

CURRENT KNOWLEDGE OF THE IMPACTS OF GENETICALLY MODIFIED ORGANISMS ON BIODIVERSITY AND HUMAN HEALTH

AN INFORMATION PAPER

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1 INTRODUCTION

Since the first commercially offered genetically-modified organism (GMO) was authorised for sale as food in 1994 (a delayed-ripening tomato in the USA), the international community has been divided over the costs and benefits of genetic modification (GM), its related applications, and associated social, political, ethical and cultural issues. Some have considered GM to be so unnatural or inequitable that it should be rejected out of hand. Others, concerned about pollution, food supply, and nutritional issues, have been more open to technological innovation. Many others have wanted more information before deciding whether to support the further release of GMOs into the environment.

While some countries have banned GMOs or placed a moratorium on their release, others are increasing both investment levels and land area devoted to cultivating genetically modified (GM) crops. In 2006, GM crops were grown commercially by 10.3 million farmers (9.3 million resource-poor small farmers in developing countries) in 22 countries, on 102 million hectares - about 4 per cent of total arable land worldwide (James, 2006). The 13 per cent global annual growth rate for 2006 conceals the developed/developing country split of 5 and 23 per cent respectively.



Global Status of GM Crops in 2006

Yet many countries, particularly developing countries, still lack both the resources and capacity to be able to monitor impacts of growing or trading in GM crops, let alone engage proactively in the debate (Ogodo, 2006). The issue is further complicated by the 2006 decision of the World Trade Organisation (WTO) that upheld claims by leading GM producer countries that the European Union's former moratorium on GM products broke international trade rules. Arguments regarding GMOs as a public good versus a private benefit, conflicting experimental findings and sensational claims have also fuelled this highly controversial and often emotional debate.

The complexity of the GM debate was reflected at the IUCN Third World Conservation Congress (Thailand, 2004) where IUCN members adopted two resolutions related to GMOs:

- WCC 3.007 called for:
 - "a moratorium on further environmental releases of GMOs until these can be demonstrated to be safe for biodiversity, and for human and animal health, beyond reasonable doubt";
 - IUCN to "promote information and communication on GMOs in developing countries"; and
 - IUCN to "compile a report on current knowledge of the dispersal and impacts of GMOs on biodiversity and human health".
- WCC 3.008 called on IUCN to:
 - "develop credible knowledge and information concerning biodiversity, nature conservation and the associated risks of GMOs";
 - and asked the IUCN Council to:
 - "develop a plan of action to guide IUCN members on biodiversity and nature conservation in relation to GMOs".

Both of these resolutions (see complete texts on IUCN's Biotechnology website) also called on IUCN to support the implementation of the Cartagena Protocol on Biosafety, adopted under the Convention on Biological Diversity (CBD). These two resolutions have considerable overlaps and this document is intended to address the knowledge and information components of both of them, and to support the ratification and further implementation of the Cartagena Protocol on Biosafety. This paper will address the two resolutions by summarizing the current, peer-reviewed scientific arguments available in the public domain, supplemented by statements from academies and professional societies that have produced consensus positions. The concerns of non-governmental organizations, organic farmers, and associations of farmers are also presented (see Annex 2).

This information paper focuses on the impact of GMOs on biodiversity and human health; it does not address the pharmaceutical applications which involve the great majority of investments and which have direct implications on human wellbeing, yet receive far less public scrutiny.

Building on previous IUCN publications (Mackenzie *et al.*, 2003; Young, 2004), this document will briefly outline the history of biotechnology and explain the principles of modern genetic modification techniques before summarizing the current state of knowledge in agriculture, forestry and animal husbandry - key sectors relating to biodiversity conservation. The impact of GMOs on biodiversity conservation issues will be explored using a framework based on three of the major threats to wild biodiversity identified in the Millennium Ecosystem Assessment (2005): habitat change, pollution, and invasive species. The main risks to human health will then be discussed. The available evidence is presented in a concise, accessible and objective manner, with links to additional information for those seeking further detail.

Although the WCC resolutions do not refer explicitly to social, ethical, cultural and economic implications, these dimensions cannot be disassociated from the debate.

IUCN recognises the importance of other issues relating to GM applications such as pharmaceuticals, gene therapy and cloning. It also recognises that GMOs could be designed specifically to undermine human and animal health, for example, as biological weapons (Alibek, 2000). Though these additional applications of GM lie beyond the scope of this particular paper, sources of further information on these important areas are provided in Annex 3. The socio-economic issues will, however, be briefly summarised before a case study on Genetic Use Restriction Technologies, sometimes called "terminator technologies," is presented to illustrate the complex and conflicting issues at the heart of the overall GMO debate. The main conclusions highlight the need for full disclosure of scientific evidence from public and private sectors, as well as sufficient biosafety and food safety regulations along with monitoring, labelling and stakeholder participation. These will enable each government to make informed choices on how it will address the issue of GMOs, and to modify its policies as additional information becomes available.

Disclaimer

As GM techniques and applications are continually evolving, constant risk assessments are required. This document is based on current scientific evidence and represents a snapshot of what is known as of July 2007. It can only offer general guidance and is not intended to replace thorough risk assessments for each GMO intended for release into the environment. This document is intended to be a "living document", updated as and when important new evidence is published. Please feel free to contact the IUCN Secretariat with any suggested updates by emailing the Head of the Global Programme at <u>gpt@iucn.org</u>.

2 BACKGROUND

2.1 History of biotechnology

Traditional forms of biotechnology – defined as any application of technology to biological systems – have been used for thousands of years, including, for example, the use of yeast to make wine or rennet for cheese. Selective breeding and hybridization were the foundation of the domestication of plants and animals that made agriculture possible. Using the principles of heredity established at the end of the 19th century, farmers and scientific breeders have used such techniques to promote individual varieties of animals or crops (breeds and cultivars respectively) with characteristics that were considered beneficial for specific purposes. Some of these, such as hybrid maize or seedless watermelons, are sterile and require new seed to be purchased each planting season. The crossing of different varieties has also been used to increase production for crops such as rice, yet these traditional methods have been pushed to the limits of what is scientifically possible (Shanahan, 2006).

2.2 Modern biotechnology

The discovery of DNA in 1954 led to breakthroughs in biotechnology. Techniques were developed that would enable individual genes that make up a DNA code to be modified to express or suppress important traits such as fruit yield, wood quality, fat content or disease resistance – a process known as genetic modification (GM). Although early applications of this technique involved the manipulation of a host's own genome (Rommens *et al*, 2004), later applications involved the transfer of genes between organisms that are not normally able to crossbreed, resulting in novel combinations. It is this ability to move genes across species barriers that gives GM important potential, but also renders it highly controversial. (For an accessible guide to the techniques involved, see <u>www.greenfacts.org/gmo/</u>.)

DEFINITION OF KEY TERMS

Genetic modification (GM) – otherwise known as genetic engineering (GE) or **modern biotechnology** – the application of:

a) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (rDNA) and direct injection of nucleic acid into cells or organelles; or

b) fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection (*Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 2000).

Genetically Modified Organism (GMO) — Often used interchangeably with **Living Modified Organism (LMO)** (Mackenzie *et al*, 2003)

Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (*Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 2000). LMOs are able to reproduce whereas GMOs are not and theseare therefore not considered under the Cartagena Protocol.

GM crop – genetically modified crop, otherwise known as transgenic or biotech crop, but can be either fertile or sterile; the latter are unable to reproduce.

However,, not all forms of modern biotechnology involve genetic modification; other, non-GM applications of biotechnology can assist in breeding plants as well as in the development and propagation of new crop varieties. These include tissue culture, molecular markers, diagnostic techniques and microbial products. Local farmers in Africa have benefited from tissue-culture technologies for banana, sugar cane, pyrethrum, cassava, and other crops (Dhlamini, 2006). According to the FAO's BioDeC database, over 60 developing countries are actively conducting research on non-GM biotechnology techniques, 29 of which are working solely on non-GM applications. These applications will not be considered further here as they do not fall under the scope of the IUCN WCC mandate, which specifically refers to the impacts of GMOs.

2.3 The GM debate

"Almost any scientific discovery has a potential for evil as well as for good; its applications can be channelled either way, depending on our personal and political choices; we can't accept the benefits without also confronting the risks." Martin Rees, President of the Royal Society (2005)

Some argue against the principles of genetic modification (referred to as GM from now on) *per se*, because of ethical or religious beliefs. However, the main arguments relate to how GM is actually applied. Proponents for GM claim that through GM crops, trees, livestock and fisheries, biomass (including food and fiber) production can be enhanced while indirectly reducing environmental impacts, for example, through less use of pesticides or fertilizers. They also contend that GM can improve the nutritional value of many crops, or reduce the possible food safety risks posed by crops such as cassava.

However, others claim that the scientific knowledge on potential risks and benefits of GM is rudimentary, the net gains in agricultural productivity and the potential profits are both uncertain, and the health and environmental risks are little understood. Opponents claim that the potential direct impacts of GM crops on biodiversity and human health are unknown and are potentially so damaging that a moratorium must be placed on all GM products until more information is available. The criteria for what data would be sufficient for making an informed decision are not yet globally defined, but the governments of the 22 countries that are growing GM crops all have regulatory frameworks that presumably meet these criteria. Indeed, it may well be that such criteria can only be defined for specific crops and applications rather than as a generality. Others emphasise the indirect impacts that GM crops can have on traditional farming patterns, conservation efforts, livelihoods and trade.

While the science supporting biotechnology in general is substantial and growing quickly, the full original function of the modified genes of GM organisms typically is unknown, or only partially understood. As genes work in tandem with many other genes and are affected by multiple influences both within and beyond the cell, it is difficult to know with precision the function of a modified or transplanted gene, let alone the ecological consequences of its introduction into a plant or animal that is released into the environment. Thus the widespread introduction of GM products could be seen as premature, presenting largely unpredictable risks to both human health and the natural environment. This argues for a precautionary approach to this powerful new technology, a position taken by IUCN's WCC through resolutions WCC3.007 and WCC3.008.

2.4 Applying the precautionary approach to GMOs

IUCN has consistently supported the idea that prevention of environmental harm is an essential foundation of sound development practice, for both ecological and economic reasons. While prevention may be costly, it is usually even more expensive to repair environmental damage once it has taken place, and sometimes the damage may be irreversible. When uncertainty over potential impacts exists, a precautionary approach facilitates decision-making and puts in place mechanisms to reduce uncertainty. It has become a cornerstone of both domestic and international environmental law, and the IUCN Council has recently adopted guidelines on the precautionary approach (Decision C/67/18 of the 67th Meeting of Council held on 14-16 May 2007).

Within the Cartagena Protocol (further information can be found in the website), the approach is specifically defined in its objective. It states,

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

Its practical application of precaution is contained in Article 11(8), which states that,

"lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects."

This article represents one of the most explicit examples of how to put the precautionary approach into operation in any multi-lateral environmental agreement (Mackenzie *et al.*, 2003). It enables a Party to ban the import of a LMO/GMO if the importing Party determines that insufficient scientific information and knowledge are available about the GMO, about the receiving environment, or about the potential interaction between them. Equally, it enables a Party to permit such import if it considers that the scientific information is sufficient, leaving that judgement up to the importing government.

Precautionary measures require sufficient scientific knowledge and clear scientific evidence as part of the risk assessment regarding the consequences of introducing a GMO. From a policy perspective, governments are then expected to determine whether the risk is ecologically, economically, and socially acceptable, or whether the risk is unacceptable and thus should be rejected. Where scientific knowledge is insufficient, then the precautionary approach becomes essential.

As stated in Principle 15 of the 1992 Rio Declaration, the precautionary approach stresses that "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". Though the Cartagena Protocol covers transboundary movements of GMOs, concerned ICUN members may choose to apply the precautionary approach to GMOs intended entirely for domestic use.

To date, scientists have found no unequivocal evidence of direct negative damages to biodiversity or human health associated with released GMOs, though some potentially negative impacts have been demonstrated in laboratory experiments (see below). However, the potential risks justify the need for a precautionary approach to minimise risks associated with releasing GMOs. On the other hand, some governments, supported by the WTO, are concerned that excessive precaution might prevent trade in GMOs that could provide real benefits to farmers and consumers, and especially the rural poor. In this context, the precautionary approach becomes a political and ethical issue based on perceptions of risk. As one insurance company acknowledges, public perception is the decisive risk surrounding this technology (Swiss Reinsurance, 2004). For them, the critical element is not whether genetic engineering is dangerous, but how dangerous it is *perceived* to be.

