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Should a biosafety protocol be negotiated as part of the Biodiversity Convention?

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Developments in genetic engineering technology are outpacing the policy debate. The Earth Summit failed in 1992 to create suitable international controls on the safe handling, transfer and use of genetically manipulated organisms (GMOs). This paper presents the case that now, with the negotiations in the Convention on Biological Diversity considering the need for and modalities of a biosafety protocol, it is time to set up a legally binding instrument. Most countries in the world have regulations, and there are real fears that countries in the developing world may be used as testing grounds for risky experiments. There is also a strong case for harmonizing the regulation of biotech at an international level, if there is ever to be effective verification and policing of the transfer and exchange of GMOs. Adding to the arguments for the need for a protocol are the scientific uncertainties surrounding the safety of environmental release of GMOs. However, given the apparent magnitude of these scientific uncertainties, it is essential that a global protocol is not cast in a light which reinforces the seductive but misleading classical mode of risk assessment and management, and its underlying epistemology.

Between 1991 and 1992 revenues for the US biotechnology industry rose 28% to US$8.1 billion. Sensing the prospect of a lucrative industry to get the USA back on top of the economic tree, the Bush administration launched in January 1992 a Biotechnology Initiative which allocated US$4 billion to biotechnology research annually. Allan Bromley, Bush's science advisor, offered the view that in the past, *Business Week* had forecast that biotechnology would be 'America's dream machine'.[1] Similar investments have been repeated in other countries around the world. Genetic engineering – otherwise also known as genetic manipulation, genetic modification or recombinant DNA technology – is the newest biotechnology scientific technique, and it is this new biotech which this paper discusses. It differs from other biotechnology methods in that it recombines the actual DNA within a cell, and between cells, making changes to the molecular structure that would not occur naturally in the environment. This technique will enable scientists to create new products in the food, pharmaceutical, chemical, waste management, agrochemical and agricultural industries. While the first known environmental release of a genetically manipulated organism (GMO) took place in Belgium in 1986, field trials of GMOs have since proliferated to now well over a thousand worldwide. And the first commercial scale releases have begun. As of January 1994 at least three pesticides incorporating transgenic bacteria had been approved for sale on the market.[2]

Multilateral negotiations began in earnest in 1990 in an attempt to create a Convention on Biological Diversity. Parallel intergovernmental negotiations were also set up to formulate a programme of action on the environment and development, known as Agenda 21. Both were aiming to achieve sustainable development through a precautionary approach. Preparations for the Biodiversity Convention involved five Intergovernmental Negotiating

Committee (INC) meetings. Agenda 21 was negotiated through five Preparatory Committee meetings (known as PrepComs). Biotechnology was addressed in both fora, particular the safe handling, use and transfer of GMOs (also known as biosafety). This issue proved to be a controversial area of discussion between the developed and developing countries. The developing countries, on the whole, were keen to see a legally binding instrument emerge from these negotiations which would protect them from becoming the testing grounds for hazardous experiments. Although almost all developed countries recognized the importance of international controls, they were also influenced by their domestic biotech industries which keenly lobbied for self-regulation in this area.

During the UN Conference on Environment and Development (UNCED) process, governments' attitudes towards biosafety ranged from barely-muted alarm over the prospect of genetically manipulated organism (GMO) releases without harmonized international regulation to, in the case of the Bush administration, complete comfort with the concept. This led to many months of tough negotiations, and eleventh hour compromises. The compromise package involved both the Biodiversity Convention, for which negotiations were completed at a May 1992 INC in Nairobi, immediately before the Earth Summit in early June, and Agenda 21, negotiations for which continued at the Earth Summit itself.

Article 19.3 of the Biodiversity Convention obliges the contracting parties to 'consider the need for and modalities of a protocol setting out ... the safe transfer, handling and use of any living modified organism resulting from biotechnology'. Chapter 16 of Agenda 21, on the Environmentally Sound Management of Biotechnology, requires governments to 'consider the need for and feasibility of internationally agreed guidelines on safety and biotechnology releases'. The positions taken by the principal governments, and the endgame in achieving the UNCED compromise package, have been covered by the author in earlier publications.[3] This paper examines the rationale for a biosafety protocol, and the key players in the ongoing debate and the basis for their positions. It presents a framework for the scope and modalities of such a protocol, and assesses the potential shape of a world which makes no effort to seize this opportunity for placing controls on rDNA technology internationally.

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This paper is based on research carried out for the World Wide Fund for Nature. Opinions expressed in it do not necessarily reflect the views of WWF.

[1]'Biotech: America's dream machine', *Business Week*, 2 March 1992, p 67.

[2]'Organic farms face dilemma over new gene technology', *Nature*, Vol 367, 13 January 1994, p 106.

[3]A Munson, 'The United Nations Convention on Biodiversity', in *The Earth Summit Agreements: A Guide and Assessment*, M Grubb *et al* (eds), Royal Institute of International Affairs, April 1993; and 'Genetically manipulated organisms: international policymaking and implications', *International Affairs*, Vol 69, 1993, pp 497–517.

[4]*Introduction of Recombinant DNA-engineered Organisms into the Environment: Key Issues*, National Academy of Science, National Academy Press, Washington DC, 1987.

Ecological risk and deliberate GMO release

Opinion varies among scientists at the most fundamental level over whether GMO releases pose ecological risk, and if so how much. Many practitioners and advocates of biotechnology argue that a GMO is in essence no different from a normal organism, or if it is different then that it is generally weaker and less able to survive than a non-GMO. According to this view, genetic engineering is a more precise technique than non-GMO breeding. An influential 1987 US National Academy of Sciences report, for example, came up with two key findings: first, that there is no evidence that unique hazards exist in the use of recombinant-DNA techniques, or in the transfer of genes between unrelated organisms; and second, that the risks associated with introducing rDNA engineered organisms into the environment are the same in kind as those associated with the introduction of unmodified organisms and organisms modified by other genetic techniques.[4]

Other scientists contest such views, and those who do tend to be ecologists. As Professor Joyce Tait observed when giving evidence for the ESRC to the House of Lords inquiry on regulation of the UK biotechnology industry,

we have noted in our research on biotechnology regulation that laboratory-based scientists tend to be much more sanguine about the risks involved in the release of GMOs than are ecologists. This appears to be related to the reductionist approach of the laboratory-based scientists, compared to the more holistic approach of ecologists. Given the uncertainty and potential complexity surrounding the release of living GMOs to the environment, it would seem prudent to give at least equal weight to the views of ecologists. However, the norm is to give more weight to the views of laboratory-based scientists.[5]

The assessment of ecological risk associated with GMO releases begins with the question of whether or not the environment can be disturbed harmfully by GMO releases. Clearly, in principle it can. The UK's Royal Commission on Environmental Pollution has warned that 'at the most extreme, new organisms could conceivably affect major environmental processes such as weather patterns, the nitrogen cycle or other regenerative soil processes'.[6]

The next question involves whether or not GMOs can become pests. Proponents of GMO releases point to the fact that genes have been manipulated for centuries by traditional plant and animal breeders, with few evident problems, and that GMOs will therefore be little different.[7] But others argue that traditional biotechnology has caused pests such as feral cats, pigs and even killer bees.[8] And according to a study carried out for the US Congress, alien plants and animals introduced to the USA this century have caused economic damage totalling US$897 billion. The miscreants, including the zeba mussel, gipsy moth and the kudzu vine, are set to produce even more in the decades to come.[9]

Next comes the question of whether or not genes can transfer from GMOs with harmful effect. US FDA official Henry Miller provides a summary view representative of the many biotechnology practitioners and proponents who profess that gene transfer in the environment between released GMOs and other organisms will more than likely be harmless.[10] Others argue, however, that gene transfers in the natural environment have already been responsible for environmental damage. For example, sorghum in Africa has been known to hybridize with weedy relatives to produce a serious pest called 'shattercane'.[11] The Ecological Society of America claims that lateral transfer among micro-organisms in nature 'is neither so rare that we can ignore its occurrence, nor so common that we can assume that barriers crossed by modern biotechnology are comparable'.[12]

In the early 1980s, with the development of the first GMOs for uses outside the laboratory, the genetic engineering community argued for a step by step procedure for biosafety testing: from lab, to greenhouse, to small-scale field trial. Given that each GMO was different, so the argument went, this should also be done on a case by case basis. To this day, despite different perceptions of risk analysis in Europe and the USA, the step by step, case by case approach has become the common regulatory approach. Critics have raised a number of problems in connection with this. These, summarized in a companion paper by the author,[13] include the problem of scaling meaningfully from field trial to commercial release, the problem of long-term uncertainty (whether a GMO which has no adverse interaction on the timescale of a field trial will necessarily have no long-term adverse effect), and the problem of the essential non-recallability of GMOs once released.

