhile, the 2nd Conference of Parties of the Convention on Biological Diversity (CBD) decided to constitute an Open-ended Ad Hoc Working Group to develop a 'Protocol on Biosafety (BSWG)'. This paper highlights the basic elements consolidated by this Group as of now, and which are to be finally negotiated in the forthcoming meeting in late August, 1998.

Key words : Biosafety, biotechnology, living modified organisms, protocol, biological resources, conservation, biological diversity

The rapid unfolding of vast opportunities for applying the tools and techniques of biotechnology in the areas of agriculture, health, industry and environmental pollution have aroused tremendous and wide ranging expectations. These technologies have the potential to provide more abundant and nutritious food, new medicines including therapy for genetically induced diseases, new environment-friendly products, and the means to clean up industrial pollution of water and soil. Some technologies are also being applied in the assessment, monitoring, management and sustainable utilisation of biological resources.

As is increasingly realised, it is necessary to create the supporting infrastructure and a congenial environment to capitalise on the potential of the new biological technologies (Brenner, 1995). It has also been acknowledged that the release of Living Modified Organisms (LMOs) in a contained or open environment could pose risks which would have various direct and indirect impacts. If the benefits of biotechnology are to be optimised without affecting the environment, effective biosafety regulations must be developed based on

*The views expressed in this paper are the author's and not necessarily that of the Government of India

sound scientific principles (Persley, *et al.* 1992; Walsh, 1993; Krattiger and Lesser, 1994).

Dealing briefly with the potential of biotechnology and its impact on the environment, in particular on biological resources, this paper traces the various developments that have taken place in developing biosafety measures, including the finalisation of the 'International Technical Guidelines for Safety in Biotechnology' (UNEP, 1995). The paper also highlights the basic elements which are being considered for inclusion in the proposed 'Protocol on Biosafety' under the aegis of the CBD, and are currently being negotiated by the Contracting Parties.

IMPACTS OF BIOTECHNOLOGY

Biotechnology provides a range of tools and methods for assessment, monitoring and managing biological resources, such as clarifying taxonomic and evolutionary relationships among groups of organisms, and assessing the effects of ecosystem disturbance on components of biological diversity and biological processes. The tools of biotechnology could also be utilised for *in situ* conservation i.e. assessment of optimal or minimal population size, and *ex situ* conservation i.e. enhancing the quality of characteristics and efficiency, through compact storage of DNA libraries and sequence databases (Apples *et al.* 1995). The tools current employed for the sustainable use of genetic resources are in the area of breeding, genetic engineering, the development of novel genes and gene products, and environmental remediations. Some areas of application of biotechnology in utilisation of biological diversity, as identified by Montagu *et al.* (1995), are given in Table 1.

a) Direct Impacts :

The introduction of any LMOs in a biological community can have various undesirable impacts (Tzotzos *et al.* 1995) :

- displacement or destruction of indigenous/endangered or endemic species:
- exposure of species to new pathogenic or toxic agents;
- pollution of the gene pool;
- loss of species diversity; and
- disruption of energy and nutrient cycling.

These impacts are largely ecological and evolutionary and can be scientifically assessed and tested through simulated conditions. As part of an overall risk assessment strategy, the main problems arising from direct impact could be dealt with, including the processes of introgression, weediness,

Table 1. Areas of application of biotechnology in the management of biological resources

*	Using technologies as sources of:
	- proteins and peptides
	- lipids and fatty acids
	- carbohydrates
	- secondary metabolites for pharmaceuticals
*	Genetic engineering, breeding and *in vitro* culture systems can be used to enhance agronomic performance.
*	Improving environmental conditions through :
	- identification of soil microorganisms and determination of best combinations for soil rehabilitation
	- use of plants to mitigate heavy metal pollution
	- engineering key genes in bacteria for pollutant degradation
	- improving plant microbe symbiotic systems for waste water treatments
	- production of biosurfactants
*	Enhancing the efficiency of microorganisms in industrial processes such as :
	- microbial-enhanced secondary recovery of oil from reservoirs
	- bioleaching: microbiological extraction of metals from low grade ores
	- production of industrial enzymes
	- production of endogenous products e.g. antibiotics

(Source : Montagu *et al.* 1995)

pathogenicity, altered nutrient cycling etc. However, there is an inadequate understanding of the possible direct impact of LMOs on soil micro flora and fauna (Angels, 1994 and Morra, 1994) and the potential of virus-resistant plants on the host range of some viruses (Rissler and Mellon, 1993).

