BIOSAFETY

Scientific Findings and Elements of a Protocol

Report of the
Independent Group of Scientific and
Legal Experts on Biosafety

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PREFACE

THIS report has been prepared by an Independent Group of Scientific and Legal Experts on Biosafety as a contribution to the growing international discussion on the implications of genetic engineering and the need for biosafety policies and regulation.

This Independent Expert Group was set up at the initiative of several environment and development groups concerned about issues relating to safety and ecological aspects of genetic engineering.

These NGOs requested the Independent Expert Group to produce a report on recent scientific findings on genetic engineering and the elements of an appropriate biosafety protocol.

More specifically, the report has been produced in the context of discussions at the Convention on Biological Diversity (under the United Nations) on the need for and modalities of a biosafety protocol.

At the second meeting of the Convention's Conference of the Parties (COP) held in Jakarta in November 1995, the governments agreed to begin negotiations to formulate a legally binding international biosafety protocol.

In the next few years, negotiations will take place on the framework, shape and content of the international biosafety protocol.

The decision to negotiate a protocol was reached after four years of efforts on the part of many developing countries and non-governmental organisations, supported by some Northern countries as well.

The member states of the Biodiversity Convention have been debating the need for a biosafety protocol since 1991, from the time the Convention itself was being negotiated. More recently, at the first COP meeting of the Convention in November 1994, a 15-member expert panel nominated by

governments was set up to produce a report as an input to the meeting of the Ad Hoc Working Group of Experts which was held in Madrid on 24-28 July 1995. This Working Group was open to all governments. The expert panel met in Cairo in May 1995 and produced a report (known, in short, as the Cairo Expert Panel Report).

Meanwhile, an Independent Group of Experts was also established by a number of environment and development organisations involved in biosafety issues. The group prepared this report as an input into the discussion on biosafety at the Madrid meeting as well as the second meeting of the COP in November 1995.

The experts in this group were chosen for their knowledge of the science and ecological implications of genetic engineering, and for their legal expertise in international instruments in the environmental area.

The members of the independent expert group are: Vandana Shiva (India), Mae Wan Ho (United Kingdom), Tewolde Egziabher (Ethiopia), Brian Goodwin (United Kingdom), Elaine Ingham (United States), Beatrix Tappeser (Germany), Regine Kollek (Germany), Nicanor Perlas (Philippines), Diana Pombo (Colombia), Gurdial Singh Nijar (Malaysia), Chee Yoke Ling (Malaysia), and Dan Leskien (Germany).

This report of the Independent Expert Group on Biosafety covers two major areas: a scientific analysis of the potential effects of genetic engineering, based on current and up-to-date findings; and a discussion on the need for and the modalities and elements of a biosafety protocol. It also contains a critique of the Cairo expert report, which is reproduced as an Annex to this report.

Earlier drafts of this report were widely circulated and became a crucial input for delegates and NGOs at the meetings under the Convention on Biological Diversity and contributed to the decision of the COP in November 1995 to begin international negotiations on a legally binding biosafety protocol.

In 1996, the draft report was revised and the final report is now being published.

It is hoped that this report will contribute to the process of formulating an international biosafety protocol, and also be useful for developing national policies to regulate activities involving genetic engineering.

As one of the groups that initiated the establishment of the Independent Expert Group, the Third World Network is pleased to publish this Report so that it can have wider circulation.

More information on this report can be obtained from: the Third World Network, 228 Macalister Road, Penang, Malaysia (fax: 60-4-2264505, email: twn@igc.apc.org or at twnpen@twn.po.my).

Third World Network
Penang, Malaysia
July 1996.

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CONTENTS

GLOSSARY

ACRE:	UK Advisory Committee on Releases to the Environment
AIA:	Advance Informed Agreement
CBD:	Convention on Biological Diversity
COP:	Conference of the Parties
CPGR:	Commission on Plant Genetic Resources
FAO:	Food and Agriculture Organisation (UN)
GEM:	Genetically Engineered Microorganism
GEO:	Genetically Engineered Organism
GMOs:	Genetically Modified Organisms
IPPC:	International Plant Protection Convention
OECD:	Organisation for Economic Co-operation and Development
PIC:	Prior Informed Consent
rDNA:	Recombinant Deoxyribonucleic Acid
UNEP:	United Nations Environment Programme
UNIDO:	United Nations Industrial Development Organisation

PART I

INTRODUCTION

Increasing concerns over the hazards posed by genetic engineering to health and to the environment, and in particular, the adverse effects on the conservation and sustainable use of biological diversity led representatives from an overwhelming number of countries as well as citizen groups and scientists to call for a legally binding international protocol on biosafety.

In recognition of the threats to biological diversity and human health as research and commercial application of gene biotechnology grows, governments from more than 150 countries agreed that the need for and modalities of such a protocol would be considered under the Convention on Biological Diversity. Soon after the Convention was opened for signing in 1992, the United Nations Environment Programme (UNEP) established four expert panels to assist Contracting Parties in identifying priority areas for the implementation of the Convention. The UNEP Experts Panel IV considered a biosafety protocol to be a matter of critical importance. An overwhelming majority of its members called for immediate work to begin on a biosafety protocol, given the fact that biosafety regulations and procedures were already far behind the technological developments, with industry pressuring for commercialisation of a range of genetically engineered products on the one hand, and growing scientific knowledge of ecological and health hazards of genetic engineering on the other. Of particular concern was the lack of regulation of transboundary transfers in experimentation or field tests, especially from industrialised countries to developing ones. The United States, while not a Party to the Convention, rejected the need for a protocol, with the OECD

representative advocating a step-by-step approach of establishing national capacities before considering an international instrument.

In the two Preparatory meetings of the Inter-governmental Committee on the Convention in 1993/94, the issue of a biosafety protocol was of key concern to the delegates. An overwhelming number of countries agreed on the need for a biosafety protocol and recommended that the Conference of the Parties (COP), at its first meeting, consider immediate work on a biosafety protocol. When the COP met for its first meeting in Nassau, the Bahamas, (28 November - 9 December 1994), its first substantive decision was to establish an open-ended ad hoc working group of experts nominated by governments. The Secretariat of the Convention was requested by the COP to establish a panel of 15 government-nominated experts, assisted by UNIDO, UNEP, FAO and WHO, to prepare a background document to be submitted to the open-ended ad hoc working group of experts nominated by governments at its meeting in Madrid (24 - 28 July 1995). This background document (known in short as the Cairo Expert Panel Report) was prepared when the panel met in Cairo in May 1995. It was then presented to and discussed by the Madrid working group.

Meanwhile, an independent group of experts was set up by a number of environmental and development organisations involved in biosafety issues, to produce a separate report. This need was urgently re-affirmed when a draft report of the Cairo Expert Panel revealed fundamental flaws in the scientific underpinnings of genetic engineering, and shockingly omitted the wealth of evidence and data in recent years on the health and ecological hazards of genetically engineered products and organisms.

This report of the Independent Group of Experts represents the joint work and contribution of scientists from Ethiopia, Germany,

India, the United Kingdom and the United States as well as the work of legal experts. The report contributed significantly to the work of the open-ended ad hoc working group of experts and the COP at the critical stage in 1995 when both the need for and modalities of a legally binding biosafety protocol were being considered under the Convention. After intense and long-drawn negotiations, the COP decided at its second meeting in November 1995 in Jakarta that a legally binding international biosafety protocol will be negotiated. The first meeting of the open-ended negotiations group, open to all governments and non-governmental observers, will be held in Aarhus, Denmark from 22 to 27 July 1996.

This revised report will hopefully continue to contribute to the formulation of a strong biosafety protocol. The report focuses on the following areas:

- The experience and knowledge of the perils presented by genetic engineering (Part III);

- The scientific requirements of, or criteria for, assessing GMOs (genetically modified organisms) and the effects of the introduction of GMOs into the environment (Part IV);

- Existing international regulatory mechanisms (Part V);

- The essential elements and modalities of a biosafety protocol (Part VI).

- The report also contains an assessment of the Cairo Expert Panel Report which is published as Annex II.

PART II

THE INSTITUTIONAL FRAMEWORK OF THE REPORT

The threats posed by the new biotechnologies to biodiversity, the environment at large and human health are major concerns under the Convention on Biological Diversity. The fundamental principles of the Convention and which bind Contracting Parties are:

- the precautionary principle;
- advance informed consent;
- access to information; and
- the overriding need for the assessment, regulation, control and management of risks arising from the use and release of genetically modified organisms which adversely affect the conservation and sustainable use of biological diversity, as well as risks to human health.

The precautionary principle is accepted under the Convention in the Preamble (Indent 9):

> " ... where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimise such a threat".

Since there is no predictive ecology with regard to genetically modified organisms, and because evidence is growing of problems with biotechnology products, there is an urgent need to put in place legally-binding national and international rules that are comprehensive and reflective of the precautionary principle.

Article 8(g), dealing with in-situ conservation, obliges Contracting Parties to

> "establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health".

Article 8(h) requires Parties to

> "prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species".

Article 19(3) states that 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 the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biodiversity. Article 19(4) obliges each Contracting Party to ensure that anyone who provides the organisms referred to in paragraph (3) also provides

> "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".

The decision by the Conference of the Parties, at its first meeting in 1994, to establish an open-ended ad hoc working group of experts to address the issue of a biosafety protocol reflects the firm conviction by governments of the urgency and importance of this matter.

Inter-governmental deliberation on biosafety and the need for a legally binding international and national regime has continued from the first meeting of the COP to the third session of the Commission on Sustainable Development in May 1995. In reviewing the implementation of Chapter 16 of Agenda 21 (on "Environmentally Sound Management of Biotechnology"), the Commission called for a balanced and objective approach to biotechnology, stressing that while benefits accrue from biotechnology,

> "Future reports should place a stronger emphasis, including more information and proposals, on the ecological, safety, health and socio-economic and ethical aspects of the application of biotechnology and the commercialisation of biotechnology products, with particular reference to genetic engineering, including genetically modified organisms when human genetic material is involved. Such reports should take into account existing uncertainties and the most recent findings of the science of genetics."
> (Chairman's Decision on Chapter 16 of Agenda 21, para 1).

The Commission pointed to the precautionary principle which makes the handling of biotechnology a "high priority" as well as the special vulnerability of developing countries in the absence of a global framework for biosafety. The legal supremacy of the Convention on Biological Diversity was reiterated when the Commission stated that work on the development of possible international voluntary technical biosafety guidelines elsewhere should not pre-judge the result of the ongoing work on a protocol under

the Convention.

The experience in the transboundary movement of hazardous wastes underscores the vital importance of a legally binding international biosafety protocol. It was precisely in the absence of international regulation that millions of tonnes of toxic wastes were exported, often illegally to developing countries, resulting in severe environmental and human health problems for the host countries. The precautionary approach, prior informed consent and a rejection by the international community of unscrupulous actions by transnational corporations that transfer hazards to countries which are unsuspecting or unable to deal with the toxic wastes, are aspects that find their parallel in the use and release of genetically modified organisms. If the international community could move so fast in confronting the toxic waste problem by concluding the Basel Convention within a short time, and quickly moving in 1994 to amend provisions that allowed circumvention of the Convention's objectives, the known and potential hazards of genetically modified organisms present an even more urgent scenario for international legal regulation.

Within the larger framework of the Convention's objectives (conservation and sustainable use of wild and domesticated biodiversity; fair and equitable sharing of benefits arising from the utilisation of such biodiversity; and appropriate transfer of relevant technologies) and Agenda 21, a critical step for every country, particularly developing countries, is the assessment of the need to introduce the new biotechnologies, and a consideration of alternatives to any proposed use of genetically modified organisms. In particular, the alternatives that conserve biodiversity and protect the rights of communities need to be considered in the light of the experience and knowledge of the perils presented by genetic engineering.

PART III

The Experience and Knowledge of Some Perils Presented by Genetic Engineering and the Biotechnology Industry

There is accumulating data that genetically engineered organisms have many negative ecological and health effects. Some of the evidence is new while earlier tests have been found to be incomplete and inadequate, thus giving the lie to findings of "no ecological impact".

The most important peril from GMOs is that the genes can multiply, mutate, recombine and spread out of control. Experiences with pest organisms, including chestnut blight, Mediterranean fruit-flies, hares in Australia, kudzu in the southern US and even with bio-control organisms released to control these pests, are unmistakable lessons that once loose, released organisms cannot be recalled. Genetic engineering and its commercial application have ecological, safety, health and socio-economic implications which are not yet adequately assessed, monitored or regulated. There is also growing evidence that public concerns over these implications are scientifically-founded.

1. SOME RECENT SCIENTIFIC FINDINGS

Recent scientific findings affirm the serious inadequacies in existing regulations and testing procedures, as well as the degree of unpredictability with regards to the ecological impacts of transgenic organisms. The following developments are of major significance:

1.1. Impact on soil organisms and plant life

At the 1994 annual meeting of the Ecological Society of America, researchers from Oregon State University reported on tests to evaluate a genetically engineered bacterium designed to convert crop waste into ethanol.

A typical root-zone-inhabiting bacterium, *Klebsiella planticola*, was engineered with the root-zone novel ability to produce ethanol, and the engineered bacterium was added to enclosed soil chambers in which a wheat plant was growing. In one soil type, all the plants with the genetically engineered microorganism (GEM) treatment died, while those in the parent and no-addition treatment remained healthy. In all cases as well, mycorrhizal fungi in the root system were reduced by more than half, which ruined nutrient uptake and plant growth. This result was unpredicted. Reduction in this vital fungus is known to result in plants being less competitive with weeds, or being more susceptible to disease. In low organic matter sandy soil, the plant died from ethanol produced by the GEM in the root system, while in high organic matter sandy or clay soil, changes in nematode density and species composition resulted in significantly decreased plant growth. The lead researcher, Dr. Elaine Ingham, concluded that these results imply that there can be significant and serious effects resulting from the addition of a GEM to soil. The tests, using a new and comprehensive system, disproved earlier suggestions that no significant ecological effects

have been seen when GEMs are added to test systems (Ingham, 1995).

Ingham emphasized the following:

(a) Only 14 genetically engineered organisms have actually been tested for ecological effects, a minimal set from which to broadly apply any principle, or to state that other engineered organisms (with extremely different genetic modifications) will not have impacts.

