Genetically Modified Organisms and Biosafety:

A background paper for decision-makers and others to assist in consideration of GMO issues[1]

IUCN – The World Conservation Union

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[1] This paper was prepared by the IUCN Environmental Law Centre. The Lead Author was Tomme Young. It reflects contributions from Rachel Asante Owusu, Françoise Burhenne-Guilmin, Martha Chouchena-Rojas, Tom Hammond, Jack A. Heinemann, Geoffrey Howard, William Jackson, Olga Krever, Sue Mainka, Jeffrey A. McNeely, Aroha Mead, John Scanlon and Richard Tapper. It also reflects the verbal comments of members of the Programme and Policy Committee of the IUCN Council, when they considered this document in May and December, 2002, and comments received from the Commission on Environmental, Economic and Social Policy and through the "biosafety comment process," which began on 11 April 2003. The lead author assumes full responsibility for errors in its content or misunderstandings of particular comments.

Acronyms used in this Briefing

AIA	Advance Informed Agreement
BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
COP	Conference of the Parties
EIA	Environmental Impact Assessment
GEF	Global Environment Facility
GMO	Genetically Modified Organism
ICCP	Intergovernmental Committee for the Cartagena Protocol
IGO	Inter-governmental Organisation
IPR	Intellectual Property Rights
IUCN	International Union for Conservation of Nature and Natural Resources (The World Conservation Union)
FAO	Food and Agriculture Organization
LMO	Living Modified Organism
MOP	Meeting of the Parties to the Protocol
UNDP	United Nations Development Programme
UNEP	United Nations Environmental Programme
WAICENT	World Agricultural Information Centre
WCC-2	Second World Conservation Congress
WHO	World Health Organization
WTO	World Trade Organisation
WWF	World Wide Fund for Nature

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Over the coming ten years, the union will also play a major role in identifying and defining the emerging issues that affect biodiversity. It is likely that particular attention will be given to the environmental impacts of biotechnology

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- IUCN Programme, adopted by the 2nd World Conservation Congress, Amman, Jordan, 4-11 October 2000

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I. Introduction

A. The breadth of the topic

Genetic modification and "biosafety" are concepts that have not been well understood by, or accessible to, the non-geneticists working in the fields of conservation science, law, administration and management, and in the scientific, legal, administrative and management aspects of sustainable use. The biodiversity debate is at the forefront of the larger question of how humanity can, in an integrated, congruent way, address human livelihoods, while at the same time fulfilling its international mandates to conserve and sustainably use the environment. In a world focused on issues such as poverty and food security, as well as species loss and ecosystem destruction, these questions are among the most important and the most difficult on the planet.

In this connection, we find many claims about genetically modified organisms (GMOs) – that they can be a basis for increasing food production, without the need to convert more land to cultivation, for example. These claims, however, are countered by the claims that GMOs may have a variety of impacts on people and animals, and especially on ecosystems and lands not under cultivation, and concerns about whether and how the benefits of GMOs are actually experienced in developing countries.

After an examination of sources and noted commentaries relating to the GMO/biosafety "debate," two things are clear:

(i) There are three basic areas in which these issues are under discussion:

- Biological/genetic science;
- Development economics and a reasoned analysis of the expected economic benefits of genetically modified organisms;
- Socio-cultural issues (including especially the impacts of modern biotechnology on (i) human livelihoods, and (ii) indigenous peoples.)

(ii) Many of the prominent voices in each of these areas are focused only on their own area, and not entirely aware of the other two, so that debates often appear rather vague and disconnected – one side of the discussion may, for example, be arguing about the scientific issue, while the other is focusing on economic or social issues, with the result that both condemn the other's arguments as unsound and/or unresponsive, without being fully aware that they are arguing entirely different points.

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[2] This paper is intended to summarise extensive initial research regarding the issues relating to biosafety and GMOs. Although any discussion of this issue necessarily requires "scientific rigour" it is also clear that, to be valuable for the target audience and purpose, it should aim for a useable level of brevity, rather than exhaustive exposition of the issue. Although citations and footnotes are used only for quotations, and specific examples, the information contained in this paper is fully documented by (and can be supplemented from) the resources listed in the bibliography and notes of the discussions with the contributors identified in footnote 1.

In using this paper, it is important to note that the "scientific debate" (*i.e.,* the question of whether GMOs are inherently safe or inherently dangerous) cuts across all other issues. The remaining discussion would be meaningless, for example, if GMOs were determined to be inherently and unavoidably dangerous, since there would then be no justification for releasing them into the natural (or uncontrolled) environment.

Consequently, this paper is divided into the three primary areas of debate listed above. It sets out the scientific debate first, because that debate is the primary crosscutting point. Then it looks at the developmental issues followed by socio-cultural issues. In both of the latter discussions, it is assumed that the reader has read the scientific discussion. Hence, the scientific safety issues are not repeated in the later discussions.

Within this framework, many of the issues that are generally viewed as "crosscutting" (across all biodiversity domains) take on a new significance, and in some cases a new meaning. For example, the concept of "precaution" is being addressed in concrete and sometimes controversial ways, in regard to biosafety. Many countries also suggest the existence of a so-called "development principle", which adds a human balance to the precautionary principle.

Similarly, modern advances in biotechnology bear a unique relation to the concept of "equitable sharing of the benefits derived from the utilisation of genetic resources,"[3] and technology transfer. Through these concepts significant changes and controversies are arising concerning the role of multinational corporations in the enhancement of lives, lifestyles and livelihoods of people, communities, and developing countries. Perhaps the single most important factor in making progress within this field is the development of reliable information and analysis, in fields of biology, ecology, law, economics, ecosystem management, and social policy. While these concepts are incorporated into the three main discussions, the special elements of their application to GMOs are separately laid out at the end of the paper, for purposes of clarity.

B. IUCN and Biosafety

IUCN's important international role is to serve as a "knowledge network" of experts and information on issues within our two conservation goals of facing the extinction crisis and restoring and maintaining ecosystem integrity, within the various disciplines that effect them most directly, where we can be effective and add value. In this role, IUCN is now facing the challenge of a major change in the underlying sciences and the manner in which they are used. As noted by Dr. Barry Commoner,

> Biology was once regarded as a languid, largely descriptive discipline, a passive science that was content, for much of its history, merely to observe the natural world, rather than to change it. No longer. Today, biology, armed with the power of genetics, has replaced physics as the activist Science of the Century …, calling forth artificial forms of life rather than undiscovered elements and sub-atomic particles.[4]

The Second World Conservation Congress (WCC-2) recognised this challenge and the potential importance of IUCN's role in it in several critical ways, the most direct of which are found in Resolution 2.31 and the IUCN Programme.

Resolution 2.31 on "Genetically Modified Organisms":

This resolution noted two key concerns regarding GMOs:

(i) the potential for significant reduction or loss of biodiversity, as a result of releases of GMOs; and

(ii) the potential role of GMOs in "achieving global food security," which it noted "have not been adequately demonstrated so far."

The resolution focuses on the "lack of knowledge on the effects of GMOs on biodiversity and the consequent importance of applying the precautionary approach as set out in *Principle 15*

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[3] Convention on Biological Diversity, Article 1. The quoted language is the Convention's description of the third of its three primary objectives.

[4] Commoner, 2002, at p.39

of the *Rio Declaration on Environment and Development* and as reflected in the *Cartagena Protocol on Biosafety* and in numerous international treaties." It specifically urges the application of the precautionary approach to GMO-related decisions. Beyond this, it requests the Director General of IUCN:

- "to support initiatives to implement the Cartagena Protocol"; and
- "to propose options for an IUCN contribution, focusing especially on biodiversity, socio-economic impact and food security."

IUCN Programme:

IUCN has already begun the process described in Resolution 2.31, in the form of the adoption of, and work under, IUCN's Intersessional Programme (also adopted by WCC-2). The Programme, specifically notes, with regard to GMOs and biotechnology, that:

> "The next few years will see intense political, social and economic struggle over these developments. What do the potential risks and benefits of biotechnology mean for the struggle to conserve, sustainably use and equitably share the benefits of biodiversity? The potential power of the biotech revolution will be one that fundamentally shapes our future. Achieving positive results will test the world's collective creativity in public-private partnerships, governance and international scientific and legal regimes."[5]

This paper arises out of the process by which IUCN's Council commissioned an initial orientation to the GMO issue. The publication of that document, in a slightly revised form constitutes an initial step in carrying out IUCN's mandate and its contribution to the international work on biosafety and GMOs in the context of conservation and sustainable use.

C. Objective of this Paper

This paper is intended to provide a basic and balanced understanding of the GMO issue, the sources of controversy and the particular issues of governance and responsible environmental action that arise from it. It seeks to provide an accessible discussion of the wide range of scientific, social, economic and other issues which are frequently expressed only in difficult technical terminology. It also seeks to find a basis for understanding how the various issues and arguments interrelate, and to examine the reasons that the current debate does not appear to be progressing towards resolution.

This paper is not expected to, and does not, reach specific conclusions or final recommendations regarding GMOs, but will offer some guidance concerning ways of approaching the issue, and the relevant concerns and available options for national and regional decision-makers and the civil society, in addressing the issue in various contexts.

[5] *Stepping into the new millennium*, (introduction to IUCN Programme), (IUCN, 2000) at p. 5.

II. Biosafety and GMOs – Technical and Technological issues

The technical and technological issues involved in biosafety are numerous and often very complex. For the purpose of this briefing paper, only the most central will be summarised, as a means of focusing on how the debate is progressing, and on the most relevant issues and informational needs, rather than on cataloguing the list of problems or recent cases.

A. Scientific Aspects of the Controversy

The scientific bases of the GMO controversies must be the beginning point of this analysis. However, even the publicly available scientific literature tends to address the GMO issue with an inappropriate lack of scientific rigour. The following discussion outlines the nature of both the scientific issue, and the problem of awareness among economists, sociologists and other activists and commentators involved in the issue.

1. Popular Viewpoints

The biosafety controversies are so complex that the full extent of the scientific debate is not generally understood. Instead, the positions of many people – even scientists and people at the highest governmental levels – are formed on the basis of a very simplified statements of the issue. At their simplest, the controversies over GMOs and biosafety are typically expressed as follows:

1) On one side are those who feel that products and processes of genetic modification are generally safe and beneficial, and that their use should be fostered and encouraged. The underlying assumption of this view is that the scientific bases for genetic manipulation and other processes are sound, well understood and can be well managed and controlled by the modern biotechnology industry.

2) Opposite in many ways to this first view, however, are those who focus on the risks and unknowns regarding GMOs' possible impact on ecosystems and species (and on human health and other factors.)

3) Yet a third view focuses on the intent behind research and development in molecular biology – *i.e.,* that it provides a potentially dangerous example of the manner in which social structures (including granting agencies, governments, NGOs, industry, and even institutions of higher learning themselves) have come to place an undue level of emphasis on "discovery that can be put to work" rather than on developing the requisite scientific understanding of the underlying processes that will be necessary to understand and predict the impact of those discoveries on humans and the planet.[6]

The foregoing simplistic descriptions constitute the general understanding in most of the world. Although expressed non-scientifically, they appear to be equally represented in the scientific community as they are in the general population. Hence, one's position on GMOs is often simply an extension of one's pre-existing general orientation:

- Those who tend to distrust government or corporations, or to believe that scientific "certainties" cannot be relied on (because they seem to change so frequently), probably ascribe to the position #2, above.
- Others, who generally believe in scientific development as a source of answers, also feel that, where a new technological solution creates problematic side-effects, science will usually be able to solve these problems. These people tend to accept position #1.

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[6] An example of this tendency is offered (by Dr. Jack A. Heinemann, Founding Director of the New Zealand Institute of Gene Ecology) "the Hort+Research adoption of gene-silencing technology for introducing virus resistance in tamarillos in the late 1990s … known as post-transcriptional gene silencing (PTGS) depends on a molecular mechanisms that is *still* unknown. … It is … known now (but not when Hort+Research modified the tamarillos) that the effect can be heritable and can transfer between species." (Letter to Wren Green, May 17, 2002).

- A third group seems to feel that scientific advances can find answers and operate in a safe manner, but are less likely to do so when the focus of that development is on the creation of commercial applications and products and the maximisation of corporate profit. Holders of this view espouse position #3.

These generic responses, however, do not suggest a way forward regarding GMO and biosafety issues.

2. A More Detailed Summary of the Main Points of Scientific Controversy

It is fair to assume that the scientific controversies regarding genetic science cannot be resolved or decided on the basis of a simple restatement of the scientific issues, and no paper can at present provide a definitive statement regarding the controversial scientific issues. In order to determine a focus for decision-making in this area, however, we must develop a more detailed collective understanding of the scientific controversy that underlies the biosafety debate.

While a usable-length background paper cannot thoroughly discuss these issues, this paper does intend to move beyond the most basic formulation of the problem, and give some idea of how it must be understood for purposes of examining its impacts on conservation and sustainable use of biological resources and ecosystems. Hence, before examining the various ecological and socio-cultural impacts and benefits of GMOs, we must briefly outline the underlying science involved, as a basis for understanding.[7]

a. Background: From selective breeding to genetic modification

For centuries farmers have used selective breeding to improve both crops and stock. The most traditional method was,

- with regard to plants, to save the seeds from the particular plant which produced the optimum yield, or otherwise exhibited the best combination of desired characteristics;
- with regard to animals, to control animal breeding, to maximise and reinforce desirable traits.