b) Indirect impacts :

The possible number and types of indirect effects of biotechnology could be immense. These effects are mostly socio- economic in nature and can be of major importance particularly to middle to low-income developing countries where people are dependent on biological resources for subsistence. Indirect impacts may be secondary or tertiary effects. Tzotzos *et al.* (1995) has listed some indirect impacts :

- Pressure on natural habitats because of the increasing value of genetic resources;

- Lack of immediately perceivable incentives for conservation;
- Moral/ethical problems of ownership of genetic resources and benefit-sharing;
- Increase in agricultural productivity;
- Replacement of traditional landraces; and
- Decline or opportunities loss for disadvantaged groups in areas of marginal production.

In addition, various sociological and socio-economic impacts could also be visualised with these impacts depending on the type of LMO, kind of release, and the precaution taken for any harmful effect.

PUBLIC UNDERSTANDING ON THE NEED FOR BIOSAFETY MECHANISM

The public debate on the applications of biotechnology has been marked by apprehensions of two kinds. The first is that there may be adverse impacts on the environment and human health. The second is the fear that control of the new technologies could give some nations or groups the power to use this in unfair ways.

The public perception of biotechnology as unpredictable and dangerous was highlighted by Perlas (1993) through examples such as the creation of a 'Super Aids Virus', super pigs and cows reporting of serious ailments using a genetically altered version of L-tryptophan and insulin; the use of biotechnologically developed bovine growth harmone (BGH); stunting in corn and other crops due to the presence of *Clavabacter xyli*, a vector used to transfer BT endotoxin gene; the requirement of six times more pesticides for Unliver cloned oil palms; novel mutant carps, catfish, trout and salmon polluting native species; and illegal trials on pseudo-rabies in Argentina. This short list of unpredictable, and negative impacts of biotechnologies clearly shows the possibility of the adverse impact of biotechnologically developed products on human health and the environment. The views of Holmes (1993), Williamson (1991) and Ellstrand and Hoffman (1990) further support these perceptions.

Berg *et al.* (1974) voiced their concern about the potential biological hazards with respect to r-DNA experimentations. This led to the finalisation of 'The Guidelines for Research Involving r-DNA' by the US Government. By the mid- 1980s, however, the context of biotechnology had shifted from research to commerce. An intense debate ensued between molecular biologists and ecologists, on controversial issues regarding risk assessment related to the release of new biotechnology products into the environment (Krimsky, 1991). The debate was also joined by prominent environmental groups, politicians,

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corporations and trade unions. This led to the formulation of a 'coordinated Framework for Regulation of Biotechnology' by the US Government. Subsequently, biosafety guidelines were developed by the OECD and European Union (EU) and its member countries. Several surveys conducted to analyse public perceptions revealed that they were very similar irrespective of the geographical situations. However, there were also considerable differences between EU countries (OTA, 1987), Hoban and Kendall (1992) and Marlier (1992).

GLOBAL STATUS OF LEGISLATIVE AND REGULATORY MECHANISMS FOR BIOSAFETY

The current global status of biosafety regulations has been extensively analysed by Virgin *et al.* (1995). As per their analysis, 24 countries with high to high-middle income economies have laws and regulations in place taking into account the specific concerns arising from new recombinant techniques. The EU countries have instituted new laws, which are similar in scope requirements and impacts.

In developing countries, the situation is significantly different. In Latin America, Argentina, Brazil, Mexico, Chile, Costa Rica and Cuba have regulatory mechanisms in place. The African continent is represented only by South Africa and Egypt. Kenya, Zimbabwe and Nigeria are at various stages of drafting regulations and are likely to finalise these very soon. In Eastern Europe, Hungary has an ad hoc review process, and Russia has submitted a biosafety law for official approval. Of the developing countries in Asia, only India, China, Thailand and the Philippines have guidelines. Malaysia is preparing new legislation, and Indonesia is in the process of drafting (Table 2).

It may be stated that the implementation of these biosafety regulations varies from developed countries to developing countries, from being very rigidly effective to non-effective because of the lack of a well-defined institutional structure. It is also pertinent that the guidelines evolved by most developing countries are very similar in scope and requirements, and have been adopted as a part of their National Environment Acts. However, these provisions are inadequate in respect of modalities/protocols for access to and transfer of biotechnology on 'Mutually Agreed Terms', procedures for 'Advanced Informed Agreements' and procedures for risk assessment and management (Chauhan, 1996).

