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New Genetics, Food and Agriculture: Scientific Discoveries – Societal Dilemmas

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New Genetics, Food and Agriculture: Scientific Discoveries – Societal Dilemmas

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The Doyle Foundation

for

The International Council for Science

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Preface

The role of science and new genetic technologies in food production is an area of considerable controversy and concern to many people across the world. It is an area in which there are strongly conflicting views and opinions, in which scientific progress and individual morals and beliefs are often opposed, and in which the science itself is sometimes uncertain and open to interpretation. However, food security is also one of the major challenges facing humanity, and new genetic technologies have real potential to ameliorate the current situation–a world in which some 850 million people lack access to sufficient nutritious food at affordable prices. Hence, the scientific community has a duty to responsibly develop and explain its research in this area. This review, and the associated web-site (www.icsu.org) are an attempt to do just that.

In recent years, there have been many national and international expert reports on genetically modified foods (GMFs) and there is a wealth of information available in these reports. This information should be informing the ongoing debate amongst all stakeholders-scientists, policy-makers and society at large. In 2001, when the International Council for Science (ICSU) first considered how it could most usefully contribute to this area, the obvious response was to try and build on this wealth of existing information. As a first step, and in the specific context of the World Summit on Sustainable Development (Johannesburg, 2002), ICSU produced a report on Biotechnology and Sustainable Agriculture[1], which was an attempt to analyse the state of existing scientific knowledge, with specific regard to new genetic technologies and agriculture.

The second step, which is presented in this review, was to attempt to bring together and analyse in a more systematic way, existing authoritative reports from national science academies and other bodies and to make them more readily accessible. In practice, this has been a very challenging task. This review gives an overview and analysis of the issues addressed in 50 recent expert reports and identifies areas of convergence, divergence and gaps in knowledge. In addition to the print version, this material is available via the Internet at www.icsu.org and on CD-ROM for individuals who do not have easy access to online materials. The internet and CD-ROM versions also provide valuable additional information in an easily searchable format. This includes an annotated bibliography, which summarizes the findings and recommendations of individual reports, as well as links to these reports to facilitate further investigation.

So, what does collecting and analysing all this information tell us? Firstly, it shows that 50 independent and authoritative scientific enquiries–carried out by different groups in different parts of the world, and for different reasons–are largely in agreement in their response on the major questions concerning GMFs: *Who needs them? Are they safe to eat? Will there be any effects on the environment? Are the regulations adequate? Will they affect trade?* This in itself is a very significant and important outcome. On some of the multiple and often complex issues underlying these questions, we learn that there is a large degree of consensus, whilst on other issues there are differing views. The identification of these areas of divergence and gaps in knowledge represent another important outcome of this review. It should help all those who are involved in defining future research agenda, whether

1. International Council for Science. 2002. ICSU Series on Science for Sustainable Development No. 6: *Biotechnology and Sustainable Agriculture.* 45 pp. ISSN 1683-3686.

they be at local, national or international levels. With regard to policy development and trade implications, the review also has a number of important implications. Whilst science is only one of many factors that influence political decisions, the scientific consensus reflected in this review helps to provide a sound basis for policy development.

ICSU is grateful to Dr Gabrielle Persley, of the Doyle Foundation, who has carried out this major analysis and written the review, as well as the many scientists and others who have advised throughout. On behalf of all of them and of ICSU, I offer this review to all those who are interested in using science for the benefit of society, and the role of genetic technologies in this context.

CARTHAGE SMITH

Deputy Executive Director
ICSU

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Acknowledgements

This overview draws on a selection of individual reports produced by various national and international agencies and individuals. We thank the authors of all the reports for making them available. We appreciate also their diligence in preparing thorough scientific analysis about the use of modern genetics in agriculture, and for their thoughtful findings as to specific issues that may affect different societies. We commend the individual reports for those interested in further study of these complex issues.

This study had its genesis in ICSU's Advisory Committee on Genetic Experimentation and Biotechnology (ACOGEB) in 2001. The ACOGEB members who initiated the study in 2001 were Drs Richard Roberts, Oscar Grau, Anne McLaren, Jim Peacock and Marc van Montagu. Their support and contributions during the initiation and conduct of the study are gratefully acknowledged.

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The professional assistance of Margaret Macdonald-Levy in the research phase, and in the preparation of the documentation and the web site is acknowledged with many thanks. The encouragement of Andrew Bennett and Simon Best in bringing this project to completion is gratefully acknowledged.

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Executive Summary

Science is a creative enterprise. It combines the exploration of the natural world with the generation of knowledge and its use in human endeavours. This combination of creativity with purpose is exemplified in the field of biotechnology. But the power of the new discoveries in genetics also raises concerns in many societies as to the ethics and safety of their use, and the risks they may pose to human health, biodiversity and the environment.

This overview, commissioned by the International Council for Science (ICSU) analyses the findings of a selection of approximately 50 science-based reviews, published in years 2000-2003, on modern genetics and its applications in food and agriculture and the environment. These reviews, which have been commissioned by national academies of science, governments, international organizations and private agencies on various aspects of modern genetics have mobilized considerable scientific expertise worldwide to examine the issues in both breadth and depth. However, a comparative assessment of their conclusions has not, until now, been performed.

The purpose of this analysis is to consider what are the issues that concern various societies, and, on the basis of the science underpinning the discoveries in modern genetics, what are the areas of commonality, what are the areas of divergence and differing perspectives, and where are the gaps in knowledge that may be able to be addressed through additional research. The ways in which scientific knowledge is communicated and influences public perceptions and policy choices about new technologies are also considered.

Key Questions

Many applications of modern genetics are being used to improve the efficiency and sustainability of present agricultural practices, in both industrial and developing countries, and there is potential for their wider use. Important applications include improving the efficiency of plant and animal breeding by enabling the use of molecular markers for early generation selection of key traits; developing molecular diagnostics for the identification and improved control of pests and diseases; and more effective diagnostics and vaccines for the control of livestock and fish diseases.

Although this review considers new genetics in the broad sense, specifically, in relation to genetically modified foods (GM Food)[1] and living modified organisms[2], this study poses five key questions:

Who needs them?
Are they safe to eat?
Will there be any effects on the environment?
Are the regulations adequate?
Will they affect trade?

Definitive answers to many of the complex issues underlying these simple questions are not yet available. However, there is a growing scientific consensus around many of these issues, as well as on the areas where further data, information, and actions are most needed.

1. Demand: Who needs genetically modified foods?

There is a continuing demand for more, cheaper, and/or better quality food worldwide. The relative importance of these factors varies within and between societies. Poor people need better access to more food. Those who are more

1. Genetically modified food (GM food): Food that contains above a certain minimum content of raw material from genetically modified organisms (GMO).

2. Living modified organism (LMO) means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology; Synonym of genetically modified organism (GMO).

affluent place more emphasis on the quality of food, in terms of appearance, variety and nutritional content.

Projections by the UN Food and Agriculture Organization (FAO) and the International Food Policy Research Institute (IFPRI) on the future demand and supply of food necessary to keep pace with population growth and changing dietary habits until 2020, predict increasing global demand for food. For example, cereal production for food and feed needs to increase by 40 per cent, while livestock production needs to double, to meet increasing demand for milk and meat by year 2020. At the same time, land available for expanding agriculture is decreasing and water is an increasingly scarce resource. Thus, more food needs to be produced per unit available land, per unit water.

New developments in genetics must be assessed as to their potential to contribute to the production of more, cheaper, and/or better quality food, in different situations, and as to their capacity to produce foods in ways that are more environmentally sustainable when compared with present agricultural practices and other technology options.

2. Are GM foods safe to eat?

Currently available genetically modified foods are safe to eat. Food safety assessments by national regulatory agencies in several countries have deemed currently available GM foods to be as safe to eat as their conventional counterparts and suitable for human consumption. This view is shared by several intergovernmental agencies, including the FAO/WHO *Codex Alimentarius* Commission on food safety, which has 162 member countries, the European Commission (EC), and the Organization for Economic Cooperation and Development (OECD).

Further, there is no evidence of any ill effects from the consumption of foods containing genetically modified ingredients. Since GM crops were first cultivated commercially in 1995, many millions of meals have been made with GM ingredients and consumed by people in several countries, with no demonstrated adverse effects.

Although currently available GM foods are considered safe to eat, this does not guarantee that no risks will be encountered as more foods are developed with novel characteristics. Ongoing evaluation of emerging products is required to ensure that new foods coming to market are safe for consumers. Food safety evaluation must be undertaken on a case-by-case basis. The extent of the risk evaluation should be proportionate to the possible risks involved with particular foods.

There are also benefits to human health coming from GM foods. These may be either direct benefits arising from the content of certain foods or indirect benefits, which arise from changing agricultural practices.

Direct Benefits
Improved nutritional quality of specific foods (*e.g.* modifying starch content in barley, oil content in rapeseed, or vitamin content in rice).
Removing allergens and/or toxic compounds from certain foods (*e.g.* peanuts).
Indirect Benefits
Pest tolerant crops can be grown with lower levels of chemical pesticides, resulting in reduced chemical residues in food, and less exposure to pesticides.
Disease resistant crops may have lower levels of potentially carcinogenic mycotoxins.

3. Will there be any effects on the environment?

Agriculture affects the environment, thus it is to be expected that new genetic technologies used in agriculture will also affect the environment. The effect of genetic technologies may be either positive or negative–they may either accelerate the environmentally damaging effects of agriculture, or they may contribute to more sustainable agricultural practices and the conservation of natural resources. It is a matter of application and choice.

To a large extent, the environmental effects will depend on the specific genetic application, the agricultural system and the environment (agro-ecosystem) in which it is used. Environmental impact should be assessed on a case-by-case basis, taking account of specific risk factors. The environmental effects of specific technologies may be direct effects of a specific trait/species combination on biodiversity, habitats, landscape, and/or other components of the environment. Or, they may be indirect effects, resulting from changing agricultural practices leading to more, less, or different use of pesticides or herbicides, and/or changing land uses.

In assessing direct and indirect environmental effects, new genetic technologies should be compared with present agricultural practices, and with other technology options. Comparison with baseline ecological data is also desirable, but difficult to obtain in many instances. Also, both the risks and the benefits of new technologies need to be considered, so as to develop a more complete picture of the options available and the implications of various choices.

Direct environmental effects

For example, in assessing the potential for direct environmental effects of plants, several factors should be taken into account: the potential for gene flow from the crop plant to compatible wild relatives in their centres of diversity, leading to the formation of hybrids that survive and may cause environmental damage; the potential of the plant to become a weed in cultivated fields or to move outside the field to become an invasive species in other habitats; the possible effects of specific traits on non-target organisms; and unexpected effects resulting from unintended genetic recombinations. These risks are similar to those carried by any plant released into the environment. Genetically modified plants that carry particular traits (*e.g.* pest resistance) should be assessed for the effects that the particular trait may have on these risk factors.

In terms of direct effects, gene flow is an issue–particularly in regions where crops are being cultivated in the vicinity of local land races, wild or weedy relatives with which they can cross in nature, in their centres of biological diversity. The ecological issue is not so much that it happens (as pollen does move in the wind and on insects, and some out-crossing occurs naturally in open-pollinated species), but does it matter? The answer to the latter question depends on whether a novel trait is introduced into a wild species that increases the fitness of the resulting hybrids between the crop and its relatives to survive and become environmentally damaging (*e.g.* to become a weed or an invasive species). Experimentally, modelling based on biological and geographic data may be useful to predict the likely behaviour of different species in various environments, either near to or distant from their centres of diversity.

Currently available evidence suggests that genes can move from GM crops into land races and related wild species, generally at low frequency and in areas where compatible wild relatives are found. However, there is no evidence of any deleterious environmental effects having occurred from the trait/species combinations currently available.

Indirect environmental effects due to changing agricultural practices

Most genetically modified crops currently used commercially have been modified for either insect resistance and/or herbicide tolerance. Insect-resistant crops should be used within an integrated pest management (IPM) system to avoid the boom/bust cycles associated with the build up of resistance in the pest population. There are some concerns as to whether IPM systems can be used effectively with GM crops in the developing world, and this is an area requiring further action.

Several studies have shown that the use of pesticides on cotton has declined globally by about 14 per cent since the introduction of Bt cotton in the mid-1990s. Country studies in Australia, China, South Africa and the USA show pesticide reductions of 40 to 60 per cent on GM cotton crops. The reduction in pesticide use is accompanied by an increase in the number of beneficial insects amongst the crop-associated biodiversity. Herbicide tolerant soy bean has been shown to increase the efficiency of weed control and reduce soil tillage, with consequent benefits for soil conservation.

In the future, other environmental effects may result from the emerging scientific developments designed to modify crops with complex traits, which are controlled by multiple genes (*e.g.* tolerance to salinity or drought). This may enable agriculture to extend into currently marginal lands and/or threaten fragile environments. For example, it may be possible to cultivate saline-tolerant rice in areas currently important as mangrove habitats. Drought-tolerant maize could increase water-use efficiency in semi-arid regions of the world. The risks and benefits of such applications highlight the need for case-by-case environmental impact assessments of specific applications in specific agro-ecosystems.

Future land use

One of the future challenges is devising ways and means–including standards–to enable proponents of different agricultural practices to coexist in areas of multiple land use. This is particularly challenging for farmers practising broad-scale agriculture and those favouring organic agriculture. For example, research commissioned by the EC over the past 15 years provides guidance on how to minimize gene flow from crop to crop, and from crops to wild relatives in Europe. Unwanted gene flow can be minimized in several ways: through spatial and temporal barriers between crops; by selecting crops with low risks of gene flow outside the crop (either because they are not out-crossing species or there are no related/wild species in the vicinity); and/or by using tissue-specific promoters to target gene expression to certain parts of plants. New scientific developments offer ways to eliminate unintended gene flow from GM crops so that they could be cultivated in biologically contained systems.

4. Are the regulations adequate?

There is broad agreement that regulatory systems need to be science-based and transparent, yet must also involve community participation. In addition, safety assessments should be undertaken on a case-by-case basis, using the best available scientific techniques.

Regulatory processes also need to be robust and sufficiently flexible so as to detect early warning signs of changing circumstances. Recent instances of food safety problems in several countries highlight the need for continued vigilance in ensuring that foods brought to market are safe to eat, irrespective of their source and production methods. These foods may come from conventional or subsistence agriculture, organic agriculture, and/or the cultivation of LMOs.

Regulatory systems for the applications of modern genetics in food and agriculture are based broadly on assessing the safety for human health and the environment of either the *product* or the *process* by which it is produced, or a combination of the two approaches. Although the data sought by regulators are similar, interpretation in risk assessment and management differs amongst countries and regions, particularly in dealing with areas of uncertainty.

