Biosafety and Genetically Modified Organisms:

Background for the Enunciation of an IUCN Position and Plan of Action

Acronyms used in this Briefing:

AIA	Advance Informed Agreement
BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
DG	Director General
COP	Conference of the Parties
EIA	Environmental Impact Assessment
GEF	Global Environment Facility
GMO	Genetically Modified Organism
ICCP	Intergovernmental Committee for the Cartagena Protocol
IPR	Intellectual Property Rights
IUCN	International Union for the Conservation of Nature and Natural Resources
FAO	Food and Agriculture Organization
KRA	Key Result Area
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
WWF	World Wide Fund for Nature

TABLE OF CONTENTS

Biosafety and Genetically Modified Organisms:

Background for the Enunciation of an IUCN Position and Plan of Action[1]

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.

- IUCN Intersessional Programme

This paper was prepared by the IUCN Environmental Law Centre (the Lead Author was Tomme Young, with contributions from Françoise Burhenne-Guilmin, and John Scanlon) and it reflects contributions from Rachel Asante Owusu, Martha Chouchena Rojas, Dr. Jack A. Heinemann, Geoffrey Howard, Olga Krever, Sue Mainka, Jeffrey A. McNeely, Aroha Mead, María Fernanda Espinosa, and Richard Tapper. It also reflects the verbal comments of members of the Programme Committee of the IUCN Council, when they considered this document in May, 2002. The lead author assumes full responsibility for errors in its content or misunderstandings of particular comments.

I. Introduction

A. Summary -- "The breadth of the topic"

"Biosafety" is a concept that has not been completely 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 that genetically modified organisms (GMOs) can be a basis for increasing food production, without the need to convert more land to cultivation. These claims, however, are often balanced by the claims that GMOs may have a variety of impacts on people and animals, and especially on lands and ecosystems other than the lands under cultivation.

After an initial 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 people and especially indigenous and traditional communities.

[1] This paper is intended to summarise extensive initial research regarding the issues relating to biosafety and GMOs. Although the former Council decision noted the need for "scientific rigour" it is also clear that a Council paper should aim for a useable level of brevity, rather than exhaustive exposition of the issue. Although citations and footnotes are limited to the use of quotations, and specific examples, all of the information contained in this paper can be supplemented from the resources and notes of the contributors.

(ii) Many (perhaps most) of the most prominent voices in each of these areas are focused only on their own area, and not entirely aware of the other two.

Within this framework, many of the "crosscutting" issues generally relevant to 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. Similarly, many countries suggest the existence of a so-called "development principle", which adds a human balance to the precautionary principle. In this context, modern advances in biotechnology bear a unique relation to the concept of "equitable sharing of the benefits derived from the utilisation of genetic resources."[2] 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

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, and within the various disciplines that effect it most directly, and within which we can be effective and add value. In this role, the Union is now facing the challenge of a major change in the underlying sciences and the manner in which it 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.[3]

The Second World Conservation Congress (WCC-2)[4] 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 Intersessional Plan.

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 notes "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* 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 DG:

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

[3] Commoner, 2002, at p.39

[4] For this paper, we have focused only on the Resolution WCC-2.31 (Amman, 2000). A more complete evaluation of policy bases relevant to this issue should also examine such of the resolutions from WCC-1 and General Assemblies 1 through 18, which remain viable as policy of the Union. Beyond the issues mentioned here, Congress and General Assembly resolutions dealing with alien species, ecosystem approach, agriculture, mariculture, benefit-sharing, forests, livelihoods, sustainable development, impact assessment, and numerous other topics may contain provisions directly relevant to GMOs.

- "to support initiatives to implement the Cartagena Protocol"; and
- "to propose options for an IUCN contribution."

IUCN Intersessional Programme:

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

> [t]he 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]

The only Key Result Area in which GMOs are mentioned directly is KRA2 (Agreements). However, a great many of the issues noted below are relevant to other KRAs, as well suggesting that there is a mandate and justification for addressing GMO and biosafety issues under all 7 KRAs To date, IUCN's primary efforts under KRA2 have been two projects specifically addressing biosafety (both focused on capacity of national decision-makers in implementing biosafety legislation and administration.) The Union is also active in other fields closely aligned with biosafety, including alien species, access and benefit-sharing, and agricultural biodiversity. (Annex 1.)

This paper provides an initial orientation to the relationship between GMOs and IUCN's mandate with the object of informing the decision required under Resolution 2.31 regarding the manner in which IUCN shall contribute to the international work on biosafety and GMOs in the context of conservation and sustainable use.

