

The use of genetically modified crops in developing countries

a follow-up Discussion Paper

NUFFIELD
COUNCIL^{ON}
BIOETHICS

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The terms of reference are as follows:

- 1 to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern;
- 2 to make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body;
- 3 in the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

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Foreword

In its 1999 Report *Genetically modified crops: ethical and social issues* the Council concluded that there is a moral imperative to make GM crops readily and economically available to people in developing countries who want them. The Council conducts regular follow-ups of all its publications. There was a particular need to do so in the case of the Report on GM crops because of the many developments in science and policy which have taken place over the past four years. We undertook this task in time to contribute to the national debate on the use of GM crops which was sponsored by the UK Government in 2003. We published a draft Discussion Paper in June 2003 and invited comments from interested individuals, organisations and the wider public in developed and developing countries. Eighty-three responses were received. The valuable points they made are reflected in this final version of the Paper.

I have been struck by the extent to which the public debate on GM crops continues to be highly polarised in a partisan way. Instead of a sober estimate of the risks and benefits of GM crops on a case by case basis, there is a view that any attempt to even consider their potential is unconscionable. This cannot be right. All forms of agriculture affect human health and the environment, including organic agriculture. GM technology needs to be considered not in the abstract, but by means of comparing its short and long term impact with the impacts of alternative technologies. In this Discussion Paper we provide examples with current and potential benefits to resource-poor farmers and communities. There may well be situations in which such benefits are outweighed by associated risks of GM technology. Intelligent public policy will seek to discriminate between the cases and find ways of developing regulation so as to help those in most need.

This is particularly important in developing countries, where issues of food security and agricultural development press hard. All too often, the situation of agricultural communities threatens to become worse, not better. The status quo is not an option unless we are prepared to see increased suffering and destitution. A precautionary approach may mean going ahead with novel technologies rather than stalling, as is conventionally assumed when the approach is applied to agricultural practice in wealthy societies. It cannot be responsible to render a technology unavailable to those whose needs are urgent. Nor can it be responsible to be partisan in a debate where empirical evidence should be decisive in settling the question.

I hope that the Paper will help to clarify these complex issues and encourage constructive discussion. I also hope that the conclusions and recommendations will provide guidance for policy makers and others who have to make difficult judgments about the use of GM crops.

Finally, on behalf of the Council I should like to express our appreciation to the members of the Working Group: Professor Derek Burke, Professor Mike Gale, Professor Michael Lipton and Professor Albert Weale, who devoted enormous amounts of their time to this review, to those listed in the Acknowledgments who assisted their work, and to the individuals and organisations who commented on the draft Discussion Paper. As always, we are much indebted to the Council's Secretariat: Dr Sandy Thomas, Ms Tor Lezmore, Mr Harald Schmidt, Ms Julia Fox, Ms Elaine Talaat-Abdalla, Ms Nicola Perrin, Ms Natalie Bartle, Ms Caroline Rogers and Ms Maria Gonzalez-Nogal for their dedication and efficiency in producing this Paper.



Professor Bob Hepple QC FBA
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Terms of reference

- 1 To examine recent, current and prospective developments in the use of genetically modified crops in developing countries, in particular:
 - i) to review recent progress of research in the use of genetically modified crops in developing countries
 - ii) to identify current and possible applications of genetically modified crops that would be of particular benefit to developing countries;
- 2 to re-examine and assess arguments set forth for and against the use of GM genetically modified crops in developing countries;
- 3 to assess the consequences of a moratorium on the use of genetically modified crops in developing countries;
- 4 to produce a short publication.

Summary and recommendations

Introduction

In May 1999, the Nuffield Council on Bioethics published a Report on **Genetically modified crops: the ethical and social issues**. One conclusion of the Report was that genetically modified (GM) crops had considerable potential to improve food security and the effectiveness of the agricultural sector in developing countries.