The substantive differences are most evident in the level of risk regulators consider ‘acceptable’ for a given society. Since biological systems do not deliver certainty, zero risk for any new technology is an unattainable standard. This reinforces the importance of risk/benefit analysis on a case-by-case basis.

Improving risk assessments

Most regulatory systems agree on the need to continually improve risk assessment methods, making use of new scientific developments to ensure they keep abreast of emerging products and processes. Regulatory systems also need to be sufficiently flexible so as to respond to accumulating experience in the behaviour of new products, once such products are in widespread use.

There is a need for continued development and improvement of food safety assessments methods, so as to assess the safety of future products that may result from more complex genetic modifications (*e.g.* foods with modifications to their nutrient content). These scientific developments will also support better monitoring of any unintended changes in the content of foods that may result from genetic modification. Such changes may occur either by conventional breeding or gene technology.

One of the areas that continues to generate debate is on the methods used to assess environmental impact, and on what constitutes an *adverse* environmental impact. One approach is to compare GMOs with organisms produced using more traditional breeding techniques. Several outstanding issues in assessing environmental impacts remain: lack of reliable baseline data; the relevance of extrapolation from small- to large-scale use, and from the laboratory to the field; the need to be able to detect rare events within a relatively short experimental time scale; lags between introduction and manifestation of environmental impacts; and lack of knowledge about ecosystem complexity, including soil ecosystems. Assessment of the impacts of GMOs on non-target organisms should reflect the complexity of different environments, and the need for comparison with other agricultural practices, such as pesticide use and IPM systems.

International harmonization of regulations

Two United Nations agencies (FAO and WHO) provide an intergovernmental forum through the *Codex Alimentarius* Commission, which seeks to achieve international agreement on standards for food safety, including GM foods. A similar forum is needed to facilitate international agreement on standards for assessing the environmental impacts of gene technology. The Cartegena Protocol of the Convention on Biological Diversity (CBD) provides an intergovernmental forum amongst the parties to the Convention for assessing the impacts of living modified organisms (LMOs) on biodiversity, one component of the environment. A broader forum is needed to enable the development of internationally agreed standards for comprehensive environmental impact assessments of the risks and benefits of new genetics in agriculture.

Benefits and costs of regulation

The cost, complexity, and uncertainty of regulation in new genetics in food and agriculture make regulatory requirements a barrier to entry for public research institutes, poor countries, and small companies. This has long been the case in the pharmaceutical and agrochemical sectors, and is becoming the case in the seed sector as well. Thus, future investments are likely to concentrate even more on those products with potential commercial value, in which the regulatory costs can be built into the product price. Less investment will be available for generating public goods, including those that may be useful in emerging economies. Regulatory requirements are limiting the choices for the use of new genetics to improve agriculture in emerging economies.

In some countries, a lack of public confidence in the regulatory systems remains, which is one of the drivers behind the increasing stringency of regulation. This raises the issue of what more should be done to improve public understanding and confidence in the regulatory and post-approval stages of the release of LMOs into the environment.

Case studies needed

In order to illustrate the relative merits of different approaches and various scenarios, it is necessary to conduct further science-based case studies that compare the risks, benefits, and regulation of crops developed through new genetic technologies and similar crops cultivated under intensive agricultural practices and/or organic agricultural practices.

5. Will GM foods affect trade?

Trade implications of new technologies are becoming increasingly important. There is a need for science-based, internationally agreed standards to enable trade in GM foods and commodities. Lack of clarity in this area is not only affecting major agricultural exporting countries, but is also having an impact on policy-makers in developing countries, in case the use of new genetics technologies puts current or future markets at risk. This will be a major issue in the forthcoming world trade negotiations. As standard-setting bodies, the World Trade Organization and United Nations agencies are key players in helping to resolve these issues.

Future Perspectives

At present, the science underpinning developments in modern genetics is not informing the public in a manner that adequately reflects the volume and quality of scientific data and analysis available. The scientific community could play a more active–and better organized–role in raising public awareness about emerging genetics and what these advances mean for different societies, in terms of choices, risks, and benefits.

Additional, publicly funded research that addresses key gaps in present knowledge would be valuable to inform the debate about the use of modern genetics. The value of this research could be increased if the key questions were framed in an 'authorizing environment' that reflects the concerns of the public, policy-makers, and politicians, both nationally and internationally.

In the regulatory area, additional research is necessary to assist in the continued development of regulatory approaches that keep abreast of new scientific advances. For example, there is a need for the continued development of food safety assessment methods to deal with emerging products such as nutritionally enhanced foods and other complex traits controlled by multiple genes. There is also a need for the development of internationally agreed standards for the assessments of environmental risks and benefits of LMOs.

In 2002, there were approximately 58.6 m Ha of genetically modified crops cultivated in 16 countries. Over this area, much post-release monitoring data has been gathered on the behaviour of genetically modified organisms in various environments but most is not publicly available. Making more of this monitoring data publicly available would be helpful in guiding future regulatory decisions.

The broad range of modern genetics applications in agriculture could contribute more toward improving the efficiency and sustainability of agriculture in emerging economies. Currently available applications have potential to improve the efficiency of plant breeding; to be used in the development of new diagnostics and vaccines for the control of pests, parasites, and diseases in crops, trees, livestock, and fish; and to generate disease-free planting material, which could lead to substantial increases in productivity.

Genetically modified crops also offer promise to contribute more toward both food security and poverty reduction. New varieties of crops and other products with useful traits, which offer much promise for addressing problems in emerging economies, may result from public or private investments or, increasingly, through public/private partnerships.

Several elements are required to support successful deployment of new technologies. These include wide public understanding of new products and their purposes; an enabling policy and regulatory environment, including means for food safety and environmental risk assessments and intellectual property management; investments in research and development; and local, private sector development for distribution and marketing of seeds and other new products.

Science is a creative enterprise, in which the ethics and values of individuals and societies play an increasingly important role in determining what are publicly acceptable and unacceptable uses of science and the new knowledge it generates. The choices these ethics and values imply differ in different societies. It is important that science contributes to an understanding of the issues, and enables individuals and societies to take informed decisions that mobilize the best of science to meet their needs.

Further Information

The complete documentation for the study is available on the ICSU web site at www.icsu.org. This includes the Executive Summary, a synthesis report, summary tables, and for each of the 50 reviews considered in this analysis, an abstract, executive summary and, where available, the full text of each report. This documentation is also available on a CD for those who do not have ready access to the Internet. For further information see also: http://www.doylefoundation.org

Executive Summary Table 1 *Human Health Effects of Genetically Modified Foods: Areas of Scientific Convergence, Divergence, and Gaps in Knowledge*

Issue	**Scientific Convergence**	**Scientific Divergence**	**Gaps in Knowledge**
Safety of currently available GM foods for human consumption	Currently available GM foods are considered safe to eat. No evidence of any adverse effects from consumption to date.	Post-market surveillance is difficult due to confounding effects of diversity of diets and genetic variability in populations.	Long-term effects unknown, both for GM and for most other foods. How to conduct post-market surveillance?
Future products (*e.g.* foods with modified nutritional content)	Need to be assessed on a case-by-case basis to ensure pre-market safety, before new foods are brought to market.	Extent of safety analysis should be proportionate to risk. Product and/or process may be assessed.	Unintended effects possible, either through conventional plant breeding or gene technology.
Methods of food safety assessment	Case-by-case analysis required, using scientifically robust techniques.	Current safety assessment methods, largely based on comparison of a limited number of compounds, may not be adequate to assess more complex products, which are not substantially equivalent to present foods.	Whole food analysis is possible, but requires further R&D to validate new techniques and interpretation of data. Need to know how much change in food content is nutritionally significant.
Health benefits	Many GM crops are now grown with less pesticide, thereby reducing exposure to chemical pesticides. In the future, crops may be used to produce new pharmaceutical/medicinal compounds (*e.g.* vaccines).	Future GM crops may have improved nutritional content (*e.g.* vitamin A rice). Need to ensure quality control of new products and keep pharmaceutical products out of the food chain. (This may be difficult).	Availability of nutritionally significant levels of vitamins and minerals in GM foods needs to be demonstrated. Need to demonstrate new crop management practices for novel products, to ensure they can be kept out of the food chain and adequately regulated.

Executive Summary Table 2 *Environmental Effects of Living Modified Organisms (LMOs): Areas of Scientific Convergence, Divergence, and Gaps in Knowledge.*

Issue	Scientific Convergence	Scientific Divergence	Gaps in Knowledge
Direct effects	Agriculture affects the environment. Environmental effects of LMOs may be negative or positive. Requires case-by-case assessment. Direct effects of GM crops may include gene flow from GM crops to local land races, and/or compatible wild or weedy relatives in centres of diversity. Other hazards to assess for plants include any increased potential for: Weediness; effects on non-target species; unexpected effects; worker safety.	Need to compare LMO effects with present agricultural practices and other options for land use. Gene flow occurs in all open-pollinated crops, at varying frequency. Real question is: Does it matter? Depends if new hybrids survive to form weeds or invasive species. LMOs may affect non-target species, but difficult to determine significance. Need to compare LMO effects with current practices and other options for crop cultivation.	Baseline ecological data for comparisons are lacking. Significance of gene flow in centres of crop diversity needs to be investigated further. Modelling approach may be useful to assess likelihood of gene flow and its significance. Effects on soil microflora are difficult to detect.
Indirect effects	GM technology may change agricultural practices. Less insecticide used on pest tolerant crops. Instances of 40% less insecticide used on Bt cotton. Need to avoid development in resistance in pest populations by crop management systems to reduce selection pressure on target pest in Bt crops.	Herbicide use may increase or decrease with use of herbicide tolerant crops. Weed biology may change in GM crop fields. Herbicide tolerant crops may be useful for low-till agriculture and improve soil conservation. Stress tolerant crops may threaten ecosystems (*e.g.* salinity tolerant rice in mangrove ecosystems).	Pest-resistance management in complex agricultural systems in less developed countries may be difficult. Need to develop integrated pest management systems, incorporating LMOs where appropriate, and monitor for any changes in populations of beneficial organisms and developments in pest resistance.
Methods of environmental impact assessment	Types of data sought for environmental impact assessment are similar, but interpretation varies in different regulatory systems.	Precautionary approaches to manage uncertainty require that new technologies demonstrate no harm. Since biological systems do not deliver certainty, zero risk is an unattainable standard. Significance of laboratory studies is debatable, as it is difficult to extrapolate from laboratory to field studies and effects of commercial use. What constitutes an adverse environmental impact?	Need comparative analysis of different systems (LMOs, intensive, subsistence, and/or organic agriculture). Baseline ecological data for different agricultural systems are difficult to obtain. Need international harmonization of environmental impact assessment methods and commonly agreed standards.
Biodiversity conservation	Molecular methods help characterize biodiversity. Genomic studies will help identify genes within species and how to switch them on/off.	Increasing efficiency of agriculture may threaten biodiversity; it may also protect biodiversity by reducing pressure on natural resources.	Molecular finger-printing of gene bank accessions would be useful, to set baseline data and monitor any genetic changes over time.

1. Introduction

Science is a creative enterprise. It combines the exploration of the natural world with the generation of knowledge and its use in human endeavours. This combination of creativity with purpose is exemplified in the field of biotechnology. But the power of the new discoveries in genetics also raises concerns in many societies as to the ethics and safety of their use, and the risks they may pose to human health, biodiversity and the environment. As a result of these societal concerns, many studies have been commissioned by national academies of science, governments, international organizations and private agencies on various aspects of modern genetics.

This overview, commissioned by the International Council for Science (ICSU) analyses the findings of approximately 50 science-based reviews published in years 2000-2003, on modern genetics and its applications in food, agriculture and the environment. The purpose of this analysis is to consider what are the issues that concern various societies, and, on the basis of the science underpinning the discoveries in modern genetics, what are the areas of *commonality,* what are the areas of divergence and differing perspectives, and where are the *gaps in knowledge* that may be able to be addressed through additional well targeted research. The ways in which scientific knowledge is communicated and influences public perceptions and policy choices about new technologies are also considered. A bibliographic list is attached *(Annex A).*

Some reviews, both national and international, are charged with advising governments on appropriate regulatory frameworks for gene technology. Several reviews concentrate on those aspects of new genetics most likely to affect food safety and human health, in terms of risks and benefits. Others are more concerned with the potential impacts of gene technology on agriculture, biodiversity and the environment, through both the direct effects of new technologies and indirect effects caused by their influence on changing agricultural practices.

Other reviews are concerned specifically with the potential impact of modern genetics on emerging economies and their potential contribution towards improving food security and reducing poverty. Several reviews look not only at the scientific issues but also consider the broader context, including the ethics and values that underpin the interaction between science and societies in different parts of the world.

The content of the reviews is analysed in terms of identifying the applications of modern genetics in food and agriculture and their implications for:

- Food safety and human health
- Biodiversity conservation and environmental sustainability
- Regulatory affairs
- Effects on emerging economies and trade implications
- Ethical issues, public perceptions and communications

Key questions in relation to genetically modified foods

Although this review considers modern genetics in the broad sense, specifically, in relation to genetically modified foods, this study seeks to answer five key questions:

Who needs them?
Are they safe to eat?
Will there be any effects on the environment?
Are the regulations adequate?
Will they affect trade?

2. Applications of New Genetics in Food and Agriculture

Applications of modern genetics are being used to improve the efficiency and sustainability of agricultural practices today. For example, recent discoveries have led to:

- Better understanding of how plants function, and how they respond to the environment.
- More targeted selection objectives in breeding programmes to improve the performance and productivity of crops, trees, livestock and fish, and post-harvest quality of food.
- Use of molecular markers for smarter breeding, by enabling early generation selection for key traits, thus reducing the need for extensive field selection.
- Molecular tools for the characterization, conservation and use of genetic resources.
- New molecular diagnostics, to assist in the improved diagnosis and management of parasites, pests and pathogens.
- New vaccines to protect livestock and fish against lethal diseases.

Such applications, which are already making substantial contributions to agriculture in both industrial and developing countries, use information derived from modern genetics and new molecular techniques. *(For examples, see: CGIAR 2000a; IFPRI 2001; ISNAR 2002b; ICSU 2002; Agricultural Biotechnology Country Case Studies, Persley and MacIntyre, 2001; Serageldin and Persley, 2003).*

New scientific discoveries in modern genetics, and particularly gene technology, also provide options for the targeted introduction of transgenic strains that are genetically modified for one or more traits. Transgenic strains are produced by means of *recombinant DNA technologies (gene technologies)* that enable the movement of genes between species that do not normally cross in nature. Although transgenic strains of various species of crops, trees, livestock and fish have been developed experimentally, only transgenic crop varieties are in widespread commercial use in agriculture today.