II. Biosafety and GMOs – Technical and Technological issues

The technical and technological issues involved in biosafety are extremely numerous, and often very complex. For purpose of this briefing, only the most central will be summarised, as a means of focusing on how the progress of the debate is progressing, and 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, initial review of the literature, even in "serious journals," appears 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 View

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 statement of the issue. At their simplest, the controversies over 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

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

underlying assumption of this view is that the scientific bases for genetic manipulation and other processes are sound, well understood and well managed 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 process that will be necessary to understand and predict the manner in which those discoveries will impact 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 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.

- A third group seems to believe that, scientific development can find answers and operate in a safe manner, but is less likely to do so where 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 for dealing with biosafety issues, particularly in the context of IUCN's mandate.

2. A More Detailed (Non-geneticist's) Understanding

It is fair to assume that IUCN's contribution on the issue of biosafety will not resolve the scientific controversies regarding genetic science. In order to determine a focus for IUCN's work in this area, however, we must develop a more detailed collective understanding of the scientific controversy that underlies the biosafety debate.

This paper will not provide a thorough discussion of these issues, but is intended to move beyond the most basic formulation of the problem, and give some idea of how it must be understood for purposes of scientific and empirical examination of 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 scientific issues, as a basis for understanding.[7]

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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).

[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 the IUCN Council, whose membership includes many who are not experts in

a. 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 maximum 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, etc.) grew more sophisticated, including processes for developing hybrids. These processes are extremely lengthy, owing to the need for "stability" in the crop variety – that is, many generations of selective breeding are required in order to ensure that undesired recessive traits are eliminated and the variety will "breed true" in future, before it can be generally introduced as a stable new variety. Both traditional breeding and hybridisation methods, however, are wholly 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 could not be developed 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 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. These characteristics, it is assumed, will continue to replicate themselves in stable and predictable dependable ways, because they have been integrated into the DNA coding, which controls the way in which cells replicate and specialise within the organism.

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.

A simplified description of one process by which GMOs are developed (recombinant DNA) is attached as Annex 2. In essence, scientists can 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.[8] This process (known as "genetic modification" or "genetic engineering").is based on the premise that the DNA code is known and 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 is expected to provide a way of giving a plant or animal new, inheritable qualities much more quickly than through the use of traditional methods. It allows the addition of qualities that are entirely new to the species.

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genetic sciences. Any misstatements in this synopsis are the responsibility of the Lead Author, and not of the contributors.

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

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 creates astounding possibilities whose very novelty and power suggest to some the need to challenge the technology *ab initio.* Description of genetic manipulation as an exercise of "nearly godlike power" is evidence of the level of discomfort felt by many commenters in response to highly publicised achievements (such as the production of the cloned sheep, Dolly, by Ian Wilmut of the Roslin Institute and Keith Campbell of the biotech firm PPL Therapeutics in Scotland in March, 1997.)

On the more scientific level, however, the debate goes beyond personalities. The concerns expressed by geneticists relate more to the belief that it is premature to introduce GMOs into the environment now, than to opposition to the idea of humans acting like gods.

Although these concerns are not new, 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, as originally postulated by Watson and Crick. 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 less simple 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, scrappie, 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 present 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 theory 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. Implications for IUCN

While IUCN is not in a position to resolve this controversy, it may be in a position to evaluate certain relevant factors, particularly with regard to species and ecosystems. As further discussed below, one of the greatest problems within the scientific debate, however, 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 in part A.3, 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 however 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 "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 use of Bt pesticides (which also may find their way onto milkweed eaten by monarch butterflies) and that of Bt maize pollen, with regard to monarch mortality,
- the relative effectiveness of the pesticide and the Bt variety, including the effect on local health and communities
- the effects of including Bt elements within the maize as opposed to using it as a pesticide.

As to the latter, 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 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 a basis for praising 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 IUCN, in its role as a "knowledge network" to develop and provide sound and balanced information regarding all aspects of the GMO question as they affect species and ecosystems.

B. Economic and Political/Institutional Aspects

A second realm of concern in this area is that of economics and political concerns. This area has seen a large volume of material regarding GMOs, although often utilising inconsistent approaches to scientific and other information, and failing to clarify the type of physical/scientific questions that are being discussed.

The economic/political debate is best understood by considering broadly two components: (i) risk/benefit analysis, and (2) risk management techniques (licensing and labelling).

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, this approach aims 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. To properly balance them, however, 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 (air, water, soil, etc.), social costs, environmental benefits, delayed benefits, etc.

Human activity has, however, 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." While the mechanism for "risk/benefit" analysis is not firmly established, all appear to agree that two factors must be considered –

- the magnitude of the potential harm involved, and
- the likelihood that it will occur.

