Regulation of Biotechnology: needs and burdens for developing Countries

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This paper addresses many of the issues that arise from the use of Genetic modification techniques that allow new living modified organisms to be produced which have characteristics that have not necessarily been found before. Genes are copied from organisms that are unrelated to those into which they are inserted. This technology has provided a concern from the very outset of its use, and most countries recognise that it needs some form of regulation to ensure safety both to human health and the environment. In many cases no need has been seen for changes to law, in others new laws have been implemented.

Introduction

The potential uses of genetic modification[1] were obvious from the moment that the techniques that enabled the transfer of genes from one organism to another unrelated organism were first identified.

Agenda 21 was agreed in Rio de Janeiro in 1992. Countries identified modern biotechnology as 'an emerging knowledge intensive field' which 'is a set of enabling techniques for bringing about specific man-made changes in deoxyribonucleic acid (DNA) or genetic material in plants, animals and microbial systems leading to useful products and technologies'[2] There was a recognition that the technology has many advantages and it was necessary to foster internationally agreed principles to be applied so as to ensure the "environmentally sound management of biotechnology, to engender public trust and confidence, to promote the development of sustainable applications of biotechnology and to establish appropriate enabling mechanisms, especially within developing countries through…

a. Increasing the availability of food, feed and renewable raw materials;
b. Improving human health;
c. Enhancing protection of the environment;
d. Enhancing safety and developing international mechanisms for cooperation;
e. Establishing enabling mechanisms for the development and the environmentally sound application of biotechnology."[3]

The Convention on Biological Diversity, agreed in 1992[4], required parties to establish national frameworks for ensuring that biotechnology is used safely. Article 8(g) states that Parties shall as far as possible and as appropriate "Establish or maintain means to regulate,

[1] Variously and at various times called genetic modification, genetic manipulation or genetic engineering
[2] Agenda 21 (1992), preamble to Chapter 16: see http:// www.igc.org/habitat/agenda21
[3] ibid
[4] http://www.biodiv.org/convention/articles.asp

manage or control the risks associated with the use and release of living modified organisms[5] 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"[6]. The wording implies that there are both environmental and possible risks to human health involved in the use of modern biotechnology, while not explicitly identifying the benefits that may accrue from the use of modern biotechnology. Article 19[7] identifies that there are great benefits that might arise and attempts to provide the mechanisms to allow developing countries to benefit. Article 19(3) calls on the parties to the Convention to consider whether there is a need for a Protocol to the treaty which would *inter alia* provide procedures between parties for the safe transfer, handling and use of living modified organisms 'that may have adverse effects on the conservation and sustainable use of biological diversity".

After many years of meetings and discussion in an *ad-hoc* open-ended Working Group set up to consider the need for the Protocol, the Parties to the Convention adopted a text in January 2000. This "Cartagena Protocol on Biosafety"[8] establishes mechanisms for Parties to the Protocol to inform each other about what they are doing in relation to modern biotechnology, and provides the systems needed to ensure acceptability of the products of the technology when living modified organisms that meet the definition in the Protocol are transferred between member states. The objective is much broader, but most of the Articles focus on transfer between countries of living modified organisms that might have adverse effects on the conservation and sustainable use biological diversity. Article 1 "The Objective" states:-

"In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."

The Protocol was agreed, with many misgivings, but in an atmosphere which had changed from that which pertained at the time the negotiations started. Europeans were no longer accepting modern biotechnology; products had disappeared from the shops, and there was a gloom and distrust in many countries not observed elsewhere. Few if any products derived using modern biotechnology are available in Europe[9]. In North America, farmers adopted transgenic organisms with little opposition, and products derived from them have been in the shops for over 5 years.