2.5 Risk assessment issues

A key unresolved issue unresolved is the concept of "scientific certainty". Science works through testing hypotheses and replicating results while constantly questioning the science and seeking to improve on existing theories and hypotheses. It can only present data that supports or refutes the hypothesis. Science works with probabilities, so most scientists use statistical measures of certainty, and state these explicitly in their publications. As Giampietro (2002) points out, it is impossible to ban uncertainty and ignorance from scientific models dealing with evolutionary processes, and as such, science can never really "prove" that GMOs in general are safe for biodiversity and human health. The "beyond reasonable doubt" provision in WCC3.007 will therefore remain more a political issue than a scientific one, though the negative result -- that a GMO has caused damage to biodiversity or human health -- can be demonstrated.

Still, risk assessment that draws on the best available science is now a well-developed process that can be applied to GMOs. The Cartagena Protocol is one such risk assessment tool. Article 11(8) of the Protocol indicates that the Parties remain concerned about the degree of scientific certainty regarding the potential impacts of GMOs on the environment and human health, particularly in the longer term. Experience from other environmental issues, such as the impact of chlorofluorocarbons (CFCs) on the ozone layer, the human health implications of asbestos, or the bioaccumulation of certain pesticides in animals, are examples of long-term effects that scientists did not sufficiently consider when developing these products, and allowing their introduction into the environment in various ways. In each of these cases, continued scientific investigation eventually led to strict restrictions on further releases and a more comprehensive assessment of risk that resulted in improved products for addressing the identified needs. In the case of DDT, a strict ban on use is being relaxed to aid in the fight against malaria.

The existence of ecological risks *per se* should not be used as a reason to stop innovations altogether, but the precautionary approach encourages scientists to carefully assess the trade-offs that may be involved (Giampietro, 2002).

Dommelen (1999) discusses the difference between hazard identification (identifying a potential bad outcome) and risk analysis (calculating the odds of a bad outcome). He suggests that the vested interests of industry raise concerns about the quality of data and relevance of any potential research questions provided solely by commercial sources. "The high political stakes and industrial interests surrounding the development of genetic engineering", he says, "are certainly an 'excellent' context for the strategic use of a scientific guise for political claims on biosafety".

Determining the acceptable degree of scientific certainty when taking risks regarding GMOs is ultimately a political decision based on a balance of the costs and benefits of the proposed introduction of the particular GMO. Such decisions require scientific input from a range of disciplines, as well as consideration of social and economic arguments, testimony from civil society, and other such factors.

As more experience is gained with GMOs, coupled with more extensive research (including publicly-funded research in developing countries aimed at benefiting poor farmers and improving crops that may be unattractive to commercial firms), the level of scientific confidence is likely to increase, enabling risk assessment procedures to be better informed. Some uncertainty will always remain, and risk assessment will continue to be based on precaution where governments deem this essential to protect biodiversity and human health.

2.6 Legal context

The legal context within which GMOs are being addressed includes legal and regulatory frameworks in addition to the Cartagena Protocol. In at least some countries, these may be deemed more legitimate or appropriate than the Cartagena Protocol (which is often implemented through ministries of environment) because they are more directly relevant to ministries of agriculture, forestry, health and trade. These frameworks can be either domestic or international.

Some of the most important international ones include the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures, which recognises the right of countries to take sanitary (human and animal health) and phytosanitary (plant health) measures to ensure that food is safe for consumers, and to prevent the spread of pests or diseases among animals and plants. International standards for plants originate from the 1951 International Plant Protection Convention (IPPC). In 2003, the scope of risk analysis for quarantine pests (ISPM 11) was revised to include risks posed by LMOs, making it compatible with the Cartagena Protocol. For food, the Codex Alimentarius Commission, jointly established in1961 by WHO and FAO, aims to protect consumer health through promoting the coordination of food standards and includes the Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology, which provides a framework for undertaking risk analysis on the safety and nutritional aspects of biotech foods. The 2004 International Treaty on Plant Genetic Resources for Food and Agriculture deals with farmers' rights, access and benefit-sharing, technology transfer, and other issues relating to major crops. It supports the gene banks held by the various research centres grouped under the Consultative

Group for International Agricultural Research (CGIAR). It is silent on GM issues. More details on these and other legal instruments are available through IUCN's Biotechnology and Biodiversity website.

An essential means for ensuring that the transboundary movement of GMOs takes place within a framework of both national and international regulations is the Cartagena Protocol on Biosafety. Launched in 2000, the Protocol entered into force on 11 September 2003 and to date has 130 Parties. The Cartagena Protocol is neutral on the topic of whether GMOs should be introduced. Rather, it is designed to increase public confidence in the safety of any proposed introductions and marketed products, while providing the public and private sectors involved in the biotechnology industry and any farmers that use GMOs with a commercially valuable legal right to import, introduce, transport, or develop GMOs. The Protocol negotiators chose a permit mechanism as the primary method of creating and mandating biosafety based on a strong commercial law basis. This may require new supporting legislation in some countries, while others may wish to adapt existing legislation to the new challenges.

The Cartagena Protocol has been subject to considerable controversy among OECD countries (particularly between the EU and the USA over issues of free trade) which can create a high level of insecurity in other countries regarding the political effects of their own ratification. It is therefore notable that the Cartagena Protocol's ratification by some 130 countries has been relatively rapid.

The Conference of the Parties on the Convention on Biological Diversity requested the Global Environment Facility to provide support to eligible countries for building capacity to implement the Cartagena Protocol. Although the Protocol entered into force in 2003, the GEF actually began supporting capacity building activities for biosafety in 1997 with pilot projects in 18 countries. The evaluation of this support, submitted to the GEF Board in November 2005, found that "the GEF has responded very expeditiously and systematically to the request from the CBD for support to the Cartagena Protocol. UNEP, UNDP, and the World Bank have taken pains to remain neutral in this dynamic debate among the various interest groups, and have succeeded in doing so." The report also found that, "the GEF has contributed to considerable progress toward implementation of the Protocol by enhancing capacity on scientific, administrative, legal and information management matters, as well as promoting cross-sectoral collaboration and collaboration between the public and the private sectors as well as the civil society". The GEF support enabled some 120 countries to prepare their own National Biosafety Framework.

However, the involvement of civil society in preparing the NBF was not universal, as only 82 per cent of the 38 countries having completed their NBF by September 2005 included appropriate provisions for public participation mechanisms. At least a third of the countries have established a biosafety website that provides information on GMOs to the general public.

A common problem found in many countries was inadequate coordination of roles and responsibilities among regulatory bodies. The lead responsibility for implementation of the Cartagena Protocol often rests with the Ministry of Environment or a similar such body, presumably because of the link between the Protocol and the CBD. Yet the actual management of the approval process of GMOs tends to rest with ministries of

agriculture, science and technology, or foreign trade. All of these tend to be more powerful ministries than that responsible for enforcing the regulations, and this imbalance may lead to some challenges in implementing the Protocol in some countries.

Another problem remains inadequate collaboration between governments within a region, even when harmonization of scientific, legal, and regulatory instruments would greatly facilitate the regulation of transboundary movement of GMOs. The exception is within the European Union and its new accession countries, including those seeking accession.

The GEF review also found that since 1999, total donor funding and government cofunding in biosafety capacity-building projects in developing countries and countries with economies in transition amounted to about US\$ 157 million, slightly over half of which was provided through the GEF and the remainder by some 16 multi-lateral and bi-lateral agencies.

Interestingly, several countries have treated biosafety in conjunction with wider issues of biosecurity, agrobiodiversity, invasive alien species, and illegal transboundary movement of endangered species. This indicates that GMOs are seen by at least some countries as being intimately related to broader biodiversity concerns.

Additional information on the evaluation of GEF support, as well as details of such support, are available from the GEF website, <u>www.gef.org/</u>. Further information is available on the UNEP Biosafety Project Support Unit website, <u>http://www.biodiv.org/biosafety</u>.

Under the GEF-supported Biosafety Project, 16 workshops were held, involving more than 800 participatants. Demonstrating broad geographic coverage, these regional and sub-regional workshops were held in Kenya, Slovak Republic, China, Argentina, Namibia, Mexico, Malaysia, Fiji, Lithuania, Senegal, Islamic Republic of Iran, Chile, Turkey, Tanzania, Burkina Faso, and Trinidad and Tobago. While the full implementation of the Cartagena Protocol will require many more national experts than have been trained to date, a significant foundation has been laid upon which further progress can be built. Many of the countries are now in a position to determine for themselves whether they are in a position to implement the Cartagena Protocol, and make informed decisions about their own activities in regards to GMOs.

The GEF review also recognized that many small island developing states (SIDS) are concerned about the potential effects of GMOs on their isolated and fragile ecosystems, which have already been significantly disrupted by invasive alien species. The limited institutional and technical capacity of these relatively small countries makes it difficult for any single nation to establish and maintain a cost-effective national regulatory system for biosafety, suggesting that the SIDS might be well served by collective action and shared capacity to implement the Cartagena Protocol.

The CBD Secretariat has established a database which addresses biosafety capacity building and has posted this on the Biosafety Clearing House (BCH) <u>http://bch.biodiv.org/</u>. The GMO issue, while having some novel elements, contains many elements that are reasonably well known in most countries. The commercial introduction of conventionally created varieties, such as hybrids and cross-bred species, and the introduction of potentially invasive non-native species have placed commercial agriculture and food security issues within the realm of potential risks to environmental health, human health, and conservation of biodiversity.

3 CURRENT SITUATION

3.1 The global biotech industry

In 2006, the biotechnology industry was 30 years old (Ernst & Young, 2005). While the United States continues to dominate the global industry, Europe and Asia-Pacific are catching up, especially through expanding markets in Germany, UK, France, China, India and Australia.

A 2005 **Nature Biotechnology** review of public biotech companies found that healthcare and pharmaceuticals dominate the biotech industry with 80 per cent of publicly listed biotech companies (Lähteenmäki and Lawrence, 2006) and likewise receive much higher levels of investment, with far more profound implications for human health, ethics and culture (Fukuyama, 2002). Such products are normally contained and not released into the environment and as such are explicitly excluded from the Cartagena Protocol; hence, they will not be examined further in this document. Agriculture and environmental applications make up a small share of the biotech industry with only a two per cent examined by Lähteenmäki and Lawrence (2006); however, this does not reflect privately owned companies or public sector government and university research organisations as data on these are hard to obtain.

According to the FAO Biotech database, as of June 2006, at least 45 countries are conducting research, development, and field-testing of GMOs worldwide; Runge (2004) identified 63 countries engaged in GMO research. In the Asia-Pacific region, 12 countries are involved in some aspect of research and development, led by Australia, China, India, Indonesia and the Philippines. More modest research activities are underway in Bangladesh, Japan, Korea, Malaysia, Pakistan and Thailand. Although not reflected in Ernst & Young's (2005) analysis (see table 1), African countries active in GM crop research include Egypt, Kenya, Morocco, Nigeria, South Africa, Tunisia and Zimbabwe. Several Latin American countries are also significant players, notably Argentina, Brazil and Mexico.

| Number of companies | USA | Europe | Canada | Asia-Pacific | Total | Total |
|---------------------|------|--------|--------|--------------|-------|-------|
| Public companies | 330 | 98 | 82 | 131 | 641 | 15% |
| Private companies | 1114 | 1717 | 390 | 554 | 3775 | 85% |
| Total | 1444 | 1815 | 472 | 685 | 4416 | 100% |

Table 1. Global Commercial Biotechnology in 2004

Sources: adapted from Ernst & Young (2005)

Ernst & Young's analysis illustrates that most biotech research is dominated by the private sector. This leads to technologies being held under patents and distributed under commercial contracts, with consequences for Intellectual Property Rights, Access and Benefit Sharing and related issues, which, though important in the GMO debate, are explored only briefly in this paper; see Juma, 2005 and Fransen, 2005 for more detailed discussion. This also has implications for the kind of research being conducted and on the types of products being developed.