Agrobacterium-mediated gene transfer in plants

In plants, the process of genetic engineering was driven by the discovery that a common soil borne bacterium and plant pathogen, *Agrobacterium tumifaciens*, had a means by which it naturally transferred some of its own bacterial DNA into targeted plant cells, and this transfer and integration of bacterial DNA into the plant cells then caused the plant cells to produce new compounds for the bacterium to use. It is this naturally occurring transformation process that provided the scientific basis for genetic engineering in plants. A recent report by the French *Academie des Sciences (2002)* highlights the importance of this fundamental discovery about *Agrobacterium*, as the basis for genetic engineering in plants.

Agrobacterium is now being used as a biological transfer agent to move one or more genes from bacteria to plants, from plant to plant, and theoretically from any other organism into plants. For example, insect resistant plants contain toxin-producing genes from the bacterium, *Bacillus thuringensis* (Bt) introduced into cotton, corn and other crops. Herbicide tolerant soy bean contains genes isolated from soil-borne bacteria. A modified strain of *Agrobacterium tumifaciens* is also being used for the biological control of crown gall disease, the first genetically modified organism to be released into the environment for commercial use *(Kerr, 1991).*

Commercial cultivation of transgenic crops

The first transgenic plants were produced experimentally in 1983, by means of *Agrobacterium*-mediated gene transfer. The commercial cultivation of transgenic crops began in 1995. By 2002, there were approximately 58.6 million hectares of genetically modified crops growing in sixteen countries *(ISAAA 2002b).* These crops are mainly soy bean, corn, cotton and oil seed rape (canola), with resistance to certain insects and/or herbicide tolerance *(Figure 2.1).* Many other crop/trait combinations are under investigation.

Broadly, the first wave of genetically modified crops, which are in commercial use, address production traits; the second wave, which are mainly under development, address quality and/or nutritional traits; and the third wave address complex stress response traits and novel products able to be produced in plants. The scientific basis of dealing with each of these groups of traits is increasingly complex *(ICSU 2002).*

Several socio-economic studies have assessed the benefits derived from specific applications of genetically modified crops and other applications of modern genetics in agriculture. For example, the benefits derived from Bt cotton are documented in several countries, including Australia, China, South Africa and the USA *(e.g. ISAAA 2002a; Pray et al. 2002, Pardey et al. 2002).*

Emerging scientific discoveries for addressing complex traits

Most characteristics of food are controlled by more than one gene. Thus taste, aroma, colour, nutritional composition and other aspects of food quality are the result of complex biochemical reactions within the plant before and after harvest. Emerging scientific developments are enabling complex traits that are controlled by multiple genes to be addressed, with the intention of developing new products of potential value for food and agriculture, human health and the environment (for examples, see Table 2.1). The attractiveness of the new targets is tempered by the fact that they are technically difficult, requiring the expression and control of several genes, which are often involved in different biochemical pathways. The scientific basis of these developments in *genomics, proteomics and metabolomics* and related areas is reviewed in a companion ICSU publication on *Biotechnology and Sustainable Agriculture (ICSU 2002).*

These emerging scientific possibilities also pose new challenges in the assessments of the risks and benefits of potential new products to human health, biodiversity and the environment. Some of the potential products are meant for food or feed use, while others are intended for use as pharmaceuticals, and others as compounds for industrial uses. Some will require inter-specific transfer and control of multiple genes. Others will rely on switching on (or off) and better regulating genes that are already present in the organism but not usually expressed. New scientific developments also offer potential means to overcome some of the risks in the cultivation of *genetically modified* crops and other *living modified organisms* (for example, by limiting gene flow to related and/or wild species).

Figure 2.1 *Commercially cultivated genetically modified crops 2002.*
Source: ISAAA, 2003

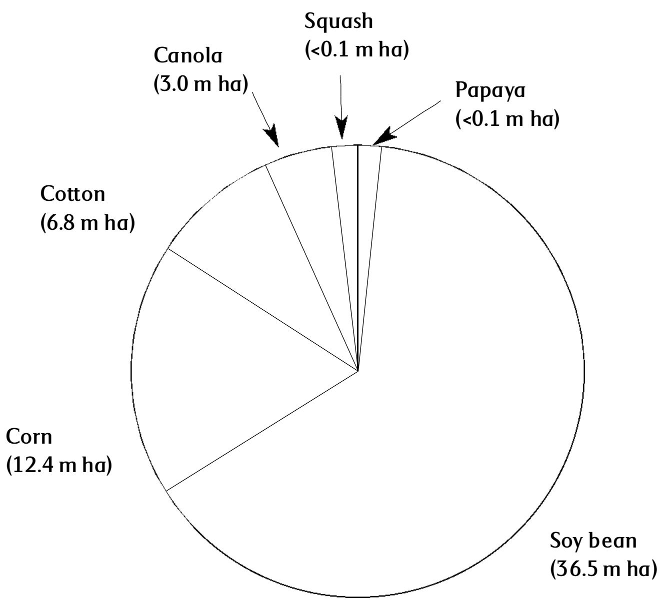

Table 2.1 *Complex traits being addressed through emerging science*

Target	Trait	Illustrative crops
Improved crop productivity	Drought tolerance Salinity tolerance Aluminum tolerance	corn rice tobacco
Health benefits	Disease resistance	rice
	Vitamin A content Iron content Reduced toxins Modified starch for low glycemic index Modified fatty acid content of oil crops	rice, mustard rice cassava barley, wheat oilseeds, coconut (enriched for omega three fatty acids)
Value added traits	Colour changes Flavour changes	flowers (*e.g.* blue roses) tomato
Plants for medicinal purposes	Vaccine production	banana , potato tomato, tobacco
Plants for industrial purposes	Biodegradable plastic production Starch production Alcohol production	corn corn sugar cane
"Self-regulating" plants	Limiting gene flow to related and/or wild species	oilseed rape
Removing toxic compounds from the environment *(bioremediation)*	Mercury pollution Cadmium contamination	*Arabidopsis thaliana* tobacco

Source: Modified from van Montagu and Burssens, 2003; ICSU 2002.

3. Implications for Food Safety and Human Health

Issues

Four issues predominate in assessing the implications of the use of modern genetics in agriculture for human health. These are:

1. *Safety* of genetically modified foods for human consumption
2. *Adequacy of the methods* for assessing the safety of presently available and possible future products
3. *Benefits* of new products for human health and nutrition
4. *Identification* of GM foods in the market place

The key points for consideration within each of the four issues above are summarized in *Box 3.1* and *Figure 3.1.* The areas of scientific convergence, divergence and gaps in knowledge are summarized in *Table 3.1.* Their implications are discussed further below.

Key Documents

The issues in relation to food safety and human health have been examined in detail by several international agencies *(e.g. FAO/WHO 2000, 2001a, 2001b; IUNS/IUTOX 2002; OECD 2000a,b; OECD 2001a).* Similarly, there are several recent studies by national agencies *(e.g. Belgium, VIB 2001; Canada, Royal Society 2001, CBAC 2002; New Zealand 2001; UK Royal Society 2001; US Society of Toxicology 2002).* The science underpinning these issues is also discussed in reviews by *Kuiper et al. 2001* and *Lehrer, in CGIAR 2000a.*

Overview

ISSUE 1: SAFETY OF GENETICALLY MODIFIED FOODS FOR HUMAN CONSUMPTION

Presently available genetically modified foods are safe to eat. GM foods presently on the market have been assessed for any risks of increased allergenicity, toxicity, or other risks to human health, using internationally agreed food safety standards. Food safety assessments in several countries have deemed these foods to be as safe as their conventional counterparts. This is the consensus view of several reports by national and international agencies *(e.g. FAO/WHO 2000, 2001a, b; IUNS/IUTOX 2002; UK Royal Society 2001; US Society of Toxicology 2002).*

Further, there is no evidence of any ill effects from the consumption of foods containing genetically modified ingredients so far. The dietary consumption of additional DNA from plants, viruses or bacteria poses no additional risks to humans, as the human diet already contains much DNA of plant, microbial and animal origin. Since GM crops have first been cultivated commercially in 1995, many millions of meals have included GM ingredients (mainly coming from maize, soy bean and oilseed rape, grown in North America and Argentina), without any reported adverse effects *(OECD 2000a).*

The lack of demonstrated ill effects to date does not mean that risks do not exist as new foods are developed with novel characteristics. Food safety assessment strategies need to be determined on *a case-by-case basis, using scientifically robust techniques, to ensure that foods that are brought to market are safe for consumers. The extent of risk assessment should be proportionate to the likely risks (Kuiper et al. 2001).*

Regulatory processes need to be sufficiently flexible so as to be able to detect early warning of changing circumstances. Recent instances of food safety problems in several countries (*e.g.* with BSE, *E.coli* contamination, and toxic chemicals in food) highlight the need for continuing vigilance in ensuring that foods brought to market are safe to eat, irrespective of their source and production methods. These foods may come from intensive or subsistence agriculture, organic agriculture and/or the cultivation of GM crops.

Issue 2: Food Safety Assessment Methods

AREAS OF SCIENTIFIC CONVERGENCE

Present methods: The United Nations Food and Agricultural Organization (FAO) and the World Health Organization (WHO) maintain an overview of the methods used to assess the safety of GM foods (through *Codex Alimentarius,* an intergovernmental commission with 162 member countries). The *FAO/WHO 2000* consultation concluded that: *"The Consultation was satisfied with the approach used to assess the safety of the genetically modified foods that have been approved for commercial use."*

Improving methodologies for assessing future product safety: New scientific developments are being used to develop improved methods of risk assessment, so that the risks and benefits of possible future GM foods can be adequately assessed. For example, new profiling methods are being developed to assess the full content of whole foods, as distinct from measuring the levels of targeted single compounds in foods. Such new methods may be useful to detect any unintended compositional changes in foods as a result of genetic modification *(Kuiper et al. 2001).* Such unintended changes may occur during conventional plant breeding as well as through gene technology.

Possible new risks in novel foods: New approaches to food safety testing are of particular interest for assessing the safety and nutritional significance of future GM foods and crops that are being developed for potential improvements in their nutritional qualities, such as increased vitamin or mineral content or modified oil or starch content *(IUNS/IUTOX 2002).*

AREAS OF SCIENTIFIC DIVERGENCE

Substantial equivalence

"The concept of substantial equivalence is a starting point for safety evaluation and contributes to an adequate food safety assessment strategy" (OECD 2000b).

Safety assessments of GM foods compare the properties of the new food with those of its traditional counterpart. This comparative approach, applying the principle of substantial equivalence, is based on the assumption that conventional foods are generally considered as safe for consumption, based on a history of safe use *(Figure 3.2).*

Any identified differences between the GM food and its conventional counterpart are assessed with respect to their safety and nutritional implications for the consumer. Thus, *substantial equivalence* is a conclusion that may be reached after comparative analysis of a genetically modified food and its traditional counterpart. If no significant differences are detected by comparison of a selected number of compounds (a *targeted approach*), a conclusion of substantial equivalence is reached. If significant differences are identified, they are used to highlight areas for further examination to see if there are any food safety concerns that need to be addressed (*e.g.* potential allergenicity) (*Kuiper et al. 2001*).

Opponents of this comparative approach consider that *non-targeted* approaches are required, which compare the content of whole foods, to better assess both intended and unintended effects.

Precautionary approaches

There are differing views as to whether a precautionary approach is a useful concept in risk assessment. One of the limitations of the precautionary approach is that it is not possible to deliver certainty in biological systems. (See Chapter 5 on regulatory approaches).

GAPS IN KNOWLEDGE

Food safety assessment methods

New methods for safety assessment of whole foods: Comparative safety assessments may be followed for the next generation of GM foods in order to establish the degree of equivalence with presently available foods. The unmodified host organism may function as the relevant comparison for testing the degree of equivalence. In some instances a safety assessment of the new (whole) food itself will be necessary. For example, detailed risk assessments may be required for GM crops with extensive modification of existing metabolic pathways or addition of new ones, or for GM plants with decreased levels of naturally occurring toxins, which previously could not be used as food sources (*Kuiper et al. 2001).*

Safety testing of whole foods is difficult. Present approaches for detecting expected and unexpected changes in the composition of GM food crops are primarily based on measurements of a limited selection of single compounds (*targeted approach*). In order to increase the possibility of detecting any unintended effects, new profiling methods (using gene expression technologies, proteomics and metabolomics) should be further developed and validated, for a *non-targeted approach.* Such new profiling techniques should enable increasingly comprehensive assessments of compositional changes in food. The principal problems associated with advanced technologies for the determination of compositional changes in food lie not in the compositional analyses themselves, but in assessing the significance of the results of those analyses *(Kuiper et al. 2001; IUNS/IUTOX 2002).*

Issue 3: Benefits

Human health benefits of genetically modified foods and crops may result from either *direct effects* of genetic improvements on the content of food, or *indirect effects,* through changing agricultural practices and/or beneficial environmental effects.

For example, *direct health benefits* lie in the potential for introducing traits for:

- Improving nutritional quality of specific foods (*e.g.* improving vitamin content);
- Reducing toxic compounds in food (*e.g.* cassava with lower levels of cyanide);
- Removing allergens from certain foods (*e.g.* peanuts).

Indirect health benefits may come from the effects of modern genetics on agricultural practices, through:

- Pest tolerant crops able to be grown with lower levels of chemical pesticides, resulting in reduced residues in food and less pesticide exposure for farm workers;
- Disease resistant crops with lower levels of potentially carcinogenic mycotoxins;
- Increased availability of food through higher productivity, with more food being able to be produced per unit of land and per unit of water;
- Plants and microbes able to remove toxic compounds from soil (*e.g. Brassicas* able to remove arsenic compounds from soil).

Issue 4: Identification of GM Foods in the Market place

Areas of scientific convergence

"Pre-market safety assessment of GM foods will need to provide sufficient safety assurance for consumers" (Kuiper et al. 2001).

Post-market surveillance of the effects of consumption of GM foods is likely to be difficult, expensive and may not yield useful data, due to the complex composition of diets and genetic variability in populations. The safety of particular foods needs to be determined *before* they are approved for commercial use, using scientifically robust techniques that are continually reviewed and improved in the light of advancing knowledge.

Areas of scientific divergence

Food labelling

Labelling: A key issue in food safety for consumers is being able to identify those foods that may contain allergens and other potentially harmful substances, so that people who have allergic or food intolerant reactions to particular foods can avoid them. Others may wish to avoid certain foods on health, ethical or religious grounds.

Labelling of foods as GM or non-GM may enable consumer choice, as to the process by which food is produced. It conveys no information as to the content of foods, and whether there are any risks and/or benefits associated with particular foods. More informative labelling of foods would disclose the nutrient content of the food, in relation to similar foods produced by conventional agricultural practices, as well as any additional protein (or other) content resulting from the specific genetic modification. Informative food labelling could enable consumers to make choices about particular foods, after assessing their risks and benefits.