(b) The test systems to determine whether addition of these engineered organisms results in ecologically significant effects have often consisted of sterile soil, soils with no plants, or systems without other organisms present that could be affected or impacted.

(c) There were often inadequate food resources in such test systems and the engineered organisms often did not reproduce during the course of the test, and did not carry out their engineered function.

The report stressed that the effects on the whole ecosystem must be understood, not just isolated portions, because biotechnology products will have a range of impacts much greater than just the engineered organism. It is critical that effects on the whole ecosystem are assessed, before any release is made. If other organisms in the foodweb are affected to the point that nutrient recycling, plant growth or important plant growth processes are altered then the risk is significant and clear.

A team of researchers from the same university subsequently assessed existing biosafety guidelines, codes and regulations, including the draft International Technical Guidelines for Safety

in Biotechnology currently circulated and promoted by UNEP, and concluded that all of these would not have been successful in capturing the risk posed by the engineered *Klebsiella planticola* (Ingham, Holmes, Johnston and Tuininga, 1995).

1.2. *Rapid transfer of transgenes by spontaneous hybridization between engineered oilseed rape and its weedy relative*

In 1994, research scientists in Denmark reported strong evidence that an oilseed rape plant genetically engineered to be herbicide tolerant transmitted its transgene to a weedy natural relative, *Brassica campestris ssp. campestris*. This transfer can take place in just two generations of the plant.

In Denmark, *B. campestris* is a common weed in cultivated oilseed rape fields, where selective elimination by herbicides is now impossible. The wild relative of this weed is spread over large parts of the world. One way to assess the risk of releasing transgenic oilseed rape is to measure the rate of natural hybridization with *B. campestris*, because certain transgenes could make its wild relative a more aggressive weed, and even harder to control.

Although crosses with *B. campestris* have been used in the breeding of oilseed rape, natural interspecific crosses with oilseed rape were generally thought to be rare. Artificial crosses by hand pollination carried out in a risk assessment project in the UK were reported to be unsuccessful. However, a few studies have reported spontaneous hybridization between oilseed rape and the parental species *B. campestris* in field experiments. As early as 1962 hybridization rates of 0.3%-88% were measured for oilseed rape and wild *B. campestris*. The results of the Danish team showed that high levels of hybridization can occur in the field (Jorgensen, R. and Andersen, B., 1994). Their field tests revealed that between 9% and

93% of hybrid seeds were produced under different conditions.

The scientists also warn that as the gene for herbicide resistance is likely to be transferred to the weed, this herbicide strategy will be useless after a few years. Like many other weeds, *B. campestris* is characterized by seed dormancy and longevity of the seeds. Therefore, *B. campestris* with transgenes from oilseed rape may be preserved for many years in spite of efforts to exterminate it. They conclude that weedy *B. campestris* with this herbicide-tolerant transgene may present economic risks to farmers and the biotechnology industry. Finally, natural ecosystems may also be affected.

Other concerned scientists add that the potential spread of the transgene will indeed be wide because oilseed rape is insect-pollinated, and bees are known to fly great distances. The existence of the wild relative of *B. campestris* in large parts of the world poses serious hazards once the transgenic oilseed rape is marketed commercially. In response to the Danish findings, the governments of Denmark and Norway have acted against the commercial planting of the engineered plant, but the UK government has approved its marketing.

1.3. Survival and spread of genetically engineered organisms/ DNA from containment

GMOs which are currently designed for commercial release are designed to be robust and vigorous. They may migrate, mutate and multiply. This self-replicating nature of genetic material and lateral spread through ecosystems result in an intrinsically unstable and unpredictable situation. In contrast, laboratory strains of GMOs are supposedly not designed to survive in an open environment. It is therefore often assumed that the environment is pro-

tected from the spread of genetically engineered organisms used in contained conditions (laboratories).

However, increasing evidence has emerged demonstrating the viability of engineered organisms thought to be unable to survive outside laboratory conditions. These organisms have been found to survive in waste water and sludge, soils and aquatic ecosystems (river, lake, and especially snow particles at the bottom of lakes). Ostensibly "crippled" microorganisms have evidently managed to survive and compete with indigenous microorganisms.

Potential hazards exist even where genetically engineered organisms survive only for a short period in natural environments, because some of them are capable of transferring part of their nucleic acids to other members of a given ecosystem by means of conjugation even if they do not possess self-transmissible plasmids (Salyers, A.A. and Shoemaker, J.B., 1994). The rapid spread of antibiotic resistance markers has now been documented. In 1982, streptothricin was administered to pigs in eastern Germany. By 1983, plasmids encoding steptothricin resistance were found in the pig gut bacteria. This has spread to the gut bacteria of farmworkers and their family members by 1984, and to the general public and pathological strains of bacteria the following year. The antibiotic was withdrawn in 1990. Yet the prevalence of the resistance plasmid has remained high when monitored in 1993 (Tschape, H. 1994).

DNA persistence in laboratories, waste water treatment plants, aquatic systems, soils and digestive systems of mammals has also been shown in a series of experiments. DNA ingested with food is not completely broken down in the gastro-intestinal tract, and is even found in the blood stream and white blood cells (Schubbert et al, 1994). The long-term ecosystem effects of these surprise survivals are unknown. In addition, there is evidence, in tests with

mice and chickens, that it is not unlikely that gene transfer will occur in the digestive system (Doucet-Populaire, F., 1992; Guillot, J.F. and Boucaud, J.L., 1992).

When bacteria that are designed for contained use (often with special demands for nutrients not easily or not at all available in the natural environment) manage to survive and compete with indigenous microorganisms, we can expect that those bacteria that are designed to survive in the natural environment will have surprises in store.

A research project at the Technical University of Zurich shows that bacteria can penetrate the soil several metres deep under rainy conditions. The perception until now was that bacteria reside only in the surface area of soil. Secondly, the study revealed that bacteria can change to a dormant state. Ninety per cent of the tested *Pseudomonas fluorescens* were in a dormant state for several months (Chem, Rundschau, 13 April 1995). The dormancy problem is receiving increasing scientific attention, since results differ tremendously according to whether there is direct counting or the counting of culturable cells only. For instance, sea water with its high salt concentrations has been found to support the dormant state.

These findings have serious implications in that engineered bacteria with adverse environmental effects could survive and spread beyond expectation. This has now been documented for a laboratory strain of E. coli K12, which when introduced into the sewage, went dormant for 12 days before reappearing, carrying a new plasmid for multidrug resistance that enabled it to compete with the naturally occurring bacteria (Tschape, H. 1994). In environments where rainfall is frequent and heavy, for example in tropical countries, the destabilising of sub-soil ecosystems could be devastating.

The danger is that bacterial populations are now known to exchange genes and plasmids at high frequencies and very promiscuously, not only among themselves, but with yeasts, fungi and higher plants. According to Salyers and Shoemaker (1994), "It is probably impossible to eliminate all [horizontal] transfer capacity from a genetically engineered strain that is going to be released into the environment." This makes it paramount to control what is being released in the first place.

1.4. Weak monitoring – the case of a virus with scorpion-venom gene

In 1994 the UK Advisory Committee on Releases to the Environment (ACRE), amidst a storm of protests, approved for test releases a virus constructed with scorpion-venom gene as pest control against the cabbage white butterfly. A catalogue of errors has since been revealed:

(a) The scientist concerned failed to inform ACRE on the host range of the virus, which include many other species of butterflies, some of which are protected species.

(b) The virus escaped beyond the trial area, which was known at the time, but no attempt was made to track the escape, nor was ACRE informed.

(c) There was a mix-up between the genetically engineered venom virus and the natural virus, resulting in the caterpillars being sprayed with the wrong one.

(d) The natural virus is almost as effective at killing caterpillars, and does not occur naturally in the UK (reported in *The Splice of Life, Bulletin of the Genetics Forum* vol.1, no.8/9, May 1995).

1.5. 2,4-D-degrading bacterium has negative effects

A genetically engineered microorganism has been constructed to decontaminate agricultural soils containing the pollutant, 2,4-dichlorophenazyacetic (2,4-D). However, it is reported that the breakdown product from the action of the bacterium, 2,4-dichlorophenol (2,4-DCP), proved to be even more toxic than the target pollutant 2,4-D (Bazin, M.J. and Lynch, J.M., eds., 1994).

This GMO was also found to have a negative impact on the fungal community when added to a desert grassland soil (Doyle, et al., 1995). In a similar soil, with lower organic matter and lower humidity, the organism did not degrade 2,4-D (Ingham et al., 1995). In agricultural soil, loss of the fungal component can signal soil degradation. In forest soils, this loss can result in regeneration problems, and in the loss of existing trees. This GMO has never been tested in forest soil. Yet, by current risk assessment standards, there is no restriction on the use of this GMO in forest systems, since at present, impacts on fungal communities are not included in biosafety assessments.

2. PERILS AND RISKS

Three major risks that are now recognized are:

2.1. Effects of transgenic products (primary and secondary) on non-target organisms

(a) Many plants are engineered to produce toxic pesticides or drugs, making them 'pest-resistant'. Even though pests are the desired targets of these new substances this does not mean that they are the only species ingesting and reacting to the new chemi-

cals in the plants. And so, these species may incur risks although they are 'non-target organisms', i.e. not meant to be affected. There may be adverse effects not only on the health of humans and of plant-eating mammals but also threats to ecologically important organisms such as beneficial insects.

(b) One class of non-target organisms are soil organisms. They are often neglected by the current practice of risk assessment but play a crucial role for soil fertility and plant health. Via the roots of GEOs or via their harvest residues new chemicals enter soil ecology and may prove disruptive.

(c) There may be evolution of new pathogens by vector recombination or mutation when large numbers of genetically engineered vectors are effectively introduced. The probability of such an event increases with the scale of the release. Vectors for gene transfer are specifically constructed to overcome species barriers. They widen the evolutionary potential for infecting a wider range of hosts. Many of the vectors which are used are modifications of pathogenic organisms but they have been deactivated and 'crippled' in various ways so as to remove their pathogenicity, i.e. their ability to cause diseases. Thus it is hoped to get rid of their risk potential. The removal of pathogenicity, however, is not guaranteed. The vectors still have the ability to recombine with the original pathogens. This means that they may give rise to superpathogens which combine regained pathogenicity with an enhanced infectivity for a wider host range.

(d) The routine incorporation of antibiotic resistance selection marker genes will have public health implications as it speeds up the evolution of antibiotic resistance. For example, kanamycin in the genetically engineered "Flavr Savr" tomato is used to control tuberculosis, which is currently on the increase worldwide.

(e) Similar risks will emerge with genetically engineered fish, shellfish and insects.

(f) Allergenic effects could be carried with the transgene or be stimulated by imbalances in the chemistry of the host plant or other organisms. Genetically engineered food products that are not labelled as such could threaten consumers with allergies, while field workers exposed to insecticidal transgenic crops could develop allergies. The dozens of deaths and crippling of hundreds in 1989 by eosinophiliamyalgia syndrome (EMS), which were linked to a batch of synthetic L-tryptophan produced by a genetically engineered strain of *bacillus amyloliquefaciens*, are a grim warning to heed on the unpredictability of genetically engineered food products.

2.2. *Establishment and spread of transgenic crop plants in non-target sites*

This is already known for ordinary non-transgenic introduced plants. Transgenic plants are expected to be more competitive due to the incorporation of pest and herbicide resistance genes, as well as genes for resistance to other environmental poisons. Such plants may then become noxious weeds, thereby reducing natural biodiversity and undermining future genetic resources for breeding better crop plants and for securing future food security. This threat is greater for many developing countries because most of the world's centres of crop origins and diversity are located in those countries.

2.3. *Transfer by hybridization and introgression of transgenes from crops into wild relatives*

Transgenic crop plants could also become a conduit through

which the transferred genes may move to wild relatives of those crops, dominate and displace the wild relatives which are essential for maintaining diversity of the breeding stock. Such transfer by hybridization has already been reported for the oilseed rape plant by Danish scientists in 1994 (see above). Again, this threatens diversity, sustainable agriculture and food security, with developing countries (where the centres of diversity are found) facing particular risks.

3. PERILS IN LIGHT OF NEW KNOWLEDGE

In the light of new knowledge on genetics, the following perils should also be considered:

3.1. Horizontal transfer of transgenes by soil, fresh-water, marine, and aerial microbes and fungi, insect and other vectors

These transfers are known to occur frequently and promiscuously in nature, crossing species genera and families among bacteria, and also kingdoms: between bacteria and higher plants. From our current knowledge, it can be predicted that kanamycin resistance, for example, will spread by at least two routes: via soil bacteria, and via the gut bacteria through sewage plants, to the general public and to pathogenic bacteria (see many papers in FEMS Microbiology Ecology volume 15, 1994). The aquatic and marine environment is particularly favourable for horizontal gene transfers. Apart from conjugation and transformation, an important route is transduction via viruses: the concentration of virus particles in sea water is extremely high: between 10^6-10^8 per millilitre (Hermansson, M. and Linberg, C., 1994).

The horizontal gene transfers may be further facilitated by the

genetic vectors used to make transgenics, which are constructed out of genetic material from widely different sources, and hence increase the likelihood of genetic recombination between modified vectors and natural viruses to generate new pathogens. For example, the construction of plants to contain parts of a virus, in order to make them virus-resistant, could generate new plant diseases.

3.2. *New knowledge of genetic instability*

Many vectors are made from viruses or jumping genes. Even though they are crippled, they can be helped to mobilize by helper viruses or helper elements. The stability of transgenes is still unknown; it could be overestimated as the procedure for creating transgenes routinely includes selection by herbicide or antibiotic markers and this would automatically eliminate those protoplasts or seedlings which have lost the transgenes.

Because the genomes of all organisms are now known to be fluid, i.e. subject to a host of destabilizing processes that mutate, rearrange and alter DNA in other ways and that can enhance instability by two or three orders of magnitude (McClintocs, 1984), whole fields of planted crops may fail to realize their promise due to such genetic instabilities. In addition, the mobilized genes will have an increased likelihood to be transferred elsewhere in the genome with unpredictable effects, or to another organism or another species.