Finally, an increasing number of academics from different disciplines have recently questioned the viability of an approach involving 'case by case, step by step' appraisals of risks by scientific practitioners of a technology. Riskiness, according to this kind of viewpoint, involves a type of uncertainty called 'ignorance'. Scientists may not even be aware of the existence of something that may or may not be dangerous resulting from the risky object.

[5]J Tait, Evidence to the House of Lords Select Committee on Science and Technology, 'Regulation of the UK biotechnology industry and competitiveness', written evidence received up to 30 April 1993, HMSO, May 1992, p 187.

[6]Royal Commission on Environmental Pollution, 13th Report, *The Release of Genetically Engineered Organisms to the Environment*, HMSO, 1989, p 18.

[7]'Safety concerns regarding genetically engineered plants and micro-organisms to benefit agriculture', Agrecetus special paper by Vice President for Research and Development, W J Brill, undated.

[8]P J Regal, 'Models of GEOs and the ecological impact', in H A Mooney and J A Drake (eds), *Ecological Biological Invasions of North America and Hawaii*, Springer-Verlag, 1986.

[9]'US counts cost of alien invaders', *New Scientist*, 23 October 1993, p 9.

[10]H I Miller, 'Regulation', in B D Davis (ed), *The Genetic Revolution*, Johns Hopkins University Press, Baltimore and London, 1991, pp 196–211.

[11]P Hatchwell, 'Opening Pandora's box: the risks of releasing GEOs', *The Ecologist*, Vol 19, No 4, April 1989, pp 130–135.

[12]J M Tiedje *et al* (Ecological Society of America panel), 'The planned release of genetically engineered organisms: ecological considerations and recommendations', *Ecology*, Vol 70, No 2, April 1989, p 304.

[13]A Munson, 'Risk associated with and liability arising from releases of genetically manipulated organisms into the environment', *Science and Public Policy*, submitted.

By definition, this type of 'unknowable' uncertainty can never be included in a risk assessment. The most striking example of 'ignorance' is provided by the Antarctic ozone hole. How many experts on panels assessing the risk associated with CFC use in the 1950s, 1960s or 1970s would have raised that as a prospective risk?[14]

Increasingly, scientific risk assessment is also criticized for being narrowed down by the scientist's cultural milieu.[15] Furthermore, increasing intra and interdisciplinary specialization has reduced an individual's expertise to such an extent that, in the words of Cambridge University social theorist Tony Giddens 'we are all lay people', on an increasing number of issues.[16] University of Lancaster social analyst Brian Wynne concludes that the idea that science is uncertainty seeking is a misperception, that on the contrary, science advances by the 'systematic limitation of its attention to known uncertainties within single frameworks stripped of their context'.[17] Risk analysis often perpetuates risk, according to the eminent German sociologist Ulrich Beck, because when credibility is at stake risk analysis – as well as attempting to measure risk – provides a 'discourse of persuasion or justification'.[18]

If these criticisms are correct, it would be reasonable to conclude that current methods of risk assessment with GMO releases are in danger of failing to incorporate worst-case analyses. The question arises as to whether or not GMO technology risks reprising the history of nuclear technology, in terms of the discordance between original safety assessments and later, experience led assessments.

The stakes might be very much higher than the biotechnology community suggest. If, after several decades of wholesale commercial GMO releases, a malign indeterminacy manifests itself, food security could conceivably be severely threatened. Declining biodiversity is already threatening food security. UNEP estimates that there are about 30 million species on earth, about a quarter of which face extinction within the next 30 years.[19] Biological diversity represents, as the FAO puts it, both the raw material for the production of plant and animal foodstocks and

> a reservoir of genetic agricultural adaptability, which acts as a buffer against harmful environmental changes. Their erosion severely increases agricultural vulnerability and threatens world food security. According to experts, since the beginning of this century around three quarters of the genetic diversity amongst agricultural crops has been lost, and according to the FAO/UNEP World Watch List for Domestic Animal Diversity, 28% of the remaining world's domestic animal genetic resources are under serious threat.'[20]

These grim statistics make the stakes associated with GMO releases, should worst case fears be realized, all the more daunting.

They beg the question of the extent to which an internationally harmonized regulatory framework, even if such an entity can be agreed, might serve to legitimize mass proliferation of a technology which is inherently risky and perhaps – unknowably, in the frame of reference of the current global knowledge base – too risky.

International policy-making on deliberate release of GMOs

The first session of the Intergovernmental Committee on the Convention on Biological Diversity convened on 11 October 1993 in Geneva. Summarizing the biosafety component of discussions, the report of the ICCBD's first session read that 'all the representatives who spoke recognized the need for international cooperation in exploring ways and means of enhancing biosafety. There was a consensus on the need to enhance national capabilities to

[14]B Wynne, 'Uncertainty and environmental learning: reconceiving science and policy in the preventive paradigm', *Global Environmental Change*, June 1992, pp 111–127.
[15]D Nelkin, *The Language of Risk*, Sage Publications, 1985, p 20.
[16]A Giddens, *Modernity and Self-Identity*, Polity Press, 1991, p 124.
[17]*Op cit*, Ref 14.
[18]U Beck, *Risk Society: Towards a New Modernity*, Sage Publications, 1992, p 22.
[19]'The state of the global environment', *Our Planet*, Vol 4, No 2, 1992, p 4.
[20]FAO Progress Report on Resolution 3 of the Nairobi Final Act, *Information Paper*, First Session of the Intergovernmental Committee on the Convention on Biological Diversity, Geneva, 11–15 October 1993.

deal with biosafety issues. Many representatives called for action to initiate the development of a protocol' covering biosafety.[21] ICCBD did not include discussion of the scope and modalities of such a protocol.

The Biodiversity Convention came into force on 29 December 1993, following its 30th ratification, and is now a binding legal instrument. The biosafety issue remains an open question. What follows is a review of the key players in the biosafety debate, and the basis for their positions.

UNEP

'Biosafety is an issue because of the dangers that genetically modified organisms pose for ecosystems', UNEP's magazine states.

> Introducing unmodified foreign organisms to ecosystems has already caused major damage: the Latin American water hyacinth has clogged many African waterways, while the European rabbit has wrought havoc in Australia and New Zealand. From these lessons, it is clear that genetically modified organisms represent potentially enormous dangers to ecosystems, so the convention must call for protection from the release of such organisms without environmental impact assessment.[22]

It is difficult to be less equivocal than this.

UNEP has set up a number of Expert Panels on the biodiversity convention. Expert Panel IV covers biosafety. The panel included government officials from Denmark, Ethiopia, Austria, Bangladesh, the EEC, Norway, Peru, Romania, Spain, Tanzania, Thailand, the USA and Venezuela; intergovernmental agencies including the International Board for Plant Genetic Resources (IBPGR), OECD, UNIDO; and two NGOs from the European Environmental Bureau and India's Research Foundation for Science, Technology and Natural Resources Policy. The majority view of the Panel was that the nature of biotechnology itself necessitates a precautionary approach, and that this was reflected in several international and national instruments, not to say Agenda 21. Hence, the majority on the panel agreed that their report should forward support for a biosafety protocol.

The protocol should not extend to alien species and organisms modified by traditional techniques, they concluded further, but should extend to the unintended release of GMOs from contained conditions, as well as deliberate release. While not covering human health issues in the broader sense, the majority view held that the protocol should extend to the possible adverse effects on human health of GMOs released deliberately or accidentally.[23]

A minority view was represented by Robert Ward of the US EPA and Mark Cantley, head of the Biotechnology Unit in the Science and Technology Policy Division of the OECD. Cantley describes his opinions as 'consistent with the statement in the OECD Council Resolution of 1986, to the effect that "there is no scientific basis for legislation specific to rDNA products", a statement which we have seen no reason to revise over the following years.'[24]

The USA

Three senior USDA officials, writing in the winter of 1992, provide important insights into the US government view, common to both the Bush and Clinton administrations, that a biosafety protocol is unnecessary. They laid heavy stress on the National Academy of Science reports, and wrote that 'harmonization of regulations and their underlying scientific basis probably is of little assistance in the resolution of some questions associated with development use, and commercialization of biotechnology products'.[25]

The consistency of this view between successive administrations has left US environmental NGOs with a complex policy problem. At the suggestion

[21]Draft report of the Intergovernmental Committee on the Convention on Biological Diversity on the work of its first session, UNEP document UNEP/CBD/IC/1/L1/Rev.1, 15 November 1993, p 16.