There have been many arguments that decisions on the use of these living modified organisms must be based on science; this is made very clear in the Cartagena Protocol. Article 15 states that "Risk assessments undertaken pursuant to this Protocol shall be carried

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[5] "Living modified organism" (as defined in the Cartagena Protocol) means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology; The Protocol applies to living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

[6] http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-08

[7] Article 19. Handling of Biotechnology and Distribution of its Benefits, http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-19

[8] http://www.biodiv.org/biosafety/default.asp

[9] The Royal Society (February 2002) Genetically Modified Plants for Food Use and human helath – an update, Policy Document 4/02 ISBN 0 85403 576 1 paragraph 2.

out in a scientifically sound manner Article 23 of the Cartagena Protocol requires public involvement in the decision making process and article 26 allows for specific socio-economic issues to be taken into account in the process:

"The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."

Responses to modern biotechnology

The European public debate resulted in rejection of modern biotechnology which in 1998 had the effect of influencing the main distribution companies to remove these products from European shelves. In the United States, there appeared to be little rejection, attributed by the US government to the openness of the American system. "In 1994 approximately 7,000 acres were planted under 593 USDA field-test authorizations, compared to 57,000 acres under 1,117 authorizations in 2001. The first biotechnology-derived crops were commercialized in 1996 and, in 2001, approximately 88 million acres were planted in the United States and 130 million acres were planted world-wide"[10]. Canada, Argentina and Mexico are the only other countries in which there has been significant use of modern agricultural biotechnology, although many other countries are starting to increase their use of living modified organisms in agriculture. China has approved a small number of transgenic varieties of cotton and expects to proceed to the commercial production of modified rice in the next two years.

Many developing countries are fearful of the impact of agricultural biotechnology. Zimbabwe and Zambia, for example, have been wary of permitting food-aid which contains transgenic maize into the country, even though many of its people are starving. This reluctance relates to the possible disappearance of major markets if crops are 'contaminated' with transgenic material.

In most circumstances the introduction of safety legislation within a country has followed a major accident or incident. Regulation has been reactive whereas for modern biotechnology the system of regulation has been proactive. There are no documented cases of harm resulting directly from the use of recombinant techniques, whether in the research environment or for commercial applications. There are many who ask whether a proactive approach to biotechnology regulation is sensible, for it places in the public domain a concern that has been translated into a fear of the new technology, particularly in Europe. Would most of the innovations that have so fundamentally modified our way of life during the twentieth century have happened had a full risk evaluation been required?

Although this paper has to consider the importance of ensuring the safe use of modified organisms in developing countries that which is happening in Europe is significant as it has a direct bearing on that which can be done in developing countries. In the first instance the concerns being expressed by Greenpeace, Friends of the Earth, Christian Aid or even the British Medical Association create a groundswell against the use of this new technology. Can it be right to introduce these 'untested' technologies in developing countries when public 'informed' opinion is so virulently opposed to their use in Europe? When even statutory

[10] Office of Science and Technology Policy (2002) - Proposed Federal Actions To Update Field Test Requirements for Biotechnology Derived Plants and To Establish Early Food Safety Assessments for New Proteins Produced by Such Plants; Notice, **Federal Register** / Vol. 67, No. 149 / Friday, August 2, 2002, p 50578 – 50580.

bodies like the Nature Conservation Organisations in Britain and France reject modern biotechnology because of a predicted negative effect on the environment, are developing countries to embrace them? The UNEP International Guidelines and the Cartagena Protocol require the public to be informed and educated about biosafety, but the virulent reaction against the technology in Europe impacts directly on any public image more easily than a reasoned argument for the safe use of the technology. The rejection of genetically modified foods by many European Supermarkets and food producers has impacted on production and growing of genetically modified crops that have to be exported to one of the largest food markets in the world. To grow rice modified so that it produces vitamin A is a wonderful prospect for nutrition in the many countries that depend on rice as a primary food. If, however, the produce cannot be exported as well, producers will be reluctant to grow it!

Such problems call into question the sustainability of the key technological paradigms on which much of the expansion of food production since 1960 has depended"[11] "It is probably fair to say that the most significant breakthroughs in recent years in the area of crop biotechnologies have stemmed from research into the genetic mechanisms behind economically important traits"[12] The FAO estimate that in South Asia 191 of the potential 228 million hectares (84%) were under cultivation in 1988-89, and there is little scope for an increase in land usage for agricultural purposes.