3.3. *Transgenic plants such as those incorporating herbicide, pest or heavy metal resistance create ecological hazards*

The evolution of herbicide/heavy metal resistance will increase

generally in weed species when transgenic crops with introduced resistance genes are cultivated in the presence of herbicide or heavy metals, thus defeating the purpose of the transgenes. Similarly, insects will soon develop resistance, rapidly and independently of any introduced transgene, due to a universal tendency of cells and organisms to mutate or amplify their own genes required for resistance (reviewed by Pollard, 1988; Ho, 1987).

As a high proportion of current transgenic plants are engineered to be herbicide resistant, this will result in the increased use of herbicides and the consequent pollution of soil and ground water.

3.4. *Transgene instability and horizontal transfer could pose health risks*

The health risks from transgenic food plants and animals have already been mentioned. In addition, secondary mobility of transgenes could further alter the characteristics of the plants and animals, and, when ingested, the transgene could integrate into human cells with harmful consequences – gene activation or inactivation, DNA rearrangements, sequence amplifications, and other effects, including cancer (Wahl, G.M., de Saint Vincent, B.R. and DeRose, M.L., 1984).

4. SOCIO-ECONOMIC IMPACTS OF GENE BIOTECHNOLOGY

Of special concern to developing countries are the socio-economic impacts of the commercialization of genetically engineered crops and products. The transgenic crop or product could replace traditional export crops such as vanilla and cotton. This would be

crippling for countries that are dependent on a limited number of crops for revenue.

For the majority of the rural communities who depend on traditional crop varieties for their survival and livelihood, transgenic crops could mean displacement of those varieties through the mechanisms described above. The ecological hazards created would have a direct adverse socio-economic impact on rural populations. In addition, the patented transgenic crop could prevent the use of non-transgenic donor or recipient species by traditional farmers, resulting in the loss of landraces (farmers' varieties) and increased production costs as farmers will then have to pay for patented seeds and their accompanying package of herbicides, insecticides and fertilizers.

Just as the biotechnology industry emphasizes the promise of economic benefits from genetic engineering, governments, especially from developing countries, need to weigh the economic potential of traditional practices to contribute to sustainable agriculture. Underpinning these policy choices should be the protection and promotion of agricultural biodiversity.

PART IV

THE SCIENTIFIC REQUIREMENTS OF, OR CRITERIA FOR, ASSESSING GMOS AND THE EFFECTS OF THE INTRODUCTION OF GMOS INTO THE ENVIRONMENT

Many scientists working on the interrelation among genes, organisms and the environment, and on ecology and risk assessment, are increasingly questioning the scientific validity of many of the basic premises of the old genetic paradigm which currently guides the practice of genetic engineering and shapes policies concerning its applications. There are increasing concerns among the scientific community about the potentially serious consequences arising from the application of this new biotechnology, given the flawed assumptions that are still being perpetrated.

This section proposes some basic scientific requirements and criteria in formulating a biosafety protocol.

1. GENETIC ENGINEERING IS BASICALLY DISTINCT FROM TRADITIONAL BREEDING, THUS POSING NEW HAZARDS AND REQUIRING WELL-DESIGNED TESTS

It is untrue to assert that there is no conceptual distinction between new varieties of organisms bred by classical methods and those created by genetic engineering involving molecular techniques that modify DNA and recombine genes between species that have little or no probability of exchanging genes in nature. As distinct from conventional breeding methods, where different forms of the same genes (alleles) are being reshuffled between varieties of the same species or close relatives, genetic engineering transfers novel genes into organisms, facilitated by vectors.

There is generally no control over where in the genome the new genes will be inserted, which makes the effects of gene transfer highly unpredictable and most often, harmful. Vectors may themselves further mobilise and cause yet other effects including cancer, and they may recombine with other viruses to generate pathogens. In order to facilitate selection of those protoplasts with transferred genes, antibiotic resistance genes are incorporated as markers. These markers are yet another novel source of hazard not present in organisms bred by classical methods. Given the high degree of unpredictability of the impact of GMOs on the environment and human health, it is therefore imperative that the precautionary principle underlie any protocol.

Following from the above, there is no basis for claims that experience has shown there is little or no risk involved in the contained use and introduction of GMOs into the environment. On the contrary, failure to acknowledge the basic distinction between genetic engineering and traditional breeding methods has resulted in field tests that are inadequately designed and inadequately monitored for environmental impact and safety.

2. NEED FOR ADEQUATE CONSIDERATION OF UP-TO-DATE KNOWLEDGE OF THE NEW GENETICS INCLUDING GENOMIC INSTABILITY AND HORIZONTAL GENE TRANSFERS WHICH DEMANDS THE ADOPTION OF HOLISTIC ECOSYSTEM APPROACHES

Genes do not work in isolation. Instead, their actions are so thoroughly interlinked that it is increasingly difficult to define a gene. Genes themselves function within a complex, integrated network of checks and balances in relationship to the internal and external environment, so that the organism can maintain and reproduce itself stably and repeatedly in its ecological community. When this complex network of interrelationships is perturbed beyond a certain threshold, it will break down, often with catastrophic consequences, including death (Saunders, P.T., 1994).

The transfer of foreign genes in creating transgenic plants and animals, which are subsequently released on a large scale into the environment, is a major perturbation both to the organisms to which the transgenes are introduced, and to the ecological community into which the organisms are released. In the case of transgenic organisms, we have already witnessed massive mortality, and among the survivors, many illnesses and bizarre effects. The consequences of upsetting the ecological balance will most likely be equally devastating, although, of course, the time-scale is much longer.

The old genetic paradigm has perpetrated an erroneous reductionist view of organic wholeness and complexity. It regards DNA or the genes as the most important, constant and stable essences of organisms. It regards genes as the determiners, in a simple, linear way, of the characteristics of organisms. Molecular genetics since the 1970s has provided steadily growing evidence to the contrary,

showing that genes are unstable, and may respond directly to the environment, when the environment is perturbed. These findings reveal hitherto undreamt of complexity and dynamism in cellular and genic processes involved in gene expression, many of which serve to destabilize and alter genomes within the lifetime of all organisms (Pollard, J., 1984; Ho, M.W., 1987; Rennie, J., 1993). These processes so impressed molecular geneticists that they coined the phrase "the fluid genome" more than ten years ago (Dover, G.A. and Flavell, R.B. eds., 1982). The main lesson to be learned from these fluid genome processes is that the stability and repeatability of development – which we recognize as heredity – does not reside solely in the genes, but is distributed over the whole complex of interrelationships between an organism and its ecological community. In reality, it is this complex of feedback interrelationships that stabilize genomes.

This makes prediction of the environmental and health impacts of GMOs inherently problematic, and requires that unusual care be exercised in drawing even the most uncertain conclusions. It also calls into question the rationale behind genetic engineering, particularly its claim to efficacy in comparison with many existing holistic approaches.

Again, the application of the precautionary principle is the best approach because it would be difficult, if not impossible, to recall GMOs with adverse effects which have been released into the environment or which have escaped from containment.

2.1. *Assessments that take account of Genomic Instability, Horizontal Gene Transfers and of the Systems Approach*

The following are proposed for assessment in recognition of

genomic instability, horizontal gene transfers and the systems approach:

(a) Data on the characteristics of the transgenic organism compared to the non-transgenic control, especially with regard to secondary unintended modifications due to gene transfer, whether it overproduces or is deficient in some constituents or whether novel constituents are synthesized which may pose a hazard to health, when used as a food source or animal feed.

(b) Secondary gene mobilizations or instability which destroy transgenic properties at the same time as they give rise to horizontal gene transfers mediated by animal/insect vectors, microorganisms and infectious viral/plasmid agents;

(c) Ability of non-target species to evolve required transgenic traits such as herbicide resistance should the transgenic be grown in conjunction with the herbicide;

(d) Ability of mobilized transgenes to jump into genomes of other species including humans, causing unpredictable harmful effects;

(e) Ability of antibiotic markers to spread horizontally, speeding up antibiotic resistance;

(f) Ability of transgenes/vectors to mutate and recombine with naturally occurring pathogens to form "new pathogens with altered characteristics". Vectors for use with higher animals are constructed from pathogenic viruses in the first place, and even though they have been inactivated, they could still easily recombine with the pathogen. The construction of 'broad spectrum vaccines' with wide ranges of genes incorporated from different pathogenic viruses is of particular concern in this regard.

3. BIOLOGICAL CONTAINMENT CANNOT BE GUARANTEED, CALLING FOR MORE COMPREHENSIVE TESTING/MONITORING PROCEDURES

Data accumulated over the last few years demonstrate that the concept of biological containment, on which existing legal regulation is based, cannot be guaranteed. The reasons are two-fold:

(a) Genetically engineered organisms can survive or transfer their transgenes to indigenous organisms, and their containment is not complete even if their biological containment is of a highly sophisticated manner;

(b) DNA persistence is stronger than imagined.

Thus assessment for ecological and health impacts cannot stop with the assumption that a given GMO will not survive. Unexpected survival, dormancy, secondary transfers of genes through conjugation, transduction and transformation and DNA persistence need to be considered in designing procedures for contained use and even work with isolated recombinant DNA-sequences (the latter is currently not subject to legal regulations and safety measures). Assessment should be extended to track the fate of GMOs/DNA which may be integrated and eventually expressed in indigenous organisms.

4. PRINCIPLE OF FAMILIARITY IS INAPPROPRIATE AND A CASE-BY-CASE APPROACH IS NECESSARY

Each engineered organism is a separate case, so there can be no generic safety test. Use of the principle of familiarity of function or resource-use by organisms in different ecosystems is thus prob-

lematical and inappropriate, especially when that function or resource-use by naturally-occurring organisms is not known. The state of "unknown" is more so for novel organisms. Given the present knowledge base that is too limited, the use of the principle of familiarity in environmental situations is dangerous. A comprehensive case-by-case approach is necessary.

Laboratory strains of GMOs are not designed to survive in an open environment. Extrapolation from laboratory data to ecosystems cannot be accepted. With the demonstrated survival and persistence of genetically engineered organisms or DNA even when they are "crippled", there is concern now that the data from "contained use" may not be reliable.

Existing field tests are not designed to collect environmental data, and test conditions do not proximate production conditions that include commercial scale, varying environments and time-scale.

The argument that the safety of field trials predicts safety at the commercial scale is thus untrue. One cannot claim that since plants in small confined and ecologically irrelevant field plots (used to study commercial features) have not 'caused problems' or have not 'caused surprises' then it will be safe to commercially release any transgenic forms. It is often claimed that there have been no adverse consequences from over 500 field releases in the US. However, the term 'releases' is completely misleading (Regal, P.J., 1994). Those tests were largely not scientific tests of realistic ecological concerns, yet "this sort of nondata on nonreleases has been cited in policy circles as though 500 true releases have now informed scientists that there are no legitimate scientific concerns".

Recently, for the first time, the data from the US Department of Agriculture field trials were evaluated to see whether they sup-

port the safety claims. The Union of Concerned Scientists (UCS) which conducted the evaluation found that the data collected by the USDA on small-scale tests have little value for commercial risk assessment. Many reports fail to even mention – much less measure – environmental risks. Of those reports that allude to environmental risk, most have only visually scanned field plots looking for stray plants or isolated test crops from relatives (Mellon and Rissler, 1993). The UCS concluded that the observations that "nothing happened" in those hundreds of tests do not say much. In many cases, adverse impacts are subtle and would never be registered by scanning a field. In other cases, failure to observe evidence of the risk is due to the contained conditions of the tests. Many test crops are routinely isolated from wild relatives, a situation that guarantees no outcrossing. The UCS cautioned that "... care should be taken in citing the field test record as strong evidence for the safety of genetically engineered crops".

The same concern is echoed by a commentary in *Nature* (Kareiva, P., "Transgenic plants on trial", *Nature* 363, 580- 1, 1993):

> " ... it is a pity that opportunities to obtain appropriate data have been missed in the hundreds of completed field trials, which have emphasised agronomic performance and have been managed in a way which discouraged multigeneration observations on transgenic populations. So although more than 300 field trials have been carried out and no evidence of 'weediness' has yet emerged, that should not be interpreted as an especially comforting observation – we have been so thorough in containing or destroying all material in field trials that we could hardly expect to see any hint of problems from these studies. The real question is what will happen when transgenic seeds are widely broadcast year after year in many different habitats, as would happen if genetically engineered crops are planted commercially."

Even where testing in one ecosystem is adequate, it does not allow extrapolation of risk assessment to other dissimilar ecosystems.

The 1994 findings of the Danish scientists on the spontaneous hybridization between genetically engineered oilseed rape (for herbicide tolerance) and a weedy natural relative provide strong evidence that transgenes could be dispersed to other plants, countering the assumption that genetically engineered crops will rarely, if ever, hybridize. It also countered the results of scientists in the UK where tests were conducted around the same time. It is such scientific work, particularly in recent years, that cautions us on the unpredictability of nature, that should guide the work of the COP and its subsidiary bodies and working groups.

5. TIME-SCALE FOR MONITORING ECOLOGICAL EFFECTS OF RELEASES OF GENETICALLY ENGINEERED ORGANISMS

In addition to the intrinsic unpredictability of the consequences of genome manipulation, the long-term nature of the response times in ecosystems also makes it necessary to have long observation periods in isolated but field-realistic conditions before release is allowed to occur.

The "exotic species model" is the only scientific model available for assessing potential long-term effects of GMOs in the environment. Existing data shows that the average time-lag between the introduction and the spontaneous spreading of non-native trees and shrubs was 147 years, the extremes ranging from 8 to 388 years. These results are based on a nearly complete survey of 184 introductions in the area of Berlin and Brandenburg

in Germany. The average time-lag for perennials was 68 years, and the average for 15 annual or bi-annual plants was 32 years.

Neither the disseminative potential of any of these plants in the exotic species model nor any of their undesirable effects on the ecosystem could have been assessed in the short monitoring periods under existing biosafety regulations, directives or guidelines. The existing standards can thus be said to be inappropriate in scientific terms.