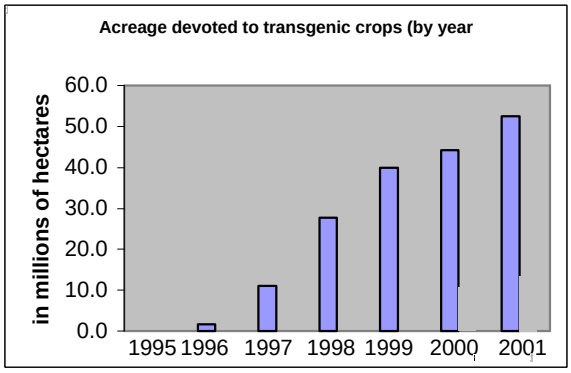
The ***magnitude*** question includes not only the extent of potential damage, but also the costs of remediation if possible, and many other factors. Magnitude of the risk, is often difficult to assess with regard to a particular activity or condition that has little or no "historical antecedent" (*i.e.,* 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 last September, that risks of very great magnitude should not be discounted, 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.

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.[9] 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[10]

[9] See generally Wolfenbarger and Phifer 2000.

[10] 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.

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% increase over the same figure for 2000, and, of course, a 100% increase over 1995.[11] 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 information, with slight modification 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.[12] 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 is 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.

Without statistical support regarding 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 scientific basis for GMO creation is false, then the risks of continuing to utilise GMOs without resolving these scientific controversies may be difficult or impossible to evaluate. Certainly, until there is a clearer understanding of 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 it interacts with, both in the environment and on the table.
- On the other hand, if alteration of DNA is a fixed process that 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 combined, without first recognising this variety. 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.

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[11] 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. (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.)

[12] 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.)

(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 3 decades (since the commercial application of genetic modification technology first appeared to be possible.)

The most prevalent examples of this are research. In most instances, the objective of the research appears to be the development of an organism that can be introduced into the uncontrolled environment. (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, drink its milk, etc.) 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 that benefit can be obtained more quickly than would be possible if relying on older, more conventional research procedures.

With very limited exceptions, 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 introduced into the environment. Here, the issues of concern include both those that centre on the "debate" and other concerns that arise regardless of which scientific picture is ultimately proven. The following non-exhaustive list of examples demonstrate the variety of these situations, and the variation in the way they must be evaluated:

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 is based on these uses.

Benefits:

The benefits expected of GM agriculture/mariculture are many and varied, for example:

- GMOs are expected to increase ***agricultural/maricultural productivity***, maximising per acre and per capita yields. This is 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.[13]

- 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.[14] Crops that can withstand known or expected blights offer a significant benefit to society. This benefit can be expressed in financial and other terms, and is a social benefit, as well.

- GM 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, etc. 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 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.[15] 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 also been applied 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.)[16] These uses are particularly important, because they are *specifically intended* to lead to interbreeding and to cause direct change to wild species.

  Similarly, genetically engineered bacteria has 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

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[13] As noted above, the extend 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 (Royal Society of Canada, 2001).

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

[15] 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).

[16] Zitner, 2001.

be to replace naturally occurring species.[17] Similar projects have developed microbes for use in bioremediation of certain kinds of soil contamination.

- An important benefit of many agricultural GMOs is the **reduced 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 have 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.[18]

- While the list of potential future benefits 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 program 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 bacterially caused diarrhoea is one of the leading causes 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 for diarrhoea and cholera, are producing encouraging early results. In future, such food vaccines might also be able to suppress auto-immunity (in which the body's defences mistakenly attack normal uninfected tissue)[19]

Controversies, however, have turned on the manner of valuing these benefits. One key issue is the extent to which they can be/have been proven. Evidence linking particular benefits to GM use has been limited, and often provided only in episodic form. For instance, as noted above, agricultural figures are difficult to find that provide appropriate linkages between GM crops and productivity – which would appear their basic *raison d'être*. 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 "specific solution" are sometimes questioned as well, regarding the extent to which these programmes 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.[20] As with all environmental decision-making, the existence of solid 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

[17] 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).
[18] U.S. Environmental Protection Agency, 1999.
[19] Arntzen, 1995.
[20] Wolfenbarger and Phifer 2000.

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 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 and the potential of horizontal gene transfer from GM fish.

In terrestrial ecosystems, the confidence in the impossibility of this type of horizontal transfer is higher, however, numerous scientists have indicated that viral transfer may be possible. In addition, the gene replacement may not be stable, so that it can have other impacts on the organism, and its surroundings.[21]

Risks Applicable under Either Scientific Paradigm: Numerous environmental risks related to GMO use, however, may apply even when applying the basic scientific analysis (of the role of DNA as 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 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.[22] 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. Many collateral impacts could, like conventional mutations, be harmful, if not fatal, to the carrier.