This response in Western Europe to the new technology cannot easily be dismissed through assertions by scientists that there is negligible risk, or that permits to market transgenic foods and crops (in particular) should be based solely on risk assessments that are science based. If all the scientific information had been available and a consensus amongst scientists could be achieved that the impact on the environment is minimal, it would be possible to argue for a totally science based risk assessment process.

In December 1996 FAO and WHO convened a consultation on Biotechnology and Food Safety. This consultation concluded that the food safety issues raised by modern biotechnology are basically of the same nature as that that might arise when other methods of modifying new plant varieties are used, including traditional methods of plant breeding. They also concluded that the comparative method used in the OECD concept of 'substantial equivalence' could be the basis for an evaluation of foods consisting of, or derived from, genetically modified plants[13] However, the same consultation meeting concluded that proper safety assessments are needed for food produced by recombinant DNA technology. The report of an OECD Workshop on the toxicological and nutritional testing of novel foods in 1998 suggests "Demonstration of equivalence of a new food to an existing food product with an established history of safe use provides assurance that the new food is as safe as the established food"[14]. "The workshop concluded that the demonstration of substantial equivalence concept provides equal or increased assurance of the safety of foods derived from genetically modified plants as compared to foods derived by conventional methods." A subsequent safety evaluation is then focussed on the identified differences due to the introduction of new characteristics. This process is not, however, sufficient to evaluate the

[11] P.A. Oram and Behjat Hojjatti (1995) in "Population and Food in the Early 21st century: Meeting Future Food Demand of an Increasing Population" ed. Nurul Islam. International Food Policy Research Institute, Washington DC p 167.

[12] FAO (2000) *Electronic Forum on Biotechnology in Food and Agriculture"* Introduction to an online conference running between March 20 – May 19, 2000 on http://www.fao.org/biotech/Cidoc.htm.

[13] FAO (1997) Biotechnology and Food Safety, Food and Nutrition Paper 61, FAO, Rome.

[14] Organisation for Economic Cooperation and Development (1998) Report of the OECD Workshop on the toxicological and nutritional testing of novel foods, OECD, Paris.

behaviour of a new food plant in the environment, especially where the modification may change the interaction of that plant with other organisms within the environment in unpredictable ways. The OECD workshop (reference 22, section 5.ii) noted that the traditional assessments of plant breeders in evaluating new varieties rarely address issues related to the safety of crop plants and "cannot therefore be considered sufficient to establish substantial equivalence or to ensure the safety of a new crop variety". The assessment of environmental risk due to a new plant variety almost always is performed on a case-by-case assessment and based on scientific intuition supplementing the wealth of data about the organism and the environment into which it is placed. In 2002 The European Union is considering no further use for the 'substantial equivalence' concept. In February the Royal Society[15] commented on its use. They state that the amount of information needed to establish 'substantial equivalence' is subjective, and the technique has therefore attracted considerable criticism[16,17]. Much needs to be done to ensure that there is an agreement on what constitutes acceptable data amongst the protagonists for and against modern biotechnology.

UNEP introduced a set of guidelines in 1995 that aimed to provide a baseline for the introduction of regulation or guidelines for countries to ensure the safe use of products resulting from biotechnology. The guidelines called for national biosafety frameworks to be introduced that would allow for governments to establish processes for identifying the uses to which biotechnology was being put within their borders and to develop the appropriate national mechanisms for dealing with any use to which the technology could be put. The guidelines provided protocols for identifying hazards and minimising harm to both human health and the environment due to the use of modern biotechnology. The guidelines provided that "Risk assessment and risk management can be based in part on knowledge of and experience (i.e. familiarity) with an organism, the intended application and the potential receiving environment." The process of risk assessment was recognised as varying from a short process of assurance of safety to an extensive review, depending on the extent of familiarity.