Over time, breeding controls in both plants and animals, and even in useful microbes (such as yeasts used in bread and winemaking) grew more sophisticated, including processes for developing hybrids.

As variety development began to have a greater commercial element, additional concerns arose. It was essential to ensure that a plant variety was “stable” – that is, through generations of selective breeding to completely eliminate undesirable recessive traits so that the variety would “breed true” in future. This was a pre-condition, if the developer of that variety wished to protect his “intellectual property rights” in that variety. In 1961, the International Union for the Protection of New Varieties of Plants (UPOV) amalgamated existing rules and principles for determining whether a variety is “stable,” creating a standard that is now, generally accepted. It has been suggested that this development (a precursor to modern work on intellectual property rights (IPRs) for traditional genetic modification of plant and animal varieties, as discussed below) may not have been a positive step, given that less stable varieties may be less vulnerable to diseases.[8]

The push for “stability” in the crop variety and other factors have caused the traditional agricultural development processes to be extremely lengthy. Both traditional breeding and hybridisation methods, however, are dependent on the availability of species that are already adapted for use in the region. If a desired trait (resistance to a particular disease or fungus, for example) is not available, it may not be possible to develop it through these methods.

The beginnings of a major change in this process came into being in the 1950s, when James Watson, and Francis Crick discovered the structure of DNA – the double helix of nucleotides

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[7] Please note that, although scientific input was sought and obtained, this summary of that input was written by a non-scientist, for use by persons who may not be experts in genetic sciences..

[8] Commentary submitted by the International Federation of Organic Agriculture Movements (IFOAM).

that, they postulated, forms the blueprint of life. This discovery provided a new theory of genetics – that by altering this genetic coding one can give organisms new characteristics not possible under natural evolutionary processes, selective breeding, or even hybridisation. The theory that they used to explain their discovery was that these characteristics will continue to replicate themselves in stable and predictable dependable ways, because they have been integrated into the DNA coding, which was believed to directly control the way in which cells replicate and specialise within the organism. (Although the basic theory of DNA as the primary code of all life has undergone significant theoretical adjustment since the days of Watson and Crick, this general view, and its current progeny will be described in this paper as the "Watson-Crick theory," to distinguish it from the developing theories discussed below that recognise a variety of other essential building blocks of life, including especially proteins such as RNA.)

By the 1970s, it became possible to isolate individual genes, refashion them and copy them in cells. The significant commercial possibilities of this capability were recognised instantly, and development began primarily through research and development programs in corporate and academic institutions. The first genetically altered whole foods (the so-called FLAVRSAVR tomatoes) appeared on the US markets in 1994. Since then, many other such commodities have been developed.

As an example, a simplified description of one of the many processes[9] by which GMOs are developed (recombinant DNA) is attached as an Annex to this paper. In essence, genetic modification " or "genetic engineering" techniques enable scientists to find individual genes that control particular characteristics, separate them from the original source, and transfer them directly into the cells of an animal, plant, bacterium or virus.[10] This process is based on the above-described premise that the DNA code is known, that it controls all of the specimen's characteristics, that it is inheritable, and that it is common to all life.

From this perspective, there are three major differences between selective breeding and genetic modification:

1. In genetic modification, scientists can take individual genes from one plant, animal or microbe and insert them directly into the DNA of the cells of another, or may modify an existing gene within that organism. This work does not rely on the Mendelian approach of traditional breeding, which seeks to standardise a characteristic by weeding out other characteristics (recessive genes) over many generations.
2. Genetic modification has been expected to provide a way of giving a plant or animal new, inheritable qualities much more quickly than through the use of traditional methods, and to allow the addition of qualities that are entirely new to the species.
3. Modification allows genes to be transferred in ways that are not found in nature, between different species and even between animals and plants.

b. The Scientific Debate

This modern life science created astounding possibilities whose very novelty and power suggested to some the need to challenge the technology before any other factors were considered. Some commenters' description of genetic manipulation as an exercise of "nearly godlike power" is evidence of the level of discomfort felt in response to highly publicised achievements (such as the production of the cloned sheep, Dolly, by Ian Wilmut of the Roslin

[9] In preparing this paper, the lead author has learned more than she ever expected to about 15 separate types of gene manipulation technology, and about the application of the science of proteins and other non-dna substances in the five currently recognised taxonomic kingdoms. She cannot provide more than a summary of the basic scientific controversy which underlies all of them – i.e., whether or not it is scientifically appropriate to rely on the current dna-centric view of biosafety (heir to the original explanation of the Watson-Crick discoveries). The bibliography lists a few of the most accessible of a large range of books and papers reviewed, and does not include lectures received in person or by telephone, from a variety of individuals.]

[10] It is also possible to produce synthetic genes.

Institute and Keith Campbell of the biotech firm PPL Therapeutics in Scotland in March, 1997.[11])

On the more scientific level, however, the debate goes beyond personalities. Concerns expressed by some geneticists focus on the belief that it is premature to introduce GMOs into the environment now, based on scientific, conservation and other concerns, and do not rest upon an objection to humans "acting like gods."

Although these concerns are not new, they are increasingly based on two recent scientific discoveries, and their apparent import. The first of these discoveries is founded on the results of the Human Genome project, which were significantly different from those predicted by the prevailing view of DNA. Those results suggest that DNA is not sufficiently varied and does not allow a sufficient number of combinations to account for all biologically replicated traits, even of simpler life forms. This suggests that there are other factors which are also "building blocks" of life.

In combination with a longer-held position regarding viral transfers, this position is bolstered by several empirical results observed in recent scientific studies, including

- Discoveries concerning the genetic make-up of "mad-cow disease," scrapie, and other degenerative brain diseases. The infectious material in those diseases, when analysed biochemically, was found to contain no nucleic acids at all – no DNA, and no RNA. This suggests that the standard claim that "DNA is the basis of all life" is, at least, inaccurate in some cases.
- Statistical information concerning the number of GMOs which fail to show the expected characteristics, or which show new characteristics and other types of instability not supported by the theory of DNA as the basic blueprint of life.

In all of these cases, the proponents of this position argue that there are other not-yet-understood processes or substances that are essential to the development or replication of life forms. The most common assertion is that the cellular reproductive proteins play this role. This would possibly account for the fact that results of DNA modifications are not limited to the particular characteristics of the replaced gene. Some theorists postulate a process called "alternative splicing" by which changes in a particular gene can be "shared" with other genes, through the medium of RNA (which has a very minor role in the Watson and Crick view of molecular genetic processes).

3. Access to Information and Other Implications for Decision makers

As further discussed below, one of the greatest problems within the scientific debate relates to informational limitations. Most of the available scientific information regarding GMOs is held by corporate and research institutions whose motives are sometimes questioned, as they are viewed as having a strong financial interest in ensuring that GMOs are perceived as positive contributions to human life. These concerns include the fact that many GMO projects suffer a high percentage of failures that are not clearly disclosed or explained. Although there are numerous reasons why these entities should retain close control on this material, it is also true that scientific analysis of the "debate" described above, is severely limited by the lack of access to this closely-held information.

On the other hand, some of the most well publicised opposition to GMOs has sometimes taken the form of high-profile press announcements that do not stand up under initial scrutiny. There was initial dramatic publication of the Bt maize story, in which "environmentalists" claimed that pollen from Bt maize spread to local milkweed, where it was eaten by monarch butterflies, more than half of which quickly died. This story, although excellent at gaining attention, was discredited by the statement that the Bt gene was inserted in maize for the *express purpose* of making that maize toxic to Lepidoptera (the taxonomic order of butterflies and moths), as a means of avoiding the need to poison the corn borer (a caterpillar that is extremely damaging to corn and maize) – another Lepidopteran species. Following the

[11] Although the process that created Dolly does not involve genetic modification, the manipulation involved in the cloning (non-sexual reproduction) a mammal relies on the current version of the Watson-Crick model

"discrediting" of the Bt maize story, publicity died away, and in the limited follow up stories, it was not possible to determine, for example,

- the statistical difference between the effects of using Bt pesticides (which also may find their way onto milkweed eaten by monarch butterflies) and those of Bt maize pollen, with regard to monarch mortality,
- the relative effects and effectiveness of the pesticide as compared to the Bt variety, including comparison of its effect on local communities, and
- the comparative health effects on consumers eating maize which incorporates Bt elements, as opposed to the health effects of using it as an externally applied pesticide.

As to the latter, there are two very serious issues that cannot be currently addressed without that data. On one hand, Bt that is incorporated into the maize's DNA must unavoidably be eaten by the ultimate consumer of the maize (although it has generally not been considered toxic to humans, the scientific basis of this statement has not been publicised in connection with Bt maize). On the other, pesticides and the manner in which they are applied are a serious environmental and health problem. If it is proven that Bt maize is "no worse than the use of Bt pesticide," that fact is not necessarily praise for the product.

In this light (and coupled with questions of precaution and responsibility discussed below), it seems apparent that, while basic underlying science involved in GMOs remains in dispute, there will be a continuing need for organisations such as IUCN –- unbiased scientific analysts and "knowledge networks" – to develop and provide sound and balanced information regarding all aspects of the GMO question, including key questions regarding their impact on species and ecosystems.

B. Economic and Political/Institutional Aspects

A second realm of concern in this area encompasses economics and political concerns. This area has seen a large volume of material regarding GMOs, much of which utilises inconsistent approaches, or fails to clarify the type of physical/scientific questions that are being discussed.

The economic/political debate is often very individual, and debated at the local level, or with regard to specific introductions or proposals. One of the best ways to understand how these issues arise and how they fit into the overall GMO controversy is by utilising two primary organising mechanisms: (i) risk/benefit analysis, and (2) risk management techniques (licensing and labelling).[12]

(As mentioned above, the basic "scientific controversy" cuts across all of these issues. Except where necessary to clarify the problems involved in trying to apply a risk-benefit analysis to the overall GMO issue at present, this section will assume that the reader has already read the previous sections, and is aware of the difficult and currently unresolved basic debate concerning the scientific understanding of the GMO process, and its relevance to any determination regarding the safety of GMOs.)

[12] This paper does not advocate addressing all GMO issues as "risk assessment" problems. Currently, such an approach may be inappropriate, for example, due to the controversy over the scientific safety of GMOs, and the lack of generally accepted basis for evaluating the risks. GMOs are a quite new phenomenon, and the only long-term "risk data" available consists of hypotheses by persons on both sides of the debate. Even accepting these, risk-benefit analysis cannot be used, since one side of the debate says in effect that there is virtually no risk at all, and the other side that the risk is incalculably high. No matter how you organise a risk/benefit formula for such a discussion, the analysis would result in mathematical absurdity.

However, risk assessment issues and the problems associated with applying this mechanism, are very illustrative of the current state of the political, economic, and institutional debates relevant to GMOs.

1. Risk/benefit Analysis

It has been typical, in examining national and commercial development, to utilise the economic approach known as the "cost/benefit analysis." In essence, the aim of this approach is to examine the value of the activity or product (its benefit) in comparison to the costs incurred in undertaking, producing, and/or using it.

To be effective, a cost/benefit analysis must consider *all* of the costs and benefits, and not be limited to financial expenditures and profits. In seeking a proper balance, economists have developed a long series of mechanisms for valuing and comparing various types of costs. In addition to direct and indirect payments, these mechanisms allow the recognition of such items as "opportunity costs" (losses of valuable opportunities, where one is committed to a particular action), the often unvalued costs of use of or damage to "free" resources (e.g. air, water, soil), social costs, environmental benefits and delayed benefits.

These intangibles, while sometimes acceptable with regard to costs, must be differently evaluated with regard to risks. Human activity has advanced to a point where it sometimes tolerates and assumes potential risks whose magnitude cannot be fully predicted, valued, or even completely understood in advance of the activity. As a result, mechanisms have been developed and are still evolving regarding the valuation of this, most critical, component of the cost side of the equation – "physical and environmental risks." Although it appears that the use of this so-called "risk/benefit analysis" is not clearly warranted with regard to all GMO decisions, it is a familiar structure around which the relevant political, social and economic issues of GMOs are often examined. The following discussion points out both the manner in which such an analysis has been presented in the context of GMOs, and the various ways in which this structure can and cannot be used as a mechanism for evaluation of GMO issues. The conversion of this concept into that of a risk/benefit analysis is not universally recognised, it too, is becoming an important tool of decision makers. While the mechanism for "risk/benefit" analysis is not firmly established, there is a general consensus that two factors must be considered in applying such an analysis –

- the magnitude of each potential harm or benefit involved, and
- the likelihood that it will occur.[13]

The ***magnitude*** question includes not only the extent of potential damage, but also the costs of remediation if possible, and many other factors. Magnitude of the risk is often difficult to assess with regard to a particular activity or condition that has little or no "historical antecedent" (*i.e.,* that have not been created or undertaken regularly over a long enough time for its impacts and long-term effects to be well documented.) For example, the magnitude of potential damage from the Y-2K computer system problem was vastly overestimated in pre-event assessments of that risk. It remains true, however, as demonstrated by events of 11 September, 2001, that risks of very great magnitude should not be ignored, even when their likelihood is perceived to be very small, so long as they are not absolutely impossible.

The ***likelihood*** evaluation is typically based on experience with similar situations in the past. Thus, one's ability to evaluate the likelihood of long-term or delayed damage will improve over time. Likelihood evaluations are least valuable where they involve an activity or science that is new or previously unmeasured. In these cases, likelihood may be calculated based on "similarity" to other situations, and the strength of this data will depend on the extent of similarity. As noted in Part II.C.1, below, however, similarity has not proven to be a very effective measure of risk.