PART V

THE EXISTING INTERNATIONAL REGULATORY FRAMEWORK

1. INTRODUCTION

1.1. Existing international soft-law instruments

There are no binding international protocols or instruments regulating GMOs. But there exist voluntary guidelines specifically covering the issue of genetic engineering. These are described briefly as follows:

(a) **UNIDO Secretariat Voluntary Code of Conduct for the Release of Organisms into the Environment**: The UNIDO Secretariat proposed a Voluntary Code of Conduct for the Release of Organisms into the Environment. The Code which was finalised in July 1991 fails to address, *inter alia*, the issue of international transfers of GMOs. Only the first version of the Code, titled "Draft for a Voluntary International Code of Conduct for Biosafety", included a short provision stating that there should be no attempt to introduce into another country products that have been refused licence in their country of origin for clearly stated reasons. However, this provision was not included in the final version.

The UNIDO Secretariat Code was watered down considerably during its development due to enormous industry pressure.

(b) **FAO Preliminary Draft International Code of Conduct on Plant Biotechnology as it affects the conservation and utilization of plant genetic resources**: In November 1991 the FAO Council endorsed the request of the Commission on Plant Genetic Resources (CPGR) that a draft Code of Conduct on biotechnology as it affects plant genetic resources be prepared for the Fifth Session of the Commission. At the Fourth Session of the Commission it was generally agreed that the Code of Conduct should address, *inter alia*, the promotion of biosafety to minimize environmental risks throughout the world.

A preliminary draft Code was presented to CPGR in the beginning of 1993 (CPGR/93/9). An earlier draft had been prepared by experts in a workshop organised by the FAO Regional Office for Latin America and the Caribbean in Santiago, Chile, in December 1991 (CPGR/91/12).

The preliminary draft Code falls into four chapters: Chapter I includes provisions concerning objectives, scope, definition and nature of the Code and its relationship with other legal provisions. Chapter II focuses on the promotion of biotechnology for the conservation and sustainable use of plant genetic resources (including monitoring and assessment of the socio-economic impacts of biotechnology, in particular on developing countries and local communities). Chapter III addresses the issue of biosafety and other environmental concerns. Chapter IV defines the duty of governments to report to CPGR on actions taken with regard to the Code.

This FAO preliminary draft Code includes safety regulations including those on transfer. Its Article 15 (2) states that,

> "no transgenic plants or other organisms that could adversely affect plant genetic resources intended for release should be imported into a

country without that country's Advance Informed Agreement. The Advance Informed Agreement procedure should apply to all transgenic plants and other organisms that could affect plants independently of the risk assessment and authorization for release in the exporting country."

However, the Commission on Plant Genetic Resources acknowledges that the issue of biosafety might be better regulated under the CBD. At its meeting in June 1993 the Commission recommended that, in order to avoid duplication and inconsistencies, biosafety and other environmental concerns which are a component of the preliminary draft Code should constitute an input to the work of the IGC/CBD on this matter (FAO CL 103/16 June 1993). FAO clearly regards the Convention as the proper forum for a biosafety protocol.

(c) **UK/Netherlands "Draft International Technical Guidelines for Safety in Biotechnology"**: These Guidelines were prepared by the Departments of the Environment in the Netherlands and the United Kingdom. A result of two meetings of "a number of international experts", the final draft is dated January 1995. These Technical Guidelines are being circulated and promoted by UNEP as a basis for developing their own Guidelines. *(See Annex I for a note and critique of the UK-Dutch/UNEP Technical Guidelines).*

(d) **Agenda 21:** Agenda 21 also makes several recommendations relating to biotechnology and biosafety. Its Chapter 16 is entitled "Environmentally Sound Management of Biotechnology". Its para 16.32 states the need for further development of internationally agreed principles on risk assessment and management of all aspects of biotechnology to be developed at the national level. It emphasizes the importance of putting in place adequate and transparent safety and border-control procedures. It states:

"Several fundamental principles could underlie many of these safety

procedures, including: primary consideration of the organism, building on the principle of familiarity, applied in a flexible framework, taking into account national requirements and recognizing that the logical progression is to start with a step-by-step and case-by-case approach but also recognizing that experience has shown that in many instances a more comprehensive approach should be used, based on the experiences of the first period, leading, inter alia, to streamlining and categorizing; complementary consideration of risk assessment and risk management, and classification into contained use or release to the environment."

More specifically, Chapter 16.35 (c) recommends the compilation, updating and development of compatible safety procedures into a framework of internationally agreed principles as a basis for guidelines to be applied on safety in biotechnology, including consideration of the need for and feasibility of an international agreement, and the promotion of information exchange as a basis for further development, drawing on the work already undertaken by international or other expert bodies.

1.2. The lack of binding international instruments

With the exception of Article 19(4) of the CBD, there are no binding self-executing international instruments regulating genetic engineering. However, there are some international treaties which may be applicable to some product categories of genetic engineering. These instruments deal only with some of the genetically engineered products. None of them address those aspects which are specific to genetic engineering.

(a) **The International Plant Protection Convention (IPPC)**: The IPPC, which entered into force in 1952 and has been revised in 1979 and 1983, aims at securing common and effective action to prevent the spread and introduction of pests of plants and plant products

and to promote measures for their control.

Pursuant to Article VI of the IPPC the Contracting Parties have full authority to regulate the entry of plants. For this purpose they may, *inter alia*:

(i) prescribe restrictions or requirements concerning the importation of plants or plant products;

(ii) prohibit the importation of particular plants or plant products, or of particular consignments of plants or plant products; and

(iii) list pests whose introduction is prohibited or restricted because they might adversely affect plants or plant products which are of potential economic importance to the country concerned.

However, the phytosanitary certificates give no information about the overall characteristics of the plants, the possible weediness of the plants or predictable interactions between the plants and the surrounding environment.

Although the IPPC is applicable to genetically modified plants and also to genetically modified seeds, it does not cover those safety considerations specific to genetic engineering. The aim of the IPPC simply is to prevent the spread of plant diseases and plant pests. However, if genetic modifications caused by genetic engineering techniques are not considered as creating a plant pest or disease, the protective safety aspects are not applicable. Its focus on plant pests makes the IPPC an unsuitable instrument for regulating those aspects of safety related to genetic engineering.

Further, the IPPC covers only plants and plant materials. Other

organisms are not covered by the IPPC. As the IPPC focuses on plant pests and diseases it cannot be recommended to include by revision aspects related to genetic engineering into the IPPC.

(b) **The Convention on Biological Diversity (CBD)**: Whereas Article 19(3) of the CBD only requires Contracting Parties to consider the need for and modalities of a biosafety protocol, Contracting Parties shall according to Article 19(4)

> "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 information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced".

Article 19(4), arguably, appears to create a bilateral obligation to provide information on GMOs which a contracting party considers as potentially dangerous to "the conservation and sustainable use of biological diversity".

Thus, Article 19(4) constitutes an obligation for Contracting Parties to establish an information procedure on transfers of those organisms resulting from biotechnology which may have potential adverse effects on the conservation and sustainable use of biological diversity. Wherever such organisms are transferred the exporting state is under an obligation to provide directly or indirectly any available information to the importing state on

(i) the use and safety regulations required by the exporting state in handling such organisms; and

(ii) the potential adverse impact of the specific organism.

This obligation exists, on one view, even if the Contracting Parties do not adopt a protocol under Article 19(3) of the Convention. However, this obligation does not make a protocol unnecessary, because, firstly, Article 19(4) needs to be implemented, and, secondly, because the scope of Article 19(4) is too narrow as it covers only aspects of transfer.

2. A GENERAL COMMENT ON THE UNDERLYING ASSUMPTIONS OF THESE INSTRUMENTS

The main instruments used as a basis for the ensuing discussion are UNIDO's Voluntary Code of Conduct and UNEP Technical Guidelines. These appear to be widely canvassed for adoption as a basis for a national regulatory system on biosafety.

2.1. *Voluntary versus binding protocol*

Both these instruments – the Code and the Guidelines – are voluntary. They are predicated on the assumptions that

(a) there is no need to subject this new technology to compulsory and binding international rules;

(b) the prime actors in this technology, the Multinational Corporations, will be responsible enough to voluntarily subsume their corporate interests for the common good.

These assumptions are not well founded.

First, it is clear that there is a need for a binding protocol. The safety, health, environmental, socio-economic risks as well as the ethical concerns have been well documented, as set out earlier.

Although dangers of different technologies are difficult to compare, those posed by genetic engineering of organisms may be even more threatening than the dangers of nuclear and chemical technologies. Organisms that are genetically engineered, once released into the environment, cannot be recalled if discovered to have dangerous effects. Such organisms can migrate and mutate with unpredictable results. Even the manipulation of harmless viruses can turn them virulent. As two researchers in this field, Wheale and McNally note, there is no real predictive ecology because the way in which genetically modified life forms interact with other organisms, and in different environments, is uncharted territory.

As has been discussed earlier at length, genetic engineering could affect agricultural diversity irreparably and commercialising transgenic crops could threaten global centres of crop diversity, located primarily in the South.

In the course of the deliberations at the open-ended experts group meeting on biosafety under the CBD in Madrid in July 1995, several arguments were advanced to suggest that voluntary guidelines were preferable to a binding protocol. It is important to examine some of these reasons. These were:

- That guidelines are flexible;

- That national capacity building should precede the adoption of a legally binding protocol;

- That any exporting country or company will voluntarily abide by the strict regulatory procedures to which they are subject in their own country;

- That voluntary guidelines are adequate for ensuring biosafety in relation to GMOs; and

- That we can adapt existing legislation to provide for biosafety of GMOs.

The following is a critique of the above reasons.

- **Flexible:** Flexibility is indeed often required especially with regard to evolving technologies. But legislation, both domestic and international, can and does provide for changing standards or requirements as and when necessary. For example, with regard to the accepted doses of exposure to radioactivity, changes to national regulatory systems have been made from time to time as and when new evidence or analysis made this necessary. The International Atomic Energy Agency (IAEA) revised the acceptable threshold level of exposure to radioactivity as a result of a reinterpretation of the data in relation to the Hiroshima and Nagasaki fallout. Many countries, including the UK, revised their domestic standards as well. (The changes were to allow for a lower level of exposure.)

The well-tried mechanism usually employed to achieve flexibility is to incorporate standards not in the main legislation but in subsidiary legislation. The appropriate authority is empowered to and can easily then, change these regulations without recourse to the cumbersome parliamentary machinery.

- **National capacity:** This capacity is for assessing risks posed by GMOs and not for handling biotechnology, as is

often vaguely stated. This capacity can, and should, be built coterminously with a regulatory mechanism. Indeed, if there is lack of capacity, then an internationally binding protocol with prescribed safety standards, will ensure that no country or company takes advantage of the lack of capacity of another country (especially in the Third World), to release or export their GMO product or industry.

● **Status of a voluntary instrument:** A voluntary document can be ignored or violated with impunity. A binding document has to be obeyed by the parties to it. Such a document may also impose a requirement that parties who do not subscribe to this protocol be excluded from (say) international trade in that particular activity. This is the position under the Montreal Protocol (Article 4).

● **Adapting existing legislation:** It may indeed be possible to adapt other existing legislation to deal with GMOs. For example, if the GMO is in some instances classified as waste, then some aspects of the Basel Convention may apply. But this is not an efficient and comprehensive way of dealing with all the problems posed by this new technology. Secondly, it is tedious and would involve an arduous and lengthy process to make amendments of all laws which could deal with this subject. On one assessment, for example, Germany would have to amend 96 of its existing laws to deal comprehensively with GMOs and the products incorporating them. For this reason, Germany has specific legislation dealing with safety with regard to products and activities related to GMOs.

● **Countries/companies with strict regulatory laws will voluntarily abide by these standards and laws when operating in other countries?:** This has been shown to be

largely untrue by past experiences. It was precisely in response to strict regulation that many companies relocated and shifted their operations to the Third World. So as regulations tightened, asbestos factories were relocated from Canada, Europe and Japan, to Mexico, Brazil and Taiwan. So too with manufacturing plants of benzidine dyes (known to cause cancer of the bladder to workers). Many other examples abound.

Past experience demonstrates clearly that Northern corporations are bound to transfer GMOs, their products and experiments, and projects and industries in respect of them to the countries of the South. Without standardised and binding international regulations, the dumping of dangerous procedures and products to developing countries could result. Again, as the experience in respect of hazardous products and industries shows, the corporations of the North practise double standards of safety, research and marketing to the serious detriment of the countries and populace of the South.

As regulations become tougher and public concern grows in the North, the temptation becomes greater for industry to relocate in Third World countries with weak regulations and technical know-how. Dr. Alan Goldhammer of the Industrial Biotechnology Association of the US states that "the pathway may be clearer in foreign nations to getting approval." The Royal Commission on Environmental Pollution of the UK, on The Release of Genetically Engineered Organisms to the Environment, expressed concern in its Report [13th, Cmnd. 720 July 1989] that restrictive regulation in some countries, notably of the industrialised West, would encourage companies and research institutes to take advantage of less strict frameworks of control elsewhere. This, it

noted, will result in "..a consequent risk to the environment and to the health in that country and more widely".

Indeed, there is evidence that this is already happening. Unregulated releases in countries where there is no scrutinization process to ensure safety have been taking place for some time now.

In 1989, for example, Monsanto had tested transgenic Roundup-tolerant soybean in the fields of Puerto Rico (Roundup is a herbicide manufactured by Monsanto). Since 1991, it has been doing the testing in Argentina, Costa Rica and the Dominican Republic. Since 1992, Monsanto has been field-testing transgenic cotton in Belize and Costa Rica. The testing is in respect of tolerance to Roundup or to plants becoming insect resistant using the Bt toxin. Field-testing of transgenic cotton varieties is also planned for Brazil, India and Zimbabwe.

Calgene released insect-resistant cotton and herbicide-tolerant cotton in Argentina and Bolivia in 1991. It plans to sell its transgenic cotton seed, tested as well in South Africa, in Australia, Spain and Greece. It also tested its delayed ripening genetically engineered tomato, the "Flavr Savr", in the fields of Mexico and Chile in 1990 and 1991 respectively.

Ciba-Geigy conducted their field trials of transgenic insect-resistant corn in 1991 in Argentina.

Greenpeace International has also documented illegal releases of genetically engineered microorganisms (GEMs) in Argentina (a vaccina-rabies virus in 1986); Kenya (3 illegal cases since 1989, one involving ornamental plants from Argentina); India (80 different genetically engineered spe-

cies of microbes imported from Japan and released into field crops); and Ireland (trials with a genetically engineered vaccine for use in fish were undertaken without the European Commission being notified – a clear violation of the EU directive on deliberate releases of GMOs).