3.2 Agriculture

Although "agbio" makes up only a small percentage of the biotech industry, most of the controversies surrounding biotechnology of interest to IUCN focus on GM crops (Rainey 2004). Commercial GM crop applications are currently concentrated on herbicide tolerance and pest resistance as well as a combination of the two through stacked genes. Few have so far been related directly to improving yields, enhancing nutrition or responding to abiotic stress, although research is being carried out on a wide range of characteristics on at least 57 crops (Runge, 2004).

3.2.1 Commercial status of GM crops

Table 2 Global area of Biotech Crops in 2005: by Country (Million Hectares)

| Rank | Country | Area (million hectares) | GM Crops |
|---------|-------------------|----------------------------|---|
| 1 | USA | 54.6 | Soybean, maize, cotton, canola, squash, papaya, alfalfa |
| 2 | Argentina | 18.0 | Soybean, maize, cotton |
| 3 | Brazil | 11.5 | Soybean, cotton |
| 4 | Canada | 6.1 | Canola, maize, soybean |
| 5 | India | 3.8 | Cotton |
| 6 | China | 3.5 | Cotton |
| 7 | Paraguay | 2.0 | Soybean |
| 8 | South Africa | 1.4 | Maize, soybean, cotton |
| 9 | Uruguay | 0.4 | Soybean, maize |
| 10 | Philippines | 0.2 | Maize |
| 11 | Australia | 0.2 | Cotton |
| 12 | Romania | 0.1 | Soybean |
| 13 | Mexico | 0.1 | Cotton, soybean |
| 14 | Spain | 0.1 | Maize |
| 15 | Colombia | < 0.1 | Cotton |
| 16 | France | < 0.1 | Maize |
| 17 | Iran | < 0.1 | Rice |
| 18 | Honduras | < 0.1 | Maize |
| 19 | Czech Republic | < 0.1 | Maize |
| 20 | Portugal | < 0.1 | Maize |
| 21 | Germany | < 0.1 | Maize |
| 22 | Slovakia | < 0.1 | Maize |
| | | | |
| Source: | Clive James, 2006 | | |

Of the 90 million hectares of biotech crops being cultivated worldwide in 2005, developing countries grew 38 per cent, up from 34 per cent in 2004. Developing countries also had a considerably higher growth in area of biotech crops from 2004 to 2005 with 23 per cent growth versus 5 per cent for industrial countries. Six of the top eight producing countries are now developing countries.



Figure 1 Global area of GM crops

As James (2005) remarks, the annual double-digit adoption growth of GM crops since their introduction in 1996 has occurred despite the continuing debate on biotechnology and GM crops. GM crops are perceived as more profitable by farmers adopting them though various kinds of incentives provided by large firms promoting GM have certainly had an impact.

Despite the wide range in potential applications of GM, the majority of GM agricultural products have been developed for Northern markets, such as maize, cotton and soy, whereas crops that are more important to developing countries for food security or livelihood reasons, such as rice, wheat, pearl millet and groundnut, have been largely neglected in large commercial research programmes. The narrow range of commercially applied traits is dominated by insect resistance and herbicide tolerance. Though Monsanto, for example, has transferred its GM technology to several universities in India free of charge, GM research programmes for the species being studied, commonly referred to as "orphan crops", tend to be small and poorly funded. Furthermore, as FAO highlights, most developing countries use constructs developed in industrialised countries – only China is using locally-developed GM crops (Fresco, 2005), though India, South Africa, and several other developing countries have active research programmes.

3.2.2 Herbicide tolerance/insect resistance

According to the ISSAA (James, 2005), the two main applications for GM crops at present are herbicide tolerance and pest resistance, or a combination of the two. The global area of biotech crops is currently dominated by soybean tolerant to Roundup Ready herbicide, known as RR® soybean (see table 3).

Herbicide tolerance (HT)

In 2005, 63.7 per cent of GM crops were designed to have herbicide tolerance, primarily soy, maize and cotton (James, 2005), primarily to glyphosate (often produced by the same company that designed the GM seed).

Insect resistance (Bt)

Crops that have insect resistance represented 16.2 per cent of the global area planted in 2005 (James, 2005). They are often known as Bt crops due to the protein genes that are introduced into a plant following extraction from a bacterium known as *Bacillus thuringiensis*. This bacterium is found naturally in soil and has been used in organic agriculture for insecticide preparations because it is toxic to specific groups of insects (Prakesh, 2005). China has field-tested GM rice varieties that are resistant to stem borer. The field tests in the provinces of Hubei and Fujian showed yield increases of 4 to 8 per cent and pesticide reduction of about 80 per cent (Lei, 2004).

| Trait(s) | Million Hectares | % Biotech |
|----------|----------------------------------|--|
| | Hectares | Biotech |
| TIT | | ===0000 |
| HT | 54.4 | 60 |
| Bt | 11.3 | 13 |
| Bt-HT | 6.5 | 7 |
| HT | 3.4 | 4 |
| Bt | 4.9 | 5 |
| Bt-HT | 3.6 | 4 |
| HT | 1.3 | 2 |
| HT | 4.6 | 5 |
| | Bt-HT HT Bt Bt-HT HT | Bt 11.3 Bt-HT 6.5 HT 3.4 Bt 4.9 Bt-HT 3.6 HT 1.3 |







Stacked genes (HT-Bt)

So-called "stacked genes" enable both herbicide tolerance and insect resistance traits to be expressed in a GM crop. The US has a much larger proportion of stacked genes than the other countries that are currently deploying the technology (Canada, Australia, Mexico and South Africa) and has even introduced the first triple-stacked construct for maize that provides resistance traits to rootworm, corn bearer and Roundup herbicide (James, 2005). These seeds can cost more than five times more than a single trait seed (Johnson, 2006), though prices are expected to decline as the technology dedvelops further.

3.2.3 Abiotic stress tolerance

The previous traits generally are benefit large-scale, commercial farmers, with the important exception of GM cotton, widely grown by small farmers in China and India. The applications which potentially will be of most benefit to small-scale farmers relate to abiotic stress tolerances.

Viruses, bacteria and fungus resistance

Viruses and bacteria cause billions of dollars of damage worldwide through prevention expenditure and lost yield. Many research projects have been directed at implementing

Source: James, 2005

Source: James, 2005

resistance. The US is currently cultivating small areas of virus resistant squash and papaya while Brazil is developing virus resistant beans (James, 2005). Wheat is the most important staple food to have been genetically modified but has not yet been released commercially; Canada has developed varieties of wheat resistant to the pathogenic plant fungus *Fusarium* (James, 2005). China and the Philippines are developing a rice variety that carries a gene that provides resistance to bacterial blight disease (Leung, 2004). Uganda, Kenya and Ethiopia are participating in an internationally-funded project to develop sweet potato that is resistant to several viruses. This result is especially significant for Africa because of the importance of sweet potatoes in the staple diet (African Centre for Biosafety, 2005).

Saline tolerance

With more of the world's agricultural land becoming more saline, and with freshwater supplies already over-exploited in many places, farmers will increasingly need to use salty water for irrigation even though high soil salinity can severely limit agricultural productivity and lower crop quality. Developing crops and trees that can tolerate salinity is therefore a key priority. The Institute of Plant Sciences and Genetics in Agriculture at the Hebrew University in Rehovot, Israel, has isolated a protein called BspA that enables aspen trees to become more resistant to saline conditions (Watzman, 2000). Another approach for engineering salt tolerance is yeast cadmium factor 1 (YCF1), which, when introduced to *Arabidopsis*, allows the plant to grow in the presence of heavy metals and are also salt tolerant (Koh *et al*, 2006).

Drought tolerance

Water stress caused by drought is a major factor limiting plant growth and crop productivity worldwide and therefore research in many countries is focusing on developing GM crops that are tolerant to drought, such as wheat in Eygpt (Sawahel, 2004), rice in India and maize in Kenya (Odame *et al*, 2003).

Heavy metal tolerance

Presence of heavy metals in soil also affects yield. Research is underway into genes that allow plants to tolerate high levels of zinc, cadmium and mercury which are generally toxic to plants; poplar trees have been a main target (Schoebi, 2005). A plant with the right characteristics could extract heavy metals out of the soil, thereby helping clean the environment (see section 3.6).

However, no GM product tolerant to salt, heavy metals or drought has yet to be field tested or commercially released, with some estimating that such crops are more than a decade away from commercial availability (Kelly, 2006).

3.2.4 Enhanced nutrition

Being able to improve the nutritional composition of food products has been promoted by agbio proponents as one of the most important potential benefits of GM crops. Rice with enhanced levels of beta-carotene, known as "Golden Rice", is one of plant biotechnology's most heralded but most controversial laboratory advances. The International Rice Research Institute (IRRI) in the Philippines is developing varieties adapted to local tastes and growing conditions around the world, with the hope that golden rice can flourish in tropical areas such as Southeast Asia, for example, where 70 percent of children under the age of five are affected by vitamin A deficiency (Council for Biotechnology Information, 2004). Both Canada and the USA have recently approved a GM maize with traits of an essential amino acid, lysine, for the animal feed industry. Known as MaveraTM High Value Corn with Lysine, was evaluated under an experimental field program in 2006 and produced on limited acreage in 2007. This enhanced trait will reduce the need for livestock farmers to add synthetic lysine supplements to their animals' diets. LY038 is the world's first crop-based quality trait produced through biotechnology for the animal feed industry (Checkbiotech, 2006).

3.2.5 Biofuels

The application of biotechnology to biofuels has been gaining momentum in recent years due to the increasingly accepted need for climate change mitigation, coupled with higher oil prices. However, concerns over issues of biofuels taking up valuable food cropland have led to attempts to use GM technology to minimise the footprint of biofuels, for example by increasing the amount of ethanol that can be produced from a given piece of land. One focus is on producing hardier strains of energy-rich switchgrass that can grow on land previously unusable for agriculture (Hamilton, 2006). Yet the ecosystem implications for industrial biofuel production in general, such as deforestation, increased water use and invasive alien species, are potentially more damaging and cannot be ignored (Pearce, 2006).

3.3 Forestry

In 2004, biotechnology was applied to forestry in at least 76 countries, with micropropagation, marker development, mapping and maker-assisted selection dominating. Genetic modification of trees represents 19 per cent of global forestry biotechnology activities. To date, only China has commercially released GM trees (resistant to leaf-eating insects), with other research confined primarily to the laboratory and a few field tests (FAO, 2004b). Genetic modification of trees is designed to provide resistance to insects, diseases, and herbicides; to improve the fibre quality and uniformity; to increase quantity of wood that trees produce; and to increase efficiency in the manufacturing processes. They potentially can also be made to grow more quickly, thereby allowing more wood to be grown on less land at lower cost.

GM poplars have been designed to more easily break down their lignin (a component of the cell wall that confers strength and is a constituent of the tree's defence system), making paper production processes both cleaner and less-energy consuming, thereby reducing costs. Paper produced from GM poplars grown experimentally in France and England required 6 per cent less alkali to process for paper and yielded 3 per cent more pulp. They can grow on land of marginal quality (Halpin, 2002).

On the negative side, such trees may become invasive, and lowering the lignin content may well impair their pest resistance capabilities, requiring the use of additional pesticides (thus obviating any environmental benefits that may have been claimed). (Eichelbaum, *et al.*, 2001). As with crops, opponents suggest that conventional breeding could produce even greater gains, and that chemical pulping in any case should be replaced with more eco-friendly options, such as biopulping and bioleaching, which can reduce electricity and chemical requirements by 30 and 50 per cent respectively (Juma and Konde, 2002).

FAO has called for greater attention to conducting environmental risk assessments before GM trees are actually released (El-Lakany, 2004).

3.4 Animals

The genetic modification of domesticated animals and fish is seen as more controversial than GM crops, with sensational stories of cloning making news headlines around the world. Yet many biotechnology applications are already incorporated into breeding programmes to accelerate genetic improvements, including DNA-based marker-assisted selection (Van Eenennaam, 2006). Some health and welfare issues associated with traditional breeding techniques have led some to believe that genetic modification for animal breeding will be instrumental in meeting global challenges in agricultural production in the future (Niemann *et al*, 2005).

According to the FAO BioDeC database, biotechnology research on animals is being conducted in many countries, primarily on cattle but also on pigs, chickens and goats. Applications include increasing wool production in transgenic sheep, leaner meat from pigs, pigs with "environmentally-friendly" manure, increasing milk production, altering milk composition to be lactose-free, and disease resistant farm animals. However, as traits relevant for animal production are often controlled by many genes, a reliable and consistent improvement is difficult to achieve (Van Eenennaam, 2006).