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[13] Mathematically, the calculation of the "value" of any risk or benefit would be expressed as follows:

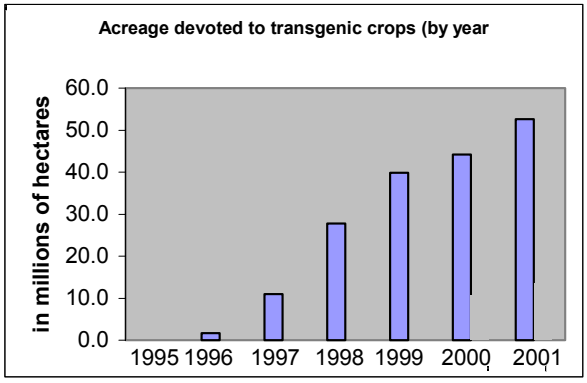
Risk (or benefit)= Magnitude x likelihood

This makes it clear (to the mathematically inclined) that no matter how enticing the claimed benefit may be or how horrendous the claimed risk may be, the ultimate weight given to it will be determined by the likelihood. In terms of GMOs, evidence proving that benefits will actually be obtained has been relatively rare, as has evidence proving that the claims of benefit are false. The same may be said, however, for regarding risks – apart from many emphatic assertions, very little evidence has been put forward to demonstrate either that significant identified risks are very likely to occur or that they are very unlikely.

In the context of GMOs, the concept of risk/benefit analysis involves controversy as to both the benefits and the risks. The following discussion briefly examines the two components separately.

a. Evaluating Benefits

Possibly the most difficult aspect of undertaking a balanced analysis of the GMO issue, particularly when charged with the mandate of applying "scientific rigour," is the evaluation of benefits of GMOs. While claims of such benefits abound, statistical and other supported documentation of them is extremely limited.[14] For example, numerous statistical databases provide clearly documented information on the use of GM seed in various parts of the world, market coverage, and similar statistics. The following table is typical of the most available data:



Source: ISAAA Global Review of Commercialised Transgenic Crops 2001[15]

From these sources we can find that the estimated global area of cropland on which transgenic or GM crops were cultivated in 2001 was 52.6 million hectares (130 million acres). This was a 19 per cent increase over the same figure for 2000, and, of course, a 100 per cent increase over 1995.[16] As of 2001, transgenic crops were grown by 5.5 million farmers.

Similar data from these sources shows that Western Europe and the US have committed an unprecedented percentage of their arable land area to GM crop cultivation, while other regions have utilised GMOs much less. This type of information is easily obtainable from a great many different sources.

Direct information about consequent increases in land productivity, farmer's livelihoods, and regional food production figures are less readily available. Even when relevant data can be found, it is not expressed in correlation to GMO usage data.[17] General data on, for example, gross and per capita food production is available from FAO's World Agricultural Information Centre (WAICENT) (www.fao.org/waicent) and reports such as "The State of Food and Agriculture" and "The State of Food Insecurity," which FAO produces annually. No conclusions can realistically be drawn from these statistics until they are linked more directly to particular crops and regions, however, it may be notable that, despite the annual increases in the volume of land devoted to GM crops (as noted above), there was also a significant drop in world production of cereal grains in 2001.

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[14] See generally Wolfenbarger and Phifer 2000.

[15] These figures may be understated, however. Reportedly, in countries such as Brazil (Bonalume, 1999), Mexico and China, farmers cultivate large areas of illegal GM crops. (See also Holland (2000), which notes that 6.7 million hectares are devoted to transgenics in Argentina and at least 300,000 hectares in China.)

[16] The first GMOs were used in 1996. In that year, approximately 1.7 million hectares were planted in transgenics. All statistics (in this footnote and in the associated paragraph of text) are quoted from Clive James at pp. 1 & 3.

[17] The Global Review of Commercialised Transgenic Crops 2001 presents comprehensive statistics about how much acreage is planted in GMOs, broken down by type of crop, trait of the GMO (herbicide resistance, etc.), etc. but does not compare yields or other data. See also, Morris, M.L. and M. A. López-Pereira, Impacts of Maize research in Latin America 1996-1997 (CIMMYT Economics Program, Mexico, 1999.)

Without statistical data to support the benefits from GM crops, one is left with only the financial benefits to analyse. Here, the benefits may be greater in developed countries than for the developing world, given that agriculture in developed countries has long utilised hybrid varieties (requiring annual seed purchase, rather than "seed saving"), and is more dependent on the purchase and use of pesticides and commercially marketed soil emoluments.

b. Evaluating Risk

The risk side of the risk/benefit analysis must necessarily involve an understanding of the scientific controversy.

- If the Watson-Crick explanation of the process of GMO creation is incorrect, then it follows that it may be difficult or impossible to evaluate the risks of continuing to utilise GMOs, without first resolving the underlying scientific controversies regarding genetic modification and its possible effects. Until there is a clear consensus on the issues described in part II.A.3 above, it may be difficult to state with certainty whether or how a GMO may impact other life forms, both in the environment and on the table.
- On the other hand, if alteration of DNA is a known process that operates in the manner described by the Watson-Crick theory, so that the alteration of a specimen's genetic structure can affect only the traits tied to the replaced gene and the replacement gene, the direct effect of the alteration is arguably limited to the changed specimen. This does not necessarily mean that there are no risks, only that the list of risks is different.

c. Examples

The applications and potential applications of GMOs vary across a wide spectrum. In examining their "risks and benefits" one must recognise many distinctions, based on the nature of the activity involved. GMOs are used in a variety of very different ways. Concerns about these uses cannot be completely understood, without first recognising this variety of uses and objectives. In particular, where a GMO is to be introduced into the uncontrolled environment, the risks to that environment are significantly greater than when it is to be utilised solely within laboratory or other controlled environments.

(i) Uses in Controlled Environments

The use of GMOs in activities within controlled environments is generally recognised as acceptable practice. GMO development (even where the product is designed for introduction outside) occurs in controlled conditions, and is subject to rules that have been in existence (and constantly under scrutiny) for more than three decades (since the commercial application of genetic modification technology first appeared to be possible.)

The most prevalent examples of contained use are research-related. In many instances, the objective of the research will be the development of an organism for introduction into the uncontrolled environments. (These uses will be discussed below.) In medical research, however, the product of the research is derived directly from the laboratory. For example, the use of genetically modified animals in medical research has increasingly become a tool for creating "models" of human disease and help in the assessment of new therapies, avoiding problems that have made modelling difficult with naturally occurring animal models. Recently, researchers have successfully created four GM mice strains each with a different mutation of the cystic fibrosis gene (the most common genetic defect in northern Europeans). (Colledge, 1995).

Risk analysis in these instances focuses around the ultimate use of the product – e.g., whether it will have any unintended health effects, create conditions or susceptibilities that can be transmitted to others, etc. Where the issues involve animal health, there may be additional questions about how that animal fits in the food chain (*i.e.,* whether it poses any health risks to humans who eat its meat or drink its milk). These risk issues fall squarely within the "debate" described in part I.A.3, above.

Benefits in these cases include not only the health benefit, but also the possibility that benefits can be obtained more quickly than would be possible if relying on older, more conventional research procedures.

With very limited exceptions,[18] these uses of GMOs do not appear to relate to the issues of concern to IUCN.

(ii) Introduction and Use in the Uncontrolled Environment

The risk/benefit analytical issues increase in complexity where the GMOs are to be introduced into the uncontrolled environment. Here, although the "scientific debate" is a great concern, there are many other concerns that arise regardless of which scientific picture ultimately receives general acceptance.

One of the most prominent developments of GM technology has been the creation of transgenic agricultural crop varieties, and commercially useful marine species. As noted above, GM agriculture is increasing almost exponentially in developed countries. Mariculture, too, is developing, with notable recent activities regarding the introduction of GM fish species, particularly in developing countries. The following examples of benefits and risks of GMOs are based on these uses.

Benefits:

The benefits that have been identified as possible outcomes of GM agriculture/mariculture are many and varied, for example[19]:

- GMOs are expected to increase ***agricultural/maricultural productivity***, maximising per hectare and per capita yields. This would be an important benefit, in a world in which demand on lands is increasing, with a burgeoning number of potential land uses applicable in even the most secluded areas. From the conservation perspective, activities which reduce the pressure to convert land from its natural state to agriculture, or from agriculture and pastoral to other uses would provide a significant benefit. Commercial aquaculture also utilises GM technology, to increase species growth and adaptability.[20]
- GM crops are frequently cited for their potential to improve ***food security***. As noted in the proceedings of WCC-2, a recent working group, including, among others, the Third World Academy of Sciences, the Royal Society of London, the U.S. National Academy of Sciences, and the Brazilian Academy of Sciences, called for further advances in agricultural biotechnology in order to promote food security.[21] Crops that can withstand known or expected blights may offer a significant benefit to society. This benefit can be expressed in financial and other terms, and is a social benefit, as well.
- GMO use also offers the potential for ***development of "issue-specific solutions"*** to problems facing particular communities, such as the advent of a new pest or disease. The ability to implant particular traits, and to undertake the process through laboratory processes, may allow these solutions to be developed and implemented more quickly.
- Another benefit claimed for some agricultural GMOs is the ***minimisation of pesticide use***. Here also, the environmental benefit can be significant, given the role of

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[18] Other potential risks may arise out of principles relating to the ethical treatment of animals, including bio-engineered animals, as well as the efficacy of laboratory containment protocols (ensuring that there are no unexpected releases into the uncontrolled environment).

[19] All of the "benefits" listed in this section are based on direct claims and statements from non-commercial sources – proponents of GMO use. As such it describes only the "purported" benefits. As noted above, the authors have not been able to find any statistical or evidentiary data proving or disproving any of these claims. Also noted above is the fact that the validity or probable validity of these claims is a matter of analysis, which should be based on broader access to scientific data (direct evidence), if possible.

[20] As noted above, the extent of data validating this assumption is rather limited, however, there are exceptions in which yield data has been well publicised. The Atlantic salmon has received most media attention, particularly those that contain an additional gene for growth hormone production and an antifreeze gene. These fish have shown three-fold growth rate increases and potential to exploit colder waters. Reports indicate that transgenic salmon have also displayed severe deformities, however. (Royal Society of Canada, 2001).

[21] Formal Statement of the US, (IUCN, publ. 2001) at 34.

agricultural pesticides in species extinctions, and in the contamination of critical ecosystems, especially riverine wetlands.

- ***Carbon-storage and climate change*** benefits may accrue from the use of GM trees. As disputes concerning the value of "carbon sequestration" within the climate change analysis have been generally resolved, the use of these trees is generally expected, and some has already begun.[22] Given that carbon sequestration is only effective if the trees are not harvested, however, serious concerns exist regarding the substitution of GM trees as a justification or replacement for more diverse and valuable forests, ecosystems and species.

- In a few instances, proposals for GMOs involve ***intentionally "invasive" uses***. Genetic engineering has been applied to insects, bacteria and other non-food life-forms to address specific agricultural needs. GM insects have been developed, with a variety of objectives, such as to reduce populations of insect pests whose damage to agricultural crops is particularly high, and to inhibit negative traits in "wild" insects (including the trait which allows anopheles mosquitoes to host the malaria parasite.)[23] This kind of GMOs should be separately considered, in light of the very different intent underlying their use. In effect, they are *specifically intended* to lead to interbreeding and to cause direct change to wild species.

  Similarly, genetically-engineered bacteria have been approved for agricultural use in the United States, with the object of increasing nitrogen-fixing properties of certain agricultural crops. The object of these introductions too will be to replace naturally occurring species.[24] Such projects have also developed microbes for use in bioremediation of certain kinds of soil contamination.

- An important benefit of many agricultural GMOs is ***reduction in the use of organophoshates and pyrethoid insecticides.*** While data on this benefit is not complete, recent reports indicate that, in the U.S., since commercialisation of Bt cotton 1996, the total volume of insecticide sprays on cotton has been reduced by approximately 3.8 million litres of formulated product per year, leading to a significant reduction in the use of hazardous organophospate and pyrethiod insecticides.[25]

- While the list of potential future benefits that it is claimed will arise from GMOs is extensive, the concept of ***"edible vaccines"*** is worthy of specific mention here, both because it is currently being tested, and because it offers a potentially inestimable value to humanity. If successful, this programme could eliminate the needs for needles and cold storage of vaccines, making them more readily available and transportable to areas of need, and eliminating one of the vectors by which local HIV/AIDS epidemics have occurred. It has been noted that diarrhoea caused by bacteria is one of the leading sources of infant mortality, particularly in the developing world, where obtaining injections in time may be difficult. Recent animal studies involving transgenic bananas and tomatoes, which produce vaccines against cholera or to address specific disease agents responsible for many prevalent kinds of diarrhoea, are producing encouraging early results. In future, such food vaccines might also be able to suppress auto-immunity (a condition in which the body's defences mistakenly attack normal uninfected tissue)[26]

Controversies, however, have turned on the manner of valuing these benefits. One key issue is the extent to which they can be or have been proven. Evidence linking particular benefits

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[22] Recent research by WWF shows that since 1988 there have been 184 GM tree field trials globally. More trials have been conducted with poplar than any other species due to its popularity as a pulp and paper species. The U.S. has released the largest number of GM trees via field trials, with 74% of the worldwide total (Asante-Owusu, 1999).