● **Conclusion:** In short, the reasons advanced against the need for a binding protocol are, with respect, specious. The binding Directives of the European Community in respect of contained use and application, as well as releases of GMOs are a clear precedent that binding documents on biosafety, are both possible and desirable.

Moreover, the UNEP Expert Panel 4, set up under the CBD to consider the need for and modalities of a protocol, concluded on the need for a **binding** protocol, stating as its reasons, the following :

(1) Developing countries could be protected from being experimental grounds for the constantly occurring new developments in the field of biotechnology.

(2) Existing legislation in industrialised countries underscored the need for similar legislation in developing countries. International cooperation could be governed by a protocol. This would facilitate cooperation and avoid unilateral decisions.

(3) A protocol would have the advantage of harmonizing existing legislation in the area of biosafety as well as facilitate the adoption of unified legislation for those countries without legislation. A protocol would also provide for legal redress in appropriate cases.

(4) A codification of a binding instrument would emphasize the importance of biosafety.

(5) Having national legislation in developing countries without capacity for oversight would merely encourage experimentation in these countries.

(6) A legally binding instrument would compel importers and exporters to recognize their responsibilities in relation to protecting the earth's biodiversity.

(7) Ethical reasons require parties to take responsibility for their actions.

(8) A protocol could encourage coordinated international research on certain neglected areas, such as the transfer of genetically modified organisms, field-tested in temperate zones, to tropical ecosystems. This is particularly important because of the inadequacy of existing scientific knowledge.

(9) A harmonized system in all countries would help the industry by clarifying and standardizing requirements.

(10) A protocol is essential to protect the environment and address environmental concerns. The Panel noted that countries arguing that there is no risk in transfers have themselves had legally binding rules on biosafety for a long time.

(11) A protocol could pave the way for safe technology transfers especially since the public is wary of the risks associated with this technology.

(12) Because of the known ability of organisms to cross

national boundaries, harmonization of national regulations through a protocol would protect against such transboundary damage.

(13) Implementation of the precautionary principle could best be done through a binding protocol. This would assist in preventing damage to biodiversity.

2.2. *Genetic engineering a traditional breeding continuum?*

Another fundamental assumption made in these Codes is that "the products of biotechnology can be considered to be part of the traditional breeding continuum." Thus is gene biotechnology equated with the more conventional biotechnology: like the use of bacteria and yeast in food and wine making. Or it is linked to ancient farming practices and ancient breeding techniques. This implies a harmless and benign technology which can serve the needs of mankind. The revolutionary nature of this new technology of genetic engineering is masked from view. As discussed earlier, this belies the discontinuity between traditional biotechnologies and recombinant DNA technology. rDNA technology allows for the disarranging and recombining of gene fragments of unrelated species at will to design new organisms for utilitarian ends. It enables gene transfer between species which would either not occur in nature or have an extremely low probability of ever occurring.

The effect of this assumption is that the dangers of an entirely new order posed by this new technology are discounted in these regulatory mechanisms by the "continuum" idiom. Agenda 21 of the UN Conference on the Environment and Development, in particular Chapter 16, is in the same vein.

It is noteworthy that no scientific data nor experimental tests support this traditional breeding continuum. This view that no greater risk is posed by products of modern biotechnologies compared to those arising from traditional ones was also explicitly rejected by the EU and G77 and China during the UNCED process, as well as subsequently in preparatory meetings leading to the first meeting of the Conference of Parties to the CBD, as well as in the CSD meetings.

2.3. *Genetic engineering: will it certainly result in improvements?*

Another assumption underlying these voluntary instruments is that the development of GMOs through biotechnology will result in improvements to the genetically modified plant or other organism and that this would assuredly serve the needs of mankind beneficially. This, of course, is not universally accepted. As the debate on biosafety at various international fora make abundantly patent, there is genuine concern – well founded as the earlier discussion shows – that genetic engineering has risks and perils. In agriculture, for example, it could well pave the way for the dismantling of sustainable traditional agriculture, particularly of the South.

2.4. *Range of risks*

These voluntary instruments also exclude from their regulatory purview economic and social consequences, as part of the risk assessment. This is done on the ground that economic consequences are not the result of the nature of the technology employed in genetic engineering. This contention is unacceptable. For it is precisely the ability of this new technology to cut specific genes

from living things and paste and replicate them in other living forms, including cross-species, that creates the kind of catastrophic consequences on the economies and societies, especially of the developing world.

The production of fructose through biotechnology, for example, has displaced agricultural sugar in the world market. The drop in the world market price of sugar has resulted in serious dislocations, especially in the Third World. Cane sugar is increasingly being displaced by sugar substitutes produced through a form of biotechnology, namely, immobilized enzyme technology. As a result many conventional sugar factories have closed and tens of thousands of workers displaced. As Nicanor Perlas notes, "When food production starts taking place in factories instead of farms, massive unemployment will result."

Countries which, because of colonization and then the World Bank's structural adjustment programmes, are dependent almost entirely on single crops for their export earnings, would suffer from the successful production of bioengineered substitutes now underway. Large-scale dislocations of an entire country's economy can be predicted.

Even in the developed North, the consequences of biotechnologically engineered products can be serious. The natural bovine growth hormone, BST, a protein hormone that cows produce in sufficient quantities, controls milk production in adult cows. Now genetically engineered BST has been produced by genetically engineered bacteria. One estimate shows that if BST is introduced, it would result in surplus production of milk, driving 10% more dairy farmers out of business.

There are also wider concerns as, through patent ownership rights of genetically engineered products, ultimate control of the world's

food security could well vest in the hands of fewer and fewer corporations whose concern for profits has never been displaced by concern for the common good; and whose accountability is not to nations but to stockholders. The financial investment for the research into genetic engineering is done predominantly by private corporations. Eighty per cent of the total investment in agricultural biotechnology in 1987 in the US was in the hands of private enterprise. The top six companies in terms of Research and Development expenditure in 1989 were chemical companies. Field trials of genetically engineered crops were also controlled by transnationals. A survey in 28 countries between 1986 and 1991 showed that 75% were carried out by large private companies. Again chemical companies dominated the scene.

Patent ownership, by which import monopolies and local production in developing countries are secured, shows that of the 3.5 million patents existing in the 1970s, developing countries were granted a meagre 200,000. Of these, 84% were owned by foreigners. Only less than 5% of the foreign-owned patents were in production in the South.

Now patents are being claimed for an entire species of crop plant which has been genetically engineered. This has happened to cotton and soya bean. A single patent taken out by an American company, Agracetus, gives it rights over all forms of genetically engineered cotton – even those not yet invented. This means that the most critical of mankind's concern, food security – could well come increasingly in the control of multinationals.

Finally, the indigenous knowledge of Third World communities and farmers is beginning to be usurped and genetically engineered and then patent claims made in respect of the product – plant varieties and seeds. This undermines the social and economic fabric of Third World societies and peoples, and results in the

destruction in the long run of their practices which have been acknowledged to be protective of sustainable development and biodiversity.

2.5. *Precautionary principle versus the familiarity principle*

The precautionary principle would prevent the release, testing or moving across boundaries of GMOs unless there is clear evidence ruling out its hazardous propensity. The familiarity principle is based on the notion that, over time, the characteristics of a GMO become known and that there is either no need to have a safety regulatory scheme in respect of it, or that any safety procedures can be minimized as a result. The familiarity principle will declare as safe the GMO based on its function or resource use.

But, as discussed earlier, the use of this principle of familiarity in different ecosystems is problematical, especially when that function or resource-use is not known, even in naturally occurring organisms. For organisms created by genetic engineering, the difficulty increases.

Organisms which exist in most ecosystems are not well documented. The organisms responsible for the majority of nutrient-cycling and energy flow processes within ecosystems, such as the bacteria, fungi, protozoa, nematodes or anthropods, are not known. Thus it is considered wholly inappropriate to rely on the familiarity principle to assess the risk posed by the impact of a GMO. Even the categories of ecosystems have not been defined, much less the function of existing species of organisms.

What is required then is a case-by-case approach. Ingham et al, cite as an example, a recent study which shows that an organism – the bacterium *Pseudomonas putida* – does not express its genetically

engineered function in low organic matter sandy soil. But that does not mean that the same information can be extrapolated to a related species – *Pseudomonas fluorescens* – in the same conditions. Nor can the fact that *Pseudomonas putida* does not express its function in low organic matter soil mean that it will not express its function in high organic matter soil. The authors state that: "If the niche requirements for both these species of bacteria were known, then extrapolation of when the engineered function would be expressed could be made. But that kind of information is not available, and thus use of the principle of familiarity in environmental situations is dangerous. Our knowledge base is too limited." The authors conclude by stating that the more conservative method of assuming potential hazard until no hazard is found seems a wiser course of action than allowing releases which may result in ecological disaster. In other words, the familiarity principle must give way to the precautionary principle if unknown, unmeasurable and potentially uncontrollable hazardous consequences are to be avoided.

The Technical Guidelines suggest a case-by-case basis for assessment "...until sufficient knowledge and experience of such organisms have been acquired" (para 19). But this leaves unanswered several critical concerns. What constitutes "sufficient knowledge and experience"? Who decides when this threshold is reached?

2.6. Contained use

It is now clear, as earlier discussed (Part IV, para 3), that GMOs can and do survive and spread from containment. Genetically "crippled" organisms can survive or transfer their transgenes to indigenous organisms even if contained by highly sophisticated methods.

Earlier regulations assumed that such "crippled" organisms could not survive. The UNIDO Code, for example, fails to address the issue of contained use operations. It focuses exclusively on deliberate releases of organisms and ignores unintended releases from contained conditions.

PART VI

THE ESSENTIAL ELEMENTS AND MODALITIES OF A BIOSAFETY PROTOCOL

1. INTRODUCTION

Because of the inherent unpredictability of the engineered organism, its impact on the organism itself, the environment and other life forms, there should be no use or release unless authorized. The authorization must be preceded by the most complete and thorough examination by a panel consisting of the widest possible interdisciplinary professionals. The widest possible range of impacts, and at various levels – from contained use, defined in the widest possible manner, to field releases – must be assessed: health, environment, socio-economic, and the ethical. Certain fluid genome processes must be included as well for assessment. The assessment of impacts must also be in relation to intact and whole environments outside where the tests were initially conducted. The effect on biodiversity centres must also be examined. As biological containment cannot be assured, as earlier noted, there should be comprehensive testing, and equally importantly, monitoring procedures for a sufficient duration. Long observation periods in isolated but field-realistic conditions are made necessary by the long-term nature of the response times in ecosystems.

Where there is no complete evidence of safety, then no approval for release must be given. The onus is always on the introducer of the genetically engineered organism to show that it is safe for

release. There should be a complete ban on the export of domestically prohibited products, processes and any industry or plant incorporating these products and processes. There must also be a ban of the said products and processes if they are safe in the exporting country but unsafe in the environment of the importing country. The most complete public participation must inform the whole approval process, which must be transparent.

2. THE ELEMENTS AND MODALITIES

2.1. Compulsory prior certification or approval

An important element to be included in a possible biosafety protocol would be a certification process, authorizing the activity in relation to the GMO, by an interdisciplinary group of professionals. This is critical, as risk assessment and management, to be effective, especially with regard to GMOs with their uncharted and difficult predictive ecology, must involve a process of giving a safety clearance prior to use or release.

UNIDO's Voluntary Code, in recommending national regulations, suggests that a researcher/proposer obtain approval from the responsible national authority or authorities prior to the conduct of an activity involving the release of a GMO. However it also allows for prior notification, in lieu of prior approval.

The Technical Guidelines state that regulatory mechanisms may include prior notification. But it goes on to state that this notification "may or may not require a positive decision from the authority before the notified use can proceed" (para 31).

Clearly, both these instruments are unsatisfactory as they do not

define with clarity the situations when approval is necessary and when mere notification suffices. This suggests the use/release of GMOs which are potentially hazardous after mere prior notification to the authorities.

The Code also emphasizes the need for the risk assessment to be made by "high level, multidisciplinary scientific competence" which would often require expertise from outside the country. In sharp contrast, the UNEP Guidelines suggest that risk assessment by a multidisciplinary body of scientific experts is merely one option for the authority to adopt. Contemplated by the Guidelines is a review of risk assessment by a non-scientific non-multidisciplinary body, such as the authority itself. This is at odds with the Guidelines' own assertion that risk assessment requires a range of expertise. In its Annex 2, the Guidelines set out a whole range of different fields of expertise needed for a scientifically sound assessment. The fields include: ecology, population genetics, taxonomy, molecular genetics, agronomy, virology, microbiology, marine biology, pathology, veterinary, laboratory applications and industrial processes.

An international protocol should consider the setting up of an international body of independent experts drawn from the various disciplines. This body should assess the risk and authorize or deny the approval of the GMO or any activity in relation to it.

2.2. *Risk assessment: Criteria to include*

The protocol should recognize that regulatory oversight and risk assessment should focus on the characteristic of the GMO rather than on the molecular or cellular techniques used to produce it. For it is to the GMO or its product that humans, animals and the environment are exposed.

Further, a protocol should also recognize that the key aspects of risk assessment should include the biological and reproductive properties of the parental organism, the characteristics imparted by the genetic modification, including secondary, unintended modifications in physiology and biochemistry of the organism due to gene transfer, and the relevant attributes of the site where the organism is to be used.

These two beneficial elements are addressed by the Code in its paragraphs 1 and 7 respectively as well as the Guidelines in its Annex 2.

The up-to-date knowledge of the new genetics identified in Part IV.2 of this report, should also be considered in assessments for the reasons therein set out.

A protocol should also provide that risk assessment in respect of contained use should be in conditions of real containment, that is, closed laboratories, inactivation of waste water, sludge, used air, etc. These should be specified in great detail. The containment procedures should reflect the level of risk posed. The higher the risk, the more sophisticated and stringent should be the minimum safety requirements. This is critical as the studies, cited earlier, show the resilience of laboratory GMO strains, demonstrating as wholly incorrect the earlier assumptions that GMOs do not survive and spread from containment [See above Part III.3.].