Box 3.1 *Issues of modern genetics in agriculture for human health*

Issue 1. Safety of genetically modified foods for human consumption
Risks: Potential of proteins and other compounds in food to increase the risks of:
- Allergenicity
- Antibiotic resistance development in human and/or animal pathogens
- Toxic and carcinogenic compounds
- Unintended effects, such as unexpected compositional changes in foods

Issue 2. Adequacy of risk assessment methods
- Appropriateness of presently available methods for current and near-term products
- Availability of new methods for food safety assessments of emerging products

Issue 3. Benefits for human health
Potential for direct health benefits through:
- Improving nutrient content of specific foods
- Removing allergenic and/or toxic compounds from certain foods

Potential for indirect health benefits through changing agricultural/environmental practices *e.g.*:
- Reducing exposure to pesticides
- Removing toxic compounds from soil

Issue 4. Identification of GM foods in the market place
- Post-market surveillance
- Food labelling

Figure 3.1 *Safety issues of GM foods*
(Source Kuiper et al. 2001)

Safety issues of GM foods

- Genetic modification process
- Safety of new proteins
- Allergenicity of new proteins
- Occurrence and implications of unintended effects
- Gene transfer to gut microflora
- Role of new food in the diet
- Influence of food processing

Figure 3.2 *The concept of substantial equivalence*
(Source Kuiper et al. 2001)

Concept of substantial equivalence

- Starting point for safety assesment
- Comparison between the GM organism and its closest traditional counterpart
- Identification of intended and unintended differences on which further safety assesment should be focused

Table 3.1 *Implications of Genetically Modified Foods and Crops for Human Health*

Issue	Scientific Convergence	Scientific Divergence	Gaps in Knowledge
Issue 1. Safety of GM foods for human consumption *Overview*	Present GM foods on market are considered safe for human consumption. (*FAO/WHO 2000, 2001a)* No documented cases of ill effects from GM food consumption. (*OECD2000a,b, 2001a)*		Long-term effects unknown for GM foods, as well as most foods. Difficult to detect long-term effects due to many confounding factors and genetic variability in foods and related effects in the population. (*Kuiper et al. 200?)*
Risk issues for GM food safety assessments Increased risks of allergenic and/or toxic compounds in foods due to presence of newly-inserted proteins or marker genes	Gene technology may increase or decrease levels in food of *naturally occurring proteins* or introduce new proteins or other compounds with potential for allergenic, toxic or food intolerant reactions. If any increased levels of allergens or potential new allergens detected, the product is not commercialized. Transfer of genes from commonly allergenic foods is discouraged. *(FAO/WHO 2000)*		Proteins from sources not previously used in human food are more difficult to assess for food safety. Present methods compare new proteins with known allergens and also test for heat stability and enzyme digestibility. If new protein is heat unstable and easily digestible, low allergenic risk. Heat stable proteins pose higher risks of allergenicity. *(Lehrer 2000; FAO/WHO 2000, 2001).* Any increases in pollen allergenicity should be checked. (RS)
Antibiotic resistance development in human and/or animal pathogens	Minimal risk of antibiotic markers increasing antibiotic resistance in human and animal pathogens. Antibiotic markers are being phased out in response to consumer concerns. (*FAO/WHO 2000; OECD 2002)*		
Unintended effects	Unintended food compositional changes may occur during genetic improvement by conventional plant breeding and/or by gene technology. Effects detected by chemical analysis of known nutrients and toxicants (targeted approach)		Possibility of unintended effects may increase in plants with extensive genetic modification and altered biochemical pathways, producing new products with modified nutritional content (*e.g.* vitamins, starch, oil content). Risks need to be assessed on case-by-case basis. New profiling / finger-printing techniques may be useful (non-targeted approach) to assay whole foods. (*Kuiper et al. 2001*)
Horizontal gene transfer from GM foods to human/animal gut microflora	Horizontal gene transfer to gut microflora may occur, at low frequency		

(Table 3.1 continued)

Issue	Scientific Convergence	Scientific Divergence	Gaps in Knowledge
Issue 2. Adequacy of methods for food safety assessments *Present products* (Main commercial products approved are corn, soy bean, rapeseed, potato, papaya and tomato modified for insect resistance, herbicide tolerance, virus resistance and/or delayed ripening).	Present risk assessments based on concept of *substantial equivalence* as part of a safety evaluation framework. This concept considers the existing food supply is safe based on a history of safe use, although many foods contain anti-nutrients and toxicants that can cause deleterious effects at certain levels and modes of consumption. Several intergovernmental panels satisfied with present approaches used to assess safety of GM foods in commercial use today. (*e.g. FAO/WHO, 2000, 2001a,b; OECD 2000).* National food safety systems have approved selected GM foods for human consumption and or/ animal feed. (*e.g.* Argentina, Australia, Canada, China, South Africa, Spain, UK, USA).	Consensus needs to be established on the practical applications of substantial equivalence concepts. (*Kuiper et al.*, 2001). Precautionary approaches to risk assessment require that in areas of uncertainty there should be evidence of no harm.	
Future products Plants may be genetically modified to change complex traits such as taste, aroma, and/or nutrient content. *New products* may result from extensive modification of biochemical pathways, addition of new pathways, and/or modified toxin-producing pathways.	*Comparativesafety assessments* are used to establish degree of substantial equivalence with most appropriate counterpart. Compositional analysis of key components (nutrients and toxicants) as well as phenotypic and agronomic characteristics of the GM plant is the basis of assessment of substantial equivalence. A GM food may be considered: (1) substantially equivalent;(2) substantially equivalent except for the inserted gene; (3) not equivalent at all. Food safety assessment strategies need to be developed on a case-by-case basis, with the extent of risk assessments being proportionate to the likely risks involved. (OECD consensus docs).	The extent of food safety assessments required for specific cases is debated. If substantial equivalent (SE) – no further testing is required. If SE except for one trait further safety testing concentrates on this trait, and its potential for increased toxicity, or allergenicity, gene transfer to gut microflora, and other risk factors (*Kuiper et al.* 2001).	*New profiling finger-printing techniques* need to be further developed and validated to assess content of whole foods. The interpretation of data from whole foods analyses, to assess significance of any compositional changes in foods needs to be refined. *(Kuiper et al. 2001; IUNS/IUTOX 2002)*

(Table 3.1 continued)

Issue	Scientific Convergence	Scientific Divergence	Gaps in Knowledge
Issue 3. Benefits of GM Foods			
Direct health benefits			Benefits need to be better documented *(ISAAA 2001, 2002a).*
Nutritionally improved foods Vitamin content	Improving nutritional content of foods possible (*e.g.* Vitamin A in rice and Indian mustard)	Need to demonstrate nutritionally significant levels of vitamins and minerals are genetically expressed and nutritionally available in new foods, and that there are no unintended effects (*IUNS/IUTOX 2002)*	
Mineral content	Micronutrient content can be varied genetically (*e.g.* iron in rice) *IUNS/IUTOX 2002*		
Oil quality	Oil content of rapeseed modified to increase lauric acid content		
Starch content	Starch quantity and quality can be modified, to increase the glycemic index of foods (*e.g.* barley)		
Pest/disease tolerant crops Less chemical pesticide use	Substantial reductions in pesticide use on broad acre crops (*CAST 2002)*		
Less mycotoxins in food (potential carcinogens)	Mycotoxin levels reduced in Bt corn		
Less toxins in food	Toxin levels may be reduced experimentally (*e.g.* cassava with lower cyanide levels)		
Vaccine and/or pharmaceutical production in crops	Vaccines able to be produced in crops		Additional crop management and regulatory issues involved for crops used to produce pharmaceuticals and/or industrial products in order to keep them out of the human food chain.
Issue 4. Identification of GM foods			
Post-market surveillance	Safety of food needs to be determined *before* new foods are approved for market, rather than seek to monitor after effects.	*Post-market surveillance* difficult and may not yield useful data on long-term and/or unintended effects, due to dietary complexity and genetic variability in the population.	May be useful for following allergenic or food intolerance reactions in specific parts of the population.
Labelling		*Labelling* can inform consumers on the *content* of GM foods, as well as on the *process* itself.	

4. Implications for Biodiversity Conservation and Environmental Sustainability

Issues

Four issues are important in assessing the effects of modern genetics on biodiversity and the environment. These are:

- Direct effects on the environment, *that may result from the release of genetically/living modified organisms into the environment;*
- Indirect effects *that may result from changes in agricultural practices, as a result of the applications of modern genetics in agriculture and the environment;*
- Adequacy of the methods *used to assess the impact of modern genetics on the environment;*
- Usefulness of molecular methods *in the characterization, conservation and use of biodiversity.*

The areas of scientific convergence, divergence and gaps in knowledge are summarized in *Table 4.1.* Their implications are discussed below.

Key Documents

The environmental issues have been examined in detail in several specialised studies published by international agencies (*e.g. European Commission, EC 2001a; European Environment Agency, Eastham and Sweet, 2002; OECD 2001b;*) and national agencies (*e.g. US NRC 2000; US NAS 2002; CAST 2002; US NCFAP 2002*). Environmental issues also form an important component of several broader studies by national agencies (*e.g. Belgium, VIB 2001; Canada Royal Society 2001; CBAC 2001, 2002; France, Academie des Sciences 2002; New Zealand 2001*).

The environmental risks associated with the release of genetically modified crops in the environment have also been reviewed by *Cook, and by Johnson, in CGIAR 2000a; Dale et al. 2002; Nap et al. 2003;* and *Conner et al. 2003.* The risks and benefits of specific cases have been reviewed for *Bt* cotton (*ISAAA 2002 and Pray et al. 2002*) and other Bt crops (*Shelton et al. 2002*). The possible effects of genetically engineered corn on the Monarch butterfly are discussed in several publications by the *US National Academy of Sciences (e.g. Zangerl et al. 2001),* and also by *Shelton and Sears 2001;* and the *Pew Initiative 2002).* The specific issues associated with the possible release of transgenic fish into the environment have been reviewed by the Pew Initiative *(Pew 2003).*

Overview

Agriculture affects the environment. New genetic technologies that are used in agriculture will affect the environment. Their environmental effects may be either positive or negative. They may either accelerate the environmentally damaging effects of agriculture, or they may contribute towards more sustainable agricultural practices and the conservation of natural resources. It is a matter of application and choice.

The environmental effects will depend on the specific genetic application, the agricultural system and the environment (agro-ecosystem) in which it is used. Environmental impact needs to be assessed on a case-by-case basis, taking account of specific risk factors. The environmental effects of specific technologies may be either *direct effects* of a specific trait/species combination on biodiversity, habitats, landscape, and/or other components of the environment; or they may be *indirect effects,* resulting from changing agricultural practices leading to more, less or different use of pesticides or herbicides, and/or changing land uses.

In assessing direct and indirect environmental effects, new biotechnology-based technologies need to be compared with present agricultural practices, and other technology options. Comparison with baseline ecological data is also desirable, but is difficult to obtain in many instances. Also, both the risks and the benefits of new technologies need to be considered, so as to develop a picture of the options available and the choices implied.

The potential environmental impacts of modern genetics may be thought of in a hierarchical manner, from consequences for the crop (or other genetically modified species) and its relatives, through to interactions at the community level, and at the ecosystem level.

Small or large genetic modifications may perturb the environment. It is difficult to extrapolate from the environmental impact assessments of the first generation of genetically modified crops (that are mainly the result of single gene modifications for pest or disease resistance) to emerging products that may be the result of genetic modifications to regulate more complex traits. For example, future traits in plants may be changes in tolerance to abiotic and biotic stresses, altered nutritional content (*e.g.* vitamins, oil, starch) and/or modified biochemical pathways to produce compounds for medical or industrial uses *(US NAS 2000).*

Environmentally friendly product design

The greater understanding of the environmental risks and benefits posed by modern genetics may lead to the better design of future crops. For example, where gene flow is a risk in out-crossing crops growing in their centre of diversity, close to wild relatives with which they may cross, it may be possible to include genetic mechanisms of pollen incompatibility to limit the risk of gene flow. Also the increased availability of tissue-specific promoters enables genes to be expressed only in the part of the plant where required (*e.g.* leaves) and not in the pollen or other parts of the plant, thus reducing the risk of inadvertent gene transfer.

Where crops are to be used for industrial purposes to produce products such as vaccines, or industrial polymers, the crop of choice should be one with which there is no risk of gene flow to related edible crops or wild species in the area of cultivation *(Johnson in CGIAR 2000a).*

Issue 1. Direct effects on biodiversity and the environment

Modern genetics is being used in the improvement of crops, trees, livestock, fish and microbial species used in agriculture. Each may have direct effects on the environment.

Plants: Several issues need to be considered in relation to the cultivation of plants in the environment. These are the potential for:

- *Gene transfer,* the movement of genes from a cultivated crop through pollen out-crossing to form hybrids with local landraces and/or related wild species.
- *Weediness,* the tendency of plants (or their derived hybrids/backcrosses formed with related or wild species) to spread beyond the field where first planted and become established as a weed amongst crops or invasive species in other habitats.
- *Trait effects,* the effects of specific traits that may be potentially harmful to non-target organisms and damage their role in ecosystem function.
- *Expression of genetic material from pathogens,* such as virus vectors.
- *Unexpected effects, due to genetic and phenotypic variability,* and the tendency of the plant to exhibit unexpected characteristics after genetic recombination.
- *Worker safety* upon exposure to new products.

These risk issues for the release of plants into the environment are similar in kind, whether the plants are the result of traditional crop improvement or modern genetics, or they result from the introduction or escape of ornamental crops.

Trees: There are potentially direct environmental effects from the release of genetically modified trees into the environment that are similar to those affecting plants. There are also added concerns, given the long life cycle of trees.

Microorganisms: The use of microorganisms in food production is usually in contained situations, such as fermentation processes. There is also potential for their use in the environment. For example, specifically designed, genetically improved microorganisms may be released into the environment as biological control agents against diseases, pests and weeds.

Fish: The possible release of genetically modified fish into aquatic environments poses another distinct set of issues, which also need to be assessed on a case-by-case basis *(Pew 2003).* A key issue is the potential ability of transgenic fish to cross with, and out-compete wild populations.

Issue 2. Indirect effects on biodiversity and the environment

CHANGING AGRICULTURAL AND ENVIRONMENTAL PRACTICES

Indirect environmental effects may result from changing agricultural and/or environmental practices that result from specific applications of modern genetics, including the use of living modified organisms with particular traits. For example:

Pesticide use: The use of GM crops with insect resistance (Bt crops) is reducing the volume and frequency of pesticide use on cotton, corn and soy bean *(Carpenter et al. 2002).* Bt cotton crops are also having demonstrable beneficial effects on human health and the environment in China, Australia and South Africa *(Pray et al. 2000; ISSAA 2002a)* by reducing exposure to chemical pesticides.