[23] Zitner, 2001.

[24] The bacterium, a strain of *Rhizobium meliloti,* contained genes from five different species and was genetically altered to enhance its ability to provide nitrogen to alfalfa plants on farmland. (Van Aken, 2000).

[25] U.S. Environmental Protection Agency, 1999. Note other issues with regard to Bt crops, discussed above.

[26] Arntzen, 1995.

to GM use has been limited, and often provided only in episodic form. For instance, as noted above, agricultural statistics are difficult to find that provide appropriate linkages between GM crops and productivity – which would appear to be the basic *raison d'être* for the introduction of such crops as elements under developing-country "food security" programmes. Claims that varieties can be developed more quickly with GM techniques than through more traditional methods are also not entirely supported by available facts. Even the materials on pesticide minimisation have been questioned, because they tend to focus on the pesticide demands of the particular farmer using GM crops, rather than more generally on the sub-region.

The benefits of food security and of the concept of "issue-specific solutions" to particular agricultural problems are sometimes questioned as well. It is argued that these programmes may engender over-dependence of a particular community or district on a smaller number of "miracle" varieties that are resistant to common pests, hazards, or conditions – leading to more serious food shortages when that variety is found to be susceptible to other (less common) events or threats.

In general, the controversies over benefits are functions of lack of specific, statistically valid information.[27] As with all environmental decision-making, the existence of reliable data is a prerequisite to making decisions that benefit all.

Risks:

The risk analysis in regard to the use of GM varieties should address both the risks that the "scientific debate" will disclose instability in GMOs, and the risks that exist regardless of the outcome of that debate.

General risk analysis based on the "scientific debate": Many variations of these concerns exist, depending on many factors. In general, these concerns revolve around the possibility that the genetic change to and subsequent introduction of one species will impact other species, or cause other changes in the introduced species.

One particular concern relates to the possibility of horizontal gene transfer,[28] in marine and freshwater ecosystems. This concern is particularly relevant because of evidence with regard to various types of species introductions (introduction of naturally or conventionally bred alien species as well as GMOs), regarding escape of mariculture species from their "farms." Evidence that, in marine ecosystems, there exist viral or bacterial agents that can re-assemble free-floating DNA, supports these concerns. . This, in turn, has raised questions about the potential of horizontal gene transfer from GM fish in "fish farms" to wild stock.

In terrestrial ecosystems, confidence in the impossibility of this type of horizontal transfer is higher; however, numerous scientists have indicated that viral transfer may still be possible. In addition, the gene replacement may not be stable, so that it can have other impacts on the organism, and its surroundings.[29]

Risks Applicable under Either Scientific Paradigm: Numerous environmental risks related to GMO use may apply even if one assumes that DNA is the sole determinant of cellular reproductive patterns. Among these concerns are the following –

> ***Ecological stability of the GMO:*** Even under the Watson-Crick view of DNA, each gene may control several different traits in a single organism. Insertion of a novel gene can have an unintended auxiliary impact on the rest of the host's genome that results in

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[27] Wolfenbarger and Phifer 2000.

[28] Horizontal gene transfer is a relatively new concept, that has been described as the capacity of genetic information to be passed between species in ways that is unrelated to the usual parent-offspring inheritance of genes. (for more technical discussion, *see* Heinemann 2003) Horizontal gene transfer occurs frequently between viruses.

[29] Researchers note that GM varieties exhibit traits not expected by virtue of the specific gene replaced. Few documented instances have been released, however, it is not clear whether this is a function of their non-existence or the fact that this information is closely held. In the most publicised example, in 2000, Monsanto admitted that its soybeans contained some unexpected fragments of genetic material. The company concluded that, since "no new proteins were expected to be observed or produced" this was a harmless discovery. A year later, Belgian researchers reportedly discovered that a segment of the plant's own DNA had been scrambled, in a way that was significant enough that it could be expected to produce a new and unexpected (and experimentally unproven) protein. (Commoner at 46.)

unforeseen side effects. For example, mustard seeds engineered for herbicide resistance were also found to be twenty times more fertile than their non-GM equivalent.[30] Not all such collateral effects are immediately recognisable.Arguably, the relatively limited life cycle of most annual agricultural crops might act as an informal safeguard against this problem. However migratory and/or long-lived species such as fish or trees differ from most agricultural crops in that they endure in or between landscapes or seascapes for long periods of time. For risk assessment purposes, it is difficult to assess this type of risk. Although many collateral impacts could, like conventional mutations, be harmful or fatal to the carrier, others may not, or may in longer-lived species be transmitted to offspring well before the defect becomes known.

- ***Genetic contamination/interbreeding***: GMOs could possibly interbreed with wild relatives and other sexually compatible species within the area in which the GMOs were introduced. Experts disagree about the impact of this type of hybridisation. The novel trait, although valuable in the agricultural context, is expected to quickly disappear in the wild, unless it confers a selection benefit on the recipient species. However, it is clearly possible that tolerance to a particular pesticide or natural pest might easily constitute such a selection benefit, and thus alter the native species' ecological relationship and behaviour.[31]
- ***Competition with natural species:*** One trait that is often promoted by GM crop developers is increasing productivity through faster growth. Fast maturation, however, can serve as a significant competitive advantage, which might allow an organism to become invasive (spread into new habitats and cause ecological or economic damage). Even where there is no likelihood that a given GM species will interbreed with wild species in the area, it may out-compete, forcing them into decline and possible extinction.
- ***Increased selection pressure on target and non-target organisms:*** Another outcome of a change of this type is that it may increase the pressure on species to adapt as if to a geological change or other natural selection pressure. Pest-resistant GM organisms have been identified as a possible biological impetus for some agricultural pests to evolve distinct populations that are resistant to particular toxins.[32]
- ***Ecosystem impacts:*** Where the above types of conditions and risks exist, they are always joined by the risk of ecosystem damage or destruction. Where a single part of a particular ecosystem is altered by interbreeding or selection mechanisms, replaced by an alien species, or otherwise impacted, the effects of that change may extend well beyond the single impacted species. A change in prey species may affect the predator and alter the balance of its use of food species.
- ***Impossibility of follow-up:*** Where a species is specifically introduced for the purpose of interacting with or replacing natural species, as in the case of GM insects and bacteria described above, there is also the problem of "opening Pandora's box." Once such organisms have been released, there may be no ability to call them back or eliminate them, should problems later be found. Through the history of humanity's attempts to address problems caused by intentional introductions of alien species, it has become

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[30] One theory is that the introduced gene not only enhanced the mustard plants' ability to withstand herbicide application but also unintentionally disrupted the recipient organism's gene sequence that controlled pollination and fertility (Bergelson,1998).

[31] Some experiments have shown that the rate of cross-pollination between conventional and GM varieties of potatoes are generally low and become negligible when the separation distance exceeds 10 metres (Rogers, 1995). By contrast, Danish field trials have shown that oilseed rape modified for herbicide tolerance can easily cross with wild Brassica species such as wild mustard (Chevre, 1997). Consequently, cross-pollination between GM and non-GM oil seed rape has been detected at distances of up to 2 km.

[32] Forty years of empirical evidence from the U.S., Japan, Central America and China demonstrates that the use of the pesticides consisting of Bt toxin (a naturally occurring pesticide, now incorporated in numerous crops for resistance to certain insects, as noted above) has allowed some agricultural pests (such as the diamond back moth Plitella xylyostella) to evolve distinct toxin resistant populations. (Tabashnik, 1994).

apparent that prediction of the possible impacts of species introduction is, at best, an inexact science.[33]

Many of these risks are essentially identical to risks incurred with regard to introductions of non-GMO species. Concerns about genetic contamination, competition, ecosystem damage, and inability to "undo" ill-advised introductions, for example, are equally significant with regard to the introduction of naturally or conventionally bred alien species.[34] Similarly, selection pressures are at least as relevant to the use of pesticides as to GMOs.

These facts do not suggest that that GMOs are safe or beneficial, however, nor that they should be less scrutinised simply because they share potential risks with other serious conservation problems. Alien invasive species are among one of the most serious environmental threats currently recognised, and have been singled out for urgent international attention;[35] while pesticides have long been targeted as environmentally dangerous.

d. Research and Sources of Information

The key factor in all of these activities is the availability of dependable, scientifically accurate information, which the decision-maker can feel confident relying on. In general, regardless of its ultimate probity, scientific information provided by the applicant – who is seeking approval of a GMO introduction, often for commercial reasons – will be viewed with suspicion if it cannot be verified by external sources, independent reproduction of test results, and other confirmations, from independent, non-biased sources.

This need is particularly evident in an evolving and expanding area such as molecular genetics. Few government agencies can afford to employ specialised experts whose level of understanding is sufficient to validate the applicant's claims internally prior to issuance of the decision. Often their only alternative is to select among a small group of experts available to them – often provided either by the proponent of GMO introduction, or by avowedly anti-GMO organisations. It may not be appropriate for the decision-maker to simply take a "middle position" between these extremes. Increasingly, it will be essential to understand the scientific, economic and social issues, and to be able to separately evaluate the evidence and scientific justifications for the competing positions, in order to make a decision that satisfies the decision-maker's ultimate duty to his/her country and constituency.

As a result, the biosafety issue offers a paradigm and justification for the continuing need to support independent research (*i.e.,* research that is not connected to commercial or industrial development). Perhaps the largest single factor contributing to the overall controversy is the fact, referred to elsewhere, that an overwhelming majority of the research and data regarding GMO development is held very closely by corporate developers.

It is likely that, as frequently noted, a company's desire to protect its research and development processes and activities against commercial "espionage," is probably the reason behind this attitude regarding data security. However, the fact that test results and materials exist, which are not available to independent researchers, creates a perception that these files contain data indicating higher levels of risk than is generally alleged – data that would, if known, negate the applicant's chance of obtaining approval for a GMO introduction. Clearly, the need for a broader understanding and verification of the current scientific status of GMO work in a particular area would ultimately benefit *both* applicants who are acting in good faith *and* civil society groups who are suspicious of GMO introductions.

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[33] One example involves the introduction of barn owls in the Seychelles, to control the population of inadvertently introduced European rats. The owls (natural predators of the rat species in their native surroundings) found other, in some cases endangered, species much easier to catch. They were able to out-compete native species that preyed on these animals, and eventually represented a much more serious threat to the island ecosystem than the rats they were imported to control. Young, T., Legislation and Institutions for Biodiversity Conservation and National Parks in the Seychelles (FAO, 1993).

[34] A number of other concerns that are generally shared with all development, agricultural or otherwise have similarly been omitted here. One of these, which arose feelingly from IUCN feedback in the preparation of this paper, is the issue of ethical treatment of animals.

[35] *See* Decisions V-8 and VI-23 of the Conference of the Parties to the Convention on Biological Diversity.

The problem, however, is not simply one of access to data from commercially motivated research and development (R&D) programmes. It is also apparent that research that is not product-oriented may take an entirely different approach, and may thus encounter an entirely different order of results. Hence, it is important for research programmes to be funded "for purposes of enhancing general scientific understanding" – something that one cannot expect of commercial R&D.

To date, there is no market-based solution to the need for this kind of research, even where it is essential to the ultimate commercial objective (such as obtaining official permission for GMO introduction or improving public perceptions of GMOs and GMO-safety.) Diversified funding for independent, non-commercial, public-sector research into molecular genetics and other issues of GMO safety seems to be the only possible solution. Promotion of this objective may be one of the most important mechanisms by which the controversies described in this paper are resolved, and effective, safe integration of GMOs into regulated national and regional frameworks for sustainable use of biological resources can ever become a reality.

FAO and its Codex Alimentarius (a series of voluntary standards for food and agriculture) are attempting to fill some of the knowledge/information gaps by providing database information about the experiences of member countries.[36] Databases under development include a comprehensive list of "biotechnology" policy documents of FAO members; attempts to compile available information which governments are able to supply concerning particular GMOs, and ongoing work for the development of standards such food labelling and related testing issues (described below). Decision-makers and the civil society may find it essential to co-ordinate with and support these initiatives.

2. Risk Management

The risk management process forms a second focus of the economic/political component of the GMO/biosafety issue. Where a risk/benefit analysis concludes that risks exist with regard to a GMO introduction or other activity, but are sufficiently outweighed by the benefits of that action, it will probably still be required both practically and legally, to take steps to "manage" the risk, and to ensure that damage will be minimised, should the risk become a reality.

Elements of currently used and proposed risk management process include a variety of different kinds of activities. To a large extent, the specific protective measures imposed on the GMO user will be determined based on scientific factors linked to specific details of the GMO and the proposed use.[37] These issues, too, turn on the ability of the decision-maker to rely on unbiased scientific experts who are able to analyse each proposal or application, and determine what controls are needed, and what the best available technologies and practices are.

Technical issues at this level cannot be examined in this paper. However three important components of risk management are impact assessment, public awareness/participation, and the design of regulatory systems. These concepts, all very important in this field, are critically important to GMO-related governance. It is not possible to overstate the importance of the public's contribution to effective decision-making, as well as the importance of public awareness, within the context of government decisions on matters and activities affecting the environment.

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[36] The International Plant Protection Convention (co-located with FAO and operating in close co-ordination with that organisation) may eventually offer another, more focused source of information and support. At present, the standards development process under the IPPC has not resulted in the level of information and capacity-supporting procedures and data that is currently available through the Codex. The development of IPPC standards is discussed in section IV.A.2 below.