[22]'UNEP and the Convention on Biological Diversity', *Our Planet*, Vol 5, No 4, 1993, p 5.

[23]Expert Panels Established to Follow-up on the Convention on Biological Diversity: Report of Panel IV, 'Consideration of 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 biological diversity', UNEP, UNEP/Bio. Div./Panels/Inf. 1, Nairobi, 28 April 1993.

[24]Letter to the author, 13 January 1994.

[25]T L Medley, S L McCammon and L V Giddings, 'Regulating the agricultural products of biotechnology', *UN ATAS Bulletin*, Issue 9, Winter 1992, pp 228–232.

of the Vice President's staff, three environmental organizations set up a working group on the Biodiversity Convention with three industry organizations in January 1993, with the aim of advising the White House on some of the language in the treaty. On 15 April the Presidents and/or CEOs of Merck and Co, Genentech Inc, Shaman Pharmaceuticals, WWF USA, the World Resources Institute and the Environmental and Energy Study Group mailed a draft interpretive statement to the president. They wrote that 'we believe that depositing an Interpretive Statement such as this with the United Nations at the time of our signature of the Convention would resolve the major substantive concerns'. Among the many suggestions for interpretations of treaty language was the following, for Article 19: 'The United States declares its understanding that paragraph 3 of Article 19 does not presume the necessity of a protocol on the procedures for the safe transfer, handling and use of living modified organisms resulting from biotechnology.'

In late April 1993 President Clinton announced that he would be signing the Biodiversity Convention, defending his reversal of the Bush administration's position by asserting that the USA could at once 'out-conserve and outcompete anyone else on Earth', while emphasizing that the Convention 'had some flaws'.[26] Clinton officials went on to draft their own Interpretive Statement, which was circulated to European governments, and was immediately leaked. While echoing language that the industry and environment groups had fashioned guaranteeing industry that 'facilitating technology transfer' did not mean biotechnology companies would have to cede patent rights to germplasm source countries, this draft interestingly did not mention biosafety.

On 4 June the UN Ambassador, Madelleine Albright, and the State Department's special counsellor, Tim Wirth, signed the Biodiversity Convention in New York. The State Department stressed that the USA was seizing the opportunity 'to realize economic benefits from the conservation and sustainable use of the planet's genetic resources'. There was no Interpretive Statement in evidence at the time of signing. 'We had hoped there would be an interpretive statement', said one biotech industry executive. 'There will continue to be fears until there is one.' Wirth said that an Interpretive Statement was not ready at the time, but would be by the time the treaty went to the Senate for ratification in the summer or autumn.[27]

Speculation continued as to what would be in it, or omitted. *Biotechnology* magazine reported that where biosafety was concerned, the US opposition to a biosafety protocol 'has softened somewhat in the face of strong European advocacy'.[28] The industry magazine also observed that 'all this maneuvering may not matter that much anyway. The treaty itself declares that signatory nations are not permitted to add individual "reservations" over its provisions, because that was seen as undermining the entire document.'[29]

None the less, the Clinton Administration worked behind the scenes during the summer to persuade the Europeans to its view of an Interpretive Statement.[30]

At the ICCBD, the US position statement reiterated that 'biosafety is not an appropriate focus for a protocol to the convention'. The statement went on to invite the IGB to consider, when the time came for the debate on Article 19, presentations by entities with experience in biosafety, ie the International Plant Protection Convention Secretariat of the FAO, the International Organization for Epizootics in Paris, the WHO, UNIDO and the OECD.

The European Union

At the ICCBD, the EU's position statement did not close the door on a protocol in the way the USA's did. It amounted to a stalling position, reflecting a diversity of opinion among member states, concluding that

[26] 'Clinton vows to take lead over conservation', New Scientist, 1 May 1993, p 7.
[27] 'Biotech helps salvage biodiversity treaty', *Bio/Technology*, Vol 11, August 1993, p 878.
[28] *Ibid.*
[29] 'Clinton likes biodiversity treaty', *Bio/Technology*, Vol 11, June 1993, p 665.
[30] 'Going gets weird with BST and Wildlands Project', *Bio/Technology*, Vol 11, September 1993, p 978.

intergovernmental preparatory work should be undertaken to inform the Conference of Parties for their consideration of the need for and modalities of a protocol on biosafety. We will also have to consider the possible legal implications of a protocol to this convention. Would it be possible to cover all aspects, or only some, of biosafety in a protocol to this convention?

There are clearly differences of opinion within the EU. The Spanish, for example, subscribe to the majority opinion of UNEP Expert Panel IV.[31] Norway and Sweden would also like to see a legally binding instrument on biosafety.[32] The Dutch position is one of support for the UNEP ED's twin-track approach, ie for track one, the 'making available to countries the already existing safety procedures, regulations and systems in order to satisfy individual needs and priorities'; for track two, to build using results from track one experiences 'a good profile of a possible instrument . . . which will enhance international biosafety'.[33] The UK intends to push for international guidelines, feeling that the negotiability of a protocol is unrealistic at present.[34]

Fiona McConnel, who headed the UK delegation during negotiation of the Biodiversity Convention, offered a carefully coded but instructive view of the differences between the Europeans and the USA in a presentation to the Royal Institute of International Affairs during July 1993. 'US experts have continued to press for biotechnology to be treated like any other technology', she said,

> or failing that to consider a range of guidelines. Other countries with a sizeable biotechnology industry, perhaps including the UK, may well agree that guidelines should precede regulation. If the IGC meets in a friendly atmosphere, with reassurances from donor countries about technology transfer and some additional finance, guidelines may prevail for the time being. Work under way in the OECD could be influential. So too could the report of the House of Lords enquiry into biotechnology. But NGOs like Greenpeace, which oppose any release of GMOs, may take a closer interest in the work of the IGC than they took in the convention negotiations. It would therefore be unwise for the US or any other government to assume that a safety protocol, with or without liability provisions, can be headed off indefinitely.

Japan

The Japanese, too, hedged their bets at the ICCBD, to a degree, on biosafety. Their statement at the ICCBD pointed out that

> safety in biotechnology has already been discussed in existing international organizations. They have concluded that questions of safety relate to the characteristics of products regardless of the process used to produce them. The COP should consider these findings of other international bodies. Consideration of the need for a Protocol as described in Article 19(3) of the Convention should only be undertaken after full discussion of the above points.

Developing countries

Opinion ranges across a broad spectrum, from China which has plans for pressing ahead rapidly with the technology come what may in the international arena, to certain African states, which favour using the biosafety protocol to ensure that development of the technology takes place with due caution.

Representatives from 11 Southern and Eastern African nations gathered in Harare in October 1993 for a conference on safety in biotechnology. At the time, only a few countries in the region had yet established any sort of biotechnology policy, and none had specific biosafety regulations. The conference, accordingly, concluded that there was an urgent need for safety mechanisms when biotechnology is applied in southern and eastern Africa,

[31]Letter to the author from Elisa Barahona, Ministerio de Olbras Publicas y Transportes, Spain, 4 February 1994.
[32]Statement by Norway on biosafety to ICCBD, Geneva, 15 October 1993; Letter to the author from Ministry of the Environment Sweden, 9 March 1994.
[33]Letter to the author from Andrea Berghuizen, Ministry of Housing, Physical Planning and Environment, 7 February 1994.
[34]Interview with a Department of Environment official, 18 February 1994.

and a committee was established to co-ordinate and support the development of national biosafety regulations.