Due to their reproductive biology, fish are relatively simple to genetically modify and have thus been the main focus of GM animal research, with more modified species than all other vertebrates combined. One GM fish is already commercially available in the USA for aquariums – the Glofish, a *Zebra danio* modified to produce a red fluorescent protein. Several companies in North America are waiting for federal approval for sale of an Atlantic salmon that grows 400 – 600 per cent more quickly for 25 per cent less feed due to the addition of a Chinook salmon gene controlled by a cold-activated promoter gene from an ocean pout fish (Van Eenennaam and Olin, 2006).

While no GM animals are yet on the agricultural market, they are increasingly being used in vivisection, representing almost one third of all animal tests in the UK, for example (BBC, 2005). Biomedical applications include pharmaceutical production (see below), antibody production, blood replacement, and models for human diseases. The potential use for xenotransplantation of organs from pigs to humans (Niemann *et al*, 2005) is the subject of much ethical debate, as well as concerns about the evolution of new diseases.

Little consideration has yet been given to the risk to human health of consuming GM animals. The prevention of pathogen transmission from animals to humans is a crucial consideration with animal-derived products (Niemann *et al*, 2005), and GM farm animals and GM fish in particular require strict standards of "genetic security". Rigorous control is also required to maintain the highest possible levels of welfare for GM animals.

3.5 Medical

Although medical biotechnology applications such as cloning and gene therapy are not being examined here, a major and relevant development in recent years is that of genetically engineering plants and animals to produce pharmaceuticals (a practice sometimes known as "pharming"). As this type of application could potentially affect biodiversity, it warrants consideration by IUCN. Both public and private sector researchers in the USA, Europe and South Africa are conducting experiments with maize, soybeans, rice, and tobacco that are genetically manipulated to produce vaccines and contraceptives, generate growth hormones, create blood clots, produce industrial enzymes, and propagate allergenic enzymes (Environmental News Service, 2002).

The first and currently only market license for a veterinary vaccine produced in plant cells was approved for the US in 2006. An edible GM maize that produces antibodies against Newcastle disease, a major killer of poultry in developing countries, was produced using modified tobacco plant cells in an indoor, biocontained production system. It was proven safe and effective in protecting chickens from the virus (Sawahel, 2006).

Animals themselves are also being used to produce pharmaceuticals. Several biotech firms in the USA are using goats to produce pharmaceuticals in their milk. For example, goats are being engineered to produce a protein to aid in preventing blood clots and anti-bacterial agents, along with more than 60 other drugs that are in the experimental stage. However, early in 2006, the European Medicines Agency refused a request to licence a drug containing an anti-thrombin gene, meaning that no pharming products have yet been approved for use (Nature, 2006).

As species that are often used for pharming generally also provide food for people and feed for livestock, many people are concerned that the genes responsible for producing pharmaceuticals could spread from pharm crops into food and feed supplies, for example becoming mixed with seed from food crops, or pollen from pharm plants could be carried to other plants. While some argue that the proteins from the produced drug or vaccine would be unlikely to survive in the human digestive tract, others deem that the potential impact of drug traits entering the food supply are too high to be justified. On the other hand, pharm plants and animals are not designed for release into the environment but are ordinarily contained in secure laboratories where the risk to the environment or human health is low. Nevertheless, sufficient biosafety processes should be in place to prevent any cross-contamination.

3.6 Industrial and environmental applications

Compared to agricultural and medical biotechnology, industrial and environmental biotechnology remains relatively unexplored though it could be applied to help reduce human impacts on the environment in many ways. Bioprocessing is one example, where controlled production of biological catalysts or enzymes can be used to improve the cleanliness and efficiency of industrial processes, such as mining (Juma and Kunde, 2002). Bioremediation uses bacteria or plants to degrade waste materials into less/non-toxic material in the environment. GM can increase the effectiveness of such remediation techniques. For example, scientists have produced GM bacteria to produce organisms that can clean up soil contaminated with toxic solvent residues and producing plants that can accumulate heavy metals ("phytoremediation") (Meagher, 2006).

However, many governments have been reluctant to embrace these technologies. While physical and chemical technology tends to dominate, public concerns over the environmental risks of uncontrolled survival/dispersal of such modified organisms have limited their application as well as new research (Paul *et al*, 2005).

4 IMPACTS OF GMOS ON BIODIVERSITY

When considering the risks and benefits – both direct and indirect – of a new technology, they should be compared against existing alternatives. To assess the impacts of agricultural biotechnology (the sector with the most potential risk for biodiversity, as highlighted above) it is necessary to look first at agriculture as it is currently practised, and particularly its effects on the environment in both developed and developing countries (Conway, 2003). Any ecological (or health) impacts of a GM crop should be balanced against the impacts of the agricultural practices the GM crops would replace. Two broad types of agriculture are relevant to the GM debate (assuming that traditional agriculture will continue to be practiced mostly in remote areas):

• Conventional agriculture

Conventional since the Second World War, the modern industrial system of agriculture is characterized by symbols of the "Green Revolution", including synthetic inputs such as chemical fertilizers and pesticides. The emphasis on maximizing productivity and profitability tends also to lead to the use of mechanization and monocultures. Analyses of the data on threats to bird, mammal and amphibian species evaluated for the 2004 *IUCN Red List* show that the most pervasive threat that they face is habitat destruction and degradation driven by agricultural and forestry activities (Baillie *et al*, 2004). With a growing global population, increasing trends in conventional agriculture present a significant threat to the environment and biodiversity conservation (MA, 2005).

• Organic agriculture

The UN and others define organic agriculture as a holistic system that "enhances agro-ecosystem health, including biodiversity, biological cycles and soil biological activity" (Scialabba, 2003). The use of artificial chemicals, fertilisers and pesticides are severely restricted, and practices such as integrated pest-management (IPM) are more favoured. The growth of the organic agriculture movement reflects growing global consumer demand for non-chemical based and environmentally sustainable food processes.

The concerns about possible risks of GM products to the environment are often similar from region to region, but the impacts from those risks may differ considerably, particularly between developed and developing countries (Pew Initiative, 2004). Environmental impacts of GMOs can be analysed using a framework based on the direct drivers of change in ecosystems and biodiversity identified by the Millennium Ecosystem Assessment: habitat change (land use change and physical modification of rivers or water withdrawal from rivers); pollution; and invasive alien species (the other drivers, overexploitation and climate change, are less applicable to GMOs, though some may argue that GM could help address these threats).

4.1 Habitat change

4.1.1 Land use change and agriculture

Over the past 50 years, the most important direct driver of change in terrestrial ecosystems has been land cover change, and in particular conversion to cropland, and the application of new technologies to agriculture, which together have significantly increased supplies of food, timber and fibre at the expense of other ecosystem services. The Millennium Ecosystem Assessment (MA, 2005) found that within terrestrial

ecosystems, more than half of the original area of many types of grasslands and forests has been converted into farmland. However, the rate of transformation of ecosystems into farmland has begun to slow down globally as opportunities for further expansion of farmland decline. In many regions of the world, most of the suitable land has already been converted, so land brought into cultivation for increased agricultural production will be more fragile and more easily damaged. Much of it will be obtained by clearing forests, grazing lands and wetlands, thereby increasing environmental damage.

GM proponents claim that GM crops will indirectly contribute to forest conservation by allowing marginal land to be cultivated, preventing further deforestation for conversion to cropland. However, actual experiences indicate that GM crop cultivation can accelerate land use change. In a study of deforestation in seasonally dry forests of northwest Argentina, Grau *et al.* (2005) conclude that the initial deforestation was associated with black bean cultivation during the 1970s and high soybean prices in the 1980s. The introduction of GM soybean in 1997 stimulated a further increase in deforestation, which has been mirrored in other Latin American countries. It appears, therefore, that in at least some cases, the spread of GMOs can lead to agricultural expansion, sometimes accompanied by intensification.

On the positive side, several studies have indicated how the use of herbicide-resistant crops has led to increases in low-tillage and zero-tillage management, particularly for soybeans in USA and Argentina, thereby increasing soil fertility and reducing soil erosion. However, this same study found that some farmers returned occasionally to tillage as a weed management tool after some weeds changed and developed resistance (Duke and Cerdeira, 2005).

Another criticism of conventional agricultural practices is the extensive cultivation of uniform, high yielding crop varieties that has led to the replacement and loss of traditional crop varieties from agroecosystems; currently, at least 1,350 varieties face extinction, with an average of two breeds being lost each week (FAO, 2003). Just as relying on monocultures may increase pest problems in conventional agricultural practices, experts warn that increasing reliance on a single gene in growing a variety of crops could also be dangerous (Jayaraman *et al*, 2005). Others contend that insect-resistant crops will eventually require an increased use of pesticides (Ramanjaneyulu, 2006).

Organic agriculture often uses a mixture of crops to increase diversity; this can also contribute to Integrated Pest Management practices. Another method to combat traditional biodiversity loss is intercropping, which has been shown to be effective in increasing the amount of traditional rice varieties being cultivated in China (Zhu *et al*, 2003). However, although this is a management issue rather than affecting GM crops per se, evidence suggests that most GM crops are often planted in monoculture formats, thus exacerbating impacts of conventional agriculture approaches on biodiversity.

4.1.2 Freshwater ecosystems

Conventional agricultural practices have had an extensive impact on freshwater ecosystems due to large-scale irrigation that drains wetlands or reduces river flows (IWMI, 2003), as well as pollution from fertilisers and pesticides (see next section). As identified above, crops that tolerate drought conditions are being developed but are not yet commercially available. In the meantime, the impact on water of GM crops that are cultivated currently is being questioned, particularly in the case of Bt cotton (see Case study).

Case study – Bt cotton in India

Bt cotton was the first GM crop to be released commercially in India, which has the largest area in the world devoted to cotton (9 million ha, about 40% of which is planted with GM varieties). Six Bt cotton varieties have been approved, though some experts estimate that 60 per cent of Bt cotton seeds grown in Punjab are illegal varieties that sell for a third of the price of officially approved varieties and have no noticeable difference in performance (Mishra, 2005).

Studies have shown mixed results from farmers who have planted Bt cotton. A study of 2002-3 data by Qaim et al (2006) on the impacts across four states found that on average, Bt cotton was sprayed with insecticide 2.6 times less often than conventional cotton. This translated into lower expenditure on insecticides but not overall costs as (legal) Bt seeds cost more than three times than that of conventional seeds. Yields of Bt cotton were on average 34 per cent higher than conventional cotton, overcompensating cost increases and resulting in higher revenue gains of over 2,000 rupees (approximately USD 45) per hectare.

Yet these averages hide the fact that in some areas, such as Andhra Pradesh, yields of Bt cotton were less than that of conventional cotton. Andhra Pradesh in particular was affected by severe drought conditions in the study year, with some claiming that the hybrid cotton used as a base for the Bt cotton there was not well suited to such conditions (Qaim, 2006), whereas Bt cotton is profitable in areas such as the Punjab where irrigation water is free. However, several districts are rainfed but lack proper irrigation facilities, resulting in poor cotton performance and high debt levels for Bt cotton farmers. In short, Bt cotton performance depends on the agroecological and socioeconomic conditions under which farmers operate, with productivity differences arising from variations in input levels, irrigation intensities and other farming characteristics – none of which, as Qaim et al (2006) point out, are related to the Bt technology per se.

The Indian Bt cotton case study illustrates how different GM crops are affected by variability in land conditions and is consistent with the Pew Initiative's conclusions that risks are often similar from region to region, but the impacts of those risks may differ considerably depending on the local ecosystem and infrastructure. As Mishra (2005) concludes, no uniform, pre-judgemental assessment of the potential of Bt cotton is possible. Bt cotton has increased yields worldwide but only in areas where water and power are plentiful. Bt cotton failed in areas with unsuitable land that is drought prone, therefore exacerbating ecological ramifications.

Further compounding the issue is the effect of the underlying germplasm of the GM cotton hybrid, as highlighted in the case study. Qaim et al (2006) concede that negative effects "have to be expected whenever conventional hybrids are better adapted to local biotic and abiotic stress factors than the germplasm into which the Bt gene is incorporated". This implies that GMOs are unlikely to be effective unless they are developed from successful local hybrids. However, in many cases, the GM crop is developed in one region and is expected to perform well in another. GMOs produced in one country are unlikely to be adapted to the local conditions of a different country.