[37] Except where the GMO use will be entirely in contained (laboratory) conditions, decisions about the permissibility of the introduction, and the permit restrictions that will be imposed in order to minimise the risk of environmental or other harm caused by the introduction, can indirectly determine whether GMOs can be used at all. For example, a common requirement is to require the maintenance of a "buffer zone" around the GMO area, so that invasions of the GMO species or of unexpected characteristics or other impacts, can be detected before they extend to surrounding lands, affect organic agricultural products, or otherwise exert an unexpected impact. Reportedly, in many cases these buffer requirements effectively eliminate any possibility of introduction of the GMO.

a. Impact Assessment Processes

Within the concept of risk management, the mechanism of impact assessment plays a crucial role. Although extending well beyond the scope and detail of many Environmental Impact Assessment (EIA) procedures, the assessments mandated under national biosafety-related legislation, and especially under the Cartagena Protocol (described below) provide a clear foundation on which at least some of a country's various decision-making, permitting, labelling and other processes relating to GMOs could be based.

Unfortunately, although the need for risk assessment is undisputed, the particular parameters of that investigation are difficult to quantify in the biosafety area, given the fact that GMO introductions are a relatively new innovation. In many cases, the primary scrutiny focuses on a concept called "substantial equivalence," under which GMO products are compared to the product they are designed to replace.

In some cases, substantial equivalence may be used as the basis only for determining whether a GM introduction must be licensed. That is, if the GM product is similar enough to the product it is replacing, then it may be introduced with minimal administrative involvement.[38]

In many more difficult instances, however, substantial equivalence is used as a basis for decisions regarding the safety of proposed GMO introductions. According to the World Health Organisation, the substantial equivalence mechanism is designed to take into account both intended and unintended changes in a plant or the foods derived from it,[39] by identifying similarities and differences between the new food and the conventional counterpart. Thereafter, safety assessments and risk/benefit analyses assess the safety of identified differences (sec. 3, para. 16) regarding the substitution of the product, as food. Risk managers subsequently judge this and design risk management measures as appropriate.

Unfortunately, this approach has very little direct relevance to any of the risks identified with regard to GMOs. Although effective in other areas (such as seed management programmes based on more traditional methods of new variety development), the reliance on the substantial equivalence test in the case of GMOs, may serve as a distraction from the more serious need to consider other measures of the safety of GMOs, and thus to develop other mechanisms for managing those risks.

In this connection, it is important to note that the development of agreed risk management measures would provide a real benefit for both the GMOs proponents and the communities and ecosystems that would be most affected by the identified risks. In general, where a government permit is given on the basis of full disclosure of risks, and where the permit-holder meets his risk management obligations, the permit-holder is not liable (or is held to a lesser standard of liability), for damage caused by the disclosed risk. Thus, if good and sufficient analytical models can be developed for determining the risk from an introduction, the proponent has a safety net of protection against liability for "the unimaginable," while at the same time, local communities are better protected against those risks.

Still, the proper application of substantial equivalence, and in particular the assumptions upon which both principles are founded and applied, are outstanding issues that may determine the extent to which the risks of GMOs can be accurately identified and subsequently minimised or eliminated. Strong arguments exist regarding scientific uncertainty, borne of relatively few but very clear technological problems that cast doubt on "substantial equivalence" as an indicator of safety or appropriateness. In the face of these concerns it has been noted that:

> "The degree to which [GMO-caused] disruptions occur is not known at present, because the modern biotechnology industry is not required to provide even the most basic information about the actual composition of the transgenic plants, to any regulatory agencies. No tests, for example, are required to show that the plant actually produces a protein with the same amino acid sequences as the original bacterial protein. Yet this… is the only way to confirm that the transferred gene does in fact yield the theory-predicted product. Similarly, no detailed analysis of the molecular structure and biochemical activity of the alien gene and its protein product,

[38] Canadian Food Inspection Authority, 1994
[39] World Health Organisation, 2000.

in the transgenic crop are required before it can be introduced. This is not even required as to the initial generations, where some commenters suggest that multi-generational testing and follow-up is also possibly required."[40]

b. Public Awareness/Access to Information

Public access to information is an important cornerstone of public participation and is one tool that could help to realise the benefits and avoid the risks of modern biotechnology. This concept is well recognised in Principle 10 of the Rio Declaration, and in the recently adopted Åarhus Convention on Access to Information, Public Participation in Decision-Making, and Access to Justice in Environmental Matters.

***Transparency and Capacity**:* Simple "transparency" and "access" to relevant documents, however, may not be sufficient in the case of biosafety issues. Arguably, the concept of access to information must include, in some way, access to the tools and expertise with which to understand that information. While merely providing "access" to the data will be sufficient in many developed countries that are home to highly specialised and active NGOs, even here the balance of expertise weighs heavily on the side of the GMO proponents – often the companies or institutions that developed the GMOs.

***Labelling, Standards and Certification**:* Beyond the public's access to governmental documents and processes, however, there are other mechanisms by which public awareness and access to information can be encouraged, including product labelling, food safety standards and general consumer protection laws, all of which are designed to foster awareness and communicate public preferences to the commercial proponents of GMOs in a way that will get their attention. These mechanisms can be effective if they are accurate, specific, clearly expressed in understandable language, unbiased, and based on full disclosure of the relevant facts by the GMO proponents.

By contrast, labelling mechanisms can become meaningless where they are allowed to become generic, are written in an overly technical style, or are known to be propounded in a self-interested manner. In California, a major referendum requiring disclosures of toxic and carcinogenic substances in public places and consumer goods was basically invalidated by regulations that allowed those disclosures to be made in generic terms.[41]

Confidential Information and "Trade Secrets": One of the key concerns in this regard relates to the proponent's need to maintain some information as "confidential." While the basic realities of modern business clearly underscore the need for confidentiality, it is also true that confidentiality provisions are often used as a means of avoiding disclosures.

In the face of increasing recognition that activities, including especially species introduction, in one country may have serious impacts on neighbouring countries, labelling and other access to information is increasingly addressed at international and regional levels. A critical institution in this field is the UN Food and Agriculture Organisation, whose Codex Alimentarius is one of the primary vehicles through which these issues are being addressed.

Direct Public Participation and Awareness Mechanisms: With regard to direct public participation in biosafety related decision-making, a small number of countries, including particularly Denmark, the Netherlands, and New Zealand, are also taking a leading role in developing mechanisms for public awareness.[42] These countries' legislative provisions require relatively broad-based stakeholder processes addressing certain aspects of modern biotechnology, including the release of GMOs. Such processes help the governments and regulatory agencies to gauge public opinion, generate dialogue, gather useful information and develop awareness within their populations on modern biotechnology.

c. Design of Regulatory Systems for GMO Development and Use

In many different fields of endeavour, technological capacity to act has moved significantly faster than has the governmental (and in some cases the technical) ability to oversee and

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[40] Commoner, 2002, at 46; see also Royal Society of Canada, 2001.

[41] Young, 1992.

[42] *See, generally,* Mulder and Ree, 1996; *and more specifically to GMOs,* Bearano, 1999; BioTIK Expert Group, 1999; and Christensen, 2001.

regulate it. As a consequence, many concerns relating to the risk of GMOs are directed more closely to the apparent lack of societal and governmental restraints on GMO developers and users, rather than to addressing particular scientific issues. This suggests that a third key element of the risk-management process involves a reconsideration of regulatory mechanisms and systems for governmental oversight of GMO development and use.

One fact, which has been identified as underlying many recent GMO-related problems, relates to the cost of the pre-production (R&D) phases in GMO development. It is generally true that the costs of the entire process from prospecting for or otherwise locating genetic material through to having a GMO in readiness for commercial production can be extremely long, and that during this period there is frequently very little return on the company's investment of personnel, technology, and money. Governmental regulatory involvement in this process usually happens at the "product" end – that is when a product is complete and its developers are seeking relevant government approvals for marketing, introduction in agriculture, etc. The combination of factors suggests that, at the time of governmental approvals, there is a great incentive on the part of the company to obtain the approval – an incentive shared by governments, given that one important part of their mandate is support to industrial and commercial growth and development.

Current initiatives have been proposed that approach this in a variety of ways, including longer-term use of containment strategies, stringent product safety criteria, etc. Ultimately, however, the most effective option may be a relatively deep restructuring of the way that governments oversee the GMO development and approval processes, such as the approach proposed by the "Safety First Initiative." In essence, this approach would attempt to "anticipate and resolve safety issues as far upstream of commercialisation as possible."[43] From the earliest stages of the development process, GMO researchers would be called upon to address and incorporate safety issues, including both safety during the development process, and planning and testing for safety and traceability of the ultimate GMO product.

The safety-first approach is currently proposed as a voluntary, industry-driven system; however, it may be that companies would find a greater incentive to use such a system if it streamlined final governmental approval processes. In order to do this, the system would have to be tied to a programme of formal governmental "milestones" which are confirmed during the various phases of the development process.

C. Socio-cultural Impacts

It is in the area of socio-cultural impacts that the controversy over GMOs and biosafety takes on its most complex aspect. On one hand food production, food security and livelihood improvement are all critical elements of sustainable development, to which GMOs and other products of modern biotechnology are often cited as important contributions. On the other hand, the introduction of GMOs can affect humans, (as well as animals and ecosystems), particularly at the community level, in many ways beyond direct physical sustenance, not all of which are beneficial.

The role of GMOs in food security and sustainable development was recognised at WCC-2:

> [T]he environmental questions surrounding biotechnology need to be addressed, yet the technology as a whole offers great promise – of environmental, social, and economic benefits – that should not be inhibited unnecessarily.[44]

Such recognition is not new, nor is the relationship between this factor and developments in agricultural technology. The 1987 Brundtland Report noted food security as a critical issue for "our common future," but noted also that merely increasing gross production is not enough:

> There are places where too little is grown; there are places where large numbers cannot afford to buy food. And there are broad areas of the earth, in both industrial and developing nations, where increases in food production are undermining the base for future production…. Agriculture does not lack resources; it lacks policy to ensure that the food is produced where it is needed and in a manner that sustains the

[43] Kapuscinski, 2003.
[44] Formal Statement of the US, at 34.

> livelihoods of the rural poor. We can meet this challenge by building on our achievements and devising new strategies for sustaining food and livelihood security.[45]

That report noted an unprecedented growth in food production in North America and Europe between 1950 and 1985, despite flattening of the rate of population growth in those regions. It attributed this production increase to two factors. On one hand, it noted an extension of the food production base ("larger cropped areas, more livestock, more fishing vessels, and so on.") But it recognised that "most of [the rate of growth] is due to a phenomenal rise in productivity…. [including] by

- Using new seed varieties designed to maximise yields, facilitate multiple cropping, and resist disease;
- Applying more chemical fertilisers, the consumption of which rose more than ninefold;
- Using more pesticides and similar chemicals, the use of which increased more than thirty-two-fold; and
- increasing irrigated area, which more than doubled."[46]

On the other side of this coin, however, food production and relationships with their lands and ecosystems are based on the balance that all cultures, from most to least developed, achieve between their physical and economic environments. Biosafety is, in all senses, an ethical issue.

Socio-cultural concerns have been the least understood side of this debate. Even where actual social and cultural impacts of GMOs have been well explained and documented, response to them has rarely involved anything more than a dismissal of "traditional mythology" and a failure to recognise the role of food and other species in the spiritual life and world view of the community. This is clearest with regard to traditional communities, where cultural practices are often integrally connected with the traditional and natural aspects of food species. This disconnection begins at a level of intervention that is much less intrusive than the introduction of GMOs –

> The cost of making available year-round seasonal resources is that the natural cycle and food chain is adversely affected and the traditions and knowledge that form the *whakapapa* (genealogy) of that resource is lost. The value of end-products developed from resources and knowledge of indigenous peoples is usually far greater than the benefits returning to those peoples…. The respect for the reproduction of life as a continuation of genealogy is a paramount concern…. Social, cultural and ethical concerns are just as important as new technologies.[47]

While the advocates of a particular scientific paradigm are not expected to espouse (or even necessarily understand) the unique world views of each cultural group impacted by the introduction of GMOs, they should, arguably, be called upon to ensure that communities, including particularly traditional communities are not negatively impacted at the cultural or social level by these introductions. Hence, GMO introductions and the social and practical mechanisms involved must, at a minimum, recognise these sensitivities.