Releases of GMOs should also not be permitted by a protocol unless they have been tested in different soil types and under different water conditions (lakes, rivers, drinking water, waste water, etc.), in the region or country of release. Testing should also have been done in real conditions, with growing plants and living soil organisms, be it terrestrial or aquatic ecosystems.

The need for the widest testing under all conditions is demonstrated by the example given earlier of the apparently harmless change made in a microbe in order to help turn crop wastes into ethanol. The then-prevailing methods of evaluating the bioengineered product later proved wholly inadequate. If experts able to assess all the organisms in the soil had not conducted the testing, the dangers posed would have gone undetected. The researchers, Dr. Elaine Ingham, Associate Professor of Botany and Plant Pathology, and then doctoral student Michael Holmes, were funded by a two-year grant. They used ordinary soils, wheat plants and sophisticated systems such as epi-fluorescent microscopy, gas chromatographs and analytical chemistry . They found that the beneficial fungi growing around plant roots were detrimentally affected by the presence of the genetically engineered microbe. If the microbe had been applied to a field, it could have spread widely, quite possibly wiping out entire agricultural crops.

The Guidelines address some of these concerns in their annexes 4 and 5. However soil organisms are not clearly delineated for assessment of effects on the processes they carry out. It is insufficient to state that the potential receiving environment is a "key parameter" (p.5, section 22[iii]), because in every application of biotechnology, soil and soil organisms will be affected. Soil organisms are critical to plant growth. Elaine Ingham et al, state that the Guidelines do not establish a clear protocol for assessing risk, and that the risk posed by the genetically engineered bacterium *Klebsiella planticola* would not be assessed by these Guidelines.

The Guidelines also offer no definition of risk nor even a mechanism for defining risk. The value for an unacceptable or acceptable risk is not specified. Much is left unexplained: When does an acceptable risk become unacceptable? Who decides? Using what

criteria? Further, the Guidelines do not specify assessment procedures for harm to human health and the environment.

The UNIDO Code also suffers from this lack of specificity. It states, for example, that researchers/developers must evaluate potential risks of the organism. But, the Code does not state what exactly is to be measured and who determines how risks will be assessed.

It is therefore crucial for a biosafety protocol to specify the quantitative values or ranges of values, or limits to the meaning of risk.

2.3. *The precautionary approach principle*

An important element to include in a biosafety protocol would be the precautionary principle. Examples have been cited in this Report of the recent studies which highlight the dangers of proceeding to approve products without firm evidence of its safety and impact on the environment. Indeed the Biodiversity Convention obliges parties to pay heed to the principle. The preamble to the Convention states that the lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize a threat of significant reduction or loss of biological diversity.

This precautionary approach is not novel and has been accepted, for example, by the United Kingdom in its Environmental Protection Act, Part VI of which deals with the regulation of potential hazards arising from the release of genetically engineered organisms. The Germans apply this principle to pollution control. The object is to safeguard against potential risks which are not, or not yet, identifiable because of the current state of knowledge. This is of particular application to GMOs as it involves technology which is evolving and whose dangers are as yet unclear.

2.4. *Case-by-case and step-by-step evaluation*

The risk evaluation should be on a case-by-case basis, and as well, separate for different situations and countries. It has been said, for example, that the results of a small field plot test to gather data for use in analyzing the risks of commercial releases cannot be the basis for concluding that because nothing happened, the GMO will be safe when commercialized or that all GMOs of that kind are safe. This is simply not scientific (Regal, 1994). The Ecological Society of America states that a case-by-case and stepwise review is currently the most scientifically sound regulatory approach because of the diversity of products that can be developed and the complexity of predicting their ecological fate. (1989)

The UNIDO Code states as well that case-by-case evaluation should be the rule but it qualifies this by stating that this may be departed from if there is sufficient experience and an adequate body of knowledge to allow for classifications and generalizations based on experience and conclusions regarding the behaviour of GMOs. This leaves undefined what this "sufficient experience" and "adequate knowledge" is and who is to determine this.

To similar effect is the Guidelines' statement that "... the risks associated with the use of those organisms (produced by modern genetic modification techniques) should be assessed on a case-by-case basis and in a stepwise manner. Then, on the basis of gained knowledge and experience, novel organisms may be classified according to whether they have the potential to cause harm to human health and the environment..." (para 19). As noted earlier, this does not state how this harm is to be assessed.

The problems of a familiarity principle approach as against the precautionary principle approach (which incorporates the case-by-case basis of risk assessment) have been discussed earlier

and the dangers of the former prevailing over the latter, highlighted.

2.5. *Evaluation of risks to health, environment, the economy, social impacts as well as to the moral ethical values of society*

A biosafety protocol should evaluate all of these consequences. It is not in doubt that a biosafety protocol should include threats to the environment and human health. But should it include socio-economic implications? The Cairo panel decidedly eschews all reference to an assessment of these consequences as do the UNEP Guidelines.

Article 19(3) of the Convention states the need for a biosafety protocol in respect of GMOs "...resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity". It is this conservation and sustainable use of biological diversity, especially in the case of domesticated plants and animals, which is dependent on the socio-economic conditions of the people who have been maintaining it. Any threat to their socio-economic well-being through the introduction of technologies of genetic engineering is therefore properly the concern of a biosafety protocol, especially in the context of the CBD. For this reason, and as is also stated by the Expert Panel IV Report, it is essential that the socio-economic risks posed by the use of GMOs be evaluated and that any probable adverse effects be mitigated.

What are these risks? These are set out by the said UNEP Expert Panel IV Report and include, among others, the replacing of traditional imports by producing them at home through the use of GMOs. This would affect the traditional exporters adversely and,

more importantly, cause the discontinuation of agricultural systems and a resulting genetic erosion.

The UNEP Guidelines talk of a risk/benefit analysis to determine whether an intended application should proceed (para 25). Such an analysis should take into account an evaluation of socio-economic implications as well. When the use of a GMO is not clearly seen to offer an advantage, in terms of the potential dangers it poses to the environment, human health, as well as to the social and economic construct of societies and communities, it should be discontinued so that traditional technologies and systems continue.

2.6. *Consideration of the need for the GMO*

As such, the panel of experts should do a needs test. This would entail a consideration of the efficacy of sustainable alternatives to the introduction of GMOs as well as safer alternative technologies. Where these exist, then a risk/benefit analysis would result in opting in favour of the more sustainable and safer alternatives.

2.7. *Public participation*

Another key element in a protocol is public participation in the approval process. This is consistent with Agenda 21. Its Chapter 16, paragraph 16.30 says that there should be the "widest possible public participation" to ensure safety in biotechnology development. The UNEP Guidelines refer to Agenda 21 to encourage public participation (para. 35). The UNIDO Code states that the national authority should ensure that the local community is informed prior to release. It also requires public access to infor-

mation on which decisions regarding the use or release of organisms are taken.

In a proposed protocol, the element of public participation would be preserved by making available to the public the results of any testing or monitoring done as part of the approval process; the public should be informed of any proposed release of GMOs, including the location and extent of the release, well in advance. The protocol should state that the public are to be given ample opportunity to give their views on the information provided to them before any approval is given for the use or release of the GMO.

2.8. Labelling

A protocol would make it mandatory for food products incorporating GMOs to state this fact on their labels, including a warning of any special hazards it may bring to any category of persons. This would include, for example, a warning as to the possible adverse reaction of the product to sensitive conditions, such as allergies, in individuals.

2.9. Modalities for the transfer/export of GMOs

Several modalities may be considered for inclusion in a protocol for the transfer or export of GMOs. These include the following:

(a) prior informed consent by the importing country;

(b) compliance with the importing country's laws as a precondition for export;

(c) requirement of notification to the exporting country's authorities who in turn then inform the importing country;

(d) total ban of exports if the products/activity in relation to the GMO are prohibited in the exporting country.

The following is an elaboration of these proposed modalities:

Advance Informed Agreement/ Prior Informed Consent

The principle of prior informed consent (PIC) requires that any export of the product that is banned or severely restricted should not proceed without the agreement (where such agreement exists), or contrary to the decision, of the importing country. It obligates the exporting state to ensure that the importing state is notified of any transboundary movement of the GMOs. The state of import then either consents or denies permission for the movement. To facilitate the importing state in making a decision, the exporting state, or the actual exporter, must furnish to the importing state, complete information of the assessment of the GMO or product or activity involving the GMO. This must necessarily include the full disclosure of any negative comments as well as information known to the introducer and which bears on questions of safety or risk assessment.

This principle is set out in Article 19(3) of the Convention as one of the modalities which the Parties to the Convention should consider for a biosafety protocol. It is referred to as an advance informed agreement (AIA).

The UNEP Guidelines set out a range of mechanisms from supply of information from one user to another, to "prior informed agreement" for certain cases. (paragraphs 39 – 44)

The UNIDO Code requires the researcher / proposer to disclose all relevant information to the responsible national authority. This is to include details of specific approvals and refusals of all trials and applications, including those in other countries, granted or denied.

The Expert Panel IV Report suggested the PIC procedure as applied in the international trade with chemicals and pesticides as a model for the transfer of GMOs. It recommended that the procedure be applied not only to GMOs which are to be released but also to GMOs which are transferred for the purpose of industrial scale operations. Amongst the elements suggested by the Panel as constituting this advance information agreement, is an obligation on the part of the competent authority of exporting countries to adopt measures to ensure that any legal person under its jurisdiction who intends to transfer a specific GMO for the first time, makes an application providing the importing country with all the relevant information. Copies of the application is then sent to the exporting country and to a clearing house, whose function it is to provide advice to the Contracting Parties and to serve as an international body for overseeing the AIA procedure. The exporting state and the clearing house will assist the importing state in making the decision.

Further, importing states must ensure any governmental measures or actions taken with regard to an imported GMO, for which information has been received, are not more restrictive than those applied to the same GMO produced for domestic use or imported from another country than the one that supplied the information. This would prevent any accusation that the exclusion of a GMO product from a particular country is a non-tariff barrier employed for a trade advantage.

The PIC option also implies that in the case of the export of a GMO:

- the importing state must not only give its consent but must also confirm that the importer has a permit to work with the imported GMO.

- as in the case of the European Community, the Community requires the importing state to give information on the safety standards required by the importing state. If these standards are not in accordance with the Community's regulations, the Community may refuse an export licence or make compliance with these standards a prerequisite for the licence.

- an export permit is given only if the importing state is capable of assessing or managing the risks associated with the GMO or any product incorporating the GMO. Thus, for example, no hazardous GMOs requiring containment measures as prescribed by the EEC's Directive 90/219/EEC for Group 3 were allowed to be exported to a country which lacks the appropriate laboratories and containment facilities.

No Export of Banned Products

As for the Basel Convention, the PIC procedure has no application to products which are prohibited.

An export ban may be considered for extremely hazardous GMOs, for those products which are banned by the laws of the exporting country as well as those prohibited by the laws of the importing country.

In the light of the earlier discussion positing the dangers of GMOs and the difficulty of predicting the potential hazards of GMOs, it

is difficult to ascertain which are, and which are not, hazardous products.

Further, having merely a PIC procedure to regulate the export of GMOs may not be entirely suitable in cases where the importing country has neither the regulatory mechanism nor the technical capacity to assess the potential dangers posed by GMOs.

In such situations, there should be a blanket prohibition against a country exporting GMOs which are prohibited in the exporting state. The importance of such a provision instead of the PIC procedure may be highlighted by reference to the experience with regard to the export of toxic wastes.

In 1989, 65 countries signed the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes. The Convention forbade a country to export wastes to another country unless there was prior informed consent. This did not staunch the flow of wastes to Third World countries. All kinds of methods were devised to circumvent the Convention. Toxic wastes were described as scrap materials for "recycling" and a thriving trade in these materials continued unabated.

Finally, in response, the Governments of the South successfully led a move in March 1994 to secure a passing of a decision under the Basel Convention to convert the "prior informed consent" principle to an outright ban on the transfer of hazardous wastes from the 25 rich OECD countries to the non-OECD countries. The ban is to take effect immediately for wastes intended for disposal and will take effect at the end of 1997 for wastes intended for recycling.

Prior to this was the resolution of the Organization of African

Unity adopted in Bamako, Mali, in January 1991. It asked all its members to prohibit the import of all hazardous wastes into Africa for any reason from non-contracting parties. It resolved that such import be deemed illegal and a criminal act. It extended this ban to the dumping of such wastes in their territorial seas as well as internal waters. An obligation was also imposed on the contracting parties to prevent the export of such wastes to states which have prohibited all such imports or which it believes will not be managed in an environmentally sound manner, according to criteria to be decided on by the contracting parties.

This principle ensures that there be no double standards practised. Exports should not be exempted from restrictions or outright bans when domestically they are so banned or restricted. This principle of non-discrimination has been emphasized by the European Parliament several times. Thus the European Commission's proposal on Novel Foods and Novel Food Ingredients was amended. By this, novel foods containing or consisting of GMOs shall only be allowed to be exported if they have been cleared for the placing on the market of the Community. [COM(92) 295 final - SYN 426]

A Gloss: Common Standards not Always Applicable

There must be a further qualification to the application of this principle. As earlier noted, a genetically modified organism or plant may be perfectly safe in the exporting country but yet be hazardous when introduced to an entirely different environment in the importing country. This means that a common standard cannot always be applied in respect of GMOs. There has therefore to be included in the Protocol, an obligation on the part of the exporting country to take into account the different environmental conditions of the importing state. This would require something in the nature of an environmental impact assessment conducted over a period of time which is considered appropriate to ascertain

the safety of the GMO. The assessment, as earlier mentioned, should be comprehensive and should address the effects and interactions of GMOs of, and with, other species, including micro-organisms. Prior to the release of the GMO into the environment, the approval from the panel of experts, as earlier described, will necessarily have to be sought.

Ban to Extend to Shifting of Industries

As bans and regulations delay the manufacture and marketing of biotechnology products, wholesale shifting of industries with an eye to the markets of the Third World, is very likely to happen. Again the past conduct of corporations of the industrialised countries is instructive, as discussed earlier. Industries causing serious environmental and health impacts were relocated in the South in response to growing regulation and greater environmental consciousness and lobbying in the West. Thus, as regulations tightened, asbestos factories were relocated from Canada, Europe and Japan, to Mexico, Brazil and Taiwan. The manufacture of benzidine dyes (known to cause cancer of the bladder to workers), has ceased in several countries including Sweden, Italy, England, Japan and Switzerland. The dyes now come from factories located in Romania, Poland, India and South Korea.