Herbicide use: The expanding use of pesticides (including herbicides) has been a major cause of the decline in farmland birds, arable wild plants and insects in the UK as suitable habitats disappeared. The more widespread use of broad-spectrum herbicides in the UK as a result of the cultivation of herbicide tolerant crops (such as oilseed rape and sugar beet) may accelerate this trend *(Johnson in CGIAR 2000a).*

Land use: The future development of new crops with improved tolerance to abiotic factors (such as drought, salinity and frost) and the advent of crops that may be used to produce vaccines and/or industrial products may also change crop management and land use practices. These trends may be either environmentally beneficial or damaging, depending on the particular crop/trait/environmental situation.

Crops with tolerance to abiotic stresses may increase pressure on natural biodiversity when crop cultivation extends into marginal lands, or into areas not presently used for agriculture. For example, salt tolerant rice may be able to be cultivated in coastal areas where mangroves presently grow, with resulting ecological changes in land and water use and associated plant and marine life. Gene technology may also be used in environmental remediation, for example in the removal of toxic compounds from soil.

ENVIRONMENTAL BENEFITS OF GENETICALLY MODIFIED CROPS

Biotechnology-derived crops provide options and potential solutions for a number of challenges in modern agriculture. The extent to which they may be the preferred option depends on many economic, social, and regional factors. Several general conclusions about the environmental benefits of biotechnology-derived soy bean, corn, and cotton have been documented by studies in the USA and elsewhere (*CAST 2002*). These studies concluded:

- Biotechnology-derived soy bean, corn, and cotton provide insect, weed, and disease management options that are consistent with improved environmental stewardship.
- Biotechnology-derived crops can provide solutions to environmental and economic problems associated with conventional crops including production security (consistent yields), safety (worker, public, and wildlife), and environmental benefits (soil, water, and ecosystems).
- Although not the only solution for all farming situations, the first commercially available biotechnology-derived crops provide benefits through enhanced conservation of soil and water, increased beneficial insect populations and improved water and air quality.

Issue 3. Adequacy of methods for assessing environmental effects

AREAS OF CONVERGENCE

There is broad agreement that there needs to be science-based environmental impact assessments of the risks posed by the release of genetically modified crops and other living modified organisms into the environment.

The types of risks posed by the release of Living Modified Organisms (LMOs) into the environment are similar in kind to those posed by the release of other biological products for agricultural purposes (*e.g.* improved crop varieties, biological control agents). This experience provides a basis for developing risk assessment methodologies for assessing the risks posed by LMOs, in comparison with their conventional counterparts.

AREAS OF DIVERGENCE

Interpretation of data: The types of data sought by regulators for environmental impact assessments are similar. The differences lie in the interpretation of the data and identifying what constitutes an environmental risk, and/or an environmentally damaging effect.

There is also divergence as to the *appropriate basis for comparison* for LMOs. Should this be comparison with present agricultural systems, and/or with baseline ecological data? Ecological data is not widely available as a basis for risk assessment.

Laboratory and field scale ecological studies: There is a lack of agreement as to the value of (small-scale) laboratory experiments, and their extrapolation from small-scale to large-scale effects. For example, Monarch butterfly larvae were reportedly damaged when exposed to pollen from Bt corn plants in laboratory experiments but subsequent field studies showed their populations were unlikely to be affected by Bt corn in the field *(Shelton and Sears, 2001; Zangerl et al. 2001).*

Monitoring of products post-release is important for environmental stewardships of new products, and to delay the development of resistance in the target pest population.

International harmonization of methodologies and standards: In contrast to food safety and human health, where the FAO/WHO *Codex Alimentarius* commission provides an international forum for developing food safety guidelines for GMOs for human consumption, there are no *internationally agreed guidelines and standards* for assessing the environmental impacts of LMOs.

GAPS IN KNOWLEDGE

Gene flow: Much debate continues to focus on gene flow between genetically modified crops and other species in the environment and on the extent to which this may lead to environmentally damaging effects, such as new weeds. To assess gene flow, when plants with which genes might be exchanged in the environment are present, more knowledge is often required on the biology and spatial location both of the LMOs and such plants. To assess the potential impacts of gene flow, the characteristics of the introduced genes and related altered traits have to be taken into account. Uncertainty about the implications of gene flow is more of a concern when there are wild relatives in the environment and most particularly when such wild relatives are within centres of diversity *(OECD 2001b).*

It is possible to construct databases of the biology and location of wild relatives, landraces and LMOs. Such databases can be used to identify areas where there is a high or a low probability of introgression following the release of LMOs, though the predictive ability of such systems for environments that have not been rigorously mapped needs to be further tested.

Many experts consider that gene flow *per se* is not harmful. However, relatively few empirical data are available on the long-term consequences of gene flow. Uncertainty about possible consequences of gene flow may be higher for these potential long-term effects than for short-term effects. Assessment of whether flow of particular genes affects fitness, for example, could be done step-wise, including prospective assessment of wild populations to determine likely selection pressures and head-to-head fitness comparisons of transgenic with non-transgenic populations. Assessment might also address whether mitigation measures could be appropriate and available *(OECD 2001b).*

Modelling, including the incorporation of data from geographical information systems may be useful to predict the likely behaviour of LMOs in different environments (*e.g.* to predict possible effects of gene flow and transmission of novel traits to local land races and wild relatives in centres of crop diversity).

International and/or regional harmonization of guidelines for assessing ecological impacts in different ecosystems is required. Soil ecosystems are the most complex in which to assess changes, and their significance.

Comparative analysis is required of new technologies in comparison with present agricultural practices and other technology options (*e.g.* Bt crops compared to pesticide use or organic agriculture).

Post-release monitoring of LMOs in the environment: Much data has been collected on the release of the first generation of GM crops in the environment (although mainly for a few crops and a limited number of traits in North America). Such data would be valuable if synthesized and made available to guide future regulation of GM crops.

Ecological research may require additional support by national governments and international agencies in their efforts to develop methodologies and undertake field studies on the environmental impact of GM crops. These assessments should be undertaken using participatory approaches so as to involve local communities in the evaluation of the risks and benefits of new technologies. Additional data could then feed back into risk assessments, so as to inform future decisions on the decisions on the appropriate technology choices in addressing specific problems, including the development and management of genetically modified crops for agricultural purposes.

The International Organization for Biological Control (IOBC) is developing a series of guidelines for ecological research on GM crops and other LMOs in the environment. The draft guidelines are presently being evaluated in different regions, for their applicability in different environments.

Issue 4. Characterization and utilization of biodiversity

Biotechnology can contribute to the characterization of biodiversity, through the use of molecular markers. The better characterization of biodiversity may lead to its improved conservation and utilization of biodiversity through greater understanding of the range and location of diversity within a species.

Gaps in knowledge

Functional genomics for gene discovery: New discoveries in functional genomics are being used to identify useful genes within species, and to understand how better to regulate theses genes to control useful traits. This approach will place more emphasis on the control of genes already existing within species rather than on inter-specific gene transfers, especially those that require gene movement amongst distantly related species.

Molecular finger-printing of genetic resources collections is a tool that could be used to characterize all the accessions in the international gene banks, such as those held in trust by the CGIAR centres. This additional genetic data would provide a molecular passport for each accession, to accompany its taxonomic description, and the geographical location where it was originally collected.

Also, molecular fingerprinting of collections would enable them to be monitored for any inadvertent introduction of novel genes. For example, Bt genes from commercial corn have been detected in land races of corn in Mexico, its centre of diversity. There has been much debate as to whether these genes may also be found in the maize genetic resources collection held at the International Center for Maize and Wheat Improvement (CIMMYT) in Mexico. The availability of molecular fingerprints for all accessions would facilitate the resolution of these issues.

Table 4.1. *Implications of Gene Technology for Biodiversity and the Environment*

Issue	Scientific Convergence	Scientific Divergence	Gaps in Knowledge
Issue 1. Direct effects **Plants** *Gene transfer*	*Does it happen?* Gene movement possible by pollen from open-pollinated crops crossing with local landraces and/or related wild species, to form hybrids.	*Does it matter?* If crop/wild relative hybrids survive, reproduce and introgress genes back into native plant populations that then cause adverse environmental effects.	If hybrids survive, do introduced traits have any negative environmental consequences? Limited long-term experimentation on this.
	Crops vary in their extent of out-crossing. The presence of wild and/or weedy relatives depends on whether the crop is cultivated close to center of diversity. (*CGIAR 2000b; EEA 2002)*	Uncertain if genes /traits moving from GM crops pose any new environmental risks or threats to biodiversity (*e.g.* maize in its center of diversity in Mexico)	Most research on gene flow in Europe. Little known about gene flow, and possible movement of traits from world's major food crops to land races and wild relatives in their centers of diversity.
Weediness	Low risk of domesticated crops becoming weeds themselves (based on history of safe use of crop plants).	Risk that GM crops/traits may escape from cultivated fields and if their traits are transferred into related wild species and form hybrids, these may survive to become weeds. Little evidence that this occurs in practice.	
Specific trait effects on non-target species	Pesticidal plants (expressing toxins, such as Bt toxin) may affect related non-target species, as well as target pests. Need to compare genetic effects on non-target species with present agricultural practices (*e.g.* pesticides, IPM, organic production).	Laboratory studies showed Bt corn may harm Monarch butterflies if pollen ingested at high dosage. Subsequent field studies showed most presently cultivated strains of *Bt* corn pose little risk to Monarch butterflies in field. *(Plant Journal 2002; Pew 2002; Zangerl 2001; Sears 2001)*	Difficult to extrapolate from laboratory studies to field. Need to develop better methods for field ecological studies, including base-line data with which to compare new interventions. *(Dale 2002; IOBC 2002)* *Ecological monitoring desirable post release, to detect any unexpected events. (US NRC 2000; US NAS 200).*
Unintended effects	Possible (also occurs through conventional breeding).	Extent of risks varies; need environmental impact assessment on a case-by-case basis.	Greater availability of monitoring data from presently cultivated GM crops (60m ha / 16 countries) would add to knowledge base *(OECD 2001b)*
Issue 2. Indirect effects through changing agricultural practices *Pesticide use*	Demonstrated reduction in pesticide use on GM crops with Bt genes (*e.g.* Bt cotton in USA, China, South Africa, Australia; Bt corn in USA). *(CAST 2002, NCFAP 2002, ISAAA 2002a, Pray et al 2002)*		
Herbicide use	Herbicide use changing, in volume and type(*e.g.* herbicide tolerant soy bean)	Risk of developing herbicide tolerant weeds and/or excess herbicide use. Herbicide tolerant crops encouraging low-till agriculture, with resulting benefits to soil conservation.	
Pest resistance	Risk that pests may develop resistance to GM crops. Important that GM crops deployed with resistance management strategy to avoid boom-bust cycle of pest resistance.	Intensive risk management strategies may be difficult to implement in emerging economies.	Appropriate resistance management strategies need to be developed for various ecologies, including tropical environments. *(OECD2001b)*
Abiotic stress tolerance *Drought tolerance* *Salinity tolerance*	Tolerance to abiotic stresses theoretically possible. Such applications may not be environmentally desirable in all instances.	May be environmentally beneficial or damaging, depending on the specific application and environment.	Need to monitor unintended effects
Crops with pharmaceutical uses (*e.g.* vaccines)	Experimentally possible to produce vaccines against certain pathogens (*e.g. E.coli*) in plants (*e.g.* potatoes, bananas)	May be difficult to keep crops out of the food chain. Needs monitoring.	Need regulatory framework
Crops with industrial uses (*e.g.* plastics)	Experimentally possible, *e.g.* maize	Need to keep industrial crops out of the food chain	Need regulatory framework

5. Regulatory Issues

Key Documents

A recent review by *Nap et al.* (2003) in the online publication, *The Plant Journal,* gives an excellent overview of the current regulatory approaches worldwide. Several recent national reviews were charged with advising governments on ways to improve their national regulatory systems *(e.g. Australia, 2000; The Royal Society of Canada, 2001; Canadian Biotechnology Advisory Committee, 2001, 2002; New Zealand, 2001; The Royal Society, UK, 2002; National Academy of Sciences, USA, 2000, 2002).* Other international and inter governmental agencies are concerned with promoting regulatory harmonization, regionally (*e.g.* EC 2001; 2002) and internationally *(e.g. FAO/WHO 2000, 2001a,b; OECD 2000b; OECD 2001a,b).*

There are several issues relating to the persistence of transgenic fish in the environment and the effects they may have on wild fish populations. These need to be resolved before any transgenic fish can be released into the environment *(Pew 2003).*

Areas of Convergence

Principles: There is broad agreement that regulatory systems need to be science-based, transparent, and involve community participation, and that safety assessments should be undertaken on a case-by-case basis, using the best available scientific techniques.

Regulatory processes also need to be sufficiently flexible and robust so as to be able to detect early warning of changing circumstances. Recent instances of food safety problems in several countries highlight the need for continuing vigilance in ensuring that foods brought to market are safe to eat, irrespective of their source and production methods. These foods may come from conventional or subsistence agriculture, organic agriculture and/or the cultivation of GM foods and crops.

Regulatory systems for the applications of modern genetics in food and agriculture are based broadly on assessing the safety for human health and the environment of either the *product* or the *process* by which it is produced, or a combination of the two approaches.

A comparison of the food safety regulations for genetic alteration of food crops in selected countries is shown in *Table 5.1.*

Similarity of data sets: Different regulatory systems base their assessments on similar sets of data requirements concerning the organism, insert, trait and environment. Though there is variability between the details of risk assessments, the issues that they address are common across many countries *(OECD 2001b).*

For plants, produced with the aid of gene technology, the type of information sought by regulators for making their risk assessments prior to environmental release is similar, whether the regulatory approach is *product based or process based (Table 5.2).*

Biosafety framework: The Cartagena Protocol on Biosafety lays down a methodology for risk/safety analysis including a number of systematic steps and a list of points to consider in relation to the possible impact of living modified organisms (LMOs) on biodiversity. A current project financed by the Global Environment Facility, and implemented primarily through the United Nations Environment Program (UNEP) is assisting many countries in implementing biosafety systems that conform to the requirements of the Cartegena Protocol of the Convention on Biological Diversity (CBD) *(ISNAR 2002a).*

Areas of Divergence

Although the data sought by regulators are similar, their interpretation in risk assessment and management differs amongst countries and regions. The substantive differences come as to the level of risk regulators consider will be acceptable for a given society. Since biological systems do not deliver certainty, zero risk for any new technology is an unattainable standard.

Managing uncertainty: There remains a difference of view in how to cope with uncertainty in risk assessments. One approach is where risk management might be applied in advance of assessment, so that risks which, based on current scientific knowledge, could not be assessed rationally are simply avoided. A number of countries apply such a *precautionary* approach. Others believe that it is not possible to manage risks that cannot be assessed rationally and that governments should focus on assessing and managing identifiable risks *(OECD 2001b).*

Extent of risk assessments required: Other regulators consider that the extent of risk assessments should be proportionate to the degree of risk involved, and that this can be determined when the new product/process is compared with its conventional counterpart with which there is some familiarity. This approach of regulating the product, and assessing its degree of familiarity or difference with present products is the basis of the regulatory system in the USA.