Beyond this, they must recognise and address critical environmental and biodiversity factors that are integrally tied to humanity's residence on planet earth. A number of concerns should be addressed through socio-cultural assessment of the impact (socio-cultural risks and benefits) of GMOs. These include:

- The nature of reliance on GMOs to solve social problems – that it is a "quick fix" that directs public finances inappropriately, solving only the most immediate concerns, but leaving the underlying causes intact. For example, rather than hoping to solve Vitamin A deficiency (the single most important cause of blindness among children in developing countries), with vitamin A-containing GM rice, it might be cheaper and more effective (addressing a broader range of local health issues) to help poor

[45] Our Common Future, at 118.
[46] Id at 120.
[47] Mead, 19__ (citations omitted.)

communities diversify their diet rather than narrowing those diets further (from an over-dependence on rice as a dietary staple, to a reliance on only one form of rice.)[48]The impact of the cost of GM crops and the fact that they create a new annual expense, where they are introduced in communities that have formerly relied on re-propagation through seed saving. Recent high-profile instances where GM seeds were provided to farmers who saved (and shared) seed from their bumper crops, are indicative of the extent to which ultra-modern GMO technology, and the ultra-modern commercial mechanisms it relies on, can conflict with long agricultural traditions still flourishing in many parts of the world. The likelihood that more expensive development processes of GMOs reflect the need to recover investments in research and development. Therefore, at least in the short-term, they are more likely to favour the relatively wealthy farmers more than the poor farmers who are most in need of improved production. It is unclear whether this will continue to be the case. Companies dealing in "engineered" agricultural products could, for example, consider a two-tier pricing policy, partly to mitigate such criticism, in which farmers in the developed world are charged more for GM seed.[49]The need to recognise and compensate the contribution of developing countries and traditional and agricultural communities, whose historical conservation of biodiversity and ecosystems has provided much of the raw material for genetic engineering. The benefit-sharing objective of the Convention on Biological Diversity, aims at ensuring that developing countries will benefit from exploitation of their natural resources in the field of biotechnology. This objective can only be met through co-operative participation by the corporations and other private institutions that are the primary users of genetic materials, and that often seek later to profit by selling it back to these original contributors. The need to ensure that communities and community life are not disrupted by introductions of agricultural varieties, of other species, or in certain circumstances of products of GMOs and other modern biotechnology.Concerns that over time non-GM varieties, which along with their wild relatives are the basis on which GMO development is founded, will begin to disappear. This may happen through voluntary action, where farmers feel that they cannot allow their productivity to drop too far behind that of their neighbours. It may also occur involuntarily, where pesticide-ready or pest-resistant crops affect neighbouring non-GMO fields by altering pest patterns (increasing stress on non-GMO crops, etc.), or affect the established system that includes the pest species (e.g., birds and other creatures that feed on insect populations or larvae, etc.) It may also result from genetic contamination, as described above.

- The biodiversity impacts of extending GMO introductions into marginal areas (which are often centres of diversity not only of wild species but of traditional agricultural species) and into protected areas and their buffer zones.

The fact that these concerns must be addressed is not, specifically a criticism of GMOs. Many similar concerns are relevant in all conventional aid and commercial transactions involving developing countries. GMOs and related research have, in a number of cases, enabled solutions to specific agricultural problems. This is a particularly hopeful phenomenon, in light of the general criticism of GM crops – that the benefits are geared toward seed companies and northern hemisphere farmers. Recent work in Kenya and South Africa has recognised a broader mandate of agriculture development programmes to help level the playing field for marginalised farmers by overcoming these constraints.

In South Africa, for example, the private and public sector have joined forces to produce drought tolerant crops and at the University of Cape Town scientists have engineered the first maize plants to resist maize streak virus. The International Rice Research Institute is pioneering efforts to develop a strain of highly productive and pest-resistant rice which, they claim, could increase poor farmers' yields from two to six tonnes an acre.

Small-scale farmers in eastern Africa have also benefited by using hybrid seeds from local and multinational companies. To these farmers, "transgenic seeds … are simply an added-value improvement to these hybrids. Local farmers are benefiting from tissue-culture

[48] Marion Nestle, 2001
[49] McNeely, 2001

technologies for banana, sugar cane, pyrethrum, cassava, and other crops. There is every reason to believe they will also benefit from the crop-protection transgenic technologies in the pipeline."[50]

Targeted research and product development which recognises and accepts traditional methods such as seed saving, and their vital importance within the marginalised farming systems of many developing countries can be a major contributor to food security and sustainable livelihoods.

[50] Wambugu (1999)

III. Crosscutting Principles

Several of the critical "crosscutting" principles that are recognised as such throughout the concepts of conservation and sustainable use, apply within the biosafety arena in a rather unique way – necessitating, in some cases, a careful balancing process. The most relevant of such principles are "precaution" and "development."[51] In addition, current focus of attention on intellectual property rights (IPRs) relating to genetic resources and traditional knowledge, and the role of bilateral and multilateral aid and assistance programmes present particular and unique problems, when applied to GMOs.

It is not the role of this paper to reiterate well-understood principles or to provide a general discussion of the current controversies relating to them. It is assumed that the reader is aware of these, or has access to some of the voluminous writing on these issues. What is relevant to this paper is the somewhat unique manner in which the precautionary principle, the "development principle," IPRs, and aid programmes operate in the area of biosafety, and the manner in which they are affected by factors such as the extent of public concern about GMOs, and the belief that GMO technology is insufficiently understood and potentially unsafe. For this reason, these concepts are briefly summarised below.

A. Precautionary Principle/Approach

The precautionary approach has been adopted in a very direct way in the biosafety area, through its inclusion in the Cartagena Protocol on Biosafety. As stated there, the precautionary concept embodies an apparent recognition that determining what is an acceptable level of risk is a matter for scientists, expressly stating that "lack of scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk or an acceptable risk."[52] Thus, where researchers have failed to investigate a potential risk because they assume it is low, this fact should not necessarily constitute evidence that the risk is zero or negligible.

The application of the precautionary approach in the realm of biosafety has been integrally connected with risk management and transparent decision-making, however that connection is also the basis of contention. In some cases, it has been stated that national reliance on stringent EIA requirements stands as the implementing mechanism for the precautionary approach, so that no further reference to precaution is necessary. Even in these instances, however, the recognition of the importance of precaution is clear. In Parliamentary debate on this point in New Zealand, the then-Minister for the Environment, the Hon. Simon Upton, in general a proponent of the assessment-is-precaution position stated:

> [The] "precautionary approach" … is a question. It is a way of thinking. It is a way of approaching uncertainty. I really would be stunned if anybody could disagree with the words of this clause, which simple states that people "shall take into account the need for caution in managing adverse affects where there is scientific and technical uncertainty about those effects." I ask whether there is any business in New Zealand that would say: "Where there is technical uncertainty we shouldn't have any regard for caution." I think that would be a most unbelievably cavalier approach. I think it would run against the grain of good business practice in every respect. These are just plain common-sense words, and no baggage or superstructure is attached to them. We should apply due caution in the light of our knowledge, and that is what everybody does every date of their lives.[53]

Despite these words, the fact remains that the application of precaution is still a controversial topic with regard to GMOs. Concerns escalate where, as generally, the governmental decision-maker's expert analysis of risk and the adequacy of existing information comes primarily (directly or indirectly) from the proponent of the GMO. Thus, an element of precaution in many minds is the need to address the fact that GMO use and introductions are

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[51] Many identify poverty alleviation as another relevant principle, however that issue is adequately dealt with in other elements of this paper.

[52] Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Nairobi, 2000) Article III.4.

[53] New Zealand Royal Commission, 2000.

controlled primarily by the private sector, whose incentives for development and marketing may be greater than for assessing potential problems, and who are heavily invested in the Watson-Crick view of genetic modification.

For these critics, a statement that the GMO licensing process is a codification of precaution, is tantamount to eliminating the application of precaution for GMOs. They stress the importance of considering, in every case, the particular level of scientific certainty or consensus and evaluating the risks individually. Proponents of this argument posit a governmental obligation to implement precaution on a case-by-case basis, as an essential check on profit-motivated activities.

B. Development

The precautionary approach, however, is not the sole transcendent principle on which GMO-related decision-making must rely. In many countries and contexts other principles are seen as equally relevant and are increasingly accepted as such in law and policy. Of these, the concept of sustainable development may be pre-eminent. Consequently, many commenters (particularly those from developing countries) argue that it is inappropriate to apply the precautionary approach as an inviolable rule; one must balance it against other needs.[54] Where the advocate of precaution notes that lost species and ecosystems can never be recovered for future generations, the development-focused environmentalist would note that future generations may not come into being to appreciate those ecosystems without effective action on development imperatives.

Seen in this context, precaution is just one aspect of a multifaceted approach to environmental management. Education, information, recycling, clean production, waste management and adaptive management are all elements of this system. The strict precautionary approach of northern application is seen in many southern regions as a simplistic tool that is insufficient to address a very complex problem. Any decision in fulfilment of the precautionary approach would need to be based on an assessment that takes into account not only issues of uncertainty and conservation, but also the objectives of resource management.

At base, this contrasts strongly to the northern approach, under which use precaution serves as an initial “filter” to eliminate proposals that present undue risk due to lack of information. Increasingly, southern writers are instead seeing precaution as a part of the risk management decision, rather than an overarching principle – a ‘threshold question’ used to determine whether to proceed to risk management.

C. Intellectual Property Rights, Indigenous Knowledge, and Traditional Agricultural Practices

Ongoing global negotiations and practices in the area of intellectual property rights to biological and genetic information are a major component of the current discussions and controversies surrounding GMOs. Global attention to this issue arose, to some extent, out of the concepts of “access and benefit-sharing” and “traditional knowledge” under the CBD. For this reason, the focus on IPRs for biodiversity was initially on the creation of such a right. In particular, developing countries and indigenous groups emphasised the need to adequately recognise and compensate

- sources (at all levels) of genetic material found in developing countries and the global commons, and
- clues concerning uses of species, as derived from the traditional knowledge of indigenous groups.

Over time, however, another side of the IPR issue has taken the limelight - the use of IPRs as a means of preventing developing country farmers from applying conventional farming

[54] Katerere, 2001

methods (especially seed saving and seed exchange) in their use those varieties.[55] Concerns have often been expressed regarding the spread of this practice, as farmers in other regions begin to grow (and save) GMO seeds, which are increasingly being made a part of aid packages or provided as part of "benefit-sharing" arrangements.[56]

On one side, these controversies are integrally tied to the commercial viability of the GMO industry, whose R&D costs are very significant, necessitating some efforts to ensure the continuity of markets for their new products while they are under patent. On the other, there may well be significant socio-cultural and economic costs where lawsuits alleging IPRs infringement (normally an issue that arises between two or more sophisticated entrepreneurs or corporate entities) evolves into a conflict between multi-national corporations and traditional farmers.

The intractable difficulties of protecting GMO-based intellectual property rights has been one of the reasons cited for the introduction of a type of GMOs that is specifically designed to prevent these traditional activities (so-called "genetic use restriction technologies" ("GURTs") or "terminator" seeds.) Clearly these and similarly intended products and activities may be a source of much wider socio-cultural economic and environmental effects, given that the significant change they introduce is directed at a basic element of human life (agriculture).

One legal provision that has been cited as a possible basis on which to resolve this growing problem is found in Article 27.3 of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights, which gives countries the right to "exclude from patent-ability…plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes." The full consequences of Article 27.3 are currently matters of intense international debate, however, it seems evident that the GMO discussion will be interlinked with the IPR issue, until this question (and the related issues of creating and implementing a "*sui generis* system" relating to the application of intellectual property rights to the use of genetic material) are finally resolved.

D. Bilateral and Multilateral Aid and Technical Assistance Programmes

Yet another difficult crosscutting issue relates to the role of GMOs in international development assistance projects. In a number of recent and well-publicised examples, the provision of assistance (in some instances direct food aid and famine relief) has been conditioned on the recipient country's willingness to accept GMOs.

There are very differing views of these activities. Some contend that this approach is justified by desires to overcome progress-paralysing resistance to a technology intended to address and resolve the world crises of hunger and poverty. The counter-perception, however, is of manipulation – using a time of national crisis as a tool for forcing governments to take action against national principles and public opinion. In effect, these offers are seen as attempts to take true policy- and decision-making (weighing risks and benefits) out of the hands of

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[55] In recent years, a number of cases have been filed by GMO-producing companies against farmers who are growing GMOs, without purchasing them. Most recently a farmer was sued who claims the seeds came to his land unintentionally from nearby farms (possibly in the form of wind-borne transgenic pollen or other natural transfer to non-GMO crops. (One article about this is headed, "Monsanto: Trouble in Bio-Paradise," http://www.lamontanita.com/docs/newsletterarticles/2000/Jul2000/geneticallymodifiedorganisms.htm); however, for a more balanced view, it may be best to search the internet for the name of this farmer "Percy Schmeiser.")

Other cases, however, involved suits against traditional cultivators who intentionally "saved seeds" after having been given GMO seeds the previous year. These issues are currently being examined in North American courts (see, for example, "Seeds of Doubt" at 41-69 reprinted in the Soil Association website at http://www.soilassociation.org/web/sa/saweb.nsf/a71fa2b6e2b6d3e980256a6c004542b4/9ce8a24d75d3f65980256c370031a2d0/$FILE/SeedsOfDoubt_3of3.pdf. Further examination of the extent of current legal actions is found in "Monsanto still suing farmers for seed saving", (Associated Press story dated 8 July, 2001) reprinted at http://www.organicconsumers.org/Monsanto/SeedSavingSuits.cfm)

[56] It is also suggested that these same approaches may be used to limit the uses of traditional varieties by farmers who have been paid by GMO developers for "access" to those varieties.

national governments, by giving them an impossible choice – accept GMOs or starve. Until some level of consensus arises concerning the various questions of scientific understanding, environmental and economic impact and socio-cultural effects, these attempts at removal of a country's unfettered right to make such a decision will appear to follow in older modes of "aid" – under which products which were banned from sale in the provider country, were then sent to developing countries as part of assistance packages. Regardless of the motivations underlying the offer, the fact remains that a decision to allow GMO introduction into the uncontrolled environment may well be irretrievable, once made. Hence, it is an essential part of the respect owed to any sovereign government that external efforts to influence that government's decisions should involve the provision of unbiased scientific evidence and expertise, including clearer evidence regarding the ability of GMOs to achieve the benefits claimed for them, particularly in the areas of food security and agricultural productivity.