Kawasaki Steel relocated its "dirty" sintering plant, which converts iron ore dust to iron pellets in a process which produces disastrous pollutants, to the Philippines. This was prompted by active opposition from the populace of Chiba City in Japan where Kawasaki had earlier planned to locate the plant.

It is these same global multinational players who are beginning to dominate the biotechnology genetic engineering industry. For example, chemical multinationals dominate the scene involving the release to the environment of genetically engineered crops -

such as Monsanto, Du Pont, Sandoz, Ciba-Geigy, Hoechst-Roussel, ICI, and American Cynamid. Why would these or other TNCs behave any differently?

For these reasons then, a protocol should extend the ban to industries involved in the production of GMOs or involved in potentially hazardous experiments, releases or research as adjudged by their impact on their own environment as well as on the environment to which the industry is sought to be shifted to.

There is also a need to provide in a protocol of modalities to control and monitor the transport of biohazardous materials, including by international air, sea and road carriers as well as by international and domestic postal services. An investigation by Greenpeace International in 1994 demonstrated quite unequivocally that GMOs could be mailed freely around the world with slim prospects of being controlled, inspected or even, apparently, noticed.

2.10. An international monitoring mechanism

To prevent the thwarting of export control regulations in respect of the transfer of GMOs, it would be necessary to institute an independent international monitoring body. To maintain transparency, there should be maintained by this body a register of all GMO transfers. This register should be accessible to the public.

2.11. Strict liability

The Protocol should also impose strict liability for any damage or loss resulting from any activity in relation to, or product of, a GMO. This means that liability is incurred upon proof of damage or loss without more. This kind of liability is commonly imposed

in respect of hazardous activities or products. Despite the intervention of any authority in giving approvals and permits, the primary responsibility for any consequence in relation to a GMO should remain with the introducer of the GMO. Liability should extend to cover damage to ecosystems as well.

2.12. Penal consequences

A protocol should also consider categorising as criminal certain conduct which results in irreparable or serious damage to human health, the environment and the ecosystem and provide for nation states to take action for such conduct within their jurisdiction. Conduct which could qualify for the imposition of criminal penal consequences should include the wilful or reckless failure to supply information bearing on the risk assessment of a GMO and the export or transportation of hazardous GMOs in flagrant disregard of prohibitions. Custodial penalties should be imposable on owners and/or managers of corporations who expressly or impliedly allowed or condoned such conduct.

In the 1994 UK approval for test releases of a virus constructed with scorpion venom as pest control against the cabbage white butterfly (and as set out earlier in Part III.4 of this paper), many culpable errors were subsequently discovered. The scientist concerned failed to inform the UK Advisory Committee on Releases to the Environment (ACRE),

- on the host range of the virus, which included many other species of butterflies, some of which were protected;

- of the fact then known, that the virus escaped beyond the trial area. Nor was any attempt made to track the escape.

2.13. Emergency plans

Comprehensive emergency measures and plans should be established to deal effectively with accidents prior to the introduction of any GMO or any activity in relation to a GMO. The introducer/user of the GMO shall bear the primary obligation of informing the authorities the moment any unanticipated or unexpected impact or accident occurs and he shall immediately provide to the appropriate authority all necessary information which can assist in the effective management of the occurrence.

3. A SUMMARY OF THE ESSENTIAL ELEMENTS AND MODALITIES OF A BIOSAFETY PROTOCOL

A proposed Biosafety Protocol should have the following elements and modalities as the very minimum basis for ensuring safety in dealing with GMOs, products incorporating GMOs and any activity in relation to GMOs:

(1) No activity of any kind in relation to a GMO is to be undertaken unless it has been given prior approval or certified as permissible.

This approval or certification process should be by an independent interdisciplinary body of experts drawn from at least the following disciplines : ecology (community and population, ecosystem, soil), molecular genetics, population genetics, taxonomy, agronomy, virology, microbiology, marine biology, micribial physiology, pathology, atmospheric physics, veterinary, laboratory applications and industrial processes.

The task of this body would be to carry out a thorough risk

assessment of the GMO in accordance with the elements and modalities described in this section.

(2) Risk assessment : Criteria to include

(a) The focus of the assessment should be on the characteristics of the GMO;

(b) This assessment should include :

- the biological and reproductive properties of the parental organism;

- the characteristics imparted by the genetic modification; and,

- the relevant attributes of the site where the organism is to be used.

(c) The fluid genome processes should also be assessed. The processes proposed for assessment are set out in Part IV, para 2.1 of this Report.

(d) For contained use, the risk assessment should be in conditions of real containment, such as, closed laboratories, inactivation of waste water, sludge, used air, etc.

(e) For releases of GMOs, testing should be in real conditions, with growing plants and living soil organisms, whether terrestrial or aquatic ecosystems; in different soil types and under different water conditions (lakes, rivers, drinking water, waste water, etc).

There must be a full assessment of ecological consequences.

(f) Soil organisms must be clearly delineated for assessment of effects on the processes they carry out.

(g) There must be specified the quantitative values, or ranges, or limits to the meaning of risk.

(3) There should be adherence to the Precautionary Principle: that is, no approval of releases of GMOs or GMO products unless there is firm and complete evidence of its safety and lack of risk.

(4) Risk evaluation should be on a case-by-case basis, and as well, separate for different situations and countries.

(5) Risk assessment should involve monitoring procedures for sufficient duration. There should be long observation periods in isolated but field realistic conditions.

(6) There must be an evaluation of risks to health and the environment, and implications to the social, economic and ethical concerns of countries must also be evaluated.

(7) There must be a cost and benefit assessment of the need for the introduction of the GMO. In particular, there must be a consideration of the efficacy of sustainable alternatives to the introduction of the GMO as well as safer alternative technologies.

(8) The public should be given ready access to the monitoring or testing done as part of the approval process; be informed well in advance of any proposed release, including all details of the release (location, extent); be given an adequate and real opportunity to give their views on the information provided to them.

(9) Food products incorporating GMOs must state this fact on

their labels, including a warning of any adverse reaction to any category of persons.

(10) There should be a total ban of the export of GMOs, products incorporating them and any activity in relation to them if:

- these are banned in the exporting country;
- these are banned by the laws of the importing country;
- although safe in the exporting country, these would be hazardous if introduced to the environment of the importing country.

This ban applies as well to industries making, processing, testing or dealing in any other way with the prohibited GMO.

(11) In all other cases, there should be strict adherence to the principle of Prior Informed Consent (PIC): that is, there should be no export of the GMO without the prior agreement, or contrary to the decision, of the importing country.

For this purpose, the exporting state, or the actual introducer, should furnish all relevant material and information which will have a bearing on risk assessment.

(12) Any wilful or reckless failure to supply such information shall result in criminal penal sanctions against the introducer by the country to which the GMO is introduced. Such sanctions shall include custodial sentences for owners and/or managers/operators of corporations, provided culpability is proven.

(13) There should be strict liability for any damage or loss result-

ing from any GMO, a product incorporating it or any activity in relation to it.

(14) There should be an international monitoring mechanism for the transfer of GMOs.

(15) Comprehensive emergency measures and plans should be established to deal effectively with accidents prior to the introduction of any GMO or any activity in relation to a GMO.

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ANNEX I

NOTE AND CRITIQUE OF THE UK-DUTCH/ UNEP TECHNICAL GUIDELINES

The Technical Guidelines of the UK and the Dutch Departments of Environment are described as "a contribution to the implementation of Agenda 21 commitments and to provide a technical instrument to assist Governments without prejudice to the subsequent development of legal instruments on safety in biotechnology". However the timing of its release and the support shown it by certain governments averse to the institution of a binding international biosafety protocol, has caused disquiet over its acceptance.

It was first launched at the second meeting of the Intersessional Committee of the Convention on Biological Diversity in Nairobi in 1994. The first meeting had eschewed all reference to a biosafety protocol. At this second meeting, in the midst of overwhelming support by the Group of 77 and China, and the East European block as well as some Nordic countries for an immediate binding protocol, the Netherlands and the U.K. whipped out these voluntary Guidelines as an alternative to a binding protocol. The US and Japan then almost instantly threw in their support for it, whilst still arguing against the need for any protocol at all.

At the First Meeting of the Conference of Parties meeting of the Convention on Biological Diversity at the Bahamas in November 1994, this document was again floated and the drafters of this document convened several briefings for delegates.

Then UNEP, which is the secretariat for the Convention, confirmed at a roundtable at the Bahamas meeting, that it will "take up and further develop" these Guidelines. UNEP has since "adopted" these Guidelines as being their own and has convened several regional consultative

meetings to promote these Guidelines. This was done at a time when, under the auspices of the CBD, an expert panel was considering the need for and modalities for a biosafety protocol and an open-ended ad hoc group of experts met to discuss this question remitted to it by the first meeting of the Conference of Parties. In the light of the intense lobbying by the US and the European Union at the Bahamas meeting that the discussion on the "need" for a protocol be revived, this posture by UNEP was seen as ominous. The fear of many Southern delegates as well as most NGOs, that the Guidelines are designed to deflect work commencing on a binding protocol, seems real. Indeed by its commitment to developing these voluntary Guidelines, there was concern that UNEP could well be undermining the work of the open-ended ad hoc expert working group and pre-empting the decision of the Conference of the Parties to be made at its 2nd meeting in Jakarta in November 1995 on the need for a binding protocol and the modalities of such a protocol.

Fortunately, the conviction of an overwhelming number of Parties supported by independent scientists and concerned non-governmental organisations led to the decision to begin negotiations for a biosafety protocol in 1996.

ANNEX II

A CRITIQUE OF THE CAIRO EXPERT PANEL REPORT

The report is very disappointing. It does not deal with its mandate. It makes assumptions that are scientifically unsound, takes no cognizance of recent scientific findings regarding the known and potential hazards of the new biotechnologies and their products, and fails to consider critical literature in the field of genetic engineering and its ecological effects. Emphasis is put on the panel playing "an educative role and infusing balance into the discussion among non-specialists" (para. 25). Unfortunately, the result is one of further imbalance. The increasing scientifically-founded concerns voiced by public organisations and many scientists seem to be regarded as "discussion among non-specialists".

1. FAILURE TO COMPLY WITH ITS PRECISE MANDATE

The Mandate

COP 1 decided that, "in order to prepare for the work of the open-ended ad hoc group of experts nominated by Governments, the Secretariat shall establish a panel of 15 experts nominated by Governments, with an equitable geographical representation, in consultation with the Bureau of the COP, assisted by UNIDO, UNEP, FAO, and WHO, to prepare a background document to be submitted to the open-ended ad hoc group of experts nominated by Governments based on a consideration, as appropriate, of existing knowledge and experience on risk assessment and management, and guidelines and/or legislation already prepared by the Parties, other Governments and by national and competent subregional, regional, and international organizations." (UNEP/CBD/COP/1/CW/1.11)

However, instead of preparing a comprehensive background document, the Panel did not even summarize existing knowledge, experience, and legislation. Instead, the Panel mainly expressed its own views, and finally gave recommendations, many of which were clearly outside the scope of the original mandate.

The panel called for a "framework" which could include legislation, guidelines, and voluntary codes of conduct. It cited Agenda 21 as the basis for its recommendation (para. 31, 79, 80), and referred specifically to guidelines currently being developed by UNEP and the FAO.

While numerous references are made to Chapter 16 of Agenda 21 and various guidelines, there is surprisingly no reference to the 1993 report of the UNEP Experts Panel IV on the need for and modalities of a biosafety protocol. Panel IV had examined the arguments for and against a legally binding international protocol, as well as set out possible modalities for international action. A logical step would have been to build on the work of that panel which had been set up specifically to address the provisions of Article 19 of the Convention on Biological Diversity. That earlier UNEP report falls directly within the terms of reference of the panel, and would have been a valuable contribution to the panel's work in Cairo.

In its conclusions the Cairo panel observes that

(a) Ecological effects and geographic ranges of GMOs transcend political boundaries;

(b) The potential risks posed are often environment-dependent and ecosystems and living organisms vary geographically and climatically. As a result, an organism that is safe in one country is not necessarily safe in another country. The commercial import and export and the inadvertent dissemination of GMOs and their genetic material across political boundaries may raise special concerns which require international cooperation and coordination; ..." (para. 81).

The panel acknowledged the importance of "a balanced perspective on biosafety based on factual and valid criteria" (para.24). It is therefore very disturbing to find not only an unbalanced perspective, but an avoidance of the primary responsibility under the terms of reference of the panel's work: the need for and modalities of a biosafety protocol.

2. OMISSION OF SOCIO-ECONOMIC IMPACTS, AS WELL AS IMPACT ON SOCIAL, CULTURAL, ETHICAL, AND RELIGIOUS VALUES

The panel "fully recognized the importance that the socio-economic effects of introducing ... new technologies can have" but dismissed them as "value judgements ... depending on considerations other than the nature of the technologies themselves" (para. 23). This is unfortunate. Their rejection, especially on the "value judgements" ground, is wholly unnecessary, if not embarrassing.

The construction and commercial production of a genetically engineered product that can substitute a natural product (sugar, rubber, vanilla and cotton are examples) would have direct adverse economic consequences for traditional producers/exporters of these commodities, most of which are developing countries. The loss of livelihood for the millions of workers or farmers involved in such production would create immense social disruptions, too.

Transgenic crops could displace or threaten traditional crops through ecological processes triggered by introducing such crops into the environment. The biological diversity of wild relatives and other species could be adversely affected. All these ecological impacts have a direct economic effect. Furthermore, the marketing of patented transgenic crops and accompanying agrochemicals (usually by the same transnational corporations) could prevent or undermine the use of farmers' varieties, especially in developing countries, and increase costs. These are certainly economic considerations that should logically be part of the assessment criteria.