The requirement to provide capacity building for developing countries in both biotechnology and in biosafety has been echoed in the Cartagena Protocol to the Convention on Biological Diversity. Article 11, which primarily deals with the procedures in relation to the movement of living modified organisms intended for direct use as food or feed, identifies a need for financial and technical assistance and capacity building. The procedures identify a need for a risk assessment, for which capacity building will be extremely important. Article 22 deals directly with capacity building, and expects the parties to the protocol "to cooperate in the development and or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety". The training that is envisaged in the Protocol includes scientific and technical capacity and the use of risk assessment and risk management in order to ensure the safe use of living modified organisms. Article 23 identifies the need to promote and facilitate public awareness, education and participation in relation to all uses of living modified organisms and requires that the public be consulted in the decision making process regarding LMOs.

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[15] The Royal Society (February 2002) Genetically Modified Plants for Food Use and human health – an update, Policy Document 4/02 ISBN 0 85403 576 1

[16] Royal Society of Canada (2001). Elements of Precaution: Recommendations of the regulation of food biotechnology in Canada. Royal Society of Canada: Ottawa

[17] Millstone E P, Brunner E J & Mayer S (1999). Beyond 'substantial equivalence'. Nature 401, 525–26

Developing countries look at that which is happening elsewhere with bewilderment and concern. It is clear that Europe does not want the technology, and that North America does. Leaving aside the need to sell products in Europe – which is a major purchaser of agricultural produce, the rejection raises the problem of dumping in these countries and governments are concerned at a possible backlash if the products are to be sold within their borders. Most countries have no legal framework to handle modern biotechnology as required by the Protocol.

Legal frameworks do not necessarily need new laws; there may well be legal systems in place that address the many issues that these countries will have to attempt to consider.

The technology appears to be designed for developed countries for it could be used to solve many of their problems. However, it is expensive to do, and the companies involved in the production of new crops using modern biotechnology have (obviously) aimed them at those who can pay for them. Most agriculture in developed countries is commercial, where farmers grow those crops, which sell well. In developing countries there are (essentially) two forms of agriculture. Firstly, commercial or industrial farms where crops are grown as in developed countries, often for export and the same needs and wants are there. The crop and the varieties designed by the biotechnology companies may solve their problems as well. There is a second form of agriculture, where crops are grown in traditional ways and often the crops (and varieties) are different from those grown commercially. These crops could benefit enormously from modern technology, whether modern biotechnology or not. Reduction in virus infection and in pests could dramatically increase their yields, but the large seed organisations may be uninterested as the profits are elsewhere.

Countries want to increase the efficiency of both of these forms of agriculture of these forms of agriculture. In theory, the first is easy if the money is there or if foreign companies can be induced to invest in farms in these countries. There remain problems if seed variety listing and biosafety legislation require that new varieties are tested for fitness and safety before introduction. The second is more difficult to solve, as it requires a technology infrastructure to design and insert new genes conferring desired characteristics into local crops or varieties and then to perform the rigorous testing necessary to ensure safety in the environment and as a food. Companies are often willing to provide ‘gene cassettes’ – set of genes and signal sequences that confer desired characteristics – but the science and legal structures necessary to use these are needed.

It is relatively simple for countries to set up a legal framework; it is a much longer process to provide the scientific infrastructure to produce new and effective food varieties.

The challenge to developing countries is not clear. Their needs are to produce a greater quantity and higher quality of food for their populace and to increase production from agriculture to provide for export markets. They also have to protect the health of their people from imports of inappropriate food and feed and to attempt to protect their environment from the introduction of alien species or new varieties of organisms that could have adverse effects on the environment. It seems that living modified organisms are subject to far stronger regulation than other ‘alien’ organisms. The use of these new varieties may increase food availability if they are the right varieties for the conditions in the countries and they may increase exports and therefore foreign earnings if countries are willing to accept exports of these varieties.