The conference also considered the question of scope for differing standards in North and South. As *Biotechnology and Development Monitor* put it,

> in general, it was felt that the African circumstances (lack of finances, weak regulatory systems and the specific ago-ecosystems) warrant proper adaptation of the internationally available regulatory systems to the specific needs of the region. However, a plea for relaxation of regulations, in particular concerning deliberate release of plants, on the basis of experience obtained with field experiments in the North, provoked the stand that it would promote double standards: tight ones in the North and relaxed ones in the South.[35]

The Food and Agriculture Organization

Resolution 3 of the Nairobi Final Act, agreed at the session of negotiations where the Biodiversity Convention was finalized, addressed the interrelationship between the Convention and sustainable agriculture, and was designed among other things to ensure active communication and co-operation between intergovernmental fora. The FAO, as part of that process, submitted a paper to the October 1993 ICCBD. The FAO established a Global System for the Conservation and Utilization of Plant Genetic Resources in 1983, and a body to oversee it, the Commission on Plant Genetic resources (CPGR). At its Fifth Session in April 1993, the CPGR considered matters arising from the Biodiversity Convention, including biosafety. It reviewed a preliminary Draft Code of Conduct on Biotechnology, which had been requested at its 1991 session, which covered both biosafety and the promotion of biotechnology. The Commission recommended that 'in order to avoid duplication and inconsistencies, the "biosafety and other environmental concerns" component of the preliminary draft Code would constitute an input to the work of the IGC/CBD on this matter'. The Commission, in other words, recommended that FAO focus on the biosafety discussions in the ongoing ICCBD process.[36]

At the ICCBD in October 1993, Hartwig de Haen spoke for the FAO. He stressed that as well as potentially enhancing productivity and diversity in domestic livestock and crops, the new biotechnologies came with risks of misuse and accidents in application. They also have the potential to increase, at least temporarily, equity problems.[37]

The International Bioindustry Forum

The IBF is an umbrella group for four major national bioindustry associations, the Senior Advisory Group Biotechnology (SAGB) in Europe, the Japan Bioindustry Association (JBA), the Biotechnology Industry Organization (BIO) of the USA, and the Industrial Biotechnology Association of Canada (IBAC). Its Statement of Principle of August 1993 on the Biodiversity Convention reads, where a biosafety protocol is concerned, that

> the IBF points out that there are several science and experience based guidelines that have been developed to provide workable frameworks for the assessment of biosafety issues. These include the work of the OECD (Group of National Experts), the UNIDO, the World Bank/International Service for National Agricultural Research and the US National Research Council. These guidelines should be used to provide the basis for flexible and workable approaches to issues of biosafety.

The environmental NGOs

WRI, IUCN and UNEP held a Global Biodiversity Forum in Gland, Switzerland, during October 1993, and relayed its results to the ICCBD. They reported that

[35]'Biosafety conference: a step towards regional co-operation in Southern Africa', *Biotechnology and Development Monitor*, No 17, December 1993, p 21.
[36]Progress Report on Resolution 3 of the Nairobi Final Act, *Information Paper*, First Session of the Intergovernmental Committee on the Convention on Biological Diversity, Geneva, 11–15 October 1993.
[37]*Earth Negotiations Bulletin*, International Institute for Sustainable Development, Vol 9, No 3, 13 October 1993.

particular concern was expressed over the safety with which biotechnologies can be traded and used, given the novel and even experimental nature of modern technologies. Their potential to both contribute to and detract from efforts to conserve and sustainably use biodiversity was discussed. It was felt that biosafety has to be interpreted widely to include social and economic implications as well as strictly biological ones. The need for a protocol on biosafety was discussed with many feelings that negotiation of such a protocol is justified.

They concluded that such a protocol must consider the social and economic, as well as biological implications, of genetic engineering, and that the technologies used are often experimental in nature.[38]

Speaking in plenary at the October 1993 ICCBD, Ashish Kothari of the Indian Institute of Public Administration, read a 'majority view obtained after extensive consultations with the NGOs present'. It strongly endorsed the majority opinion of the UNEP Expert Panel IV.

The rationale for a biosafety protocol

The most comprehensive case for a protocol has been that of the majority report by UNEP Expert Panel IV. Their central argument is based on the precautionary principle. On page 14 of their report, they argue that

> the safety of modern biotechnology is still to a much larger extent than that of traditional techniques, connected with scientific uncertainty. This uncertainty is caused primarily by the fact that new gene combinations are especially made from different, including unrelated species, *with more or less unpredictable effects* [author's emphasis].

It is probably fair to say that a majority of governments (based on a qualitative perusal of interventions during the UNCED process), and a majority of the public (based on available opinion poll data) accept this view. And if such a view is accepted, then the case for attempting to rationalize international regulation via multilateral negotiation is clear, and the need for a protocol to the Biodiversity Convention compelling. French microbiologist Dr David Tepfer has articulated a rather extreme rationale for unifying regulation: 'if you don't have basically the same regulations governing the release of microbes in all countries over the face of the Earth, there's no point having any regulations at all. The Earth is too small. You can't autoclave everyone coming into Kennedy airport.'[39]

Many, including this author, would disagree with this absolutist line, feeling that unilateral regulation is better than no regulation at all. But the basic point made by Tepfer remains valid, if it is accepted that GMOs are indeed different at a fundamental level from non-transgenic organisms. As Shell has written in a management briefing on this subject, 'clearly, ecological effects and the geographic range of organisms transcend political boundaries, and it is therefore important to develop *international* standards of assessment, regulation and control' (author's emphasis).[40]

Even if the argument that GMOs differ from non-transgenic organisms is rejected, as it is by the community of advisors and policy makers in the Bush and Clinton administration, the need for a protocol is not necessarily obviated. For some analysts, the release of GMOs invites is not necessarily different from the introduction of non-transgenic organisms to new ecosystems as aliens. And alien species have had demonstrably devastating ecological impacts in a number of areas. A clear example is provided by the proliferation of aliens in and around ports, transported there in the ballast water of ships, and multiplying unchecked without their natural predators in the new enviroment.[41] Such invaders have, in Tasmania for example,

[38]Presentation by the WRI/IUCN/UNEP Global Biodiversity Forum to the Intergovernmental Committee on the Convention on Biological Diversity, 11 October 1993.
[39]S Witt, *Brief Book: Biotechnology, Microbes and the Environment*, Chapter 7, 'A greening world debates releases', Centre for Science and Information, 1990, p 135.
[40]*Biotechnology: Risks and Rewards*, Shell Management Brief, October 1989.
[41]'Aliens slip through international "safety net" ', *New Scientist*, 3 July 1993, p 5.

included toxic dinoflagellates responsible for closing shell fisheries and Japanese starfish decimating bivalves. The director of the Australian Bureau of Rural Resources professes that 'the environmental problems caused by ballast water are chronic, irreversible and cumulative'.[42]

Another example involves the biota of Hawaii, which has seen devastating losses of species in the face of foreign invaders such as the rat, the pig and the rabbit.[43] This ongoing threat is even compounded by pests arriving by post, which according to Hawaii's Department of Agriculture have included a host of prohibited species. From 1984 to 1989 an average of seven pest species of economic significance reached Hawaii each year. They include the yellow sugar cane aphid and the lesser cornstalk borer, which have both been responsible for huge crop losses.[44]

The full case for a protocol involves much more than what UNEP Expert Panel IV calls 'the most urgent problem of safety', or the question of whether or not introducing non-transgenic aliens to new environments can be compared to GMO releases, however. Another key argument for those keen to see smooth development of the technology is that internationally harmonized regulations enhance the prospects for effective international collaboration. The EC and China are already working in concert on GMOs under the EC/China Science and Technology Programme. Ten European and 14 Chinese experts in GMO release recently agreed that harmonized biosafety procedures would benefit both China and the EC.[45]

Other arguments for a protocol include the need for comprehensiveness in risk assessment, for transparency, for monitoring and verification, for prior informed consent, for capacity building and for understandings on liability. All these issues, and more, are elaborated in the section which follows.

Scope and modalities of a biosafety protocol

Scope

The protocol would need to cover all transgenic organisms, and its chances of workability would be heightened if the growing problem of alien species was considered elsewhere. The majority view of UNEP Expert Panel IV was that the protocol should not extend to alien species and organisms modified by traditional techniques, even though 'alien species can raise the same kind of safety concerns as GMOs'.[46] They recommended that risks arising from transfer of alien species be addressed in a separate international context.

The Panel also concluded that GMOs should be defined in line with EEC Directive 90/220 'on the Deliberate Release into the Environment of Genetically Modified Organisms'. This Directive defines GMOs as organisms in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination, a definition also accepted by the Council of Europe Convention.