In making choices for the most appropriate technologies, governments need to weigh the economic, social and environmental aspects of each

option. For example, sustainable agriculture is a declared objective of most countries. While the products of genetic engineering are promoted as one option, there are other options that do not require these new technologies and their products. The economic costs and potential of each option are dependent on the nature of the technologies themselves and are thus critical for decision-making, and cannot be dismissed as "value judgements".

The panel notes that under some legislation "risk management procedures may depend on comparisons of potential risks and benefits, including economic considerations" (para. 45). If economic considerations can figure in risk management, they should also be incorporated in risk assessment.

Moreover, if the biotechnology industry claims that their products will "feed the hungry" and cure diseases, they are allegedly pursuing social objectives, too. Accordingly, those claims need to be assessed.

With regards to public concerns based on social, cultural, ethical and religious values, the impact of genetic engineering includes unprecedented changes to nature, effects on human health and well-being, as well as laws that allow ownership of life forms. The nature of the industry also puts critical decisions on these fundamental issues in the hands of a small handful of corporations and regulators. Thus any assessment of the new biotechnologies must necessarily be truly broad-based. The panel itself acknowledges that "past experience emphasizes the need for public consultation and transparency" (para. 57), which we strongly support.

3. SCIENTIFIC FLAWS AND DISCREPANCIES OF THE REPORT

Following from our discussion of the experience and knowledge of the perils presented by genetic engineering, and the scientific requirements/ criteria for assessing genetically engineered organisms and their ecological effects (see Parts III and IV above), we are extremely concerned that the report of the experts panel contained some fundamental scientific flaws and discrepancies.

3.1. Failure to distinguish between recombinant DNA technology and traditional technologies

The report does not accept that there are greater risks attached to products from gene biotechnology based on the assertion that biotechnology does not differ from other technologies. It takes great pains to reiterate that "the risks arising from the development and use of GMOs resulting from biotechnology is [sic] not fundamentally different from that used [sic] in other technologies" (para. 63) and asserts this again in paras. 30 and 67. Still more seriously, it suggests in para. 68 that "as a result of the progressive development of an GMO, there would in many cases be sufficient information at the time of commercialization to allow the removal of any distinction between GMOs and organisms produced by traditional methods".

Experience informs us that many GMOs constructed by genetic engineering differ fundamentally from GMOs produced by traditional methods. It is the failure to acknowledge the basic distinction between the technologies that has resulted in field tests that are inadequately designed and inadequately monitored for environmental impact and safety. Hence the failure to capture the environmental effects in many cases.

Even where a transgenic crop or product has been approved for release, unforeseen effects can occur. For example, there has been worldwide release of glufosinat-resistant plants with the pat-gene (Hoechst AG, Germany is the patent-holder) for several years. To our knowledge, it was only recently that the Technical University of Munich discovered that the recombinant DNA inserted in maize plants is more stable to breakdown than the rest of the genomic DNA. This may increase the incidence for horizontal gene transfer several orders of magnitude, but until now there are no further experiments done to study and monitor the effects.

Increasing evidence informs us that genetically engineered organisms constructed for the laboratory and other contained use have higher survival abilities than previously assumed. Unexpected DNA persistence has also been found. The health and ecological effects of these genetic material are still unknown, and their existence is possible because of

genetic engineering. Traditional technologies would not have generated such organisms or material. (For a fuller discussion, see Part IV, above).

We are also concerned that by failing to make this basic distinction, the panel in paras. 75 and 76 seems to suggest that existing regulations (e.g. those dealing with non-transgenic plants and vaccines, environment, human health and pesticides) that are not biosafety-specific may be an acceptable option. The reverse is necessary: the unprecedented hazards and risks related to genetic engineering precisely require different assessment criteria and test procedures, starting from the truly contained stage to field trials, commercial scale and post-release monitoring.

3.2. A distortion of the precautionary principle - lack of ecological knowledge in risk assessment needs to be recognised

The safety of the product cannot be assumed to be finally determined at the end of the development phase, as suggested by the report (para. 68). As discussed above in section III of our report, field trials often do not come close to resembling actual environments, and the response time for novel organisms in the environment (on a commercial scale, too) is longer than that prescribed by existing standards. Thus observations of "no environmental effects" by many field tests in actual fact often mean that the tests were not designed in the first place to collect environmental data.

There are enough demonstrable ecological effects and new knowledge of the unpredictability of genetically engineered organisms to confirm that existing testing procedures and risk assessment methods are incomplete and inadequate. The recent findings of German scientists regarding glufosinat-resistant maize plants after the transgenic plant has already been in commercial use for several years in many countries call for urgent consideration of post-release assessment. Yet the panel concludes that existing "methodologies for risk assessment are well defined" (para. 63) and "are not fundamentally different from those in other technologies" [para. 82(a)].

The report also asserts that "Since the advent of recombinant DNA technology, many of the initial concerns and fears have been allayed as

experience and knowledge has accumulated" (para. 25). In reality there is no ground for this assumption, as little or no relevant knowledge has been gained through inadequate experimental design and monitoring in field trials (see Part III, above).

In para. 65 the panel "considered that the nature of hazards associated with GMOs produced by biotechnology can usually be well characterised, although this is less so in the area of aquatic systems and soil microbiology". We would like to stress that experience is showing that the same holds true for plants where the following may occur: cross-hybridization with wild relatives, virus-resistant plants giving rise to new viruses, horizontal gene transfer to soil microorganisms, transgenic plants having effects on animals that feed on the plants, allergenic effects when humans consume transgenic products.

The report calls for existing international documentation on risk assessment and risk management to be made available in more languages, but fails to inform the COP that much of the data is incomplete even in the field tests conducted in industrialised countries. The panel fails to address both the means and the ends of biosafety, except with regard to the development of gene biotechnology. Although para. 32 considers that adequate mechanisms for risk assessment and risk management can contribute significantly to safety in biotechnology, the report does not address what data should be used for risk assessment nor how they can be obtained, as such data do not yet exist, according to the most authoritative account. Thus, in the absence of relevant data (due to lack of ecological knowledge or lack of adequate design and monitoring of field trials), the precautionary principle should be invoked against potential hazards foreseen from sound scientific principles. The report acknowledges that existing documentation "often does not take into account of [sic] the full range of environmental and climatic conditions throughout the world" and "cannot, therefore, always constitute a comprehensive source of advice applicable to all countries" (para. 63). The panel also recognizes that "in some cases it can be difficult to estimate magnitudes and the likelihood of effects were the hazards to be realised" [paras. 65 and 82(a)]. However, it does not identify the scientific principles and criteria that should be applied (see Part IV above).

Instead the panel proceeds to be "firmly of the view that it was not necessary to apply risk management measures to all uses and releases of GMOs solely because the organisms were produced using modern biotechnological techniques, but that risk management should be applied in order to minimize any identified risks or to take account of uncertainties" (para. 67). It is precisely because enough risks have been identified, and unpredictability being the trait of genetic engineering, many more risks are still unknown, that comprehensive risk assessments have to be made. That is why the COP incorporated the precautionary principle into the Convention. The panel has turned this important principle on its head by advocating use of genetically engineered products in the face of uncertainty when it states that "uncertainties or lack of knowledge about any particular GMO does not mean that the GMO should not be used" (para. 67). This is dangerous and very disturbing indeed.

3.3. Advocating the principle of familiarity: inappropriate and dangerous

The report notes that familiarity with GMOs is a key feature in risk assessment, that acquisition of information will reduce the degree of uncertainty and thereby increase familiarity (para. 67), and refers to the principle of familiarity in Agenda 21 (para. 79). However, the scientific knowledge accumulated since the negotiation of the Convention and Agenda 21 (and existing knowledge which was not brought to the attention of negotiators at that time) point to the inappropriateness and danger of this principle.

As part of living material, genes can multiply, mutate, recombine and spread out of control. Different environments and climatic conditions, as well as different time-scales, affect genes differently. The products of recombinant DNA technology thus belong to a category in which it is impossible to quantify the risks. It follows that familiarity in the laboratory or field trials cannot be extrapolated to familiarity with the behaviour of an organism in the environment.

In para.41 the panel points out that "risk assessment of GMOs with the potential to adversely affect the conservation and sustainable use of

biological diversity might best be approached on a case-by-case basis" but in the footnote it is stated that "Case-by-case means that each proposal is reviewed individually. This does not imply that every case requires review by national or other authority since various classes of proposals may be excluded." However, no criteria are given for exclusion. Para. 41 also refers to the assessing of "category of organisms", a term that is not defined or explained.

We would like to reiterate that each engineered organism is a separate case, and a comprehensive case-by-case and step-by-step approach is a necessity. There can be no generic safety test, and even where testing in one ecosystem is adequate, it does not allow extrapolation of risk assessment to other dissimilar ecosystems. In addition, time-scale may also impact on the response of an organism in the same ecosystem. For a more detailed discussion on the inappropriateness of the principle of familiarity, please see Part IV(4) above.

3.4. Relaxation of rules not always scientifically-founded and justifiable

The report states that "Since the advent of recombinant DNA technology, many of the initial concerns and fears have been allayed as experience and knowledge has accumulated. Experience has led to the relaxation in the rigidity of operational guidelines where it has shown that this is appropriate" (para. 25). It is disturbing that the conclusion in the first statement seems to have been drawn without addressing the wealth of knowledge from the new genetics and experimental data that proves the exact opposite, i.e. there have been unpredicted effects and hazards which are beyond early expectations or even imagination, and more potential hazards are being identified.

The basis for the relaxation of existing guidelines is also not reviewed in the report. For example, at the beginning of the debate on risk assessment, the criteria for risk were the survival and persistence of genetically engineered organisms. Survival was perceived as risk. This was because it was not possible to predict the consequences of GMOs which are able to survive and reproduce in the environment, due to lack of knowledge on the ecological networking and interdependence of different organisms.

the influence of organisms on each other, and the interactions between organisms and their environment. Today, data has accumulated that GMOs can survive, and they are in fact constructed to be robust. The accumulation of this knowledge led to a change in risk perception: it is not survival but the outcome of GMOs that is now considered the risk criterion. Since prediction of the outcome is still extremely difficult, if not impossible in some cases (more knowledge has led to an appreciation of more complexities in organisms and ecosystems as new genes are added to organisms which are not fully characterised), new means to assess risk were introduced in order to bypass science. Events such as horizontal gene transfer – which would lead to a further spread of recombinant genes – were characterised as 'natural' events. By the new rules, potentially hazardous gene transfers were changed to 'natural' risks, and as such judged to be risks unnecessary to regulate.

It is equally worrying that, based on "experience", "there is a development trend to identify low risk categories of GMOs and to simplify administrative requirements for such organisms" (para. 48). The criteria for "low risk categories of GMOs" are not defined. There are no data offered to justify simplified procedures for genetically engineered organisms in industrialised countries. It would not be acceptable to apply simplified procedures (from experiences in industrialised countries) to release experiments in developing countries because each differing environment requires its own thorough risk assessment procedure to take into account the conditions of the area into which release is planned. Further, more adequate assessment could mean that some additional laboratory or greenhouse experiments have to be conducted in order to determine the potential for cross-hybridisation, gene transfer, etc.

Para. 51 also raises concerns. The panel notes that, "A new trend is that, except where pathogens are involved, separate regulation of GMOs in contained use may become unnecessary over and above current good laboratory practice." Again, there is no data to justify this. Indeed, the opposite is true. As can be seen in section III above and especially the case of *Klebsiella planticola*, an organism does not have to be pathogenic in order to have negative environmental effects. Contained use under existing regulations and practice includes use in fermentation plants and the tolerated release of GMOs with waste water, sludge, solid waste and

used air. However, increasing data on the survival of genetically engineered organisms and DNA persistence in waste water, sludge, aquatic systems, soil and even digestive systems and blood streams of mammals raises serious questions of environmental and health risks of such "contained use".

The panel acknowledges that it is "not prudent to abandon all caution and extrapolate beyond what is warranted by experience and experimental design" (para. 25) by the relaxation of rules. However, the report in critical paragraphs seems to legitimize deregulation without assessing the scientific validity of doing so. It would have been very useful if the scientific findings of the workings of transgenic organisms and their known and potential hazards had been more comprehensively examined by the panel.

3.5. Distinction between contained use and deliberate release into the environment

The general distinction between contained use and release into the environment referred to as a principle of risk assessment in para. 43(c) can only be justified if contained use means containment measurements which do not imply tolerated (as opposed to deliberate) release with sludge and waste water. As discussed above in Part III, it has been demonstrated that laboratory strains of genetically engineered organisms, which were not designed to survive in an open environment, have unexpectedly survived for long periods in different environments. In addition, DNA persistence has also been found while dormancy of organisms is increasingly of concern to many scientists. Such tolerated release, on the assumption that the GMOs have been deactivated or crippled, may have environmental and health hazards, but the GMOs concerned are not subject to risk assessment and management (decontamination or sterilisation) under existing regulations.

The case of *Klebsiella planticola* is a valuable lesson, too (see Part III above). If the scientists concerned had not conducted the tests that they did (not required under existing regulations), they would not have detected the unexpected adverse effects of the engineered bacterium on

critical soil fungi. If that bacterium had been commercially applied for ethanol conversion and the sludge then spread in the fields (as a form of tolerated release and so not subject to biosafety management), the consequences would have been devastating.

Again, these are scientific findings that the panel should have considered in defining "contained use" and "deliberate release". Instead, the panel uncritically states in para. 51 that the trend is to not regulate GMOs in contained use, except where pathogens are involved.

4. CONCLUSION

The terms of reference for the panel expressly requested the panel to consider "existing knowledge, experience and legislation in the field of biosafety". Regrettably, the report reveals a lack of consideration of existing knowledge and experience. It would have been helpful if the panel had fully examined the following:

(a) The adequacy of existing risk assessment and management procedures in the light of new knowledge on genetics and findings from actual tests;

(b) The extent to which there is compliance even with existing procedures;

(c) The situations that warrant the relaxation of rules based on considerations of (a) and (b); and

(d) The new situations that urgently call for more stringent rules and procedures, including in particular the transboundary aspects.

The report hints at these issues, and concludes vaguely that they are "best addressed by an appropriate international framework" without any assessment of a legally binding protocol. Therefore, it is hoped that the open-ended ad hoc working group of experts will examine all the critical scientific, socio-economic and legal issues that have been omitted or inadequately dealt with by the panel.