IV. Institutions and Administrative Frameworks

The development of institutional and legal frameworks for managing certain aspects of GMOs and biosafety at the national, regional and international levels is a critical part of the overall process of addressing biosafety concerns. For purposes of this already lengthy paper, however, a detailed accounting of the provisions of the relevant instruments would not be a useful addition. The following is a very brief summary of the relevant international instruments and institutions, followed by some critical questions that must be addressed both nationally and internationally, if the international framework is to be successfully implemented.

Readers who are interested in more detail concerning the international instruments relating to biosafety are encouraged to obtain copies of the newly published Explanatory Guide to the Cartagena Protocol, (F. Burhenne-Guilmin and R. Mackenzie, editors) IUCN Environmental Policy and Law Paper No. 46 (2003).

A. International Instruments and Institutions

Although many international agreements and institutional mandates are very relevant to the topic of biosafety, the Cartagena Protocol on Biosafety, a protocol under the Convention on Biological Diversity, is pre-eminent, both because it addresses several key GMO issues specifically, and because it is the product of the most comprehensive global debate so far relating to GMO concerns. For this reason this section will begin with an examination of the Cartagena Protocol, before turning to a brief summary of other important international forums and instruments that are relevant to the GMO issue.[57]

1. The Cartagena Protocol on Biosafety 2000

From the date of adoption of the Convention on Biological Diversity (CBD) in 1992, the apparent need for a protocol on biosafety was recognised internationally. This is reflected in the fact that Article 19(3) of the CBD specifically mandated the Parties to consider the need for a Protocol on biosafety. After eight more years of negotiations, that protocol was adopted in January 2000.

The Protocol focuses only on specific elements of the GMO issue, namely, all critical aspects of the transboundary movement, transit, handling and use of Living Modified Organisms (LMOs)[58] that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account the risks to human health. Other key issues remain open, including liability for GMO-engendered damage or injury to people, animals, and ecosystems.

Although not a primary topic of discussion, one of the Protocol's most important provisions is found in indirect references in Articles 9, 14, and 26, which note that the Parties should each have a "domestic [biosafety] regulatory framework" to serve as a basis for the national implementation of the Protocol. It is clear from the text of the Protocol that this framework, which must be "consistent with the Protocol"[59] will encompass more than the implementation of the Protocol – that it will embody and implement the broader national policy and practice regarding GMOs and biosafety within national jurisdiction.

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[57] The Protocol received its 50th ratification on 13 June 2003. It will enter into force on 11 September 2003. Its first Meeting of the Parties will be held in February 2004 in Kuala Lumpur, immediately after CBD-COP-7.

[58] The Protocol speaks of LMOs instead of GMOs, presumably to ensure that the terminology was not burdened by current imprecise uses of the latter term in public and government circles. It defines LMO to mean "any living organism that possesses a novel combination of genetic material, obtained through the use of modern biotechnology". For these purposes, a "living organism" is "any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;" and "modern technology" includes in-vitro nucleic acid techniques (recombinant DNA and direct injection) and "fusion of cells beyond the taxonomic family. " (Article 3(g), (h), and (i).)

[59] Cartagena Protocol, Art. 9.3.

Within its mandate, the Protocol generally requires its Parties to regulate all introductions of LMOs, subject to a limited number of exceptions. LMOs that are "pharmaceuticals for humans" are excluded from the Protocol's scope, to the extent that they are addressed by other international organisations or agreements. Other more specific exclusions apply as well, including most notably "LMOs intended for direct use as food or feed, or for processing," which are excluded from certain aspects of the AIA mechanism, discussed below. And other LMOs may be excluded from the scope in future, if agreed by the Meeting of the Parties to the Protocol (MOP), if they are "unlikely to have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health."

The Protocol's centrepiece is the establishment of an Advance Informed Agreement procedure (AIA), for the transboundary movement of GMOs intended for introduction into the environment. This requires the exporter to notify the Party of import of its intention and also to provide information (detailed in the Protocol) permitting the Party of import to accept or refuse the import, or impose certain conditions to it, based on a risk assessment. Connected to the AIA, the Protocol creates a Biosafety Clearing House (BCH), which is designed to address capacity problems of developing countries, as well as to serve as a registry for critical information. The BCH has a specific role in the implementation of the Protocol in addition to one of facilitating the exchange of information on GMOs. It also contains provisions on capacity-building, financial resources and provides for institutional arrangements within the framework of the CBD.

As noted above, the Protocol is one of the most significant advances in the promotion of Precaution, incorporating the "precautionary principle" into operative provisions of the Protocol. In addition, it provides relatively lenient, but firmly required provisions for labelling LMOs in transit. These provisions may be adjusted, given that detailed requirements on documentation will be revisited by the MOP within two years after the Protocol enters into force.

2. Other Relevant Instruments and Institutions

The Cartagena Protocol on Biosafety represents the first attempt to regulate LMOs internationally. Beyond it, however, a limited number of standard-setting, binding and non-binding instruments have been adopted or are being developed, that address a broader range of biosafety issues:

- ***UNIDO Voluntary Code of Conduct for the Release of Organisms into the Environment*** 1992. The Code establishes general principles in respect of the introduction of organisms into the environment and in that regard encourages the establishment of regulatory regimes at national level.

- ***UNEP Technical Guidelines on Safety in Biotechnology*** – adopted pursuant to the Global Consultation of Government-Designated Experts in 1995. The Guidelines refer to the evaluation of biosafety, risk management, information exchange, research and monitoring The motivating factor behind the preparation of the Guidelines, was that they should be used on an interim basis pending the adoption of the Protocol.

- ***Codex Alimentarius*** —a non-binding code adopted under the auspices of FAO/WHO, the Codex relates primarily to food issues and has adopted Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods. These Guidelines particularly note that GMO foods cannot generally be given this label, and also established a Committee on General Principles, now preparing Working Principles for Risk Analysis.

  The Commission which oversees the development of the Codex has established a task force on foods derived from biotechnology, which is expected to complete its work in around 2004. Other Committees of the Codex Commission are currently examining a number of key labelling issues, including

- Proposed Draft Guidelines for the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering,

- a Proposed Revised Code of Ethics for International Trade in Food and the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants, and

- a Proposed Code of Practice on Good Animal Feeding.

- Food Labelling, recommendations on this subject for foods obtained from biotechnology.

❖ The ***International Plant Protection Convention*** (IPPC)[60] is primarily a "trade" convention, focused, like the Cartagena Protocol, on the ways in which countries can reasonably control plants and pests that might enter their territory. It is presently developing (among its body of international standards for phytosanitary measures) a standard to address the plant-pest risk of products of modern biotechnology.[61]

❖ Within the framework of the ***UN/ECE Convention on Access to Information, Public Participation in Decision-Making an Access to Justice in Environmental Matters***, which entered into force on 30 October 2001, discussions are taking place on how to address GMOs.

❖ As the financial mechanism of the Convention on Biological Diversity 1992, the ***Global Environment Facility*** is also called upon under the Biosafety Protocol to serve as its financial mechanism. At its meeting in November 2000, it adopted the "Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety", the main objectives of which are: to assist countries in the establishment of national biosafety frameworks; to promote information sharing and collaboration (in particular at the regional and sub-regional level); and, to promote collaboration with other organisations to assist in capacity building for the Protocol. It is envisioned that these objectives should be achieved through:

- assisting in biosafety capacity building at the domestic level;

- applying the guidelines established by the Intergovernmental Commission on the Cartagena Protocol (ICCP – the interim body addressing the Biosafety Protocol, which will now be subsumed into the bi-annual Meetings of the Parties (MOPs) to the Protocol);

- applying biosafety procedures with a view to enhancing environmental management;

- harmonising or co-ordinating regional and sub-regional regulations;

- involving all stakeholders in the adoption of national regulations;

- assessing technological capacity in relation to national regulations; and

- involving the public in an informed and transparent debate on biosafety matters.

A GEF/UNEP project for the 'Development of National Biosafety Frameworks' is now being implemented in co-ordination with IUCN-ELC to assist GEF eligible countries that have signed the Cartagena Protocol on Biosafety to prepare national biosafety frameworks and promote regional and sub-regional co-operation.

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[60] Adopted in 1951, revised in 1997.

[61] See discussion of the issues of standard "risk analysis" above.

V. Recommendations: Responsible Decision-Making Regarding Biosafety and GMOs

The most important conclusion of this paper is also the simplest: GMOs exist, and cannot be unmade. Regardless of one's personal, institutional or national position on the GMO issue, the most important objective of any responsible decision-maker will be to find a way of responding to the existence of, and requests regarding, the promotion of products, commodities, and technologies that are, at minimum, both important and controversial.

In this connection, decision-makers are already the recipients of untold reams of written advice, and hours of testimony, advising them on their responsibilities, and the particular choices they should make. It is not the objective of this paper to add to that volume of literature. Instead, the following is a discussion of the nature of the decision-maker's obligation and objective, and the manner in which decisions on this issue can be responsibly undertaken.

A. Procedural Responsibility

Given the breadth of opinion on GMOs – ranging from a belief that they are inherently dangerous to a belief that they are the best hope for continued human survival – it seems clear that the only acceptable governmental responses will be those that are

- transparent,
- participatory, and
- based on freely available scientific and statistical information.

Accordingly, it is strongly suggested that decision-makers give immediate attention to the implementation of the Cartagena Protocol on Biosafety. As noted above, even before turning to the primary focus requirements of the Protocol (public processes for "risk assessment" and "advance informed agreement,") it will be essential to undertake the critical step of developing an overall national policy on biosafety and the manner in which the risks and potential of GMOs will be analysed, addressed and communicated.

1. Procedures and the "Scientific Controversy" — Accessing Closely-held Scientific Information

Explained in terms of the approach of this paper, it will be essential, initially, to address the most significant uncertainty – the uncertainty regarding the science underlying GMOs and the proposals for their introduction outside the laboratory (the "scientific controversy".)

This issue is dubbed "most significant" regardless of the view one takes on the inherent safety or danger of GMOs, for the simple reason that it requires the decision-maker to directly address an extraordinarily technical issue. The difficulty of this task is enhanced by the fact that very little direct scientific information is made available, apart from characterisations of the scientific situation, whether by industry or by avowed opponents to GMOs.

The availability of dependable, unbiased information is the key to the decision-maker's ability to make a responsible science-based decision. Yet the serious deficiency in available information may be quite difficult to remedy.

It may be necessary to call for action in support of decision-makers at the international level, before any serious difference in the way information is guarded and used will be felt, Even when such information is freely available, it will be critically important to develop institutional capacity to understand and assess it, and thus to apply it to policy development and decision on GMO-related proposals.

In the meantime, the decision-maker is faced with a difficult problem – how to determine whether sufficient information is available to support a final decision – and possibly the even more difficult choice: Whether to make policy choices and other decisions before sufficient information is available, or to refuse to take a decision on an action that might have significant current benefits for the decision-maker's country and constituency.

These factors affect some of the most basic procedural decisions as well. For example, as noted in II.B.2.a, above, the adoption of specific standards and procedures for risk assessment is a matter of significant expert disagreement at present. This means that even the decision to apply a risk-assessment standard must be addressed through substantive technological analysis.

2. Procedures for Addressing Economic and Socio-cultural Controversies Regarding GMOs

As noted above, the decision-makers' task only increases in complexity, when they turn to the socio-cultural and economic issues. Procedurally, these issues require attention first to the need for good and sufficient data (economic and social analyses, as well as geographic-region- and crop-specific data concerning the direct impacts of GMO introduction) on particular factors and claims such as volume or dependability of production. In addition, however, the process must also address more difficult issues, including determining whether there are social, cultural or economic risks, and how to balance those risks against the potential gains that are offered by the proponents of introduction.

Most important, the process must not only be transparent but reciprocal. Informed public participation (input) processes are essential to effective decision-making, particularly with regard to difficult and controversial issues such as GMOs. Particularly, where such a decision involves some kind of weighing of risks and benefits, it is essential that parties on all sides of the issue clearly understand how these choices will be made, and that the process is rigorously and publicly followed. Moreover, it is absolutely essential that all legitimate input bearing on the issues relevant to the decision-making process, including especially that of local people and all sectors of the civil society, be accepted and seriously considered. More than anything else, this will help those who oppose the final decision to recognise its validity within the institutional system.

Because of the nature of the controversy surrounding GMOs, and the call for special mechanisms to address it under the Cartagena Protocol and other international instruments,[62] (as well as in some parts of the domestic and international press), it is important to ensure the maximum transparency, receptiveness, and procedural rigour in all decisions involving GMO policy and applications for GMO use.

B. Beyond Basic Decision-making – Applying Crosscutting Principles

Even after fully addressing the above issues, however, the task of GMO decision-making remains a process of extraordinary complexity. It is not enough simply to consider the basic scientific, economic, and socio-cultural issues, or to design models for addressing them. There remain larger, overarching concerns, including precaution, development, and national sovereignty whose application must overlay (but still through a clear, transparent process, which is rigorously applied) individual consideration and disposition of specific questions of fact, eligibility, or other matters.