Comparative risk assessments: Other issues that remain under debate are whether assessment of risk and uncertainty should be applied primarily to new technologies or should also be applied to conventional agricultural practices *(OECD 2001b; US NAS 2002).* Others consider that both the risks and benefits of new technologies need to be considered, in comparison with present agricultural practices.

Hazard identification: While the likelihood of harm is a function of both hazard and exposure, the public debate is dominated by hazard identification, often neglecting issues such as exposure and the likelihood of harm, an evaluation of the final consequence and a comparison with the present situation. The coverage of potential harm to the Monarch butterfly by Bt maize is an example of this focus on hazard identification *(Pew 2002; Shelton and Sears 2001).*

Gaps in Knowledge

Most regulatory systems agree on the need to continually improve risk assessment methods, making use of new scientific developments, so they keep abreast of emerging products and processes. Regulatory systems also need to be sufficiently flexible so as to respond to accumulating experience in the behaviour of new products once they are in widespread use.

Improving food safety assessments: There is a need for continued development of *food safety assessments methods*, so as to assess the safety of future products that may be the result of more complex genetic modifications (*e.g.* foods with modifications to their nutrient content). For example, new scientific developments in areas such as metabolomics and proteomics may enable the content of whole foods to be assessed, thus improving on the present concept of *substantial equivalence* whereby a limited number of targeted compounds are compared between the new product and its conventional counterpart food. These scientific developments will also enable better monitoring of any *unintended changes* in the content of foods that may result from genetic modification. Such changes may occur either by conventional breeding or gene technology.

Improving environmental assessments: One of the areas where there is most debate is on the methods used to assess environmental impact, and on what constitutes an adverse environmental impact. One approach is to compare GMOs with organisms produced using more traditional breeding techniques. Some of the outstanding issues in assessing environmental impacts are the lack of reliable baseline data, the relevance of extrapolation from small- to large- scale use, and from the laboratory to the field, ability to detect rare events within a relatively short experimental time scale, lags between introduction and manifestation of environmental impacts and the lack of knowledge about the complexity of ecosystems, including soil ecosystems. Assessment of the impacts of GMOs on non-target organisms needs to reflect the complexity of different environments, and the need for comparison with other agricultural practices.

Centre of diversity data: Risk assessments of genetically modified crops have focused mainly on agronomic characteristics in temperate regions. Comparative risks and benefits of the introduction of LMOs with alternative cultivation methods need to be assessed on a case-by-case basis, taking into account regional agricultural practices and, where appropriate, socio-economic considerations. Baseline data required for environmental impact assessment, including information on native species and existence of sexually compatible wild relatives of agricultural crop plants are limited in centres of crop diversity (*OECD 2001b*).

Ecological experimentation: In ecological impact assessments, it is difficult to extrapolate from small-scale field trials to commercial-scale cultivation. Countries have taken a number of approaches to dealing with this issue. In the UK, the approach has been to hold farm-scale field trials that address scale, and integrate regional cultivation practices and farmer behavioural issues. The cost of these issue-targeted farm-scale field trials may be prohibitive for routine assessments of impacts of individual LMOs. Regulatory requirements may impose a cost barrier for development of minor crops or those important in the developing world.

Towards Coexistence of Different Agricultural Systems

One of the future challenges is devising ways and means, including standards, for different forms of agriculture to be able to live together in areas of multiple land use. This is particularly challenging for farmers practising broad scale agriculture and/or organic agriculture. For example, research commissioned by the EC over the past 15 years is giving guidance to ways to minimize gene flow from crop to crop and from crops to wide relatives *(Eastham and Sweet, EEA 2001).* Different crop species have different rates of autogamy (self-pollination) and out-crossing. In addition, some crops have hybridising wild relatives in Europe while others do not. The characteristics of the main crop types crops when cultivated in Europe are summarized in *Table 5.3.*

Unintended gene flow can be minimized by spatial and temporal barriers (with guidance as to the necessary distance between crops); by selecting crops with low risks of gene flow outside the crop, either because they are not out-crossing species, or there are no related or wild species in the vicinity; and/or by targeting gene expression to certain parts of plants (*e.g.* leaves) and having no target gene expression in pollen.

Risks of Regulation

Regulation can itself be a risk and a benefit for new technology development. The products of modern genetics in agriculture are regulated more stringently than their counterparts coming from traditional breeding programs or the products of other production systems such as organic agriculture.

The cost, complexity and uncertainty of regulation in new genetics is making regulatory requirements one of the barriers to entry for public research institutes, poor countries and small companies. This has long been the case in the pharmaceutical and agrochemical sector. It is becoming the case in the seed sector as well. This is increasing the trend for future investments to concentrate on those products with likely commercial value where the costs of regulation will be built into the price of the product. Less investment will be available for generating public goods, including those of possible value in emerging economies. Biosafety regulatory requirements are limiting the choices for the use of new genetics to improve agriculture in emerging economies.

However, there remains a lack of public confidence in the regulatory systems in some countries and this is one of the drivers behind the increasing stringency of regulation. This raises the issue of what more needs to be done to improve public confidence in the regulatory and post-approval stages of the release of genetically modified organisms into the environment.

Further science-based case studies that compare the risks, benefits and regulation of crops developed through new genetic technologies with similar crops cultivated under intensive agricultural practices and/or organic agricultural practices, would be useful to illustrate the relative merits of different approaches and various scenarios.

International Harmonization of Regulations

Setting standards and regulatory harmonization: The FAO/WHO sponsored intergovernmental commission, *Codex Alimentarius,* is playing an important role in setting internationally agreed guidelines and standards for the safety of genetically modified foods for human consumption

(FAO/WHO 2000, 2001a,b). No comparable internationally agreed guidelines and standards exist for evaluating the environmental safety of living (genetically) modified organisms. The Cartegena Protocol of the Convention on Biological Diversity (CBD) provides an intergovernmental forum amongst the parties to the Convention for assessing the impacts of living modified organisms (LMOs) on biodiversity, one component of the environment. A broader forum is needed to enable the development of internationally agreed standards for comprehensive environmental impact assessments of the risks and benefits of new genetics in agriculture. FAO, UNEP and other international agencies could play an important convening role here, supported by the scientific community, in developing internationally agreed guidelines and standards for assessing the environmental impact of living modified organisms.

Table 5.1 *Comparison of food safety regulations for genetic alterations of food crops*
Source: Kuiper et al. (2001)

		Gene alterations[a]				
Nation	**Legal act**	Insertion of genes (general)	Insertion of genes coding for previously approved gene products	Insertion of genes from same plant species (self-cloning)	Cross between approved transgenic lines	Mutation breeding and somaclonal variation (non GM)
Australia [b]	ANZFA Food Standard A18	+	–	+	– [c]	–
Canada [d]	Food and Drug Act	+	+	+	(+)	+
EU [e]	Regulation 258/97/EC	+	+	+	+	(+)
Japan [f]	Food Sanitation Law	+	+	–	+	–
New Zealand [b]	ANZFA Food Standard A18	+	–	+	– [g]	–
USA [h]	FFDCA	+	–	(+)	(+)	(+)

a. +, To be evaluated; (+), should be evaluated unless substantially equivalent; –, evaluation not required.
b. ANZFA, Australia-New Zealand Food Authority: ANZFA (1998).
c. Notification required: OGTR (2001).
d. Health Canada (1994).
e. EU (1997a); EU (1997b); EU (1990).
f. MHW (2001).
g. The New Zealand Hazardous Substances and New Organisms Act 1996 does not specifically provide for the breeding of approved genetically modified plant lines; however, the Australian Gene Technology Act 2000 does allow for this as "dealings" with GMOs: Australia (2000); New Zealand (1996).
h. FFDCA, Federal Food, Drug, and Cosmetic Act: FDA (1992); Maryanski (1995).

Source: Kuiper et al. (2001) in Plant Journal 2001

***Table 5.2** Typical information required for assessment of environmental release of GM plants**

General information

1. The name and address of the applicant
2. The title of the project

Information relating to the parental organism

3. The full name of the plant: family, genus, species, subspecies, cultivar
4. Information on the reproduction of the plant: mode, generation time and sexual compatibility with other cultivated or wild plant species
5. Information on the survivability of the plant: survival structures, dormancy etc.
6. Information concerning dissemination of plant: means, extent and factors affecting dissemination
7. The geographic distribution of the plant
8. If the plant species is not normally grown in Member States, describe the natural habitat
9. Information on any significant interactions of the plant with organisms other than plants in the ecosystem where it is usually grown, including toxicity to humans, animals and other organisms

Information relating to the genetic modification

10. A description of methods used for genetic modification
11. The nature and source of the vector used
12. The size, function and donor organism(s) of each DNA sequence intended for insertion

Information relating to the genetically modified plant

13. A description of the trait(s) and characteristics of the GM plant which have been modified
14. Information on sequences inserted or deleted: size/structure, copy number of insert, information on any vector sequences or foreign DNA remaining in the GM plant. The size/function of any deleted regions. Cellular location of insertion (*e.g.* chromosomal, mitochondria, chloroplast etc.)
15. Information on the expression of the insert: expression and parts of the plant where expressed
16. How does the GM plant differ from the recipient plant in mode/rate of reproduction, dissemination, survivability
17. The genetic stability of the insert
18. The potential for transfer of genetic material from the GM plants to other organisms
19. Information on any toxic/harmful effects on human health and the environment arising from the genetic modification
20. The mechanism of interaction between the GM plants and target organisms
21. Any potential significant interactions with non-target organisms
22. A description of detection and identification techniques for the genetically modified plants
23. Information about previous releases of the GM plants

Information relating to the site of release

24. The location and size of the release site or sites
25. A description of the release site ecosystem, including climate, flora and fauna
26. Details of any sexually compatible wild relatives or cultivated plants present at the release sites
27. The proximity of the release sites to officially recognized biotopes or protected areas

Information relating to the release

28. The purpose of the release
29. The foreseen dates and duration of the release
30. The method by which the GM plants will be released
31. The method for preparing and managing the release site, prior to, during, and after the release
32. The approximate number of GM plants (or plants per m^2) to be released

Information on the control, monitoring, post-release plans and waste treatment plans

33. A description of any precautions to minimize or prevent pollen or seed dispersal from the GM plant
34. A description of the methods for post-release treatment of the site or sites
35. A description of post-release treatment methods for the GM plant material including wastes
36. A description of monitoring plans and techniques
37. A description of any emergency plans

Information on potential environmental impact of the release of the genetically modified plants

38. The likelihood of any GM plant becoming more persistent or invasive than recipient plants
39. Any selective advantage or disadvantage conferred to other sexually compatible plant species, which may result from genetic transfer from the genetically modified plant
40. Potential environmental impact of the interaction between the GM plant and target organisms
41. Any possible environmental impact resulting from potential interactions with non-target organisms

* *Prescribed questions from Schedule 1 of the 1995 Regulations for the Deliberate Release of GM Higher Plants of the UK. Source: Nap et al., 2003. In Plant Journal 2003*

Table 5.3. *Frequency of gene flow from out-crossing in selected crops in Europe*

Crop	**Frequency of gene flow from out-crossing**	
	Crop to crop	**To wild relatives**
• Oilseed rape	High	High
• Sugar beet	Medium to high	Medium to high
• Maize	Medium to high	No known Wild Relatives
• Potatoes	Low	Low
• Wheat	Low	Low
• Barley	Low	Low
• Fruits – strawberry, apple, grapevines and plums	Medium to high	Medium to high
• Raspberries, blackberries, blackcurrant	Medium to high	Medium to high

Source: Eastham and Sweet, EEA, 2002

6. Effects on Emerging Economies and Trade Implications

Overview

The United Nations 2001 Human Development Report analysed the opportunities and the risks emerging from new technology developments in the biosciences, information and communications, and how these may be mobilized for the benefit of people in poor countries. The report concluded that there is an explosion of technological innovation in food, medicine and information, which, if harnessed effectively, could transform the lives of poor people.

The UNDP report further concluded that the challenge the world faces is to match the pace of technological innovation with policy innovation both nationally and globally. Without innovative public policy, these technologies could become a source of exclusion, not a tool of progress. The needs of poor people could remain neglected and new global risks left unmanaged. Yet, if managed well, the rewards could be much greater than the risks and deliver real benefits to poor people. The main findings of the UNDP report are summarized in *Box 6.1.*

Key Documents

Several reviews of the implications of new developments in modern genetics for emerging economies agree that no single strategy is likely to be suitable for all countries, given the range of variation in country size, economic development, strength in science and technology, importance of the rural sector, extent of poverty, and issues in food security *(e.g. ADB, 2001; Academies of Science, 2000; CGIAR 2000a, b; DANIDA, 2002; IDB 2002; IFPRI, 2001; ISNAR 2002b; UNDP 2001.)*

However, there are several elements that need to be taken into account in developing strategies that make optimal use of new developments in technology, as part of overall approaches towards reducing poverty, increasing food security, conserving natural resources and improving trade competitiveness for emerging economies. The appropriate mix of these elements will depend on the situation in a particular country.

Elements of Future Strategies

Policy dialogue is needed with governments as to the importance of the rural sector, the need for public investments in rural development, including investments in the development of public goods for poor people and the need for governments to provide an enabling framework that encourages private sector investments in rural areas.

Priority species: The continued availability of sufficient nutritious food at affordable prices for poor people is an essential component in ensuring food security and reducing poverty in the developing world. Twelve species provide over 90% of the world's food. These twelve *(banana, barley, cassava, groundnut, maize, oilseed rape, potato, rice, sorghum, soy bean, sweet potato, wheat)* include the staple foods of the majority of the world's population and provide almost all the food for the world's poor people. There is also increasing demand for livestock, fish and forest products, as important sources of food and income.

While recognizing that other species also play important roles at a regional and sub-regional level, these key species could provide an initial set of priorities to assess how their productivity could be improved in different environments through the applications of modern genetics.

Priority traits to address food security and poverty reduction: Future food security will require producing more food on less land with less water, and with less reliance on chemical pesticides and fertilizers. This will require crops that are able to make more efficient use of water and tolerate abiotic stresses, such as drought and salinity that reduce productivity in marginal lands. Pests, weeds and diseases also cause substantial pre- and post- harvest losses and the use of chemical pesticides for their control is both costly and environmental damaging. Improving the nutritional quality of staple foods would also help address the problems of malnutrition especially important in women and children.