Since then, a highly polarised debate on the risks and benefits associated with the use of GM crops has continued and intensified. This debate has focused predominantly on the needs of European countries, with little attention paid to the impact of research on GM crops for agriculture in the developing world. However, the total acreage planted with GM crops in developing countries has more than doubled since 1999 and research has continued.

In October 2002 the Council decided that the implications of these developments deserved further examination. In order to contribute to the continuing debate in the UK and elsewhere, we have reviewed relevant recent evidence. Our objective has been to reassess the potential contribution that GM crops could make towards improving the effectiveness of agriculture in developing countries.

Background

Between 1970-90 the Green Revolution brought about greatly improved crop yields in many, but by no means all, parts of the developing world. Poverty and hunger fell dramatically. However, Africa and parts of Asia saw little gain, and the initial rate of improvement of the Green Revolution was not sustained between 1985-90. The best areas had already been saturated with semi-dwarf wheat and rice. Further yield increases were held back by water shortages, soil problems, and the emergence of new types of pest and disease. Population growth had slowed down sharply (in Asia since the mid 1970s, and in Africa since the mid-1980s). In contrast, the rapid and widespread growth in the numbers of people of working age was sustained (paragraphs 2.7-2.8). These trends look set to continue.

Food insecurity prevails, even in developing countries with food surpluses. One proposed solution, the redistribution of surpluses among and within countries poses serious practical and political challenges. Food aid programmes and efforts towards land reform have achieved much and should continue. However, improving the productivity of small farms is by far the best means of achieving a substantial reduction of food insecurity and poverty. Many people are poor, and therefore hungry, because they can neither produce enough food on their small farms, nor obtain enough employment by working on those of others. Enhancement of yields on small farms tends to increase the demand and hence rewards for poor labourers (paragraphs 2.4, 2.9-2.11).

Main findings

We have explored the potential of GM crops to improve agriculture in developing countries by means of eight case studies. These concern the use of GM cotton, rice, sweet potato, banana and soybean, and the production of biopharmaceuticals. Most GM crops have been developed by companies to suit the needs of large-scale farmers in developed countries. With the exception of GM cotton, soybean and maize, only a limited number of commercially available GM crops are currently suitable for conditions in developing countries. However, of the approximately six million farmers who grew GM crops legally in 2002, more than three-quarters were resource-poor, small-scale cotton farmers in developing countries, mainly in China and South Africa (paragraph 3.21).

Our main conclusion is that possible costs, benefits and risks associated with particular GM crops can be assessed only on a case by case basis. Any such assessment needs to take into account a variety of factors, such as the gene, or combination of genes, being inserted, and the nature of the target crop. Local agricultural practices, agro-ecological conditions and trade policies of the developing country in which GM crops might be grown are also important. **We therefore recommend that in considering whether GM crops should be used or not, it is essential to focus on the specific situation in a particular country, asking the question: 'How does the use of a GM crop compare to other alternatives?'** All possible paths of action must be compared, including inaction, in respect of improving, in a cost-effective and environmentally sustainable way, human health, nutrition, and the ability to afford an adequate diet (paragraph 4.49).

The improvement of agriculture and food security depends on several factors. These include stable political environments, appropriate infrastructures, fair international and national agricultural policies, access to land and water, and improved crop varieties which are suited to local conditions. In focusing on current and potential uses of GM crops we therefore consider only part, albeit an important one, of a large and complex picture. However, we are clear that **in particular cases, GM crops can contribute to substantial progress in improving agriculture, in parallel to the (usually slow) changes at the socio-political level. GM crops have demonstrated the potential to reduce environmental degradation and to address specific health, ecological and agricultural problems which have proved less responsive to the standard tools of plant breeding and organic or conventional agricultural practices. Thus, we affirm the conclusion of our 1999 Report that there is an ethical obligation to explore these potential benefits responsibly, in order to contribute to the reduction of poverty, and to improve food security and profitable agriculture in developing countries** (paragraph 4.48).