When the Cartagena Protocol comes into force, countries will, in general, have to have in place legal and administrative systems to ensure that they are able to deal with both exports and imports of living modified organisms. If a scientific infrastructure to produce new

varieties adapted for their environment is not in place, the development of the capacity will take much longer.

Adverse Effects on the Environment and on Human Health

There are a number of steps that need to be taken to ensure that any adverse impacts on the environment or on human health are minimised. The **trigger** for beginning the process is usually but not exclusively the technique by which the organism has been made. If an organism is novel, but not made through the use of 'modern biotechnology' it may not trigger the whole risk process.

Once the process has been triggered, a risk assessment needs to be implemented. Risk assessment and risk management are addressed in the Protocol in Articles 15 and 16 and the Annexes. Article 15 explains that where risk assessment is required it should be carried out in a scientifically sound manner. Information identified in the Annexes to the protocol (particularly Annex III) is used to identify and evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biological diversity (and any risk to human health). The Protocol is clear that risk assessment should be based on recognised techniques. What is most important is that the risk assessment process is based on science.

Science does not have all the answers, and the Protocol requires that a 'precautionary approach' be taken where complete information is not available. There is disagreement at a scientific level about the manner in which an inserted gene is likely to modify characteristics of the organism or its impact on the environment. This results in an incomplete scientific evaluation of the risks because there is an insufficiency of data, or they are incomplete, inconclusive or imprecise, and it may be that it is not possible to determine with sufficient certainty what the risks actually are[18]. The risk assessment will be incomplete, and the risk management that follows must allow decisions as to mechanisms for minimisation of risks. This is usually interpreted as requiring that each new living modified organism is considered case-by-case; that a stepwise approach be taken to allow impacts on the environment to be assessed – first in a greenhouse or equivalent, then a limited release, possibly a further limited semi-contained release and finally approval may be given for commercial release. Monitoring to ensure that assumptions made during the risk assessment are borne out in the environment is also part of the precautionary approach.

The risk assessment may indicate changes that need to be made to the organism or to the manner in which it is handled in the environment. If these changes are implemented, the assessed risk will change; hence the approach to risk assessment is iterative.

Assessment of risk is an important first step in any attempt to minimise harm to the environment, and risk management provides the tools to ensure that any risk identified during the assessment process is minimised. The two are not completely separate processes, and it is necessary to iterate between risk assessment and management to achieve the desired goal – minimisation of any risk to an acceptable level.[19] Although the Protocol has as a primary focus the transboundary movement of living modified organisms that may have an adverse effect on biodiversity conservation and its sustainable use, these provisions cannot be implemented without considering the adverse impact of the use or handling of these organisms in general.

[18] Communication for the European Commission on the Precautionary Principle, February 2000, Com 2000 (1).
[19] Framework for Environmental Risk Management (1997) The Presidential /Congressional Commission on Risk Assessment and Risk Management, Final Report, Volume 1, United States of America.

Although risk assessment is science-based in many countries the decision as to whether to permit or not to permit use under specified conditions may be separated from the assessment process. Often it is a minister responsible to a parliament that makes the decision which might be based on considerations other than science. It is the transboundary movement of living modified organisms that the Protocol focuses on. It does not provide a comprehensive system for the management of living modified organism at the national or international level. However, the risk assessment (and risk management) procedures require consideration of the adverse impact on conservation and sustainable use of biological diversity in any environment into which the organism is placed. Risk assessment must not only concern itself solely with transfer between Parties to the Protocol, but to the introduction of a new organism into an environment, and the risks posed during the transfer and handling of the living modified organisms.

Risk

Risk may be defined as the likelihood that an organism introduced into the environment may cause harm to that environment and can be seen as comprised of two factors,

a. the consequence of a particular event
b. the likelihood of the event occurring

Risk arises from exposure and hazard. There is no risk, regardless of how hazardous a particular organism may be, if there is no exposure. Hazard may be regarded as the potential to cause harmful effects[20].