The majority view of UNEP Expert Panel IV was that the protocol should extend to the unintended release of GMOs from contained conditions, as well as deliberate release. The Panel recognized that the risk of GMOs from laboratories and other contained environments proliferating in the environment is in general low. Their main reason for recommending the inclusion of contained use involved human health.[47]

Support for such a view comes from a 1992 study by Dutch scientists at the Dutch National Institute of Public Health and Environmental Protection. They found that lab coats sent out to local laundries provided an ideal escape route for genetically engineered microbes. The scientists isolated viable *E. coli* bacteria from dry lab coats, which would have no problem surviving until the coats were immersed in water at 35°C, water which would then be

[42]'End of the line for deadly stowaways?', *New Scientist*, 24 October 1992, p 12.
[43]'Under siege', *The Economist*, 10 April 1993, p 97.
[44]'Pests in the post threaten crops in Hawaii', *New Scientist*, 21 November 1992, p 10.
[45]'EC/China meeting on transgenic plants', *European Biotechnology Information Service*, Vol 3, No 4, December 1993, p 55.
[46]UNEP Expert Panel IV, 1993, p 15.
[47]UNEP Expert Panel IV, 1993, p 15.

flushed directly to the sewers. 'The potential for genetic exchange with other bacteria is great', the researchers concluded.[48]

The Biodiversity Convention parties, in exploring their mandate under Article 19.3 where biosafety is concerned, should at minimum be aiming for a protocol which erects a framework for comprehensive control and oversight of the use of rDNA technology and the release of GMOs to the environment. To be comprehensive, the protocol would clearly have to cover domestic safe handling and use.

UNEP Expert Panel IV found the language of Article 19.3 of the Biodiversity Convention on safe transfer, handling and use subject to alternative interpretation as to whether domestic handling and use of GMOs were covered. The majority concluded that they were, invoking the recommendations of Article 8(g) for harmonization of national safety procedures, and related language in Agenda 21. Additionally, they concluded, such an interpretation would encourage the many countries still without national safety regulations to adopt such regulations, and this was to be desired.[49] A minority on the Panel, however, interpreted the mandate in Article 19.3 'including in particular advance informed consent' as only covering international transfer of GMOs. Should a protocol be negotiated this will undoubtedly need to be clarified.

The protocol would pose countries with the difficult task of effectively harmonizing standards of biosafety. Any such harmonization process would have to avoid basing standardization of assessment procedures on one cultural or national regime. For example, ecological risk assessment procedures appropriate for the USA are not necessarily appropriate for Ethiopia. Different questions and agendas arise and require co-ordination at both ecological and social levels. Otherwise there is a danger, as Dembo *et al* pointed out, that risk assessment assumes that the 'exposure level and hazard potential are generally constant around the world and that there are not significant social, economic, and technological structures that may affect the degree of danger in a given situation'.[50] This need to incorporate different perspectives and priorities in risk assessment in each region and cultural area is highlighted by the different socioeconomic positions of different countries, as well as the different potential socioeconomic impact the same GMO may have on different countries' economies.

Modalities

Advanced informed agreement. The operability of a biosafety protocol would build on the principle of advanced informed agreement (AIA) being recognized and observed by all parties, and this is implicit in the wording of Article 19.3, which reads

> The parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of 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 biological diversity.

Other multilateral environmental agreements operate on the basis of the directly analogous principle of prior informed consent (PIC). These include the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, and the FAO International Code of Conduct on the Distribution and Use of Pesticides. The exporting state is obliged to obtain PIC for any export of a regulated substance, meaning that the permission of the importing state is needed before the export is shipped.

[48]'Clean white coats spread mutant microbes', *New Scientist*, 21 March 1992, p 11.
[49]UNEP Expert Panel IV, 1993, pp 16–17.
[50]D Dembo *et al*, *Nothing to Lose But our Lives*, New Horizons Press, New York, 1988.

In order to seek that permission, relevant information is required of the exporting state.

In the case of the FAO Code of Conduct on pesticides, for example, the exporter is required to inform the importing country of the chemical composition and safety record of the pesticide in question, including whether or not it has been banned in the exporting country. This works moderately well, but is not ideal – the initial list of pesticides, which came into force in 1991, contained only 17 pesticides, and compliance was only voluntary.[51]

UNEP Expert Panel IV erected a useful hierarchy of elements for AIA under a biosafety protocol. It would begin with the 'competent authority' (see later) of an exporting country ensuring that any individual exporter under their jurisdiction notifies the competent authority of the state for which their intended export is destined. The notification would include a full description of the characteristics of the GMO in question, information on prior related releases of the organism, regulations concerning safe handling of the organism in the exporting country, information relating to the conditions of the release, and the full risk management procedure.[52] A copy would also be sent to an international clearing house (see later). Thereupon the importing country would make its decision, assisted by advice from both the exporting country's competent authority and the international clearing house. The decision – to allow the release, allow it under certain stipulated conditions, or ban – would then be relayed back.

AIA alone would not be sufficient to guarantee effective operability of a biosafety protocol. This is because of the unique characteristics of GMOs. A dangerous chemical cannot migrate from one importing state into a neighbouring state, whereas a GMO, in principle, can. AIA, along the lines of the scheme described by UNEP Panel IV, is therefore an important first step towards the transparency and openness that will be needed if an operable biosafety protocol is to be fashioned by the international community; but further measures would be needed. The ultimate requirement of operability is the full participation of all states under the terms of the biosafety protocol. Short of that, important safeguards can be put in place by requiring parties, in the manner of Article 4 of the Montreal Protocol, to ban the import or export of any controlled substances (and in the case of the biosafety protocol ideally any GMOs at all) from states not party to the protocol.

Transparency and exchange of information. There was general agreement in UNEP Expert Panel IV that public awareness and participation should be encouraged in a biosafety protocol.[53] A survey of public attitudes towards production and use of GMOs shows why this should be the case. The European Commission's Eurobarometer survey in 1992 found that 70% of Europeans were 'somewhat' (32%) or 'very' (38%) concerned about possible risks to the environment from biotechnology.[54] The 1993 survey questioned 12 800 persons across Europe. Impressions of biotechnology's ability to make a positive contribution to life and living conditions had dropped since the same survey was conducted in 1991 in every EC country except Denmark, where they had remained even. In 1991 52.6% of respondents had said they trusted environmental organizations most to tell the truth about biotechnology, ahead of 6% for industry and 4.9% for political organizations. In 1993 60.8% across Europe said they trusted environment organizations most in this regard, ahead of 5.6% for industry, and 4.0% for political organizations. Support for research had decreased since 1991, with the strongest rejection in Germany.[55]

In the UK another 1993 survey, commissioned by the Department of Trade and Industry, suggested that four out of five Britons did not trust the

[51] B Dinham, 'Production and trade in dangerous chemicals', paper presented at a Catholic Institute for International Relations seminar on Agrarian Reform and Environment in the Philippines, London, 22 January 1992.
[52] See Appendix IV of UNEP Panel IV report, 1993 for details.
[53] *Ibid.*, p 22.
[54] 'Eurobarometer: worries about biotechnology and environment', *European Biotechnology Information Service Newsletter*, Vol 2, No 4, 1992, p 4.
[55] 'Second Eurobarometer survey on awareness and attitude about biotechnology', *European Biotechnology Information Service Newsletter*, Vol 3, No 4, December 1993, pp 51–52.

biotechnology industry to tell the truth about genetic engineering, and that three-quarters felt the industry 'kept quiet' about what it is doing. More than two in three thought industry took short cuts with safety, and almost as many felt industry put profits ahead of morals.[56]

In the Netherlands, a panel representative of a broad cross-section of the public, and organized by a government-funded foundation, decided they would rather scientists stopped their transgenic experiments altogether until the risks of genetic engineering were better known. The panel identified as a particular concern the chance that genes would cross between organisms.[57]

In the USA a 1992 report by the Office of Technology Assessment on the impact of new technologies on agriculture warned that public concern may prevent for commercialization of biotech products even if they pass regulatory scrutiny.[58]

A vital ingredient in improving transparency is the issue of food labelling. In May 1992, the FDA ruled that companies need not label food products produced by genetic engineering.[59] Despite this, in 1993 Chicago became the first US city to pass a local law requiring all such food to be labelled. As of June 1993 New York also had such a law in the pipeline. The response of Calgene, about to put a genetically engineered 'stay hard' tomato on the market, was to label its product regardless of the law.[60] Recently, the FDA has issued guidelines which make it illegal to label milk produced without genetically engineered bovine somatotropin as 'hormone free'.[61]

Food labelling was not an issue covered by UNEP Expert Panel IV, but these developments suggest that a requirement for labelling could usefully be included in a biosafety protocol as part of the manifest requirement for greater transparency in the biotech industry, but also to facilitate monitoring of transported GMO products. Genetically engineered micro-organisms are sent regularly through the post. Though GMO parcels are supposed to be carefully packed and labelled, Dutch investigators found many carelessly packed and without labels. They estimated that this was a route for 15 or so accidental releases of GMOs into the environment each year in Holland alone.[62]

Overseeing the flow of information involved in a biosafety regime dedicated to transparency and information exchange on the level envisaged here would require considerable infrastructure, both at the national and international levels, quite apart from the infrastructure which would be needed for reporting, inspection and monitoring. UNEP Expert Panel IV referred to the need for every party to have an adequate national competent authority to attend to these tasks domestically, and an international clearing house, to co-ordinate and link national competent authorities, provide advice to parties, compile and collate relevant databases, and oversee the AIA process. This issue is considered further in a later section.