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, will quickly disappear in the wild, unless it confer a selection benefit on the recipient species. However, it is clearly possible that tolerance to a particular pesticide or natural pests might easily constitute such a selection benefit, and thus alter the native species' ecological relationship and behaviour.[23]

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[21] 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.)

[22] 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).

[23] 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.

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 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. 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.[24]

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, alter the balance of its use of food species, etc.

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 will be no ability to call them back or eliminate them, should problems be later found. Through the history of humanity's attempts to address problems by introducing alien species, it has become apparent that prediction of the possible impacts of species introduction is, at best, inexact.[25]

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. 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 the one of the most serious environmental threats currently recognised, and have been singled out for urgent international attention;[26] 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.

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[24] 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).

[25] 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).

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

This need is particularly evident in an evolving and expanding area such as molecular genetics. Few government agencies will employ experts whose level of understanding is sufficient to validate the applicant's claims internally prior to issuance of the decision.

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 controversy over biosafety is the fact, referred to elsewhere, that all 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.

To a large extent, this issue is closely connected to ongoing work on intellectual property rights to biological and genetic information. IUCN is giving intense attention to these questions under KRA 4 of the Intersessional Programme, primarily in connection with concepts of "access and benefit-sharing" and "traditional knowledge"[27] under the CBD.

The problem, however, is not simply one of access to data from commercially motivated 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 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 the objective of obtaining official permission for GMO introduction or of 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 are attempting to fill some of the gaps by providing database information about the experiences of member countries. 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). As IUCN develops and implements a plan of action on GMOs, it will be important 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

[27] In this paper, as elsewhere under the CBD, the phrase "Traditional Knowledge" will be used as shorthand for "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles" as used in Article 8(j) of the Convention.

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 the 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. As such, these issues cannot be examined in this paper.[28] However two important components of risk management are impact assessment, public awareness/participation. These concepts, both very important in this field, are strongly within IUCN's mission, vision and programme. In particular, KRAs 1, 4 and 5 underscore the importance of the public's contribution to effective decision-making, as well as the importance of public awareness of the issue, within the context of government decisions on matters and activities affecting the environment.

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 EIA procedures, the assessments mandated under national biosafety-related legislation, and especially under the Cartagena Protocol (described below) provide the entire basis on which the various decision-making, permitting, labelling and other processes will 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 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.[29]

In most instances, however, substantial equivalence is used as a basis for approval or disapproval of proposed GMO introductions, primarily in the food safety area. According to the World Health Organisation, this mechanism is designed to take into account both intended and unintended changes in the plant or foods derived from it,[30] 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, taking into consideration unintended effects due to genetic modification (sec. 3, para. 16). Risk managers subsequently judge this and design risk management measures as appropriate.

Unfortunately, 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 may be inappropriate in the case of GMOs, serving 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

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[28] We note, however, that these are important issues, with many aspects of relevance to IUCN's work.. Except where the GMOs are to be kept in contained (laboratory) conditions, decisions about the permissibility of the introduction, and determining the permit restrictions that will be imposed in order to minimise the risk of environmental or other harm caused by the introduction, can indirectly be determinative of 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 and unexpected impact. Reportedly, however, in many cases these buffer requirements effectively eliminate any possibility of introduction of the GMO

[29] Canadian Food Inspection Authority, 1994

[30] World Health Organisation, 2000.

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, however, 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, 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."[31]

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 an Access to Justice in Environmental Matters.

Simple "transparency" and "access" to relevant documents, however, may not be sufficient in the case of biosafety issues, however. 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 information and expertise weighs heavily on the side of the GMO proponents, which are often the companies or institutions that developed the GMOs.

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.[32]

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

[32] Young, 1992.

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 – a series of voluntary standards for food and agriculture – is one of the primary vehicles through which these issues are being addressed.

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.[33] These countries' legislative provisions require relatively broad-based stakeholder processes addressing certain aspects of modern biotechnology, including the release of GMOs. These processes help the government to gauge public opinion, generate dialogue, gather useful information and develop awareness within their populations on modern biotechnology.

