INTERNATIONAL COUNCIL FOR SCIENCE

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Executive Summary[1]

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

G. J. Persley, The Doyle Foundation
for The International Council for Science

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)[2] and living modified organisms[3], 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 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.

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1. 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

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

3. 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).

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.