The risk analysis process. UNEP Expert Panel IV outlined an approach to ensuring the safe handling and use of GMOs, recognizing the varying overall characteristics of organisms, the potential receiving environment, and the interaction between these. The Panel recommended a case by case, step by step approach to regulation, and that complementary consideration be given to risk assessment and risk management. Risk assessment elements in the protocol, they concluded, should ask at least three fundamental questions of information supplied for review prior to release:

- What is the ability of the modified organism(s) or its/their later generations to disseminate, and what might the consequences be if it/they did?

[56] 'Gene industry fails to win hearts and minds', *New Scientist*, 19 June 1993, p 4.
[57] 'Dutch doubts over "runaway genes" ', *New Scientist*, 5 June 1993, p 8.
[58] 'Public confidence still the issue', *Biotechnology Notes*, US Department of Agriculture, Vol 5, No 8, August 1992, p 5.
[59] 'FDA considers labels on bioengineered food', *Science*, Vol 260, 14 May 1993, p 883.
[60] 'Stay hard tomato carries its label with pride', *Nature*, Vol 365, 9 September 1993, p 96.
[61] K Kleiner, 'US bans "hormone free" milk label', *New Scientist*, 26 February 1994, p 5.
[62] *Agscene* No 107, Summer 1992.

- What is the ability of the modified organism(s) or its/their later generations to exchange genes with other organisms, and what might the consequences be if it/they did?
- Might there be any other possible interactions between the modified organism(s) or its/their later generations and the environment?

Risk management elements in the protocol, they recommended, should specify:

- safety procedures such as step-by-step appropriate confinement measures;
- mitigation procedures;
- systematic reporting;
- independent inspection and monitoring.

Domestic regulation should also include

- transparency of and public participation in decision-making;
- facilitation of exchange of information to the public.

All of the above, the Panel recommended, should be conducted in the context of a socioeconomic framework which ensures that the socioeconomic risks of introducing a GMO do not threaten to undermine the societal conditions of the people who act as guardians of biodiversity, thereby indirectly eroding genetic diversity. The Panel further concluded that replacing traditional imports by use of GMOs at home can affect traditional exporters adversely, perhaps causing the run-down of agricultural systems in a manner which also indirectly causes erosion of genetic diversity.[63] That issue is considered in more detail later.

The three questions involved in risk assessment, and the first two points under risk management in UNEP Expert Panel IV's scheme, however, raise fundamental questions. They assume a classical approach to risk analysis, ie that science can adequately assess risk according to the knowledge base of the day, and political decisions on risk management can then be based comfortably upon that assessment. But there is a growing body of criticism of that approach in the policy studies community. The implications of that critical view of risk analysis are substantial, and extend to the type of information reported, how it is presented, the inspection and monitoring efforts, and transparency in general. This issue is examined in the next section. The infrastructure for systematic reporting, independent inspection and monitoring, transparency and facilitation of exchange of information is then examined in a subsequent section.

The critical view of risk analysis. Policy analysts are increasingly recognizing a dichotomy in the approach to risk analysis which can be summarized as follows. The idea that a basic distinction can be drawn between a quantifiable, value-free and objective analysis of risk (risk assessment) and a process by which risk assessment findings are evaluated in terms of political values (risk management) can be seen as the 'classical view'. The approach advocated by UNEP Panel IV to GMO releases very much falls in this camp. As Robinson puts it, 'implicit in the classical view is the idea that risk assessment should be left up to the experts, who should not be influenced by the political values of risk managers'.[64] But equally,

> the critical view suggests that much of current risk debate is misconstrued, that describing social choices about technology as 'risk' distorts their nature by singling out for attention only a single aspect of the problem. To the extent that this is so, risk

[63]UNEP Expert Panel IV, pp 17–18.

[64]J B Robinson, 'Risks, predictions and other optical illusions: rethinking the use of science in social decision-making', *Policy Sciences*, Vol 25, 1992, p 240.

debates are not fundamentally about risk, at least not as conventionally defined, but are instead about issues like social and technological choice, trust, credibility, power, legitimacy and control.[65]

A leading exponent of the critical view, Brian Wynne, has classified uncertainty into four classes. To recap his view, 'risk' applies only where we can *know* the odds; 'uncertainty' is where we don't know the odds, though we may know the main parameters; 'ignorance' is where we do not know what we do not know, a class of uncertainty which inreases with increased commitments based on given knowledge; finally, 'indeterminacy' arises where causal chains or networks come into play, and are open.[66] Wynne and Mayer describe the relevance of the critical view to GMO field trials as follows.

> The assumption is that the parameters and effects being observed are the important ones. Such scientific ignorance is particularly insidious when research leads to policy. In the case of GMOs, for example, it will allow experimentation in the wider environment to be pronounced fully scientifically evaluted and safe, when by definition it can only be safe according to the body of existing knowledge available to the scientists on the licensing committee.[67]

Grove-White describes how processes like this can lead to what he calls 'blind commitments' where technology is concerned, and not just involving genetic engineering.[68]

Wynne anticipates the policy relevance as follows.

> I would see risk, uncertainty, ignorance and indeterminacy as overlaid one on the other, being expressed depending on the scale of the social commitments ('decision stakes') which are bet on the knowledge being correct. Science can define a risk, or uncertainties, only by artificially 'freezing' a surrounding context which may or may not be in this way in real life situations. The resultant knowledge is therefore *conditional* knowledge, depending on whether these pre-analytical assumptions might turn out to be valid. But this question is indeterminate – for example, will the high quality of maintenance, inspection, operation, etc of a risky technology be sustained in future, multiplied over replications, possibly many all over the world?[69]

These are sobering arguments when it comes to biosafety. Even diehard proponents of large-scale GMO releases do not profess that such releases are devoid of the potential for risk. Few would question that the political momentum generated by the bioindustry is great; the risk of technological determinism therefore non-trivial. Proponents of large-scale GMO releases argue instead that the risk is very low, and that the potential economic and societal benefits easily outweight them. Given the scientific uncertainties, this may be correct, or it may not.

How, then, to encompass the critical view of risk within a biosafety protocol?

First and at minimum, it provides a key rationale for a strict regime of reporting, inspection and monitoring. In several decades time, say, the risk associated with GMO release should/may indeed prove to be greater than is currently envisioned by release proponents. That such under-assessments of risk associated with new technologies have occurred historically, particularly in the field of halocarbon and nuclear technology, few would dispute. CFCs and the ozone hole provide the classic example of one of Wynne's 'indeterminancies'. And if this proves to be the case with GMO technology, the international community will be in far worse shape to deal with resultant problems if it has little idea of what GMOs have been developed, by whom, and what GMOs have been released, where then would be the case if such questions were answerable by referral to a mandatory database, established under a biosafety protocol.