Virgin *et al* (1995) also studied the rate of adoption of guidelines by different countries. Analysis revealed that 67 per cent of countries with high to upper-middle income economies and 12 per cent of lower-middle to lower income countries have regulatory procedures in place. It is expected that less than 30 per cent of the lower-middle to lower income countries will have

Table 2. Status of adoption of biosafety regulations in different countries

Industrialised Countries:	Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Isreal, Italy, Japan, Luxembourg, New zealand, Norway, Portugal, South Africa, Spain, Sweden, Switzerland, The Netherlands, United Kingdom, United States
Developing Countries:	Argentina, Brazil, Chile*, China*, Costa Rica*, Cuba*, Egypt*, Hungary**, India*, Indonesia*,**, Kenya*,**, Malaysia*,**, Mexico, Nigeria*, Philippines*, Russia**, Thailand*, Zimbabwe*,**

*Lower-Middle to Low Income Economy
**Currently drafting regulations
(Based on Virgin *et al.* 1995)

biosafety procedures by the year 2005. The accrual of benefits from biotechnological applications would be facilitated by the harmonised adoption of biosafety regulations.

POST-UNCED SCENARIO

The issues relating to safe application of biotechnology in relation to conservation and sustainable use of biological resources found prominent place in the negotiations towards finalising the text of the CBD, which was adopted at the UNCED Earth Summit held at Rio de Janeiro in Brazil in June 1992. Chapter 16 of Agenda 21, which deals with 'Environmentally Sound Management of Biotechnology', specifically seeks to ensure safety in biotechnology development, application, exchange and transfer through international agreement on principle to be applied on risk assessment and management. Articles 8(g) and 19(3) & (4) of the CBD also address the issue of safety in biotechnology. Article 8(g) calls upon each Contracting Party to "establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology which are likely to have adverse environmental impacts that could effect the conservation and sustainable use of biological resources, taking into account the risks to human health".

Keeping this in view, the Governing Council of the United Nations Environment Programme (UNEP) "affirmed the desirability of UNEP contributing to international efforts on biosafety, including the development of international guidelines (decision 18/36 B)" which may be used by the national governments, inter-governmental, private sector and other relevant organisations to provide safety in biotechnology.

The non-legally binding 'International Technical Guidelines for Safety in Biotechnology (ITGSB)' were finalised, in 1995, under the aegis of UNEP,

through extensive discussions among most countries which had ratified the CBD. Six chapters of these Guidelines spell out various elements dealing with general principles, assessment and management of risks, mechanisms at national and regional level for providing safety, information supply and exchange, and capacity building. These are based on common elements and principles derived from relevent national, regional and international instruments, regulations, and guidelines. The Guidelines also address the human health and environmental safety of all types of applications of biotechnology, from research and development to commercialisation of biotechnological products containing or consisting of LMOs. The adoption of these guidelines is expected to facilitate Governments in taking appropriate actions towards developing mechanisms for evaluating biosafety, identifying measures to manage foreseeable risks, and monitoring research and information exchange, all of which improve safe application of biotechnology (UNEP, 1995). This would also facilitate the implementation of Article 8(g) in those countries which have ratified the CBD.

The general principles followed in the Guidelines are based on identifying any hazards: assessing and managing the risks (case by case and in a step-wise manner); and monitoring. The Guidelines provide details relating to the assessment and management of risks, safety mechanism at national and regional levels, safetymechanism at international level using information supply and exchange, and capacity building. It also highlights the step-wise approach and provides a framework on each aspect which is to be developed by the countries either based on already existing mechanisms or totally new ones. It is expected that implementation of these Guidelines will provide an impetus to the uniform development of capacity at the international level for risk assessment and management associated with the release of LMOs arising from biotechnological applications and harmonisation as emphasised by the UNIDO (UNIDO, 1990).

ON-GOING EFFORTS FOR DEVELOPING BIOSAFETY PROTOCOL

Article 19(3) of the CBD, dealing with handling of biotechnology and distribution of its benefits, states that "The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of safe transfer, handling and use of any LMOs resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity".