Thus to increase the success of a given trait application requires developing local varieties, consequently raising research costs.

4.1.3 Coastal and marine ecosystems

The main threats of GMOs to aquatic ecosystems concern over fishing, introduction of non-native species and pollution. As a substitute for fishing from natural stocks, aquaculture has improved protein levels in developing countries and reduced pressure on native species, particularly salmon. However, coastal aquaculture is already causing ecological damage by spreading fish diseases, modifying habitats, causing nutrient pollution, and changing ecosystems through the escape of exotic farmed fish (Reichardt, 2000). Fast-growing GM salmon present higher food-conversion efficiency and reduced effluent, but the indirect impacts need to be taken into account and minimised further.

Moreover, as fish are highly mobile and difficult to contain, GM fish could pose a threat to natural populations of related fish upon escape or accidental release (Van Eenennaam and Olin, 2006; McNeely, 2005). Careful risk assessment is required to determine the ecological risks of each transgene, species and receiving ecosystem combination in addition to sufficient security measures like multiple containment to prevent any escape of a GM fish (Van Eenennaam and Olin, 2006).

4.2 Pollution

Modern agricultural practices of applying herbicides, pesticides, and fertilizers have resulted in severe environmental damage in many parts of the world (Third World Academy of Science, 2000; Millennium Ecosystem Assessment, 2005).

4.2.1 Reduction in chemical use

One of the main indirect environmental benefits claimed of GM technology is that it can reduce the need for herbicides and pesticides in comparison with conventional agricultural practices, which dominate worldwide. For example, cumulatively over the first profitable decade of GM, farmers growing GM crops applied 172,500 tonnes less pesticides than they would have used on conventional crops (Coghlan, 2006).

The positive environmental indirect impacts of reduced pesticide use on biodiversity are highlighted in trials with sugar beets in Denmark. Research from Denmark's National Environmental Research Institute found that GM plots had twice as much weed biomass compared with conventional beet, and were also richer in insects, spiders, and other arthropods, thereby providing more food for birds than conventional plots, suggesting that GM crops may be less damaging than conventional crops. Researchers also found that delaying the application of pesticides until relatively late in the growth cycle produces a ten-fold increase in weeds and a doubling of insect populations without damaging yields (Toft, 2004). However, it is not clear what the implications are for other species of crops, such as maize or canola, nor how this compares to organic crops and the use of integrated pest management processes.

These results are not consistent for all GM crops. For example, Bt strains of cotton only target American bollworm and do not provide resistance to other species such as the pink and spotted bollworm. The Bt trait is also ineffective against sucking pests such as whitefly and aphids, thus requiring additional pesticides to be applied to Bt crops. Although pesticide applications are less for Bt crops than for conventional ones, Bt

cotton farmers in Andhra Pradesh still needed to apply pesticides an average of 3.5 times (Qaim et al, 2006).

The spread of herbicide-resistant crops, which cover 68% of the land devoted to GM crops (James, 2007) has been accompanied by the spread of glyphosate herbicide. Benbrook (2003) found that herbicide use in the US has increased in areas dominated by GM crops, and that several weeds have evolved tolerance to glyphoste, requiring other herbicides to be applied.

4.2.2 Resistance

Some target species have been shown to develop resistance to the particular diseaseresistance trait, as has occurred with conventional chemicals, thus requiring extra pesticides or herbicides to be applied. A US study found that at least 15 species of weeds have developed resistance to glyphosate, the herbicide used with the most widely grown herbicide-resistant GM crops (Nandula et al, 2005). Although none of the 15 weeds has yet been shown to have any economic impact on farmers in whose fields they have appeared (Coghlan, 2005), this still presents a potential problem, as they effectively become a "superweed", needing increased tilling or additional weed control programmes.

However, it is noteworthy that pests and diseases are as likely to develop resistance regardless of whether the crop was developed using traditional breeding or using GM. The problems cited above tend to be a farm management issue rather than the GM application *per se*. For example, the rotation of crops has been proposed as a potentially effective strategy for dealing with the problem (Coghlan, 2005).

A second US study found that planting "refuge areas" of unmodified cotton plants near the Bt crops may dilute the pressure for resistance genes to be selected, resulting in one in 50,000 pink bollworms, a major pest species in Arizona, developing resistance and insecticide use reduced by 60 per cent (Tabashnik et al, 2005). This is reflected in India, where farmers are being encouraged to grow conventional cotton on at least 20 per cent of their land, thereby delaying the spread of resistance to their main cotton pest, the American bollworm (ironically an invasive alien species) (Qiam and Zilberman, 2003).

Nevertheless, the MA identified pollution related to conventional agriculture through excessive nutrient loading related to nitrogenous fertilizers (MA, 2005) as one of the major drivers of change in ecosystem services, though little research currently addresses this aspect of GM crops.

4.3 Invasive Alien Species

Invasive alien species (IAS) have been cited as a leading cause of species endangerment and extinction and second only to habitat loss as a major cause of damage to the planet's biodiversity (CBD Decision VII/13; IUCN/SSC ISSG, 2004). For this reason, any potential for GMOs to become invasive must be taken seriously.

GMOs are not *a priori* considered to be invasive but GM can potentially create changes that enhance the ability of an organism to become invasive. While GM transfers only short sequences of DNA relative to the entire genome of a plant or animal, the resulting phenotype, which includes the transgenic trait and possibly other accompanying changes, can produce an organism novel to the existing network of ecological

relationships, and can therefore be potentially invasive (Wolfenbarger and Phifer, 2000). However, the key to invasiveness is not the modification *per se*, but the trait that is introduced and where the GMO is introduced.

One way to assess the potential invasiveness of GM crops is through the IPPC's Invasive Species and Pest Management risk criteria (based on IPPC's ISPM 11 Annex 3):

- Changes in adaptive characteristics (that may increase the potential for establishment and spread);
- Adverse effects of gene transfer/flow (that may result in the establishment and spread of pests, or the emergence of new pests);
- Adverse effects on non-target organisms (direct or indirect);
- Genotypic or phenotypic instability (that could result in the establishment and spread of organisms with new pest characteristics, e.g. loss of sterility genes designed to prevent outcrossing);
- Other risks, e.g. enhanced capacity for virus combination.

In order to be categorized as a pest, a GMO has to be injurious or potentially injurious to plants or plant products under conditions in the pest risk analysis area.

4.3.1 Gene flow

Just like conventional crops, GM crops have been shown to crossbreed with crops or native plants growing nearby. Gene flow in itself is not a risk and often plays a part in plant breeding and evolution, though this evolution can lead to plants that are more difficult to control and increases the extinction risk for rare species (Elsstrand, 2006).

Crop plants typically do not have the characteristics of invasive species, being highly dependent on humans for their survival and putting more of their energy into production rather than adaptation. Rawley *et al.* (2001) carried out a long-term study of the performance of GM crops of canola, potato, maize, and sugarbeet grown in 12 different habitats in the UK and monitored over a period of 10 years. Their experiments involved GM traits such as resistance to herbicides or insects that were not expected to increase plant fitness in natural habitats. In no case were the genetically modified plants found to be more invasive or more persistent than their conventional counterparts. The survey concluded that GM crops do not survive well in the wild and are no more likely to invade habitats than their unmodified counterparts. Their results do not mean that other genetic modifications could not increase weediness or invasiveness of crop plants, but they do indicate that arable crops are unlikely to survive for long outside cultivation.

However, many perennial grasses are known to have invasive tendencies. Bentgrass modified especially for use in golf courses to be resistant to Roundup herbicide has been found up to 3.8 kilometres outside the test area. As the GM grass is unlikely to encounter herbicide in the wild, it is doubtful that the GM grass would have much advantage over wild grasses, but hybridization is possible (Hopkin, 2006) and eliminating these from the wild would prove to be very difficult. On the other hand, plants with GM traits such as drought tolerance or pest resistance might be better at competing, so their ecological impacts will need to be assessed experimentally under field conditions as and when such plants are developed. In short, some genetic modifications are more likely to increase invasiveness than others (McNeely, 2005).

The potential gene flow of GM crops to traditional varieties of crops such as maize and rice in particular has caused heated debates due to their potential impacts on both biological and cultural biodiversity (Soleri, Cleveland and Cuevas, 2006).

4.3.2 Impact on non-target species

Findings are mixed on the impacts of GM crops on non-target species. For example, a three-year German study found that herbicide-resistant genes in the canola transferred across to the bacteria and yeast inside the intestines of young bees (Kaatz, 2000). Although not peer-reviewed, these findings imply horizontal gene transfer between species that are not normally compatible and at least points to uncertainties which require further investigation (Steinbrecher, 2003). However, research in China found that insect-resistant cotton had no direct adverse impact on honeybees (Liu et al, 2005), illustrating that although GM may increase the probability of horizontal gene transfer (Steinbrecher, 2003), this is not the case for every GM application. One review of laboratory and field studies found no indication of direct effects of Bt plants on natural enemies of target species (Romesis, et al 2006).

A four-year long BRIGHT study (Botanical and Rotational Implications of Genetically Modified Herbicide Tolerance in winter oilseed rape and sugar beet) in the UK at five agricultural research stations found that herbicide resistant crops could make weeds easier to manage without destroying valuable biodiversity. The scientists found that the number of weed seeds on the plots, a measure of biodiversity, increased over the four years in all cases. On half of the study plots, growing Round-Up resistant GM canola gave the lowest weed numbers throughout the four years, indicating that this could make it easier and cheaper for farmers to keep weeds under control. However, in other fields, neither conventional nor transgenic crops were consistently better for battling weeds. Given that the researchers alternated between transgenic sugar beet or winter canola and conventional wheat or barley on the same plots of land, the study again emphasizes the fact that it is the way the crop is farmed, not the crop *itself* determines its effect on biodiversity, thus making it difficult to determine whether a GM crop is "good" or "bad". A holistic approach to evaluating biodiversity is far preferable than simply considering the effect of a single crop strain or weed-killing chemical (Hopkin, 2004).

The issue of IAS having an advantage over wild species is also of concern for GM animals, such as GM salmon that can reach adult size three times faster than their non-GM relatives. While few studies have yet been done on the environmental impact of the transgenic salmon, the concern is that they could have severely negative impacts on other wild species of fish, rather like invasive alien species have had in many river systems in various parts of the world. However, GM animals are not designed for release into the environment, so this issue does not represent a major concern for biodiversity as long as sufficient safety systems are in place. The inevitability of accidental releases, however, remains a real risk.

Perhaps the main area for concern is that of soil ecosystems, which experts believe represent the biggest source of unknown life on Earth, highlighted by the fact that a current project on soil biodiversity led by CIAT is unearthing many new species (UNEP, 2006). According to an FAO Expert Consultation, "no real impact on soil ecosystems have been detected from the cultivation of GM crops. [We have] no reason to believe that GM crops present any undue risk to soil ecosystems as agricultural practices, nor any single gene-construct, affect soil systems" (FAO, 2003).

However, a 2004 Australian government study found evidence that Bt-toxin is expressed in roots at a similar level to leaves and that fine roots have higher levels of toxin than bulk roots. This research also found that cotton roots appear to release Bttoxin, which has previously been shown in maize, although the amount of toxin released is difficult to quantify. While this increased predicted level of Bt toxin is still unlikely to result in toxicity to organisms other than from the target insect order with the majority of Bt-toxin degrading within 2-4 weeks of plant biomass being incorporated into leaf decomposition in soil, Bt toxin could potentially enter the soil environment faster if degraded by microbes, eaten by invertebrates or inactivated in some other way, thus accumulating in agricultural soils. The potential for adverse impacts to non-target organisms and soil ecosystems would then need to be evaluated. More research is being carried out to determine the likelihood of adverse impacts on agricultural soil microorganisms and function and on production (Gupta and Watson, 2004).

4.4 Risk management

In the same way that every alien species needs to be treated for management purposes as if it is potentially invasive (McNeely, 2005), GMOs should also be sufficiently managed wherever they are introduced, though the risks are also dependent on whether the GMO is intended for contained use or for deliberate release, either for experimental analysis or to be marketed.