In additional support for a stringent international biosafety regime is the

[65] *Ibid.*, p 242.
[66] B Wynne, 'Uncertainty and environmental learning', *Global Environmental Change*, June 1992, p 114.
[67] B Wynne and S Mayer, 'How science fails society', *New Scientist*, 5 June 1993, p 35.
[68] R Grove-White, 'The emerging shape of environmental conflict in the 1990s', *RSA Journal*, June 1991, p 440.
[69] B Wynne, 1992 *ibid.*, p 116.

fact that lessons from other multilateral agreements with relaxed or absent agreements on reporting, inspection and monitoring suggest that to play down the importance of verification is to risk an inadequate or unenforcable treaty. The Biological Weapons Convention is a good example. Since its agreement in the early 1970s, without effective verification conditions, the UK Ministry of Defence estimates that the number of states with biological weapons capability has risen to 10.[70] Now that European countries are trying belatedly to set up a verification regime, it is interesting to note that countries such as Brazil argue that it might be used to stop them setting up a modern biotechnology industry.[71]

Perhaps the most important corollary of the critical view of the risk debate, however, involves the clear need to apply the precautionary principle more effectively where biosafety is concerned. The whole process of risk analysis needs to involve more openness in scientific assessments as regards ignorance and indeterminancy. This has important implications for the make up of GMO release review panels, and for the staffing and mandate of national competent bodies and the international clearing house, in none of which should there be a monopoly, or even necessarily a majority, of practising genetic engineers or biotech industry secondees. Equally important should be, for example, economists and others charged with the wider societal assessments of risk, and indeed the holistic desirability of particular rDNA developments.

Transport of GMOs. The international community has fashioned a wide range of agreements on the transport of potentially dangerous substances. These begin with the Recommendations of the UN Committee of Experts on the Transport of Dangerous Goods. These, contained in the UN Economic and Social Council's so-called 'Orange Book', deal with recommendations covering the transport of dangerous substances including 'infectious' microorganisms, which are defined as those known or suspected to be capable of causing disease in animals or humans. The recommendations focus primarily on packaging. The UN Committee of Experts on the Transport of Dangerous Goods are discussing extending the scope of the agreement to include GMOs at present, but the UNECE Committee on the Transport of Dangerous Merchandise has already agreed that GMOs should be treated no differently from infectious substances.[72]

Other potentially relevant agreements and bodies include:

- The Universal Postal Convention, which has laid down Detailed Regulations for the Transport of Non-Perishable Biological Substances (NPBS) and Infectious Perishable Biological Substances (IPBS) by mail.
- The International Air Transport Association (IATA), which has established specific regulations for the transport of infectious substances. Recently, the IATA regulations have been modified to incorporate GMOs. 'Non-infectious' GMOs, defined as those 'which are capable of altering animal, plants, or microbiological substances in a way not normally the result of natural reproduction' can be transported if packaged a particular way. 'Infectious' GMOs, defined as those 'known or suspected to be dangerous to humans, animals or environment must not be transported by air unless exempted by the States of origin, transit, and destination'.[73]
- The International Maritime Organisation (IMO), which has adopted International Guidelines for Preventing the Introduction of Unwanted Aquatic Organisms and Pathogens from Ships' Ballast Water and Sediment Discharges, July 1991.

[70] M Dando, 'Towards a verification protocol for the Biological Weapons Convention', *Pacific Research*, November 1993, p 11.
[71] 'How to police germ warfare treaty', *New Scientist*, 9 October 1993, p 5.
[72] 'Transport of biological agents: genetically modified organisms (GMOs)', *Biotechnology in Europe*, March 1991, p 10.
[73] *ICECC News*, Information Centre for European Culture Collections, Braunschweig, Germany, No 5, p 19.

- The Geneva Convention on Civil Liability for Damage Caused During Carriage of Dangerous Goods by Road, Rail and Inland Navigation Vessels (not yet in force).

There is no overall regime for control of the transport of GMOs, and building on the patchwork of these existing potentially relevant sectoral agreements would seem to offer scope for confusion. The need for a Biosafety Protocol to harmonize these regulations, and agree a strict universal model for transport, is strong. Where the mail is concerned, *New Scientist* observed 'scientists may not be allowed to release genetically engineered organisms into the environment willy-nilly, but they can send them to each other through the post'. The article goes on to describe in the UK, for example, how modified *E. coli* can be sent packaged according to the same rules as ordinary *E. coli*.[74]

Infrastructure for systematic reporting, independent inspection and monitoring. A clearing house would obviously be needed, as mentioned above, to provide advice to contracting parties, with regard to the specific of particular organisms, risk assessment and management, and the maintenance of databases on the releases themselves. The developing countries in particular would need help and advice. As a recent conference on the subject concluded,

> the institutions necessary to manage biosafety are still nascent in most developing countries. The ability of these countries to effectively implement the biosafety provisions of the Convention will depend largely on their institutional capacity in the field. There is therefore a need to incorporate biosafety considerations into biotechnology development programmes.[75]

And as UNEP's Executive Director observed at the October 1993 ICCBD, 'many countries are likely to require technical and financial co-operation over an extended period to build the internal capacity needed'.[76]

Among the economies in transition, the Russian Federation has professed a need for help. The National Committee for the Legislation of Works with Genetically Modified Organisms of the Russian Federation asked the ICGEB for help and advice regarding the scope, administrative form and mechanisms for implementation of regulatory oversight in biotechnology.[77]

The ability to answer the questions regarded as fundamental to domestic regulation of GMO release by UNEP Expert Panel IV depends on scientific understanding of biodiversity and the interactions between species in ecosystems. The ability to monitor the ongoing effect of releases will in large measure be dependent on continuing evolution in understanding of these fields. Systematic biology (the classification of species), as well as ecological research, are vital in this regard, and therefore an ideal biosafety protocol would emphasize the need for research to be expanded in these fields, and for the fullest possible ongoing assimilation of that research by national competent authorities and the international clearing house. There are indications at present, however, that such research is suffering from inadequate and declining support. In the UK, for example, the government recently rejected an appeal from the science and technology committee of the House of Lords for more money for systematic biology.[78] In the USA, for example, the army's Walter Reed Biosystematics Unit, which identifies disease carrying insects of concern to soldiers, was threatened by closure as of May 1993. Its head of entomology notes that there is 'a great lack of modern biosystematic information for most vectors in all areas of the world'.[79]

Clearly, the breadth of material needing to be covered by the international clearing house, and by competent national bodies, is considerable. For this

[74] 'Legal loophole allows altered organisms to travel by post', *New Scientist*, 25 May 1991, p 13.
[75] Conference Report, 'Convention on Biological Diversity: National Interests and Global Imperatives', Held at the UNEP headquarters, Nairobi, 26–29 January 1993, organized by the Biopolicy Institute of the African Centre for Technology Studies (ACTS), and the Stockholm Environment Institute, p 10.
[76] 'Issues before the Inter-governmental Committee on the Convention on Biological Diversity: note of the Executive Director', Intergovernmental Committee on the Convention on Biological Diversity First Session, Geneva, 11–15 October 1993, UNEP/CBD/IC/1/3/Corr. 1, 26 August 1993, p 11.
[77] *The IGCEB Newsletter*, October 1993, p 9.
[78] 'UK rejects call for more systematic biology', *Nature*, Vol 363, 17 June 1993, p 571.
[79] 'Budget may sting insect unit', *Science*, Vol 260, 28 May 1993, p 1238.

reason, and because of the need to widen the compass of risk analysis, a number of disciplines would need to be represented among the staff. There would also need to be a geographic spread among staff. As Harvey Brooks, Professor of Technology and Public Policy at the Kennedy School of Government, has observed in this connection, there may be 'conflicts in the assessment criteria used by donors and recipients, and it is important that the recipients be able to hold their own in the resulting negotiations'.[80]

The clearing house begins to emerge in this analysis as a large and highly significant body. An attractive option would be to integrate such a clearing house within the convention secretariat. To what extent should it be empowered by the Conference of Parties? Ideally, there can be little doubt that the prospects of a workable international biosafety regime would be enhanced if its powers extended to the potential for banning certain GMO applications or releases, if it deemed such action necessary, and the option to demand snap inspections in fulfilling its monitoring role, so as to encourage vigilance in reporting duties among the parties to the protocol.

Socioeconomic implications of releases. The wider assessment of risk advocated here would certainly factor in socioeconomic implications more than is the case today, as UNEP Expert Panel IV advocated.

For many environmentalists, the fact that rBST has recently cleared what appears to be a final hurdle before marketing in the USA would tend to strengthen this case. Monsanto was given the go ahead by the US FDA to market rBST, a growth hormone which can increase milk yields in cows by 10–20%, in December 1993.[81] Meanwhile, in the EC, the European Commission in 1993 proposed an all out ban on the product.[82] The hormone is known to increase the incidence of mastisis in cows, and despite the FDA's assurances that there are no human health risks, surveys have shown that should farmers begin using the product, 15–40% of US consumers would be likely to stop or reduce their milk consumption.[83]

With the progressive control of markets in the hands of transnational organizations, some have argued for strengthening laws which guard against distorted priorities. TNCs' activities involve one-quarter of the world's most productive assets, and 70% of products in world trade.[84] Just one TNC, Bayer, was as of September 1990 set to spend more on biotechnology research than the whole of Latin America.[85] The top 10 transnational corporations already command more than 12% of the global seed market, and one estimate suggests that by the year 2000 as few as ten companies may control all of the global seed market.[86] The big agrochemical companies are undoubtedly buying seeds with the intention of manipulating them to become tolerant of the pesticides they themselves sell.