Further, Article 19(4) states that "Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the

Contracting Party into which those organisms are to be introduced". In the second meeting of the Conference of Parties to the CBD, held in 1995, it was decided to establish an Open- ended Ad Hoc Working Group (BSWG) under the Conference of Parties to develop a protocol on biosafety taking into account these two paragraphs of Article 19, the principle enshrined in the Rio Declaration on environment and development, and in particular the precautionary approach contained in Principle 15. In this regard, this Working Group has had four meetings (most recently in February, 1998), and has consolidated the text of

Table 3. Summary of the Major Articles of the Proposed 'Protocol on Biosafety'

a) Some Major Articles

Article 3.	Application of Advance Informed Agreements (AIA) Procedure	Article 15.	Unintentional Transboundary Movement
Article 4.	Notification Procedure for AIA	Article 16.	Emergency Measures
Article 5.	Response to AIA Notification	Article 17.	Handling
Article 6.	Decision Procedure for AIA	Article 18.	Competent Authority Focal Point
Article 7.	Review of Decision Under AIA	Article 19.	Information Sharing/Biosafety Clearing House
Article 8.	Notification of Transit	Article 20.	Confidential information
Article 9.	Simplified Procedures	Article 21.	Capacity Building
Article 10.	Subsequent Imports	Article 22.	Public Awareness/Public Participation
Article 11.	Bilateral and Regional Agreements	Article 23.	Non-Parties
Article 12.	Risk Assessment	Article 24.	Non-Discrimination
Article 13.	Risk Management	Article 25.	Illegal Traffic
Article 14.	Minimum National Standards	Article 26.	Socio-economic Considerations
		Article 35.	Monitoring and Compliance

b) Other items (text to be consolidated and negotiated)

Preamble,Objectives and Jurisdictional Scope	Accession
Use of terms/Definition	Depository
Relationship with other international agreements	Reservation and declaration
Entry into Force	Review and adoption
Settlement of disputes	Authentic Texts
Financial issues	Annexes
Right to Vote	Withdrawal; and Signature

some major articles (Table 3) dealing with various substantial matters. In addition, negotiating countries would need to finalise legal definitions of various crucial terms on the basis of mutual agreement. These terms include: LMOs, Transboundary Movement, Transfer, Safe Transfer, Competent Authority, Familiarity, Adverse Effects, Contained Use, Intended/Deliberate Use, Unintended Release, Focal point, Risk Assessment, Risk Management, Modern Biotechnology, Advanced Informed Agreement, Prior Informed Consent, Minimum National Standards, Biosafety, Limited Trial, Handling of LMOs, Use of LMOs, Centres of Origin, Centres of Genetic Diversity, Compensation, Open Environment, Open Field Trial and Accidents.

The majority of countries believed that 'AIA' procedures constituted a very important part of a protocol dealing with transboundary movement of LMOs, taking into account the provisions of the Basel Convention and the operational guidelines and principles developed by the Forest Stewardship Council. The procedures should also include the notification of components, and must deal with transboundary movements of LMOs and data relevant to safety and information contained therein. The other important aspect associated with this is capacity building, which must be an integral part of the notification in a manner that the AIA mechanism is workable and practical.

The priority activity regarding relevant categorisation of LMOs resulting from modern biotechnologies is to establish a clear understanding of, and early agreement on, the classes of organisms under consideration in the negotiation process. An agreed categorisation would help to establish which existing international agreements might be applicable to some categories of LMOs and relevant to developing a protocol on biosafety. In addition, categorisation according to the degree of assessed potential risk to biological diversity would appear relevant in considering AIA procedures. Apprehensions have also been raised that risk classification for LMOs would be unrealistic, as biosafety risks associated with a given LMO would be different under different geographical, ecological and climatic conditions.

The fourth meeting of the BSWG, held in February, 1998, has consolidated the substantial text of the major Articles of the proposed 'Protocol on Biosafety'. However, most of the contentious issues remain bracketed, for further extensive negotiations. This has to be accomplished in the forthcoming meeting of this Group in late August, 1998. The agreed text has to be presented in the ordinary or extra-ordinary session of the next COP.

It is now the special responsibility of global molecular biologists and ecologists to facilitate the negotiation process, so that the protocol on biosafety can be finalised early. This would help in the suitable development of biotechnology to meet the objective of sustainable development including global food security on the one hand, and the sustenance of biological diversity for

future use on the other. This is one of the most difficult challenges, for the entire global scientific community, because the development of a protocol on biosafety will be turning point of our modern times. It is expected that the same spirit that brought about agreement on the complex issues contained in the CBD would also be evident in finalising the protocol on biosafety.

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