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 seen as important contributions. On the other hand, however, the introduction of GMOs can impact humans, 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:

> "The resolutions working group on GMOs was clear the 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."[34]

Such recognition is not new, however, 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 livelihoods of the rural poor. We can meeting this challenge by building on our achievements and devising new strategies for sustaining food and livelihood security.[35]

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

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[33] *See, generally,* Mulder and Ree, 1996; *and more specifically to GMOs,* Bearano, 1999; BioTIK Expert Group, 1999; and Christensen, 2001.
[34] Formal Statement of the US, at 34.
[35] Our Common Future, at 118.

recognises that "most of [the rate of growth] is due to a phenomenal rise in productivity…. [including] by

?? Using new seed varieties designed to maximize yields, facilitate multiple cropping, and resist disease;

?? Applying more chemical fertilizers, 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."[36]

On the other side of this coin, however, food production and relationships with their lands and ecosystems are basic on the balance that virtually all cultures, from the most developed to the least, 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. Although the 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 much less than that of 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."[37]

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 in tact. 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 in terms of addressing a broader range of local health issues to help poor 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.[38]

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[36] Id at 120.
[37] Mead, 19__ (citations omitted.)
[38] Marion Nestle, 2001

- 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 farmer 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 that it relies on, can come into 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.[39]
- 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 are, with their wild relatives, the basis on which GM development is founded, will begin to disappear. This may happen through voluntary action, where farmers feel that they cannot allow their productivity to drop to far behind that of their neighbours. It may also occur involuntarily, however, 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, and many similar concerns are relevant in all conventional aid and commercial transactions involving developing countries. GMOs and related research have been a tremendous force enabling solutions to specific agricultural problems. This is 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.

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[39] McNeely, 2001

Small-scale farmers in eastern Africa have also benefited by using hybrid seeds from local and multinational companies. To these farmers, "transgenic seeds in effect are simply an added-value improvement to these hybrids. Local farmers are benefiting from tissue-culture 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."[40]

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.

[40] Wambugu (1999)

III. Crosscutting Principles

Several critical crosscutting principles apply within the biosafety arena, necessitating, in some cases a careful balancing process. The most relevant such principles are Precaution and Development.[41] While these are generally well understood, the conflict between them is particularly relevant in the area of biosafety, given the extent of public concern and belief that GMO technology is insufficiently understood and potentially unsafe. For this reason, the two 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."[42] 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 precautionary approach is 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 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.[43]

Despite these words, the fact remains that the application of precaution is still a controversial topic with regard to GMOs. Concerns focus around the fact that GMO use and introductions are controlled primarily by the private sector, whose incentives for development and marketing may be greater than for assessing potential problems. These concerns indicate that governmental implementation of a precautionary approach will be an essential check on profit-motivated activities.

B. Development

The precautionary approach, however, is not however the sole transcendent principle on which environmental 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

[41] Many identify poverty alleviation as another relevant principle, however that issue is adequately dealt with in other elements of this paper.
[42] Cartagena Protocol on Biosafety, to the Convention on Biological Diversity (Nairobi, 2000) Article III.4.
[43] New Zealand Royal Commission, 2000.

concept of sustainable development may be pre-eminent. Consequently, many commenters (particularly those from southern developing countries) argue that it is inappropriate to apply the precautionary approach as an inviolable rule; one must balance it against other needs.[44] 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 recognition of 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 determine whether to proceed to risk management.

[44] Katerere, 2001

IV. Institutions and Administrative Frameworks

The development of institutional and legal frameworks for biosafety at the national, regional and international levels is a critical part of the overall process of addressing biosafety concerns, and one that is already reflected in the IUCN Programme.[45] 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 forthcoming Explanatory Guide to the Cartagena Protocol, (F. Burhenne-Guilmin and R. MacKenzie, editors) to be published in IUCN's Policy and Law Series this fall. Advance copies of this publication will be made available to members of Council, upon request).

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, even though it has not yet received enough ratifications to enter into force.[46]

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 addresses all critical aspects of the transboundary movement, transit, handling and use of Living Modified Organisms (LMOs)[47] that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account the risks to human health. LMOs that are "pharmaceuticals for humans" are excluded from its scope, where 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,

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[45] IUCN Intersessional Programme, KRA 2.

[46] As of this writing, a total of 110 countries have signed, and 16 countries have ratified or acceded to the Protocol. 50 ratifications are needed for entry into force.

[47] 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).)

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 labeling 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 that have been adopted or are being developed, addressing 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 FAO/WHO auspices relating primarily to food issues has adopted Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods, which particularly note that GMO foods cannot generally be given this label.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 Code of Practice on Good Animal Feeding proposed.
- Food Labelling, recommendations on this subject for foods obtained from biotechnology.

✍✍The International Plant Protection Convention (IPPC)[48] - 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.

✍✍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, pending its entry into force);
- applying biosafety procedures with a view to enhancing environmental management;
- harmonising regional and sub-regional regulations;
- involving all stakeholders in the adoption of national biosafety regulations;
- assessing technological capacity in relation to national biosafety 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 to assist GEF eligible countries that have signed the Cartagena Protocol on Biosafety to prepare national biosafety frameworks and promote regional and sub-regional cooperation.