There is surely scope in these developments for an unhealthy concentration of control over food security. The UN Centre for Transnational Corporations, noting that 'more research and exchange of information is necessary in order to better understand the work of transnational corporations in the area of biotechnology and the implications of their work in this area, especially in developing countries', has observed that 'the international community has an opportunity to develop guidelines on the use of biotechnology and genetic engineering'.[87] Al Gore, in *Earth in the Balance*, has gone further, and called for 'a new generation of environmental anti-trust laws', citing several examples where these might be needed 'to protect against distorted priorities and promote sound decision-making by corporations'.

What about chemical companies that produce pesticides and fertilizers buying up seed companies and selecting and breeding seeds that maximize use of their chemical products, neglecting other varieties that might feature a greater degree of natural

[80] H Brooks, Technological assessment: risks, costs and benefits', *UNATAS Bulletin*, Issue 9, winter 1992, p 12.

[81] 'FDA finally approves BST for milk production', *Bio/Technology*, Vol 11, December 1993, p 1502; 'Milk hormone clears final hurdle', *Nature*, Vol 367, 20 January 1994, p 210.

[82] 'European Commission proposes ban on BST', *Bio/Technology*, Vol 11, August 1993, p 869.

[83] 'Milk hormone faces new hurdles on way to market', *Nature*, Vol 366, 18 November 1993, p 129.

[84] *Ongoing and Future Research: Transnational Corporations and Issues Relating the Environment*, report by the UN Commission on Transnational Corporations (UNCTC), April 1989, p 5.

[85] *Biotechnical and Development Monitor*, September 1990, p 1.

[86] G Kidd, in D Goodman and M Redclift, Refashioning nature', Routledge, London, 1991, p 172.

[87] UN Centre on Transnational Corporations, 'Environmentally sound management of biotechnology', Submission to UNCED PrepComm 4, 1992.

resistance to pests? In neither case should there be an automatic prohibition against cross-ownership, but there ought to be a requirement to consider the potential for harmful consequences to the environment and, if necessary, the right to prevent such mergers.[88]

Funding of the protocol. There are two particularly important questions regarding funding: how much funding would be needed to make a biosafety protocol operate effectively, and who should administer the funds? For a protocol to be effective, non-trivial funding implications arise. Making specific estimates is beyond the scope of this paper, but the clearing house/monitoring agencies, as envisaged, would all require significant budgets if they were to do their jobs properly. In a post-UNCED environment in which most OECD countries look further away than ever from allocating the 0.7% of GNP commonly regarded as an acceptable goal to overseas development aid, this is clearly a potential problem.

The second question, that of who should administer funding, touches on a well known contemporary controversy. The Global Environment Facility (GEF) is the interim funding agency for the biodiversity and climate conventions, and might be the obvious agency to handle the funding for a biosafety protocol. The GEF already handles the Multilateral Fund of the Montreal Protocol on ozone depletion. But the GEF has come under severe criticism for its handling of its responsibilities. Recently it appointed a committee to evaluate its work, and that committee called first for the work of the GEF to be put on hold, and second for control of the GEF to be taken away from the World Bank.[89] The committee recommended that the GEF should be run by an independent secretariat.

Discussion

The release of GMOs to the environment may be low risk, and have minimal impact on the environment, as many scientists – most of them practitioners – profess. Or it may not. For environmental reasons alone, the benefit of future hindsight may cause the human community to rue development of the technology, as has been the case where indeterminancies involving other technologies, such as halocarbons, have dealt malign wild cards. The precedents of environmental harm involving alien species, the essential unrecallability of GMOs, their ability to proliferate in the environment, and their ability to ignore international borders during that potential proliferation, all add to the stakes, even if the risk is indeed very low. For these reasons alone, allowing piecemeal development of the technology from its present nascent stage to a global, pervasive entity – and the basis for a multimillion dollar industry – would seem to be unwise. Equally, any harmonized regulatory regime that a biosafety protocol might set up should not be regarded as a holy grail guaranteed to ensure safe use of GMOs in perpetuity. Indeed, there would be a real danger that institutionalizing the treatment of biosafety in this way would engender an illusion of control where in fact indeterminancies allow no such thing. This would be a danger that advocates of a biosafety protocol would need to keep constantly in mind.

Additionally, there is much more to the development of rDNA technology than the direct impact on the environment. A number of socioeconomic considerations tie in directly to development and, as so many have pointed out in recent years, ignoring the needs of development in the developing countries is one of the main guarantees of continued deterioration of the global environment. As the Dutch Ministry of Foreign Affairs has put it, 'the currently available biotechnology is not adapted to the needs of small producers

[88]Al Gore, *Earth in the Balance*, Earthscan, 1992, pp 342–343.
[89]'Poor management could cost the Earth', *New Scientist*, 4 December 1993, p 4.

or their limited ability to invest, and is thus unsuitable for them'.[90] Profound problems for the South, such as substitution of traditional commodities by transgenic products in the North, may be just around the corner if wider questions of risk associated with the development of the technology are not addressed substantively. And allowing rDNA technology to develop in a manner which accelerates, rather than remediates, the economic balance between North and South would stand to be an indirect assault on the environment, irrespective of the magnitude of direct ecological risk from GMO releases themselves. Ladislav Kovac, a biochemistry professor and Czech Ambassador to UNESCO, concludes that with the large-scale development of biotechnology

> the increase in economic and spiritual disequilibrium would have global consequences, affecting humankind as a whole. This is why to see the dangers and to prevent them should be also a concern of the developed countries. Concern for the Third World should be for them not a matter of compassion and charity but a matter of enlightened self-interest.[91]

The enlightened self-interest might extend to fields other than environmental and food security. Unscrutinized, uncontrolled development of rDNA technology could have profound implications for military security, since the ongoing scientific revolution in genetic engineering undoubtedly opens up the prospect of a whole new generation of biologically based weapons of mass destruction. As the author has described elsewhere,[92] rDNA technology invokes the spectre of using specifically targeted disease against a vulnerable monoculture, say, as an instrument of economic warfare; against a particular population, even potentially against a specific ethnicity. Such weapons of the future would be easy to hide and to mass produce, obviating stockpiling. This is all too far from the realm of the unrealistic, when we consider, for example, that in March 1992 Armenian helicopters dropped packages containing biological material and insects on an area of Azerbaijan.[93]

Such considerations raise the ethics of legitimizing global proliferation of an unquantifiably risky technology. Is there a risk that a biosafety protocol would establish international controls on the release of genetically engineered life forms, only to discover at some time in the future some significant unforeseen, perhaps unforeseeable, and entirely malignant ecological impact; or that some future oligarchy had capitalized on the march of technical discovery to develop an ethnically targeted lethal virus? In that event would the protocol have merely legitimized a technology which, with the benefit of future hindsight, might look an obvious candidate for keeping locked in Pandora's box? Arguably, the relationship between the Non-Proliferation Treaty, the nuclear industry and nuclear weapons provide a precedent here. As a well-known nuclear analyst has commented, 'in the end it seems that as quickly as new detection methods can be developed, would-be proliferators will find ways round them. The plain fact is that nations, such as the present nuclear weapons states, and treaties, such as the NPT, which both legitimize possession of nuclear weapons, also legitimize and make inevitable their spread.'[94] The future scope for genetic engineering technology to be used in the development of biological weapons capabilities should make this a more than academic question, irrespective of environmental and economic questions.

[90] *Biotechnology and Development Co-operation*, Directorate General International Co-operation, Ministry of Foreign Affairs, The Hague, May 1992.
[91] L Kovac, 'Biotechnology: expectations, disappointments, dangers', *UNATAS Bulletin*, Issue 9, winter 1992, p 144.
[92] *Op cit*, Ref 3, *International Affairs*, pp 515–517.
[93] *Arms Control Reporter*, Cambridge MA, May 1992, 701.B.90.IDDS.
[94] J Hassard, 'Arms and the ban', *New Scientist*, 28 November 1992, p 41.