Risk Assessment Strategies:

The risk assessment strategies adopted by all the international and national systems are very similar, and are predominantly based on *familiarity* with the wild-type, unmodified, organism and the likely impact due to the changed characteristics of the organism. Article 15 of the Protocol requires that 'risk assessment techniques' already used must be taken into account.

It is assumed in all systems that have been put into place that a risk assessment will start from a consideration of the wild type organisms from which the living modified organism has been derived, and that variations in the behaviour of the modified organism are those that require specific attention. For example, if the non-modified precursor of an LMO, its seeds or pollen do not survive a harsh winter, a crucial test when considering the likelihood of the new variety becoming a weed would be whether the modification results in an increased likelihood of survival during a harsh winter. Information about the behaviour of donor (those from which the inserted genes have been derived) and host organisms (those into which genes are inserted) form the baseline for assessing hazards and therefore risks. If an organism or part of an organism is used in the transfer of genes from donor to host, its behaviour within the environment must also form part of the information upon which the risk assessment is based. An example is the use of a plasmid[21] derived from a plant pest, *Agrobacterium tumefaciens*. The plasmid is one of the main vectors used in transferring to a plant cell, yet its normal host is a plant pest. The regulatory system in some countries is triggered by its use simply because it is derived from a pest, even though the plasmid actually used does not contain the genes that would assist the bacterium. A trigger is simply a mechanism for starting the risk assessment process

[20] Ibid, page 1.
[21] A plasmid is a piece of DNA that is capable of autonomous replication in a prokaryote or eukaryote cell. It is commonly dispensable to the cell and can be transferred between cells.

Where a living modified organism that could pose risks is exported, it is the clear duty of the country of export, or where so designated, the exporter to provide a risk assessment to the authorities in the country of import. The Party of import receives a notification from the Party of export (or the exporter if so required by the Party of export) identifying that which it is intended to move across a boundary (Article 8). The information that must accompany the notification is detailed in Annex I (as a minimum). If a living modified organism is to be exported from one country to another, it will have been produced somewhere, possibly in the country of export, and may have been subjected to a full risk assessment for contained use and/or for release if released into the environment. Therefore, the exporter or party of export must provide a previous and existing risk assessment report consistent with Annex III (Annex I(k)). This provision applies to any further risk assessment to take account the environmental conditions that apply within the country to which the living modified organism is to be imported. The importing country could perform this assessment, or the exporter may be required to perform the risk assessment, and the cost of risk assessment could be borne by the notifier if required by the Party of import.

In some countries government, on the basis of information provided by the applicant, performs a risk assessment. In deciding on risk, the authorities have the responsibility to review the information provided and request further information or clarification in order to arrive at a satisfactory risk assessment. In other countries the authority responsible for decisions acts as an auditor of the risk assessment provided by the applicant. The applicant must provide a dossier containing all the information used in arriving at the risk assessment (and management); the authorities review the data and the assessment and again may ask for further information or clarification in order to decide on the validity of the risk assessment. This provision permits a government to request of an exporter a full risk assessment that it may then consider or audit, and if necessary, require further work to assure that the assessment applies to any possible risks to the environment as defined in the Protocol that may not have been considered in a risk assessment undertaken in another country or by the exporter in attempting to meet the requirements of the importing government.

The mechanism for handling either risk assessment or audit of risk assessment in Government varies between countries as well. In some the process occurs totally within the responsible government departments, with civil servants performing the risk assessment or audit; in other jurisdictions Governments appoint independent committees of experts who advise it on the risk assessment. The EU and US Biotechnology Consultative Forum, when reporting in December 2000 stressed that it was less important as to 'who' is involved in the decision making process than that the 'function be specifically delineated and competently executed'. They recommended that "The individuals charged with risk assessment should be well qualified to make decisions in the area under review, be individuals of the highest integrity, and meet stringent requirements for public disclosure of actual and potential conflicts of interest"[22].