4.4.1 Contamination

One of the major worries of GM crop opponents is that of contamination, though it is not GM risk per se, but a risk management issue, depending on the crop involved. As has been discussed above, some GM crops are unlikely to spread beyond their area of planting, while some other species are far more likely to spread. For example, blightresistant GM potatoes that are currently being tested in several European countries have a minimal contamination risk as they reproduce through tubers, whereas pollenproducing plants are more likely to contaminate nearby fields.

A form of creeping bent grass has been developed to be resistant to Roundup (glyphosate), but recent research has shown that it can easily spread to areas where it is not wanted. US Environmental Protection Agency scientists found that the GM bent grass pollinated test plants of the same species as far away as they measured, 21 km downwind from a test farm in Eastern Oregon. Natural growths of wild grass of a different species were pollinated nearly 14 km away. The US Forest Service has complained that the grass has the potential to have adverse impacts on all 175 national forests. Others are concerned that it will displace native species in some protected areas. As a perennial grass, it is more difficult to control than annual crops such as maize, soybeans, cotton, and canola (Watrud *et al*, 2004).

Farm practices can be put in place to reduce the likelihood of contamination, such as buffer zones, which also have implications for protected areas. Syngenta, a large biotech firm, was heavily fined for illegal field trials of GM soy found in a buffer zone six kilometres from the Iguacu Falls World Heritage Site on the Brazil-Argentina border, where national law expressly prohibits the planting of GMOs within buffer zones of at least ten kilometres from conservation areas, based on the precautionary approach (GM Watch, 2006). However, in 2007, the fine was overturned when the Court was convinced that Syngenta had been given permission to plant the GM crops by the National Commission for Biosafety (an example of conflicting institutional mandates).

Clear testing and labelling procedures are required to prevent contamination of non-GM stocks after harvesting, particularly for non-authorised GM plants (see section 7 for more discussion).

4.4.2 Coexistence

Given the potential negative impacts of GMOs on the environment and surrounding landscape, an important question to answer is how to minimize the likelihood of GM crops mixing with conventional or organic crops in countries where they have already been introduced, in order to control contamination issues.

In the same way that organic farmers cannot guarantee that products are free of pesticides they do not use themselves, they cannot guarantee that their products do not contain traces of GMO. Europe has taken the lead on this issue and introduced a law on certification for organic producers, which allows a contamination threshold of 0.9 per cent for produce to be labelled as organic. For example, Germany has introduced a Genetech Law to cover coexistence and liability after monitoring of maize fields found contamination levels for samples taken from more than 20 metres away from a GM field were less than the 0.9 per cent threshold.

In 2005, Denmark introduced a tax law based on the polluter pays principle, which requires farmers growing GM crops to pay an annual tax of Euros 13.40 per hectare of land into a fund to compensate conventional and organic farmers whose crops are contaminated by GM crops. This will enable Denmark to enforce its coexistence law, under which the funds will be used to pay compensation to conventional or organic farmers whose crops have more than 0.9 per cent of GM material as a result of gene flow from the GM fields of neighbouring farmers. The amount of the compensation will be limited to the price difference between a crop for which no labelling is required and the market price of a crop that exceeds the threshold and is labelled as containing GM material, as established by the EU (UNEP, 2005).

Despite these mechanisms, organic farmers claim that coexistence with GM crops will spell the end of organic farming countries, as reflected in the 2006 IFOAM Submission to Cartagena Protocol on Biosafety Regarding GMO Liability Issues. They broadly reject the European Union's concept of "co-existence" between cultivation of genetically modified organisms (GMO) and GMO-free agriculture as "misleading and illusionary".

4.4.3 GMO-free zones

IFOAM is the main representative of the organic agriculture movement. It rejects the use of GM in organic agriculture and advocates a total ban on GMOs in all agriculture. While recognising that GMOs are already in use in some countries, IFOAM maintains that risk of contamination should be minimised, with the burden of solving problems to be with the GM producers and users. To this end, they and environmental NGOs such as Friends of the Earth advocate the establishment of GMO-free zones, not just in Europe

http://www.gmofree-europe.org/ but worldwide www.gmo-free-regions.org/ (IFOAM, 2002).

In Europe, more than 100 regions and 3500 sub-regions are now GMO-free Zones, although their legal basis is unclear and they are not officially recognised by the European Commission, which rejected Upper Austria's attempt at becoming a GMO-free zone as illegal in 2005 (GMO Free Europe, 2005).

Some developing countries have also declared themselves GM free, partly because of a worry that growing GM crops would limit access to European markets. Zambia, for example, refused food aid that included GM maize and neighbouring countries would accept only milled grains that could not be planted.

4.5 Conclusions

Not all GM plants are equal in terms of their potential environmental impacts. The complexity of ecological systems presents considerable challenges for experiments to assess the risks and benefits and inevitable uncertainties of GM plants. Collectively, existing studies emphasize that these can vary spatially, temporally, and according to the trait and cultivar modified (Wolfenbarger and Phifer, 2000). Objectively assessing such risks is extremely difficult, because both natural and human-modified systems are highly complex, and fraught with uncertainties that may not be clarified until long after an experimental introduction has been concluded.

The FAO Expert Consultation carried out in 2003 concluded that the cultivation of GM crops, with their potential benefits and hazards to the environment, should be considered within broader ecosystems. Environmental risks and benefits depend on a) the specific GM constructs and the crop into which it is introduced; b) the geographical location of the crops; and c) the period or timescale of its cultivation (FAO, 2003).

Nevertheless, as an Opinion piece in *Nature* points out (Anon, 2003), "amid all the fuss about GM crops, there's been little acknowledgement that similar questions about biodiversity and gene flow must be asked about conventionally bred varieties". Conventional breeding of crops and animals appears as likely as genetic engineering to create new plant varieties that might lead to the development of super weeds.

Given the significant parallels between GMOs and other invasive species, greater efforts are required to address IAS, in the same way that concerns about GMOs are being addressed. This should be resolved based on good agricultural management, regardless of whether the herbicide-resistant crops are genetically modified or are traditionally bred. The risks for the introduction of a GMO into each new ecosystem need to be examined on a case-by-case basis, alongside appropriate risk management measures, such as through the precautionary approach in the Cartagena Protocol and the IPPC's Pest Risk Assessment (PRA).

5 IMPACTS OF GMOs ON HUMAN HEALTH

While human health is not an area where of IUCN has great expertise, it represents one of the major concerns for IUCN members and opponents of GMOs worldwide. This is reflected in the IUCN GMO resolutions as well as surveys results from Europe and Japan in particular, where consumers worry about potential human and environmental effects (Li *et al*, 2002).

5.1 Evaluating human health risk

At least some of the genes used in GMOs may not have been used in the food supply before, so GM foods may pose a potential risk for human health. Analysis of this risk is based on the concept of "substantial equivalence" that is supported by the FAO/WHO Codex Alimentarius Commission, where the identified difference between a conventional product and the product produced through GM is tested for risk. The compositional analysis of the GM crop is compared to a conventional counterpart, and any additional components are thoroughly tested for their potential to cause allergies and toxicity. However, this concept is deemed insufficient by critics given that foods are complex and unexpected differences arising from genetic modifications may be overlooked (Raney, 2004).

Much of the GM production currently grown worldwide is destined for animal feed. According to the UK's Food Standards Agency, food from animals fed on these crops is as safe as food from animals fed on non-GM crops (FSA, 2005). The FAO has also concluded that risks to human and animal health from the use of GM crops and enzymes derived from GM microorganisms as animal feed are negligible (FAO, 2004).

Following an evidence-based study, the World Health Organisation (WHO) concluded that "GM foods currently available on the international market have undergone risk assessments and are not likely, nor have shown, to present risks for human health any more than their conventional counterparts" (WHO, 2005). To date, the consumption of GM foods has not caused any known negative health effects. In the US and Canada, objective estimates suggest that 70 to 75 per cent of processed food contains GM ingredients (Phillips and Corkindale, 2003). Some 300 million people have been eating genetically modified crops for a decade or more, and no health problem has yet been identified as being caused by the consumption of GM products (Soupcoff, 2004).

However, this does not take into account the fact of differing consumption habits around the world. It cannot be assumed that consumption of GM maize in one country will have the same seemingly inconsequential effect on consumers in another country where that crop makes up a far greater portion of their diet.

Scientists also acknowledge that little is known about the long-term safety of consuming food made from GM products. WHO recognizes the need for continued safety assessments on genetically modified foods before they are marketed to prevent risks to human health (WHO, 2005) and for continued monitoring.

The main potential risks to human health are discussed below.

5.1.1 Allergenicity

The potential of GM crops to be allergenic is one of the main suspected adverse health effects, due in part to research by Hi-Bred in the mid-1990s. They discovered that soy bean plants engineered with a gene from Brazil nuts produced beans that caused an allergic reaction in some people.

Similar allergenic effects of GM crops was not published until 2005 when scientists from CSIRO, the national research arm of the Australian Government, reported that genetically modified pest-resistant peas caused allergic lung damage in mice, resulting in them abandoning the decade-long project. The researchers had transferred into the pea a gene for the protein from the common bean that is capable of killing pea weevil pests. The innocuous protein does not cause an allergic reaction when extracted from the bean, but when expressed in the pea it is structurally different to the original bean. This subtle change may lead to the unexpected immune effects seen in mice, thus illustrating the unpredictable impacts of gene transfer and the importance of using animal models to test the allergenic potential of GM foods (Young, 2005).

On the other hand, GM offers the potential of removing the allergenic or toxic elements from some food crops, thereby preventing many needless deaths, for example removing the allergenic traits of the peanut and the cyanide properties of cassava.

In this debate, it is important that all foods containing GM are clearly labelled in order for consumers to avoid particular GM food types if they are found to be allergenic.

5.1.2 Toxicity

Another of the risks that opponents of GMOs cite is the potential for GM changes to result in changes that are toxic to humans and animals. One of the most recent GM crops to be suspected of causing toxicity is the GM maize line known as MON 863 (YieldGard Rootworm Corn), which received approval in the US in 2003 and specifically targets the corn rootworm. MON 863 contains less Bt toxin than most Bt maize varieties, producing the toxin primarily in the roots, which is the site of entry for the western corn rootworm (Alexander and Van Mellor, 2005). The European Commission approved MON 863 for food use in January 2006 but the approval process sparked considerable debate over the safety of MON 863 after findings of a feeding study conducted on rats by scientists from France's Commission on Genetic Engineering, CGB, may have revealed potentially pathological changes to internal organs and signs of inflammation. However, the results of the experiment were reviewed by two independent experts, and in the end, both EFSA and the CGB scientists came to the conclusion that the differences observed between rats fed conventional maize and those fed genetically modified maize did not exceed the differences normally observed between any two individuals, and any differences were not biologically relevant. Based on the data provided in the approval application, which included the disputed feeding studies, EFSA declared that MON 863 is as safe as conventional maize for consumption (GMO Compass, 2006).

Concerns in the Philippines of a toxic reaction to the pollen of Bt maize were raised in 2004 when about 100 people living adjacent to a GM maize field were documented to have developed symptoms of headache, dizziness, extreme stomach pain, vomiting and allergies, only while the pollen was airborne (Estabillo, 2004). Although research is still being carried out, one researcher presented preliminary findings at the Malaysian

CoP/MoP 2 conference on GM food safety that the blood had developed an antibody response to the Bt toxin, confirming that GM promoters function in human cells. This suggests that if promoters were to transfer out of GM food and integrate into human DNA, they could switch on random genes inside of humans, leading to an overproduction of a toxin, allergen or carcinogen (Smith, 2006). Although potentially worrying, to date, no study has adequately shown a commercially released GM crop to be toxic.

5.1.3 Antibiotic resistance

In order to increase the success rate of genetic modification, scientists have used a technique involving antibiotic resistance genes in addition to the desired gene to identify which plants have successfully absorbed the introduced gene. The antibiotic *kanamycin* is a frequently-used marker for plant modification yet is still used for treating many human infections (Third World Academy of Sciences, 2000). As the genes have traditionally come from bacteria, human pathogens could increase their antibiotic resistance.

Related to these concerns, the UK's Food Standards Agency (FSA) conducted a series of research projects to investigate the transfer and survival of DNA in the bacteria of the human gut. They concluded that it is extremely unlikely that genes from GM food can end up in bacteria in the gut of people who eat them (FSA, 2002). The most recently completed study shows that in real-life conditions with human volunteers, no GM material survived the passage through the entire human digestive tract. Although some DNA survived in laboratory-created environments that simulated human or animal gastrointestinal tracts, the research concluded that the likelihood of functioning DNA being taken up by bacteria in the human or animal gut is extremely low but possible, given earlier cited evidence of gene transfer to bacteria in honeybees.