B. Other Institutional Concerns

The building of a framework for biodiversity legislation, however, requires more than simply accession to, or even implementation of, these international agreements. Many of the most important needs are already apparent from the earlier sections of this paper. Florence Wambugu argues compellingly that African countries must 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 checks and balances are required to avoid patenting local germplasm and innovations by multinationals; to ensure policies on

[48] Adopted in 1951, revised in 1997.

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."[49]

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 public demand.[50]

A few examples are provided of how governments and others can prepare to meet these challenges:

- *Development of mechanisms to address 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 countries is how they will deal with liability (or will pay for remedy) where the introducer has met their disclosure and permit obligations.

- *Ensuring prompt response (containment, removal, etc.) in the event of an inappropriate introduction, or a need to 'rescind' an introduction*. Here also, legal 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 imposed in Africa or other areas in which farms are often 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 to amenable to local social conditions.

- *Expediting decision-making*. As with alien 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 suggest the need for broader institutional and legal development. One such issue is the need for post-approval monitoring of species introduction, as a risk management technique. In general, modern scientific and administrative mechanisms do not exist that would satisfy the need for ongoing assurance regarding the performance and safety of GMOs.

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

[49] Wambugu (1999)

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

are reportedly in development. In the meantime, compilation of information regarding GMO behaviour[51] may provide a basis for reasonable decisions regarding liability for harm.

Finally, 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.

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

V. Suggestions and Conclusion

This paper had two ultimate objectives – to inform the Council regarding the biosafety issue, and to suggest areas of action for its consideration. With regard to the latter mandate, WCC Resolution 2.31 offers specific guidance to the DG and Council, regarding the objectives that should be served by IUCN's participation in this issue. Specifically, IUCN's contribution must

(iii) "advance leadership, research, analysis, and the dissemination of knowledge regarding the potential ecological impact of the release of genetically modified organisms into the environment"; and

(iv) focus especially on "biodiversity, socio-economic impact and food security."[52]

Accordingly, in light of the information presented above, the following are possible avenues through which IUCN can make a significant contribution on this issue, offered in tentative order of priority:

High Priority:

A Promote ratification of the Cartagena Protocol through IUCN membership;

B Assist in the development of national and regional frameworks, both to implement the Protocol, and more generally to address critical biosafety issues, through IUCN membership and networks, in all countries in which GMOs may be introduced, regardless of whether they have signed or ratified the Protocol.

Lower Priority:

C Build the capacity of scientific and administrative departments and experts, in dealing with these issues, and within the agricultural sector and civil society, with regard to understanding of and participation in relevant decision-making and monitoring processes;

D Develop data and case studies relating to the impacts of GMOs on wild and traditionally bred species;

E Promote 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.

F Co-ordinate 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 ensure that issues of species conservation, ecosystem protection and the rights of indigenous people and communities are adequately addressed therein.

G Collect and disseminate other reliable, well vetted information on the current state of GMO use, and its known impacts on ecosystems and conservation;

H Undertake research and provide specific guidance for addressing social, cultural and patrimonial impacts of GMO use (IPRs traditional agriculture, impacts on indigenous communities, etc.);

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[52] Resolution 2.31 was adopted by visual vote, with four state members abstaining. Two of these members provided formal statements for the record, relating to the substance of the resolution. The Canadian statement objected to the use of the phrase "precautionary principle," preferring the term "precautionary approach." This issue is addressed above, and the wording of the resolution was based on the wording of the various international instruments referenced. The United States' formal statement memorialised it's objection to the phrasing of the resolution, which, it said "appears to prejudge, in a negative and unbalanced manner the question of the potential risks and benefits of biotechnology." The US also joined in Canada's opposition to the use of the phrase "precautionary principle." Proceedings of the Second World Conservation Congress (IUCN, publ. 2001), page 33-34.

I Address, at the institutional level, the need to ensure that conservation, equity, and sustainable use issues are given primary attention in national, regional and international work on biosafety, including through the CBD, both as "parent" of the Biosafety Protocol, and in terms of its broader provisions;

J Support and encourage programmes for training in evolutionary biology and taxonomy, and financial support for relevant in-country works.

The field of biosafety is, above all else, an area in which much activity is ongoing, even though it is extremely controversial. The possible benefits of GMOs are enormous, and suggest possibilities such as hunger alleviation, and universally available medical care, within our lifetimes. Yet significant risks are also evident.[53] IUCN's resolution and other documents 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.