The costs of regulation of modern biotechnology are high, both to a government (that assures that possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health, are minimised) and to the applicant (for permission to use or release the organism). Governments vary as to their approach to recovering the costs of the procedures. In some no charge is made for the regulatory processes within government, in others the full costs (insofar as they can be

[22] The EU-U.S. Biotechnology Consultative Forum Final Report (December 2000) http://europa.eu.int/comm./external_relations/us/biotech/report.pdf

determined) are recovered from those proposing to use, handle or move living modified organisms. Article 15 of the Cartagena Protocol enables a Party, if it so wishes, to charge exporters the full cost of the regulatory system needed to assess the proposal put to them.

Risk Management

Risk management, which includes the system by which decisions are made is considered to be separate from risk assessment. "Risk management is the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risks while taking into account social, cultural, ethical, political, and legal considerations"[23]. The management of risk includes the need to consider the risk assessment by considering the nature and magnitude of all identified risks and identifying procedures that eliminate or reduce these risks. There is a need to ensure that risk management decisions take into account the many different views of those affected by the introduction into the environment of LMOs that meet the definitions in the Protocol, so as to ensure that differing "technical assessments, public values, knowledge, and perceptions are considered".[24]

Risk management is based on "a careful analysis of the weight of scientific evidence that supports conclusions about a problem's potential risks to human health and the environment." The techniques used need to be feasible, insofar as is possible to prevent rather than simply control risk, are sensitive to political, legal, social and cultural issues and can be implemented with stakeholder support.[25]

Most risk management procedures that have been imposed have not sought to *prevent* risk, but rather to minimise any danger. Prevention is difficult to attain, as risk can never be zero.

Many of the living modified organisms grown within the borders of a Party to the Protocol will have been produced, and possibly grown commercially in other countries which may have very different eco-systems and indigenous organisms. Although these new organisms may have been subject to risk assessment and risk management procedures in all the countries where they are already used, (particularly in the country of manufacture and first use) these risk assessments may not be adequate to protect the environment and biological diversity and ensure the sustainable use of biological diversity in a new and different environment.

A great deal has been said about the need for predictability in decision making. If the risk assessment procedure is clearly defined and followed the science-based advice on adverse impacts may be different in different countries, but is defensible. If the decision making process is open, with clear guidelines the system is mostly predictable. In some countries the decision making process is made by officials without reference to ministers following an agreed protocol. In other countries a system has been set up where the decision making process is open and transparent and not accountable to political whim. In Australia, for example, the regulator is responsible to the Parliament rather than to ministers; In the United States Government has delegated its powers to agencies with clear guidelines on the decision making process. In other countries the decision is made by ministers taking account many factors including non-science-based information.

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[23] Framework for Environmental Risk Management (1997) The Presidential /Congressional Commission on Risk Assessment and Risk Management, Final Report, Volume 1, United States of America. Page 1.
[24] Ibid, page 10.
[25] Ibid, pages 4.

All the above indicates that the processes that need to be instituted to ensure that any living modified organisms are used safely are complex. A country needs

1. A system for receiving notifications about the intended introduction of a living modified organism. That system must provide for informing the applicant of the receipt of the dossier of information. This system may be the same for applications received from applicants working on the modification of organisms within the country or for those from applicants wishing to import products into the country.
2. The systems set up may be different for different uses – if a product is to be used only for food and feed, and for which there is no intention to grow the organism, the procedure may be very different from those instituted with organisms that are intended to be released into the environment.
3. The administrative system must then examine the dossier submitted by an applicant to ensure completeness – is all the necessary information provided?
4. Either the Government performs a risk assessment based on information in the dossier, or the Government audits the risk assessment provided by the applicant. In either event, it must set up a system of scientific oversight of the dossiers received. If information is absent a system for requesting further information from applicants must be put into place.
5. There is an obligation to set up systems to allow public and stakeholder comment to be considered.
6. A system for evaluating the risk assessment and/or the audit report and any public comments must be instituted. Changes to the design of the 'release' or marketing programme may have to be requested.
7. The decision making process, including the manner in which the decision is communicated to the applicant and to the general public must be implemented

All of this must be in place before the first decision is made….