Although there is no definitive evidence that these drug-resistant strains are necessarily more dangerous for humans, public health officials still view them with concern because they are more difficult to cure in people who need treatment. The British Medical Association, for example, opposes the use of antibiotic resistance markers in food. The risk is considered serious enough to encourage scientists to adopt techniques to remove the marker genes before a crop plant is developed for commercial use (Scutt, Zubko and Meyer, 2002). Scientists have also recently developed an alternative marker derived from tobacco rather than bacteria (Mentewab and Stewart, 2005).

5.2 Potential benefits

5.2.1 Improved nutritional value

One of the most direct ways that GM crops and animals can affect human health is through improved nutritional value, which WHO asserts "can contribute directly to enhancing human health and development" (WHO, 2005).

The idea of adding specific nutrients or substances to processed foods to make them healthy has been around since the 1940s when vitamins, iron and calcium were added to flour and more recently dairy products and eggs. The so-called functional food or nutraceutical market is a dynamic and growing segment of the food industry. It was estimated to be worth US\$7-63 billion in 2004, depending on sources and definitions and is predicted to be worth \$167 billion by 2010 (AROQ, 2004).

One frequently cited example is that of "golden rice", which contains extra vitamin A. Other examples include a rice developed by the International Rice Research Institute that is high in iron. This 'bio-fortification' is designed to improve the nutritional status of women who are often affected by anaemia. A nine-month feeding trial involving 192 non-anaemic religious sisters in the Philippines found that the iron status of women who ate bio-fortified iron-rich rice was 20 per cent higher than in women who ate traditional rice (Hass *et al*, 2005).

India is also developing a GM potato which contains nutrients lacking in the diets of millions of poor children in an effort to reduce the problem of malnutrition. The potato contains a third more protein than normal, including essential high-quality nutrients. It has been created by incorporating a gene from the amaranth plant, which is high in protein. While the so-called "*protato*" has received strong support from the Indian government, opponents point out that alternatives should be explored, such as pulses which are naturally far higher in proteins and already abundant in India, and should therefore be given preference over GMOs (Coghlan, 2003).

Similarly, crops may also be engineered to tackle aspects at the other end of the malnutrition scale, for example, the "escalating global epidemic of overweight and obesity" (WHO, 2005). For example, Monsanto announced in 2005 a new variety of soybeans which produces very low levels of linolenic acid, which reduces the amount of saturated fat when used in processed food. As of 1 January 2006, US food processors must label the trans-fatty-acid content of foods, so that manufacturers will be able to claim that the new crops are healthier. Monsanto is also working on soy that produces omega-3 fatty acids that are normally found in fish and are credited with helping to prevent heart disease. The soy has been designed specifically to help make processed foods and snacks healthier by reducing saturated fats that can clog arteries (GMWatch.org, 2005).

Nevertheless, many commentators suggest that focusing on GM to seemingly address nutrient deficiencies in one step may discourage or prevent efforts to target the underlying causes of malnutrition through broadening dietary practices. This argument is reflected further in the later section on food security.

5.2.2 Reduced chemical use

As seen above, some Bt crops have led to a reduction in the use of other pesticides that are highly toxic to humans and animals, resulting in indirect health benefits. This is of particular benefit to farm workers, especially in developing countries where human-crop interactions are higher, manual labour is widespread and quality controls tend to be more lax. For example, more than 50,000 Chinese farmers are poisoned annually in farm fields, of which 400 to 500 die. Trials before the commercial approval of GM rice found that farmers growing GM rice reduced pesticide use by 80 per cent and thus saw a fall in pesticide-related health problems being reported (Huang, 2005). However, since herbicide resistance covers the majority of land devoted to GM crops, it is difficult to conclude that chemical use overall has declined.

6 ETHICAL CONSIDERATIONS

The dispute over GM food is about much more than human health and the environment, being rooted in deeply conflicting views about democracy, capitalism and global trade

(Charles, 2001). WHO therefore has called for evaluations of GM foods to be widened to include ethical, social and cultural considerations (WHO, 2005). These issues receive far more attention than ecological issues from most of those who are campaigning against GMOs. This section briefly reviews several of the key issues.

6.1 Hunger and development

One of the principal arguments cited by proponents of modern biotechnology is its ability to increase food security and "feed the world". This is a serious challenge; about one third of all adults in sub-Saharan Africa are currently undernourished and food production has actually been declining in 31 of 53 African countries (Paarlberg, 2005). According to Brown (2003), the world grain harvest has fallen short of consumption four years in a row, dropping world grain stocks to the lowest level in 30 years. Global sea fish catches have also been in steady decline since 1990.

With the UN projecting an increase in the human population of 40 to 80 per cent over the coming four decades, increasing pressure on food production systems is inevitable, thereby putting increased pressure on the remaining wildlife habitats. A strong consensus is that by the middle of next century, the world will be facing a food crisis.

A commitment to tackle world hunger is contained in Millennium Development Goal 1 which states that the signatory countries will aim to "Reduce by half the proportion of people who suffer from hunger by 2015". At the present rate of progress, this will only be achieved in 2150. A 2006 review found that agriculture-related biotech partnerships in sub-Saharan Africa are often fragmented and supply-driven not end-user oriented, and therefore have had limited impact in achieving the target of halving hunger (Ayele *et al*, 2006).

This view is echoed by Trewavas (1999) who points out, "the future will demand agriculture to be both flexible and diverse in technology, but efficient in land use. Farmers will have to be highly skilled at using technologies that must sustain farming for thousands of years. Increasingly, farm resources will need to be recycled; green manure and crop rotation will underpin soil fertility. Integrated pest management systems and zero tillage will be essential to minimise losses due to pests and weeds, and to limit soil erosion. Water will become an increasingly expensive commodity, and a premium will emerge on crops that use water efficiently without loss of yield. In all this future agriculture, genetic manipulation has a unique and intimate role".

FAO Director-General Jacques Diouf, however, says that GMOs are "not the priority for reducing the number of hungry people by half by 2015. People in developing countries suffer from chronic hunger and malnutrition because they lack water, other inputs and credit to produce food, employment and income to access food. Lack of political will and financial resources are today's main obstacles to resolving the world's hunger problem" (Diof, 2005).

Furthermore, to date, most of the benefits of GM crops have gone to the farmers who are best placed to take full advantage of the new technologies (Conway, 2003). Little has been invested in developing new technologies that would benefit the rural poor, especially in Africa. A study by Third World Network Africa on the potential impact of GM crops for dealing with famine and poverty in Africa found that GM is an ineffective and expensive tool and as such inappropriate for Africa and does not address the real
causes of poverty and hunger (deGrassi, 2003). For example, GM sweet potato that was introduced in Kenya does not address weevils – the major problem for farmers.

Yet proponents maintain that biotechnology can speed up conventional breeding programmes and offer solutions where other methods have been less successful. Genetic engineering could also improve yields on marginal lands and reduce reliance on toxic chemicals in pesticides as well as improve the nutritional content of food (Diof, 2005). FAO concludes that when appropriately integrated with other technologies for the production of food, agricultural products and services, biotechnology can be of significant assistance in meeting the needs of an expanding and increasingly urbanized population in the next millennium (FAO, 2000, updated on website).

Though they can potentially offer significant productivity gains and nutritional benefits, GM crops are not a magic remedy. Farmers also need access to this technology in order to benefit from it but they will only do so if the new technology is applied in a way that enhances local communities, fits in with local practices and cultures, and recognizes the need for complexity and diversity (Taverne, 2001). The Nuffield Council on Bioethics (2003) went further in suggesting, "there is an ethical obligation to explore these potential benefits responsibly, in order to improve food security, economically valuable agriculture and the protection of nature in developing countries".

Although the CGIAR system encourages open access to research into developing GM crops for developing countries, their GM programmes are small and poorly funded (Raney, 2004) because they give greater attention to the conventional means of improving the productivity of poor farmers. A high-level African Panel on Modern Biotechnology examined the opportunities that biotechnology presents for Africa to transform its economies. It recommended African countries to work together to build capacity needed to harness and apply biotechnology to improve agricultural productivity and public health, increase industrial development and economic competitiveness, and take into account the importance of promoting the conservation and sustainable use of Africa's biodiversity (High-Level African Panel on Modern Biotechnology of the African Union, 2006).

Some commentators suggest that the private sector can combine commercialisation and philanthropy to support poor and small-scale farmers to benefit from the potential that GMOs may hold, though a more systematic approach to public-private partnerships is needed (Osgood, 2006). A basic principle is that the right of farmers to chose for themselves should be recognised and supported.

6.2 Socio-economic impacts

Another reason cited by biotech companies for promoting GM crops is the savings that farmers make in reducing the use of herbicides and pesticides. Brookes and Barfoot (2005) found that net economic benefits of GM crops at the farm level amounted to a cumulative total of US\$ 27 billion. The amount of pesticides sprayed was reduced by 172 million kg, and the environmental footprint associated with pesticide use decreased by 14%. The findings of Benbrook (2003) on the other hand, showed increased herbicide use on lands devoted to herbicide-resistant GM crops.

Yet many conflicting claims on the local level suggest that the savings provided by reduced pesticide use do not always fully compensate for higher GM seeds costs, which

can be more than three times the price of conventional seeds (Qaim *et al.*, 2006). For example, research in China initially suggested that farmers growing Bt cotton between 2001 and 2003 cut their pesticide use by 70 per cent and earned 36 per cent more than conventional farmers. However, the profits were short lived when numbers of pests not affected by Bt increased (Zi Xun, 2006). This is reflected in the US, where an analysis of the first decade of commercially released GM crops found that Bt cotton and corn were very profitable when insect pressures were high, but in years when pest pressure was low, the returns were negative.

The US report also highlighted where the benefits from herbicide tolerant soybeans go: the majority of which (40%) go to seed firms, 28% for biotech firms, 20% for farmers and 5% for consumers. Increasing benefits for farmers and consumers remains a major challenge (Fernandez-Cornejo and Caswell, 2006). Furthermore, poor farmers are increasingly being threatened by corporate control of agriculture. Trade rules, subsidies and patents are all undermining the ability of small farmers to produce enough food to survive (Action Aid, 2003).

Gómez-Barbaro and Rodríguez-Cerezo (2006) in a global review of the economic impact of dominant GM crops worldwide carried out on behalf of the European Commission found that the net economic benefits for farmers are variable in regional terms, but point out that both small and larger farmers have benefited. Detailed analyses (for example of Bt cotton in China), "show that increases in gross margin are comparatively larger for lower income farmers than for larger and higher income farmers." They found that Bt cotton adoption has resulted in a significant decrease in the use of insecticides in all cases studied, providing a significant economic benefit. Similar benefits were not seen in maize because the pests that Bt maize is designed to resist were not usually controlled by insecticide applications. The adoption of herbicide tolerance has resulted in the displacement of several herbicides by one single product that may be less toxic that the herbicides its replaces; yet the use of this herbicide, usually glyphosate, has increased; the potential increase in cost has been associated with reduced fuel consumption per hectare and with the adoption of reduced soil tillage practices.

In short, it cannot be assumed that using GM crops will automatically lead to increased profits and poverty reduction. Aside from the technology, variations in pesticide levels, irrigation intensities and other farm characteristics lead to productivity differences and therefore profits. In addition, the price of GM products is subject to normal global markets and is affected by consumer demand.

6.3 Private sector, trade regulations and intellectual property rights

One of the major reasons for civil society concern is that the private sector and powerful agribusiness companies control the majority of research and GM markets, leaving all farmers vulnerable to their technological strategies. Some opponents claim that the Trade Related Intellectual Property Rights (TRIPS) agreement under the WTO is insufficient to protect traditional knowledge and biodiversity and undermines basic human rights by allowing large biotechnology companies to purchase and patent seeds, medicines and traditional knowledge. This is the crux of the concern of many of those who oppose GMOs and is supported by the pre-existing significant discussions of 'farmer's rights' under the 1983 FAO International Undertaking on Plant Genetic Resources (IU) and International Union for the Protection of New Varieties of Plants (UPOV) (see Wendt and Izquierdo, 2001 for further discussion).