[53] No less than Bjørn Lomborg (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:

> GM goods have been claimed to be a potential disaster or something we should outright love. Why this wide gap in judgement? No doubt, part of the reason is caused by a lack of information…. We know by far the most important human allergens, but we do not know the consequence of using genes from non-food organisms. We should make allergy tests for these, but since we do not know what we are looking for we can never be absolutely sure to find everything…. The basic argument both from biology and economics is that the focus should be on making the best possible regulatory system, yet we need to realise that no system can provide absolute certainty. Science cannot *prove* that something is not dangerous. Technology cannot provide absolutely risk free products…. Thus, 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 (based on "selected readings" with no explanation of the methodology by which his readings were selected nor his own qualifications for assessing them) goes on to conclude, without cited support, that cost-benefit analysis of risks involved will probably prove to be sufficient to resolve these controversies. Without agreeing with Mr. Lomborg's full conclusions, it is valuable to observe that such a noted critic of environmentalists and environmental concerns still recognises the biosafety area as one in need of environmental attention.

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Annex 1: Activities of IUCN directly addressing GMO issues

The following projects are in their final stages:

Environmental Law Programme: The IUCN- Environmental Law Centre and the Foundation for International Environmental Law and Development (FIELD) are jointly preparing an Explanatory Guide to the Protocol (Guide), with a view to assisting in raising awareness of the Protocol, and facilitating the understanding of the legal obligations established by it. The purpose of the Guide is to contribute to capacity-building by providing an information base on the origin and content of the Protocol, accessible to the non-specialist. Generally, the Guide aims to:

- describe the content of the Protocol, article by article, and theme by theme;
- explain the terms used and the corresponding provisions – drawing as need be on the discussions and rationale which led to their final wording;
- describe the provisions of other international instruments which are relevant to the Protocol, including but not limited to those of the Convention; and
- point out options, if any, left open by the text, in particular those which might play a role in the decisions of the Parties will have to make in their implementation of the Protocol.

Asia Region: The IUCN Regional Programme for Asia is working on capacity building in Asia to implement the Biosafety Protocol. This initiative, supported jointly by the German Federal Agency for Economic Development and Co-operation (BMZ) and the Swiss Agency for Development and Co-operation (SDC), aims to:

- Help countries in Asia implement national and international regulations concerning biosafety;
- Build capacity to integrate provisions of international and national level regulations; and
- Support activities aimed at implementing the Cartagena Protocol.

The following activities are being planned under this initiative:

- Capacity mapping and needs assessment in the region;
- Establishment of a list server;
- Development of a Resource Kit for developing and implementing national level biosafety protocol;
- Development of information and awareness raising material;
- Adoption and translation of IUCN's Guide to developing and implementing the Biosafety Protocol to meet Asian regional needs;
- Organisation of national level training workshop(s) on risk assessment and implementation of biosafety protocol provisions;
- Development of 'media packages' on related issues; and

✍✍Establishment of an information Resource Centre to feed into a thematic clearing house mechanism for the Asia region on Biosafety.

Other work: In addition to the above, the Species Survival Commission is developing guidelines on alien species introductions; and the Global Invasive Species Program (GISP – a collaborative group of international organisations, of which IUCN is a founding member) has been active in the development of international guidelines on alien species. Both documents could be considered to have direct impact on GMOs which are, by definition, alien everywhere.

In addition, IUCN's work on ecosystem management and the ecosystem approach, as well as in the development of sustainable development principles will be directly relevant to the issues addressed in this paper, as will work on agricultural biodiversity, currently ongoing in at least two regional offices.

Annex 2: Excerpt from the *Draft* Guide to the Cartagena Protocol on Biosafety,[54] (not for publication or distribution.)

In short, the genetic modification process may be summarized as follows:

Cells that contain a gene to be isolated are broken open and the strands of DNA are extracted. Then proteins called restriction enzymes are added to break the DNA at particular points, until the short lengths that are individual genes are obtained.

The wanted gene is added to plasmids, small molecules in bacterial cells that contain DNA that is not part of the chromosomes of the cell. The plasmids to which the wanted gene has been added are put in with the cells (usually bacteria) where the wanted gene is to go. The plasmids get inside the bacteria and add their genes to the genes of the bacteria. This means the bacteria are then used to transfer the new genes into plant or animal cells. This process of gene splicing creates recombinant DNA.

Another way to create genetically modified products is to use the bacteria themselves as factories for the introduced genes, producing such things as enzymes used in food production (e.g. chymosin for cheese-making) and vitamins for use in making processed foods, or hormones for use in medicine and animal husbandry.

Stages in making a new living modified organism using insertion of recombinant DNA

There are usually at least four stages in making a new living modified organism using insertion of recombinant DNA (rDNA), which is currently the most commonly applied in vitro nucleic acid technique. It should be noted that other techniques of modern biotechnology, some of which also involve application of in vitro nucleic acid techniques, and others which involve cell-fusion, may also be applied to produce LMOs, including such techniques in these categories that may be developed in the future.