Specific conclusions and recommendations

The precautionary approach

It has sometimes been suggested that GM crops should not be used because there may be a very low probability of the occurrence of an unpredictable adverse effect on the environment or on human health. This case is frequently argued in terms of the so called *precautionary principle*. The argument is that, irrespective of possible benefits, a new technology should never be introduced unless there is a guarantee that no risk will arise. If this line of thought is pursued to its logical outcome, there should be a delay (i.e. a moratorium) in the use of the technology until a complete assurance of absence of risk is available. However, no one can ever guarantee an absolute absence of risk arising from the use of any new technology. In our view, such a principle would lead to an inappropriate embargo on the introduction of all new technology. We have come firmly to the view that the only sensible interpretation of the precautionary principle is comparative, i.e. to select the course of action (or of inaction) with least overall risk. We use the term *precautionary approach* to indicate that it is not a single inflexible rule, as often portrayed, but a way of applying a set of interacting criteria to a given situation. We make the following observations in offering this interpretation.

- An excessively conservative interpretation of the precautionary approach, demanding evidence of the absence of all risk before allowing the pursuit of a new technology is fundamentally at odds with any practical strategy of investigating new technologies. In fact, **such interpretations are essentially impractical.** There are countless cases which show that if it were essential to demonstrate complete absence of all risk before the introduction of a new technology, then technical achievements such as vaccination, aeroplanes or mobile phones, which have become accepted by almost everybody, would never have entered regular use.

- **It is easier to forgo possible benefits in the light of assumed hazards, if the status quo is already largely satisfactory.** Thus, for developed countries, the benefits offered by GM crops may, so far, be relatively modest. However, in developing countries the degree of poverty and the often unsatisfactory state of health and agricultural sustainability is the baseline, and the **feasibility of alternative ways to improve their situation must be the comparator.**
- **To hold to the most conservative interpretation of the precautionary approach invokes the fallacy of thinking that the option of doing nothing is itself without risk.** Yet, food security and environmental conditions are actually deteriorating in many developing countries. Restrictive interpretations of the precautionary approach that imply a general prohibition on the use of GM technology therefore require very strong justification.

In some cases the use of a GM crop variety may well pose fewer risks than the agricultural system already in operation. **We therefore conclude that an adequate interpretation of the precautionary approach would require comparison of the risks of the status quo with those posed by other possible paths of action.** Such assessments must be based on sound scientific data (paragraphs 4.35-4.42).

The use and governance of GM crops in developing countries

It is important that any country should have in place appropriate mechanisms to determine whether it is desirable to introduce any new crop, GM or non-GM, into the environment, and to monitor its impact. Many already do. Systems that enable the views of farmers and relevant stakeholders to be taken into account by policy makers are also required.

Availability of choice

When a decision is made to introduce new varieties of crops, whether GM or non-GM, problems might arise because the new seed might be more costly. Problems can also arise in cases where one single monopolistic seed supplier controls the provision of seed. It is therefore desirable that as far as possible farmers have a genuine choice. **To provide a genuine choice it is important that support for the public sector be sustained, so that suitable seeds (whether GM or non-GM), which can be retained by farmers with minimal yield losses, are available. Policies also need to be in place to keep the private supply of seeds reasonably competitive** (paragraph 4.19).

Decision making processes about the use and regulation of GM crops

Local communities must be included as far as possible in processes of decision making. The dissemination of balanced information, and the education and training of those involved is essential. In particular, farmers need to be informed about the technological potential and management requirements of GM crops. Expectations are sometimes inappropriately high, and knowledge about specialised farm management practices may be absent. **We recommend that companies marketing GM crops in developing countries share, with governments, the costs of:**

- **locally appropriate schemes to elicit the preferences of small-scale farmers regarding traits selected by plant breeders;**
- **their participation, where appropriate, in plant breeding; and**
- **subsequent mechanisms to improve dissemination of balanced information, education and training about the use of GM crops** (paragraph 5.33).