For example, key crosscutting issues, such as the "development principle" and principled action in the area of bilateral and multilateral aid may unite within the biosafety realm. Florence Wambugu argues this point compellingly regarding the need for African countries to avoid exploitation and participate as stakeholders in the transgenic biotechnology business:

> "They need the right policies and agencies, such as operational biosafety regulatory agencies, breeders' rights, and an effective local public and private sector, to interface with multinational companies that already have the technologies. Consumers need to be informed of the pros and cons of various agricultural biotechnology packages, the dangers of using unsuitable foreign germplasm, and how to avoid the loss of local germplasm and to maintain local diversity. Other

[62] Technically, there is no specific requirement in the Cartagena Protocol or elsewhere that would mandate the creation of new Protocol-implementing legislation. In practice, however, in order to ensure that the Protocol's rather specific risk-assessment provisions are met, at least some "biosafety-specific" provisions are typically adopted by countries implementing the Protocol, whether by amendment of existing legislation or by adopting new.

checks and balances are required to avoid patenting local germplasm and innovations by multinationals; to ensure policies on intellectual property rights and to avoid unfair competition; to prevent the monopoly buying of local seed companies; and to prevent the exploitation of local consumers and companies by foreign multinationals. Field trials need to be done locally, in Africa, to establish environmental safety under tropical conditions."[63]

C. Creation and Use of Institutional and Legal Frameworks

Beyond these basic commercial and informational needs, however, are the needs for institutional mechanisms to address less obvious or expected issues. In light of the fact that the GMO issue is relatively new, there is a need for a broader level of institutional controls, to address issues that have not arisen yet, but will in future. Experience in other "new" fields of law (those relating to computer software, electronic business transactions, nuclear power, telephones and space travel, to list a few) suggests that unexpected results can cover a gamut from unintended perverse incentives to overvaluation of national commercial markets due to drastic alterations in public demand.[64]

In this connection, it is important to remember that the most important arbiter of GM issues will be national law.[65] And within the national legislative arena, there are basically five different key policy venues in which choices made can have a significant impact on the various opportunities and incentives for the development, marketing, and use of GM crops and other GMOs. These are:

- National **biosafety** law and policy;
- National **trade** law and policy;
- National **intellectual property rights** law and policy;
- **Food safety, health, and consumer choice** law and policy; and
- **Public research** policy.

Awareness of the manner in which each of these can address GMO issues will be a key type of capacity-building, and help assure responsible decision-making and informed public participation.

Examples of how governments and others can prepare to meet these challenges might include:

- *Development of mechanisms to address legal and financial responsibility for approved introductions "gone bad."* In general, one who introduces a specimen is held liable for damages it causes, unless s/he properly disclosed the risks, and complied with government permits and requirements. One serious concern for many developing (and even developed) countries is how they will deal with liability (or will pay for remedy) where the introducer has met their disclosure and permit obligations, but the introduced species still proves to be harmful under any of the scenarios alluded to above – whether as described under the "scientific controversy", or caused in other ways (unpredicted invasiveness and secondary impacts on traditional agriculture).
- *Ensuring prompt response (containment, removal, etc.) in the event of an inappropriate introduction, or a need to 'rescind' an introduction*. Here also, legal

[63] Wambugu (1999)

[64] Another introduced species, the tulip, caused this kind of impact, nearly destroying the Dutch economy some 250 years ago.

[65] Matters of agricultural and commodity regulation, as well as those of health and human welfare, are necessarily within the realm of direct national regulatory responsibility. Although the WTO processes operate as a limiting factor for countries engaged in global trade, they specifically do not prevent countries from taking any legislative or policy choices, so long as those choices meet standards relating to non-discrimination and other key issues.

provisions that limit the liability of an introducer who takes prompt remedial measures may encourage such action.

- *Imposing restrictions on safe use*. As noted in other contexts, some kinds of GMOs are suggested for use only on a specified percentage of total land under cultivation in this particular crop. These restrictions work in areas which utilise large industrial farming techniques, but may not be effective if imposed areas in which farms are typically very small. Legal and institutional arrangements should pre-evaluate socio-cultural conditions relevant to farming communities and regions, and identify types of restrictions and approaches that do not appear amenable to local social conditions.

- *Developing a GMO risk analysis model that addresses the issues of protein transfer and other kinds of risks unique to GMOs.* Current risk analysis mechanisms rely on conventional analytical processes used for other introduced plant varieties.

- *Expediting decision-making*. As with invasive species and a number of other environmentally damaging situations, the possibility of a "GMO accident" suggests the need for contingency plans, relating to how these situations will be addressed.

In addition to these, instantly addressable issues, a number of other issues will require broader institutional and legal developments, including the scientific advances necessary to enable them. Such issues include:

- *The need for post-approval monitoring of species introduction, as a risk management technique.* In general, scientific and administrative mechanisms do not currently exist that would satisfy the need for ongoing assurance regarding the performance and safety of GMOs.

- *Legal systems addressing liability for failed or damage-causing GMO introductions* may be the most important tool for motivating proponents of GMOs to act responsibly. However, liability depends on the ability to obtain evidence, not only of the damage caused, but of the source of the material or organisms that are causing it. In this connection, traceability is seen as an emerging risk management tool within the biosafety and food safety areas. By and large, specific tracing techniques do not currently exist that would allow identification of the source of a particular GMO problem, but they are reportedly in development. In the meantime, compilation of information regarding GMO behaviour[66] may provide a basis for reasonable decisions regarding liability for harm.

In all such situations, it is essential also to ensure greater accountability in the decision-making process. Greater accountability can be supported by

- clarifying the specific responsibility of particular officials with regard to permit decisions and oversight,

- specifying criteria for decision-making,

- requiring public disclosure of the rationales underlying each decision taken, and

- providing a right for affected members of the public (in addition to the proponents themselves) to seek judicial or administrative review of decisions.

D. International, Intergovernmental and Nongovernmental Support and Assistance

There remains one additional point to address in these recommendations – the role of national and international assistance, including specifically NGOs and IGOs, in filling the current informational and capacity gaps – that is, in promoting and developing the level of understanding and non-biased scientific capacity needed in order to responsibly address these issues. One might list the following among the areas of need that these organisations can help to fill:

[66] Such work is in development at FAO, although it is not yet clear what form the ultimate database will take.

- Assisting with the development of national and regional frameworks, both to implement the Protocol, and more generally to address critical biosafety and GMO-related issues, in all countries in which GMOs may be introduced, regardless of whether they have signed or ratified the Protocol.

- Promoting projects for *in-situ* conservation of genetic resources and undertaking projects with NGOs and local communities to facilitate their work in the conservation, development and sustainable use of genetic resources.

- Implementing key instruments for addressing the ecological impact of GMOs and other agricultural advances, including the Leipzig Global Plan of Action, the CBD programme of work on Agricultural Biodiversity, the Global Strategy on Farm Animal Genetic Resources, and the Code of Conduct for Responsible Fisheries.

- Increasing awareness, particularly of local communities, natural resource-dependent communities and individuals (farmers, fishermen, forest communities, etc.), consumers and policy-makers, regarding issues and controversies relating to GMOs and the manner in which they can knowledgeably and effectively participate in relevant decision-making.

- Building the capacity of scientific and administrative departments and experts who may be called upon to deal with these issues, and more generally within the agricultural sector and civil society, with regard to understanding of and participation in relevant decision-making and monitoring processes.

- Developing data and case studies relating to the impacts of GMOs on wild and traditionally bred species of plants and animals.

- Promoting the diversification of research and research funding relating to biosafety and molecular genetics, to encourage the development of a clearer understanding of the processes underlying these technological innovations (including supporting and encourage programmes for training in evolutionary biology and taxonomy) outside of corporate R&D departments, and inside national governments.

- Co-ordinating with and support the work of FAO and its Codex Alimentarius in the development of standards, recommendations and databases for the safe and effective regulation of GMOs and their use; and ensuring that issues of species conservation, ecosystem protection and the rights of indigenous peoples and communities are adequately addressed therein.

- Collecting and disseminating reliable, well vetted information on the current state of GMO use, and its known impacts on ecosystems and conservation.

- Undertaking research and provide specific guidance for addressing social, cultural and patrimonial impacts of GMO use (intellectual property rights, traditional agriculture (including participative breeding), impacts on indigenous communities.)

- Undertaking research and provide specific guidance regarding the social, economic, political and livelihood implication of "free trade" in GMOs on developing countries.

- Developing an informed scientific assessment of the state of GMO technology, and about the reliability and completeness of evidence offered on all sides of the “scientific debate” over the accuracy of current understandings regarding GMO processes and safety, and the impact of GMOs on food insecurity, sustainable agriculture, agricultural yield and the environment.

- Developing a rigorous assessment of the comparative advantages of genetic sciences and GM technologies, particularly with regard to whether GMOs, the science

of genetics, and the new biotechnologies can positively contribute to solving production problems in agriculture.

VI. Conclusion

In sum, the field of biosafety is, above all else, area in which much activity is ongoing, even though it is extremely controversial. Proponents identify possible benefits of GMOs that are enormous, including possibilities such as hunger alleviation, and universally available medical care, within our lifetimes. Counter-arguments identify a level of possible risks well beyond anything that has ever been deemed "acceptable" in the past.[67]

It is essential that decision-makers and others seeking to progress beyond the current stalemate demonstrate a strong commitment to the position that, in the absence of sufficient scientific certainty surrounding the commercial application of modern biotechnology, preventive and precautionary measures based on risk assessment and management are called for at all international and national levels.

[67] Even Bjørn Lomborg (a non-scientist statistician, who achieved fame by publishing his belief that the concerns of modern environmentalists are generally spurious) has suggested the need for more information and a regulatory framework for GMOs, noting that " choosing sensibility in the GM debate requires us to see the risks but also to compare them thoughtfully with all other risks…. It is only with this information that we can weigh the risks and benefits in order to make an informed decision." Lomborg (2001) at page 346. Lomborg's paper is based on "selected readings" with no explanation of the methodology by which his readings were selected nor his own qualifications for assessing them, and cannot rationally be cited as dispositive on any scientific or policy issue. It is interesting that an outspoken opponent of environmentalists and environmental concerns still recognises biosafety as an area in need of environmental attention.

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In addition, research for this paper included a wide-ranging survey of internet papers and websites in which GMO and biotechnology issues are addressed in an in-depth or substantive fashion. These include websites of –

Convention on Biological Diversity: http://www.biodiv.org

Environment News Service: http://ens-news.com

Food and Agriculture Organization: http://www.fao.org;

Friends of the Earth Europe: http://www.foeeurope.org

Friends of the Earth Australia: http://www.foe.org.au

International Plant Protection Convention: http://www.ippc.int

Institute of Science In Society: http://www.i-sis.org

Southeast Asian Regional Initiatives for Community Empowerment (SEARICE): http://www.searice.org.ph/

Union of Concerned Scientists: http://www.ucsusa.org

Institute for Social, Economic and Ecological Sustainability: http://www.fw.umn.edu/ISEES

NOTE: The above list of websites is not exhaustive, in that it was not generated at the time of the research, but out of the print-outs and other documents on hand at the time of the final revision of this paper. Other sites of great value are available. It is hoped that this list will provide a starting place for further research, when undertaken.

Annex: Excerpt from the Guide to the Cartagena Protocol on Biosafety,[69]

Description of gene constructs used in *in vitro* nucleic acid techniques

Once a gene has been isolated from a donor organism, it is modified in the laboratory so that it can be inserted effectively into the intended recipient organism. The modifications include making a large number of copies of the gene to be introduced, and possibly introducing changes to the sequence of nucleotides in the isolated gene in specific ways to enhance the expression of the gene once it is introduced into the intended recipient organism.

Following this, the gene to be introduced is built into a "gene construct". The gene construct includes a "promoter sequence" which is necessary to ensure that the gene is expressed correctly in the recipient organism. Different promoter sequences control gene expression in different ways – some allow continuous expression of the gene, while others switch expression of the gene on or off at different stages of the life-cycle of the organisms, or control the particular tissues or organs in which the gene will be expressed. "Termination" and "signalling" sequences are also incorporated into the gene construct. The termination sequence acts as a signal that flags where the end of the introduced gene is located: like the promoter sequence, the termination sequence is also important in ensuring that the introduced gene is expressed correctly. The signalling sequence provides information about the processing of the product produced from the gene construct.

A "marker gene" is often incorporated into the gene construct – this helps to make it easier to identify which individuals of a recipient organism have been modified by the introduction of the gene construct. Commonly used markers genes are those for antibiotic resistance: following introduction of the gene construct, individuals of the recipient organism are grown in the presence of antibiotics, and under these conditions, only those individuals that have been modified by the gene construct will show antibiotic resistance and therefore will be able to grow. Marker genes may be removed from the LMOs formed by this process at a later stage. Because of concerns over possible spread of antibiotic resistance traits, the use of antibiotic resistance marker genes is being phased out. Finally, a vector may be incorporated into the gene construct. The purpose of the vector is to assist transfer the gene construct into the recipient organism. An example of a gene construct including a bacterial DNA vector (*Agrobacterium* plasmid), is shown below. The following diagram gives an example of a very simple gene construct: (Note: Gene constructs currently used may include multiple elements – for example, several promoter sequences and desired genes) The gene construct is built from genetic material isolated from several different organisms, for example, a promoter from the Cauliflower Mosaic Virus, a bacterial DNA vector (*Agrobacterium* plasmid), one or more genes that may have been modified artificially in the laboratory, termination and signalling sequences, and a selectable marker gene, for example for resistance to the antibiotic kanamycin.

[69] From Article 3, Use of Terms, paragraph 216, and Box 16, of the Explanatory Guide.