Stage 1

An organism with a desired characteristic is found, and a gene (or more than one) is identified that confers that trait. An example might be tolerance of a particular herbicide or a particular pesticidal characteristic. The gene is abstracted from the "donor organism" and sequenced.

Stage 2

Copies of the gene are made, possibly changing the sequence to take into account the preferential codon usage found in the intended recipient organism. Other genes that may be needed for the system to work (e.g. promoters and other control units) may be added to form a package, termed a "gene construct": the new genes and control units may be derived from different organisms. The new gene(s) and any necessary control units are inserted into some form of vector system, and the vector then is used to introduce the modification into the recipient organism.

Stage 3

A laboratory method that may involve other organisms (termed vectors) is used to insert the package into the recipient organism.

There are a number of methods used to insert the genetic material. In bacteria and fungi changes are easily accomplished. The single-cell organisms are transformed[55] – genes are usually inserted into a plasmid that is then inserted into the cell, effecting the desired change in phenotype.

The most common method for modifying animals is micro-injection. This involves the injection of the foreign DNA into a fertilized egg, which is then inserted into a mother (in the case of mammals) and allowed to develop to term. The DNA may be incorporated into the chromosome or exist as an autonomous DNA fragment which may be replicated and passed on to offspring which will contain the inserted

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[54] From Introduction, paragraph 28, and Box 3, of the draft Guide.

[55] *Transformation* is a process whereby DNA is taken up by a cell or organisms from outside and is incorporated into the genetic material of the organism.

characteristics. The first animal modified in this way was made in the early 1980s and the technique has been applied to many animals, including cattle, pigs, sheep, fish and insects. DNA targeting is now being used, where random mutations are deliberately created and screened for desired phenotypes.

Another method uses retroviruses – a widespread group of viruses – as vectors for transferring information into animal cells. Retroviruses have been isolated from a wide variety of vertebrates, including mammals, birds and reptiles and similar organisms have been found in insects. Retroviruses are RNA molecules that are copied to form a complementary DNA molecule that is then transported to the cell nucleus and one or more copies inserted into the recipient's DNA. This integrative step is apparently an essential step in virus replication and appears to occur at random sites in the recipient DNA. If particular genes are removed from the virus and replaced by those genes that need be inserted into the organism, the integration of the desired genes into the genome of the recipient organism may occur.

For plants two methods are currently primarily used. The first, often called biolistics, involves the direct insertion of the nucleic acid package using a ballistic method. Very small metal particles (usually gold) are coated with the nucleic acid and fired at a high velocity into plant cells. For reasons not fully understood some of the DNA enters a proportion of the cells and is incorporated into the genome.

The second method uses a bacterium, *Agrobacterium tumifaciens*, that infects plants by inserting a small plasmid (or circular piece of DNA) into the plant. The genes that this plasmid contains then become incorporated into the genome of the plant. Scientists have adapted the system that this bacterium has evolved, to provide a tool to insert novel genetic material, modified by in vitro nucleic acid techniques, into plants. Not all plants are susceptible to infection by *Agrobacterium*.

Stage 4

One or more of the inserted genes will have been inserted to assist in selection of those organisms that have been modified by the technique used, and in which at least some of the inserted genes are now working.

An example of genes normally inserted secondary to the main function of the insert are those for antibiotic resistance. Often these are not significant in the organism once ready for release, but are very important in the selection procedures as only a very small proportion of the organisms subjected to modification are successfully transformed. The European Union, for example, has decided that the presence of antibiotic-resistance genes needs to be considered carefully, and that their use should be phased out because of a potential impact on the viability of antibiotics.

The cells that have been modified by the technique are selected, and those that best display the desired characteristics are further selected from the set of changed organisms. If a plant, the cells are treated and cultured under appropriate conditions (including chemical treatments) such that they grow into a complete plant. These modified plants and their offspring may be grown for several generations to ensure that they are stable and maintain the inserted characteristics over a period of time. During this stage many individuals of the modified organisms may be excluded from further use as they display unwanted characteristics or the change introduced is not as effective as desired. Changes that work in the laboratory may also not be effective when tested in the field.

Although it is possible in principle to modify all varieties of an organism, there are variations and it may be easier to transform a variety that is not particularly useful commercially and then use traditional breeding techniques to introduce the new genes into commercially useful varieties. It may also be possible to use techniques to remove genes that were transferred with the desired genes or to ensure that only a small number of copies of the gene package are present in the final living modified organism.