Examples of the traits that could enhance food security and reduce poverty are:
- *Drought tolerance,* especially in maize, rice and wheat that lack the inherent drought tolerance of sorghum and millets
- *Pest and disease resistance,* especially for those pests and diseases that are presently controlled by the use of pesticides
- *Post-harvest quality* to extend the shelf life and reduce post-harvest losses of perishable commodities (*e.g.* banana, cassava, potato, sweet potato)
- *Improved nutritional quality* (*e.g.* improving vitamin and mineral content of cereals)
- *Apomixis,* an enabling trait that would enable seed to breed true (*e.g.* cassava)

Investment priorities: In order to maximize the benefits that may be gained from public and private investments in biosciences in emerging economies, it is important to identify and invest in the priority species and the traits that would be most valuable to poor people living in different environments, rather than relying on spillovers of technologies developed primarily for other purposes elsewhere. There is also a need for identifying those priorities that require additional public investments and/or public-private partnerships for their development. There is also a need to link research efforts with the development and delivery of new products that will make a difference to food security and poverty reduction in specific cases.

Enhancing present applications in agriculture: Discoveries in genetics and related sciences are contributing to improving the productivity and sustainability of agriculture today in many countries. Wider use could be made of such practical applications of plant biotechnology in emerging economies; for example by enabling:
- More targeted selection objectives and the use of molecular markers to enable early generation selection in breeding of improved strains
- The molecular characterization of genetic resources
- The improved diagnosis and management of parasites, pests and pathogens by the use of molecular diagnostics
- Use of improved micro-propagation techniques to develop clean planting materials, especially for vegetatively propagated crops

Smarter plant breeding: To fully realize the benefits of modern genetics, there needs to be viable plant breeding/crop improvement programs at the national and international levels that are able to develop locally adapted varieties with desirable traits. There also needs to be seed sectors able to produce and deliver quality seed of improved crop varieties to farmers. Regretfully both plant breeding and the seed sector are weak in many countries where food security is most at risk. The key targets for breeding in selected crops in Africa are summarized in *Table 6.1 (De Vries and Toenniessen 2001; ISNAR 2002b).*

More targeted public investment is required in modern plant breeding, nationally and internationally, to develop the public goods that will not come from private investments in plant biotechnology and plant breeding. Private investments are primarily concentrated on developing products for markets in industrial countries.

Seed sector: Countries need to have a suitable enabling environment to encourage the development of the private seed sector. This includes suitable intellectual property management, such as plant variety protection or other *sui generis* systems.

Cultivation of transgenic crops: Some countries are exploring the options for the targeted introduction of transgenic crop varieties. The present applications of transgenic crops in emerging economies are largely locally adapted spillovers of technologies developed for broad scale agriculture elsewhere, with traits for insect resistance and herbicide tolerance being most widely available. The most widespread transgenic product in emerging economies is cotton modified for insect resistance (Bt cotton), which is being cultivated by some 5 million cotton farmers in China, and a smaller number in South Africa. Bt cotton has demonstrated economic, social, human and environmental health benefits that have been documented in China and South Africa (*Prey et al. 2002*).

Importance of genomics for gene discovery: New developments in genomics are seen as the basis for future gene discovery. It is important that the basic information on the genome structure of the world's staple crops and other agriculturally important species is available in the public domain, able to be used for studying the function of genes, and understanding their role in the control of important traits. This is critical for addressing the constraints in those species and/or traits in which the private sector is unlikely to invest.

State of the genomes: There is a need for a systematic assessment of the status of the genomic information of the world's major food species, who is generating genomic data, who has access to the data, who has the capabilities to use the data in future crop and livestock improvement and what additional investments are required. Such an assessment may provide the basis for ensuring that the genomes of the world's major food species are molecularly mapped, and that this information is available to those concerned with improving the use of these species for food security and poverty reduction.

Capacity building: Many people from emerging economies have been trained in various aspects of genetics and biotechnology. A large proportion, perhaps more than 50%, are no longer working in their home countries, largely due to lack of career opportunities, poor infrastructure and limited financial resources for R&D. More support to these scientists would enable more to continue working in their own countries while also enabling them to have access to the latest developments worldwide through modern communications technology (*UNDP 2001*).

Biosafety and regulatory systems: Substantial multilateral and bilateral resources are being directed towards building capacity in biosafety and establishing regulatory systems to manage the products of biotechnology in emerging economies, especially genetically modified organisms (GMOs). These programs are designed to help countries meet their obligations under the Convention on Biological Diversity and its Cartagena Protocol on Biosafety (*e.g.* UNEP/GEF programs)*(ISNAR 2002a).*

These efforts on building capacity in biosafety need to be complemented by assessments of the risks and benefits of specific applications of biotechnology, including but not restricted to genetically modified organisms. These assessments may include the preparation of *dossiers on potential products* that summarize the data and other information needed by regulatory authorities to make informed decisions.

There is also a need for harmonization of guidelines, legislation and best practices for the regulation of the safe use of biotechnology in agriculture and the environment. This may best be done initially at the regional and sub-regional level where the benefits of regulatory harmonization are most evident.

Trade implications of biotechnology policies and regulations for emerging economies: Biotechnology's most important contributions in emerging economies may be allowing the expansion of production of major crops without increasing the pressure on fragile environments. It is also likely to be important in increasing opportunities for agro-industrialization that may arise from increased production and diversification of crops (*IDB 2002*).

Biotechnology also holds potential for improving the competitiveness of agricultural production in world markets, as well as reducing the incidence of urban and rural poverty, since the nutritional and income status of the poor are highly dependent on the efficiency of staple food crop production *(IDB 2002).*

However, in order for developing countries to realize these benefits, an increasingly important policy issue is the effect that restrictive regulatory regimes for genetically modified organisms are having on emerging economies. Some countries are not pursuing the use of new technologies in agriculture; even for producing more food for domestic consumption, in case this affects their access to present or future export markets for other products.

***Table 6.1** Demands for improved breeding of seven African crops*
Source: De Vries & Toenniessen 2001

Maize	Sorghum	Pearl millet	Rice	Cowpea	Cassava	Banana
Drought resistance	Resistance to downy mildew	Resistance to downy mildew	Drought tolerance	Virus resistance	Early bulking, stress resistant varieties	Development of Sigatoka and Fusarium resistance
Nutrient use efficiency	Phosphorous acquisition efficiency	Resistance to low phosphorous soils	Increased national breeding capacity	National breeding programmes	Improved root quality	Identification of useful markers for breeding applications
Multiple resistance to foliar diseases and ear rot	Insect resistance	Resistance to head miners	Increased understanding of rice agro-ecologies	Insect resistance	Improvement to mid-altitude	Multi-location testing for improved varieties
Resistance to stem borers	Resistance to anthrax-cnose	Development of non-traditional hybrids	Rapid deployment of line with resistance to major pests	Transformation and gene expression systems	Pest and disease resistance	Further research on banana streak virus
Post-harvest resistance to insect pests	Pest/disease complexes	Bird resistance	Increased capacity in molecular breeding	Identification of resistance genes	Decentralization of cassava breeding programmes	
Striga resistance	Striga resistance	Striga resistance		Improved nutritional characteristics	Improved nutritional characteristics	
	Heterosis in adapted materials Seed systems	Study of farmer varietal preferences		Gene flow studies	Characterization of cassava breeding environments	

Box 6.1 *Conclusions of the UNDP Human Development Report 2001 (UNDP 2001)*

1. The technology divide does not have to follow the income divide. Throughout history, technology has been a powerful tool for human development and poverty reduction.
Investments in technology, like investments in education, can equip people with better tools and make them more productive and prosperous. Technology is a tool, not just a reward, for growth and development.

2. The market is a powerful engine of technological progress, but it is not powerful enough to create and diffuse the technologies needed to eradicate poverty.
Technology is created in response to market pressures, not the needs of poor people, who have little purchasing power. As a result research neglects opportunities to develop technology for poor people. Inadequate financing compounds the problem. Lack of intellectual property protection can discourage private investors.

3. Developing countries may gain especially high rewards from new technologies, but they also face especially severe challenges in managing the risks.
Consumers in countries with no food security problems tend to focus on food safety and environmental concerns. Farmers in developing countries tend to focus on increasing food production and reducing input costs. While some risks can be assessed and managed globally, others must take into account local considerations. Environmental risks are often specific to individual ecosystems and need to be assessed case-by-case. Technology-related problems are often the result of poor policies, inadequate regulation and lack of transparency. Lack of skilled personnel can constrain a country's ability to create a strong regulatory system. The cost of establishing and maintaining a regulatory framework can also place a severe financial demand on poor countries.

4. The technology revolution and globalization are creating a network age and that is changing how technology is created and diffused.
Two simultaneous shifts in technology and economics are combining to create a new network age. It also encourages migration of skilled workers, which generates a diaspora that can provide valuable networks of finance, business contacts and skill transfer for the home country.

5. Even in the network age, domestic policy still matters. All countries need to implement policies that encourage innovation, access and the development of advanced skills.
Not all countries need to be on the cutting edge of global technological advance but every country needs the capacity to understand and adapt global technologies for local needs. In this environment the key to a country's success will be unleashing the creativity of its people.

6. National policies will not be sufficient to compensate for global market failures. New international initiatives and the fair use of global rules are needed to channel new technologies towards the most urgent needs of the world's poor people.
The lesson is that at the global level it is policy, not charity, which will ultimately determine whether new technologies become a tool for human development everywhere.

7. Ethical Issues, Public Perceptions and Communications

Ethical Issues

Many peoples' concerns about modern genetics are based on ethical issues and the values inherent in particular societies. The Nuffield Council on Bioethics has examined the ethical issues that are raised by the development and application of GM plant technology in world agriculture and food security. Its perspective on GM crops was guided by consideration of three main ethical principles: the principle of general human welfare, the maintenance of people's rights and the principle of justice. Some of these considerations, such as the need to ensure food security for present and future generations, safety for consumers and care of the environment were considered to be straightforward and broadly utilitarian. Others, stemming from the concern that GM crops are 'unnatural', are more complex.

The Nuffield Bioethics Working Party accepted that some genetic modifications are truly novel but concluded that there was no clear dividing line which could prescribe what types of genetic modification were unacceptable because they were considered by some to be 'unnatural'. It took the view that the genetic modification of plants does not differ to such an extent from conventional breeding that it is in itself morally objectionable. GM technology does, however, have the potential to lead to significant changes in farming practices in food production and in the environment (*Nuffield Council on Bioethics 1999*).

The Nuffield Bioethics report further concluded that GM crops represent an important new technology that ought to have the potential to do much good in the world provided that proper safeguards are maintained or introduced. All those who are involved in developing the new technology, whether they are researchers in the public sector, in agrochemical or agricultural businesses or farmers, or food manufacturers and retailers need to recognize and accept a broad responsibility to the public. They need to ensure that ethical concerns are taken account of, that their new technologies and products are safe for human consumption and avoid further harm to the environment, that the potential of GM technology is harnessed to meet the most urgent food needs of the world as well as commercial benefit, that impartial information is made widely available to the public and that consumer choice is fully respected. The Nuffield Council on Bioethics is presently examining the ethical issues further, as they relate specifically to the applications of modern genetics in developing countries.

Other studies that considered the ethical issues associated with the applications of modern genetics in human health, agriculture and the environment have been undertaken by the Pontifical Academy of Sciences, and their findings on Science and the Future of Mankind have been published by the Vatican (2001). The Pontifical Academy makes several recommendations in relation to the challenge of world hunger, the potential contributions of genetically modified food plants, and the conditions for the beneficial use of this new technology. The study expresses the concerns of the scientific community about the sustainability of present agricultural practices and the certainty that new techniques will be effective. It also stresses the need for the utmost care in the assessment and evaluation of the consequences of each possible modification. The study also expresses concern about excesses with regard to the establishment of intellectual property rights in relation to widely-used crops, which could be detrimental to the interests of developing countries. It also recommends that the examination of the safety of newly-developed cultivars should be based on well-documented methods and that the methods and results should be openly discussed and scrutinized by the scientific community.

The Pontifical Academy of Science also recommends the greater involvement of the international scientific community, through its worldwide umbrella organizations, in facilitating the beneficial use of GM food crops to combat hunger and to facilitate the development of common standards and approaches in both developing and industrial countries (*Vatican 2001*).

Public Perceptions and Communications

The scientific knowledge and experience accumulated in managing the potential or perceived risks associated with the applications of modern genetics and biotechnology in agriculture has not calmed public disquiet. Some uncertainty persists with respect to the long-term impacts of GM food and of both the short- and long-term environmental effects and ecological interactions of LMOs, particularly in tropical regions. This implies a need to keep current concepts and practices for risk assessment, management and monitoring under regular, open review and revision. While it is not possible to guarantee total elimination of risk, potential risks must be assessed and managed safely, and in ways that inspires public confidence in regulatory systems.

This implies that public concerns must be addressed and that the policy and regulatory processes need to be transparent and participatory. Continuing efforts need to be made by regulatory authorities to engage public opinion, to elicit the views of a wide range of stakeholders and to ensure that stakeholders' views are taken into account in the decision-making and the policy processes. A growing number of efforts are now being made worldwide to engage public opinion and to stimulate dialogue among all interested parties, including: members of civil society, governments, scientists, regulators, farmers, the biotechnology industry and the media.

8. Future Perspectives

The science underpinning developments in modern genetics is not informing the public in a manner commensurate with the volume and quality of the scientific data and analysis available. The scientific community could play a more active and better organized role in raising public awareness about emerging genetics and what it means for different societies, in terms of choices, risks and benefits.

Much data has been generated over the past decade on the behaviour of genetically modified organisms in various environments. It would be helpful to guide future regulatory decisions if more of this data was made publicly available. For example, there is a wealth of data that has come from the monitoring of the commercial cultivation of genetically modified crops over the past several years. In 2002, there was approximately 60 m ha of genetically modified crops cultivated in 16 countries.

Additional, publicly funded research that addresses key gaps in present knowledge would be valuable to inform the debate about the use of modern genetics. The value of this research may be increased if the key questions are framed in an "authorizing environment" that reflects the concerns of the public, policy-makers and politicians, nationally and internationally.

In the regulatory area, additional research is necessary to assist in the continued development of regulatory approaches that keeps abreast of new scientific developments. For example, there is a need for the continued development of food safety assessment methods, to deal with emerging products such as nutritionally enhanced foods and other complex traits controlled by multiple genes. There is also a need for the development of internationally agreed standards for the assessments of environmental risks and benefits of genetically modified organisms.

The broad range of applications in modern genetics in agriculture could contribute more towards improving the efficiency and sustainability of agriculture in emerging economies. Currently available applications of new genetics could improve the efficiency of plant breeding; develop new diagnostics and vaccines for the control of pests, parasites and diseases in crops, trees, livestock and fish; and generate disease-free planting material, with substantial increases in productivity.