On one hand, modern biotechnology and the seed sector that are using genetic resources and traditional knowledge to develop new products should recognize and respect the rights of the traditional users of these resources resulting from their contribution in terms of conservation and development; on the other hand the producers should respect the rights of the plant breeders. A balance needs to be found between respecting and protecting rights of traditional users and modern innovators (Wendt and Izquierdo, 2001).

The trade regulations pose further challenges to proper handling of GMO issues as they are not designed to ensure environmental safety and socioeconomic benefits, but rather serve the interests of the powerful corporations who enforce them. For example, Monsanto successfully sued a farmer in Canada for growing Round-up Ready Canola, which was a trademarked and copyrighted intellectual property of Monsanto. Although the farmer claimed that the pollen was blown on to his field from an adjacent farm rather than being planted by the farmer himself, the court did not agree (GMWatch.org, 2003). This is potentially a serious problem, particularly for small farmers, whose livelihoods are threatened by circumstances beyond their control if sufficient biosafety regulations are not put in place. (For further discussions on IPRs, see Juma, 2005 and Fransen, 2005.)

Trade regulations need to be designed to incorporate the precautionary principle and peoples' rights to chose what technology they want to use – or not use at all.

6.4 Genetic use restriction technology

One controversial issue that continues to dominate debates on GM is that of the socalled "terminator technology". Officially known as Genetic Use Restriction Technology (GURT), it is designed to produce sterile seeds, thereby avoiding the problem of escape into non-target fields as well preventing farmers from freely harvesting seeds that have been developed by biotech companies at considerable costs. According to Via Campesina, a worldwide movement of peasant farmers, "terminator seeds are a weapon of mass destruction and an assault on our food sovereignty. GM technology poses a serious and immediate threat to our life security and livelihoods, our food security, health of the environment and the people. We recognize that this is being thrust on us solely to promote the interests of agri-business corporations (farmers of Karnataka, Andhra Pradesh, Tamil Nadu, Maharashtra, Haryana, Uttar Pradesh, Kerala, Chattisgarh and Uttaranchal, along with farmers' groups from Italy, Spain, South Africa, Canada and France)" (Etc. Group, 2006).

Proponents argue that the application of this technology could provide an important mechanism for environmental containment, and ensure that GM plants could not spread or cross-pollinate with naturally occurring varieties (National Research Council, 2004). On the other hand, opponents cite potential impacts on traditional livelihoods of over 1 billion farmers worldwide who are dependent on saved seeds but would be unable to collect and reuse seeds from GM plants, and the majority of whom would not be able to afford to buy new seeds every season. They are also concerned about inadvertent seed contamination and gene flow from GM to traditional crops, along with the potential negative impacts on diversity. Because of these risks, in addition to the fact that GURTs primarily benefit the GM industry and offer few obvious benefits to poor farmers, the Consultative Group on International Agriculture Research (CGIAR) has adopted a policy of rejecting the use of the technology in its research.

Massive public opposition in the late 1990s led the CBD to agree an international defacto moratorium on use of GURTs in 2000. The CBD's Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) was clear in its assessment: "In the current absence of reliable data on GURTs, without which there is inadequate basis on which to assess their potential risks, and in accordance with the precautionary approach, products incorporating such technologies should not be approved by parties for field testing" (CBD, 2006). The 8th Conference of the Parties of the CBD meeting in Curitiba, Brazil, in March 2006, reviewed and maintained its moratorium on GURTs.

The Global Environment Facility (GEF), as the funding mechanism for the CBD, has provided considerable funding to implement the Biosafety Protocol. It began by providing support to some 124, later 140 countries, to prepare National Biosafety Frameworks (NBFs). A NBF involves a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements, in accordance with the Cartagena Biosafety Protocol. Although they vary in format from country to country, the common objective is to strengthen national capacity to implement the Protocol. It is up to each country to determine for itself how it promotes this objective. As of March 2006, 66 countries have finalised draft NBFs (UNEP News, 2006).

7 BIOSAFETY

Although the issues discussed so far are all important, the main question posed by the Cartagena Protocol is not whether GM crops should or should not be eaten, imported or grown, as these activities are already taking place. Rather, it focuses on how governments should regulate and oversee these activities in order to protect both consumers and the environment. It also provides a means for informing consumers and enables countries to reject the technology.

7.1 Weaknesses in testing and regulations

As discussed earlier, most biotechnology research is done by the private sector (China is a major exception) and therefore scientifically assessing the impacts of GMOs is hindered by the fact that 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 wellbeing (Young, 2004). These concerns include the assertion that GM projects suffer a high rate of failures that are not clearly disclosed or explained. Although firms want to protect their trade secrets and the investments committed to research and development, scientific analysis of the "debate" described above is severely constrained by the lack of access to this closely-held information.

The two negative findings relating to allergenic properties of GM crops among thousands of positive examples (see above) underline the need to evaluate new GM crops on a case-by-case basis. Some commentators have made the point that this

research was published in peer-reviewed journals because it was carried out by public research institutes, and that private companies are much less likely to make their negative findings publicly known. This may be a reasonable supposition, but no evidence has been provided to support the claim although the paucity of industryderived publications in peer-reviewed journals may be indicative.

Numerous reports have indicated that seed companies often make mistakes in field trials of genetically modified crops, neglecting to follow proper procedures, such as failing to plant trees to act as a windbreak, not planting a buffer of hybrid maize to prevent pollen spread, or planting maize in locations too close to other crops. The USA, whose Animal and Plant Health Inspection Service (APHIS) has overseen more than 10,000 GMO field tests since 1987, was found to have some weaknesses in its processes, not knowing where some of the field tests were being undertaken and increasing the risk that GMOs will "inadvertently persist in the environment before they are deemed safe to grow without regulation" (Biosafety Information Centre, 2006). Although the Department of Agriculture's Office of the Inspector General found no evidence of any negative environmental impacts as a result of these weaknesses, it still serves to highlight potentially significant gaps in the processes of testing and regulation.

Yet the dangers of genetic contamination of areas intended for growing GM-free or organic products, especially for export, could lead to potentially devastating impacts if the GM crop accidentally travels from one country or region to another. The recent and widely reported example of long grain rice contamination with an unauthorised GM rice "LLRICE601" field tested more than five years earlier has served to highlight why biosafety regulations and checks are necessary and should be expanded to all countries.

Investments in biotechnology need to go hand in hand with biosafety regulations that safeguard human health and the environment, as recognised by The Economic Community of West African States (ECOWAS) meeting at a 2005 Ministerial Conference on Biotechnology (ICTSD, 2005). This need is reflected in the implementation of National Biosafety Frameworks (see Annex 5).

7.2 Public participation

Each country and consumer should be able to make their own informed choice on whether or not to use or consume GMOs – but accurate information is required to enable them do so. Given the controversy of GM technology, more transparent ways of making public policy decisions are required, such as national policy dialogues, regulatory frameworks, approval of individual GM products, and post-release monitoring. Under the CBD, it is the responsibility of governments to inform and consult the public before allowing the introduction of GMOs. Other international instruments that are relevant to public participation include the Codex Principles on Risk Analysis and the Aarhus Convention on access to information, public participation in decision-making and access to justice in environmental matters which agrees to the legal right of the public to participate in environmental decisions relating to the release and placing on the market of GMOs (a right that previously was not included under the Convention).

The public worldwide has mixed opinions on biotechnology. Many favour genetic screening for inherited diseases, the use of GM organisms to clean up pollution, and genetic engineering to develop medicines and vaccines; but far fewer support the

production of GM foods, cloning human cells or tissue to treat patients, and cloning animals for medical applications (EFB Task Group on Public Perceptions of Biotechnology, 1999).

Consumers need to be informed of the pros and cons of various GM traits and crops and how to avoid the loss of local of local diversity. Consumer attitudes to GM products are more particularly affected by information on both product benefits and risks. When provided with such information, consumers have been found to be less likely to consume the GM food products than those who were only provided the product benefits information (Onyango, 2004). For example, the importance of consumer power is illustrated by the rejection of GM ingredients by many food-manufacturing companies such as Frito-Lay Inc. who rejected buying GM maize for its Doritos chips and other maize-based snacks. The company was not concerned about health risks, but the risks of consumer rejection (Pollack, 2000).

Wambugu (1999) argues that African countries need to avoid exploitation and to 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. Other checks and balances are required to avoid patenting local germplasm and innovations by multinationals; to ensure policies on intellectual property rights and to avoid unfair competition; to prevent the monopoly buying of local seed companies; and to prevent the exploitation of local consumers and companies by multinationals corporations. Field trials need to be done locally, in Africa, to establish environmental safety under tropical conditions.

7.3 Labelling

The right of the consumer to choose whether to consume foods containing GM ingredients should be considered alongside risk and benefit analysis, requiring products to carry labels that inform the consumer. The legal onus is currently on products that contain GMOs, rather than products that are GM-free. In the European Union, for example, a product containing GMOs or substances derived from GMOs must be labelled as such unless the GM content is below 0.9 per cent. Labels declaring a product to be GM-free are not yet included in the relevant EU directives, so their legal status remains uncertain. However, certain brands, including organic and health foods, voluntarily carry a GM free label, to differentiate themselves and reassure customers.

Efforts to promote the safety of international trade in GMOs were aided in 2004 with the adoption of labelling and documentation requirements. Under the new system adopted by the 87 member States of the Cartagena Protocol on Biosafety all bulk shipments of living or genetically modified organisms intended for food, feed or processing (such as soybeans and maize) are to be identified as "may contain LMOs." As the Protocol's former Executive Secretary, Hamdallah Zedan, said, "This rigorous system for handling, transporting, packaging and identifying GMOs is in the best interests of everyone - developed and developing countries, consumers and industry, and all those who care deeply about our natural environment" (UN, 2004). For some countries, particularly the USA, the labelling goes too far and threatens to curtail GM trade and development. For others, these regulations do not go far enough, suggesting that products should contain no GMOs whatsoever.

8 CONCLUSIONS

Some 10.3 million farmers in at least 22 countries are planting GM crops, and at least 45 countries are conducting GM research. Commercial planting rates of GM crops have increased by more than 10 per cent per year over the last decade (James, 2005). We must recognise the fact that GMOs are present in the environment and are unlikely to removed in the near future – if ever.

Scientists to date have found no conclusive evidence of *direct* negative impacts on biodiversity of GMOs that have been commercially released; nor does evidence currently prove that GMOs are either inherently dangerous or inherently safe for human health. Laboratory experiments have demonstrated the potential harm of GM applications though direct impacts on non-target species and gene flow, but they also indicate that biosafety processes in place are generally working. Cases of contamination or indirect impacts through monoculture applications have generally been due to poor management. This reaffirms the importance of effective governance structures including the Cartagena Protocol's requirements relating to application of the precautionary approach and further support the idea that precaution should be applied to each new GM application in each new ecosystem. Research into GM applications should continue and indeed accelerate but with 'eyes wide open', assessing each GM application on a case-by-case basis. Equal funding should also be devoted to promoting and fully implementing biosafety frameworks for every country that is developing or importing GM products, or that chooses to exclude GM products.

However, the *indirect* impacts of GMOs currently in use are significant and deserve more attention. Whether GM or conventional crops, the damage that monoculture techniques causes for biodiversity and ecosystems is incontestable and should be avoided. GM crops may encourage the further spread of agriculture into lands now used for conservation purposes. It is in the interests of biotech and agritech industries to employ sustainable farming techniques when cultivating GM crops to avoid the potential direct risks as well as minimise the indirect impacts.

Applying GMO technology to crops is likely to benefit the poor only if the right technology is developed in an appropriate way and put into the right hands. Public institutions need to lead the way with an ethical research agenda for poor farmers, with poverty reduction as the primary objective, coupled with increased information exchange between private institutions that generally own the science and the general public who ultimately pay the costs. Strong environmental and health safeguards need to be based on strengthening institutions and regulatory frameworks, with most countries needing help to develop the relevant public institutions and adequate biosafety law. The lack of public involvement, particularly in developing countries, means that society as a whole has been unable to participate fully in a debate that may potentially have significant impacts on their livelihoods and environment. Individuals, whether consumers or farmers, have the right to know whether the food or seeds that they buy contain GM ingredients, in order to make responsible decisions.

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