Genetically modified crops also offer promise to contribute more towards food security and poverty reduction. New varieties of crops with useful traits may result from public or private investments or, increasingly through public/private partnerships, which offer much promise for addressing the problems in emerging economies in which private companies would not normally invest. However, the successful deployment of new products will require public acceptance of new products; an enabling policy and regulatory environment, including safety assessments and intellectual property management; investments in research and development; and local private sector development for distribution and marketing of seeds and other new products.

ETHICS, VALUES AND CHOICES

Science is a creative enterprise, in which the ethics and values of individuals and societies play an increasingly important role in determining what are publicly acceptable and unacceptable uses of new knowledge. The choices these ethics and values imply differ in different societies. It is important that the values of one society or groups therein are not imposed on others, and thus restrict their choices to mobilize the best of science to suit their needs.

April 2003

Annexes

A. Bibliographic List

B. Web Resources

C. Glossary

D. List of Tables, Boxes and Figures

A. Annotated Bibliography List

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B. Web Resources

AgBioForum
AgBioForum publishes articles that enhance the ongoing dialogue on the economics and management of agricultural biotechnology. The purpose of AgBioForum is to provide unbiased, timely information and new ideas leading to socially responsible and economically efficient decisions in science, public policy, and private strategies pertaining to agricultural biotechnology.
http://www.agbioforum.missouri.edu/

AGBIOS
AGBIOS *Essential Biosafety* CD-ROM includes a comprehensive database of safety information on all genetically modified plant products that have received regulatory approval. It also includes training tools in the form of case studies for food and environmental risk assessment of GM plant products and a library of pertinent biosafety references and online documents.
http://www.agbios.com

AgbiotechNet
AgBiotechNet, a service provided by CAB International, publishes current and past information about agricultural biotechnology and biosafety. The site provides access to research developments in genetic engineering and updates on economic and social issues. Free visitor areas. Full access requires subscription.
http://www.agbiotechnet.com

Asian Development Bank (ADB)
ADB is a multilateral development finance institution dedicated to reducing poverty in Asia and the Pacific. Its publications section provides free access to on-line books, reports and studies on agricultural biotechnology, poverty reduction and food security. The ADB report on Biotechnology, Food Security and Poverty Reduction in Asia is available on line.
http://www.adb.org/Documents/Books/Agri_Biotech/default.asp

Biosafety Information Network and Advisory Service (BINAS)
BINAS is a service of the United Nations Industrial Development Organization (UNIDO). BINAS monitors global developments in regulatory issues in biotechnology. BINAS works together with OECD towards a common resource on harmonization in biotechnology. A joint page, BIOBIN, helps navigating between OECD's BioTrack Online and UNIDO's BINAS.
http://www.binas.unido.org/binas

BioTrack Online
BioTrack Online focuses on information related to the regulatory oversight of products of biotechnology. Provides information on regulatory development of countries, product database, field trials, and free documents.
http://www.oecd.org

BIOBIN (BioTrack Online and BINAS)
A cooperative resource on safety in biotechnology, developed between OECD's BioTrack Online and UNIDO's BINAS
http://www1.oecd.org/ehs/biobin/

CAB International (CABI)
CABI is a treaty-level, international, intergovernmental, non-profit organization owned and governed by its member countries. Its mission is to help improve welfare worldwide through the dissemination, application and generation of scientific knowledge in support of sustainable development, with emphasis on agriculture, forestry, human health and the management of natural resources, and with particular attention to the needs of developing countries.
http://www.cabi.org

Cambridge Healthtech Institute's (CHI) Genomics Glossaries & Taxonomies
CHI's Genomics Glossaries & Taxonomies website. Access is free.
http://www.genomicglossaries.com

Checkbiotech
Checkbiotech.org is an Internet platform sponsored by Syngenta providing up-to-date information on agricultural biotechnology. The site is updated daily and also has a collection of documents in the database that gives an overview of ongoing discussions in agbiotech.
http://www.checkbiotech.org

Consultative Group of International Agricultural Research (CGIAR)
The CGIAR's mission is to contribute to food security and poverty eradication in developing countries through research, partnerships, capacity building, and policy support, promoting sustainable agricultural development based on the environmentally sound management of natural resources. The site has links to the 16 International Agriculture Research Centers, and their research programs, as well as ISNAR's Intermediary Biotechnology Service.
http://www.cgiar.org/research/index.html

Convention on Biological Diversity (CBD) Cartagena Protocol on Biosafety
Homepage for the CBD's Cartagena Protocol on Biosafety
http://www.biodiv.org/biosafety

Council for Agriculture, Science and Technology (CAST)
CAST assembles, interprets, and communicates science-based information regionally, nationally, and internationally on food, fiber, agricultural, natural resource, and related societal and environmental issues to legislators, regulators, policy-makers, the media, the private sector, and the public. Contains reports, publications and a list of events on agbiotechnology.
http://www.cast-science.org/biotechnology/index.html

DANIDA, Royal Danish Ministry of Foreign Affairs
DANIDA plays an active role in international efforts to resolve the world's growing environmental problems and to make the principle of sustainable development an integrated part of global social development and development in individual countries.
http://www.um.dk/english/

Doyle Foundation
The Doyle Foundation provides a forum for analysis and advocacy of the role of science in international development with special regard to the safe applications of modern biotechnology.
http://www.doylefoundation.org

Electronic Journal of Biotechnology (EJB)
Electronic Journal of Biotechnology is an international scientific electronic journal that publishes papers from all areas related to Biotechnology. EJB is sponsored by the UNESCO / MIRCEN network and contains a new section on «Biotechnology Issues for Developing Countries».
http://www.ejbiotechnology.info/

Food and Agriculture Organisation of the United Nations (FAO)
FAO's forum on Biotechnology in Food and Agriculture.
http://www.fao.org/biotech/forum.asp

Inter-American Development Bank (IDB)
The Inter-American Development Bank, the oldest and largest regional multilateral development institution, was established to help accelerate economic and social development in Latin America and the Caribbean. The goal of the Rural Development Unit of the Sustainable Development Department is to assist in the preparation, execution and evaluation of programs related to loans and national and regional technical cooperation in the rural sector. Provides links to IDB publications and events. The IDB 2002 report on biotechnology in Latin America is available online.
http://www.iadb.org/sds/ENV/site_47_e.htm

International Council for Science (ICSU)
ICSU's mission is to identify and address major issues of importance to science and society, by mobilizing the resources and knowledge of the international scientific community. The ICSU's publication on *Biotechnology and Sustainable Agriculture*, prepared by ICSU's advisory committee on genetic experimentation and biotechnology for the 2002 World Summit on Sustainable Development is available on line.
http://www.icsu.org

International Food Policy Research Institute (IFPRI)
IFPRI's mission is to identify and analyze policies for sustainably meeting the food needs of the developing world. IFPRI is a Future Harvest centre supported by the CGIAR. IFPRI has several biotechnology policy documents available.
http://www.ifpri.org/

International Service for the Acquisition of Agri-Biotech Applications (ISAAA)
ISAAA is a not-for-profit organization that delivers the benefits of new agricultural biotechnologies to the poor in developing countries. It aims to share these powerful technologies to those who stand to benefit from them and at the same time establish an enabling environment for their safe use. ISAAA hosts a global crop knowledge center on line.
http://www.isaaa.org

International Service for National Agricultural Research (ISNAR)
The products and services provided through ISNAR's activities in biotechnology are based on the systematic analysis of policy, management and organizational requirements of countries considering their plans for biotechnology. This work is unique among CGIAR centers and other international agricultural biotechnology programs.
http://www.cgiar.org/isnar/ibs.htm

Information Systems for Biotechnology (ISB)
ISB provides information resources to support the environmentally responsible use of agricultural biotechnology products. The site contains documents and searchable databases pertaining to the development, testing and regulatory review of genetically modified plants, animals and microorganisms within the US and abroad.
http://www.isb.vt.edu

International Rice Research Institute (IRRI) Functional Genomics Working Group
IRRI's International Rice Functional Genomics Working Group website provides information on the rice genome.
http://www.irri.org/genomics/

MaizeDB
MaizeDB is a public Internet gateway to current knowledge about the maize genome and its expression. It is supported by the USDA-ARS, the NSF and the University of Missouri.
http://www.agron.missouri.edu/

National Academies Press (NAP) Publisher for National Academies of Science (NAS) of the USA.
NAP publishes reports issued by The National Academies. Publications can be read online free of charge.
http://www.nap.edu

Nature's genome gateway
Nature's genome gateway is a web resource devoted to genomics. Access to all material is free.
http://www.nature.com/genomics/

Nuffield Council on Bioethics
The Nuffield Council on Bioethics is an independent body established by the Trustees of the Nuffield Foundation to consider the ethical issues arising from developments in medicine and biology. Publications are available free of charge.
http://www.nuffieldbioethics.org

OECD (Organisation for Economic Co-operation and Development)
OECD is an international organization helping governments tackle the economic, social and governance challenges of a globalized economy. OECD homepage provides links to a variety of themes including Biotechnology. Biotechnology homepage provides details of all OECD work pertaining to biotechnology, including events and publications.
http://www.oecd.org

Pew Initiative on Food and Biotechnology
Established to be an independent and objective source of credible information on agricultural biotechnology for the public, media and policymakers; supports informed public dialogue on

ways that the regulatory system may need to evolve to address the issues posed by the anticipated development of this new technology and the growing body of scientific knowledge.
http://pewagbiotech.org

SciDev.Net

SciDev.Net provides news and information about science, technology and development. It has a section devoted to Science and Sustainability and a GM Crops Dossier.
http://www.scidev.net/

The Arabidopsis Information Resource (TAIR)

TAIR provides a resource for the scientific community working with *Arabidopsis thaliana*. TAIR consists of a searchable relational database, which includes many different datatypes. The data can be viewed using an interactive MapViewer. In addition, pages on news, information on the Arabidopsis Genome Initiative (AGI) and Arabidopsis lab protocols are provided.
http://www.arabidopsis.org/info/

The Plant Journal: Plant GM Technology Special Issues

The Plant Journal is providing an accumulating series of authoritative academic articles to inform debate on the GM issue. All articles are freely available.
http://www.blackwellpublishing.com/static/plantgm.asp

The Royal Society (UK)

The Royal Society is the independent scientific academy of the UK dedicated to promoting excellence in science. Statements and publications by the Royal Society are freely available. The website has a section dedicated to the GM plants debate.
http://www.royalsoc.ac.uk/gmplants/

National Science Foundation (NSF) Directorate for Biological Sciences (BIO)

The Directorate for Biological Sciences (BIO) promotes and advances scientific progress in biology largely through grants to colleges, universities and other institutions. The Foundation is a supporter of academic research on plant biology, environmental biology and biodiversity.
http://www.nsf.gov/bio/start.htm

United Nations Environment Programme (UNEP)

UNEP works to encourage sustainable development through sound environmental practices everywhere. Its activities cover a wide range of issues, including biodiversity.
http://www.unep.org

UNEP-GEF Project on Development of National Biosafety Frameworks

The UNEP-GEF global project on the development of National Biosafety Frameworks began in June 2001. This three-year project is designed to assist up to 100 countries to develop their National Biosafety Frameworks so that they can comply with the Cartagena Protocol on Biosafety.
http://www.unep.ch/biosafety

VIB - Flanders Interuniversity Institute for Biotechnology

VIB is an entrepreneurial research institute comprising more than 720 researchers and technicians dedicated to gene technology research in various domains such as human health and plant genetics.
http://www.vib.be

World Health Organisation (WHO)

WHO's Department of Food Safety website provides access to publications and documents on food safety.
http://www.who.int/fsf

C. Glossary

Bioinformatics: the assembly of data from genomic analysis into accessible forms. It involves the application of information technology to analyze and manage large data sets resulting from gene sequencing or related techniques.

Diagnostics: more accurate and quicker identification of pathogens using new diagnostics based on molecular characterization of the pathogens.

Functional genomics is the knowledge that converts the molecular information represented by DNA into an understanding of gene functions and effects: how and why genes behave in certain species and under specific conditions. To address gene function and expression specifically, the recovery and identification of mutant and over-expressed phenotypes can be employed. Functional genomics also entails research on the protein function (proteomics) or, even more broadly, the whole metabolism (metabolomics) of an organism.

Gene chips (also called DNA chips) or microarrays. Identified expressed gene sequences of an organism can, as expressed sequence tags or synthesized oligonucleotides, be placed on a matrix. This matrix can be a solid support such as glass. If a sample containing DNA or RNA is added, those molecules that are complementary in sequence will hybridize. By making the added molecules fluorescent, it is possible to detect whether the sample contains DNA or RNA of the respective genetic sequence initially mounted on the matrix.

Genetically modified food (GM food): Food that contains above a certain minimum content of raw material from genetically modified organisms (GMO).

Genomics: the molecular characterization of all the genes in a species.

High throughput (HTP) screening makes use of techniques that allow for a fast and simple test on the presence or absence of a desirable structure, such as a specific DNA sequence and the expression patterns of genes in response to different stimuli. HTP screening often uses DNA chips or microarrays and automated data processing for large-scale screening, for example to identify new targets for drug development.

Insertion mutants are mutants of genes that are obtained by inserting DNA, for instance through mobile DNA sequences, transposons. In plant research, the capacity of the bacterium *Agrobacterium* to introduce DNA into the plant genome is employed to induce mutants. In both cases, mutations lead to lacking or changing gene functions that are revealed by aberrant phenotypes. Insertion mutant isolation, and subsequent identification and analysis are employed in model plants such as *Arabidopsis* and in crop plants such as maize and rice.

Living modified organism **(*LMO*)** means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. (Synonym of GMO).

Modern biotechnology means the application of: a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) 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.

Molecular breeding: identification and evaluation of useful traits using marker-assisted selection.

Shotgun genome sequencing is a sequencing strategy for which parts of DNA are randomly sequenced. The sequences obtained have a considerable overlap and by using appropriate computer software it is possible to compare sequences and align them to build larger units of genetic information. This sequencing strategy can be automated and leads to rapid sequencing information, but it is less precise than a systematic sequencing approach.

Single nucleotide polymorphisms (SNPs) are the most common type of genetic variation. SNPs are stable mutations consisting of a change at a single base in a DNA molecule. SNPs can be detected by HTP analyses, for instance with DNA chips, and they are then mapped by DNA sequencing.

Transformation: introduction of single genes conferring potentially useful traits.

Vaccine technology: using modern immunology to develop recombinant DNA vaccines for improved control of animal and fish disease.

D. List of Tables, Boxes and Figures

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ICSU's Mission

In order to strengthen international science for the benefit of society, ICSU mobilizes the knowledge and resources of the international science community to:

- Identify and address major issues of importance to science and society.
- Facilitate interaction amongst scientists across all disciplines and from all countries.
- Promote the participation of all scientists–regardless of race, citizenship, language, political stance, or gender–in the international scientific endeavour.
- Provide independent, authoritative advice to stimulate constructive dialogue between the scientific community and governments, civil society, and the private sector.