Regulation of GM crops in developing countries

There is considerable evidence of illegal planting of GM crops in a number of developing countries including Brazil, India and Mexico. In view of the alleged risks posed by the use of GM crops, many argue that stringent systems of governance should be implemented, which could then be

deregulated. We do not share this view: such regulations are unlikely to stop illegal planting. In addition, amendments to regulations in the light of new research findings are often delayed by unrelated political and administrative disputes. It is therefore important that all developing countries which are currently involved in the implementation of the *Cartagena Protocol on Biosafety* consider carefully how to interpret the provisions which concern the precautionary approach, to allow for appropriate regulation before the need arises. **Any highly restrictive interpretation of the precautionary approach is likely to ignore the possibility that in some cases, the use of a GM crop variety may pose fewer risks than are implied by current practices or by plausible non-GM alternatives. In applying the precautionary approach, risks implied by the option of inaction (or by alternative actions) must also be considered** (paragraph 5.10).

The most appropriate approach would normally be a centralised and evidence-based safety assessment at the national or regional level. Environmental and health risks should be assessed on a case by case basis. Wherever possible, such assessments should consider information which is available from international sources, particularly with respect to data about food safety, which are more transferable than environmental risk assessments (paragraph 5.34).

In most developing countries, it will be a major financial and logistical challenge to provide the capacity and resources to undertake such evaluations. The proliferation of diverse regulations, resulting in every new GM crop being assessed for possible risks to human health and the environment in each developing country will cause problems. **We therefore recommend that particular attention should be given to measures that will enable the sharing of methodologies and results. An example is environmental risk assessments for countries which have similar ecological environments. It should also be considered whether harmonised regional policies can be established, for example, by the Southern African Development Community (SADC) and the Common Market for Eastern and Southern Africa (COMESA). We welcome the recent initiative by SADC to produce guidelines on food safety assessment and management of GM crops. Developing countries should be encouraged where possible to implement standardised procedures for the assessment of environmental and health risks. Established international guidelines such as the *Cartagena Protocol on Biosafety* and the guidelines of the Codex Commission should be considered. Care must be taken to avoid an overly restrictive interpretation of the precautionary approach** (paragraph 5.27). **In this context we welcome and endorse initiatives to promote the strengthening of capacity in relevant regulatory and scientific expertise, which have recently been launched jointly by the United Nations Environment Programme and the Global Environment Facility (UNEP/GEF), and the Food and Agriculture Organization (FAO)** (paragraphs 5.24-5.25). However, since duplication of effort can be counter-productive, and since administrative resources in developing countries are scarce, it is essential that international development efforts are coordinated.

Current and future research

For a variety of reasons, many of the crops such as rice, wheat, white maize, millet, sorghum, yams, cocoyams and others, which provide food and employment income for the poor in developing countries, have been ignored by the private sector. Much of the current privately funded research on GM crops serves the interest of large-scale farmers in developed countries. Consequently there is a serious risk that the needs of small-scale farmers in developing countries will be neglected. It appears that research on these crops will have to be supported primarily by the public sector.

We therefore affirm the recommendation made in our 1999 Report that genuinely additional resources be committed by the UK Department for International Development (DFID), the European Commission, national governments and others, to fund a major expansion of public GM-related research into tropical and sub-tropical staple foods, suitable for the needs of small-

scale farmers in developing countries. In determining which traits and crops should be developed, funding bodies should be proactive in consulting with national and regional bodies in developing countries to identify relevant priorities (paragraphs 6.16-6.17).

There is not enough evidence of actual or potential harm to justify a blanket moratorium on either research, field trials, or the controlled release of GM crops into the environment at this stage. **We recommend that research on the use of GM crops in developing countries be sustained, governed by a reasonable application of the precautionary approach. Accumulating evidence from new scientific developments must be used to inform discussions about the current or future use of GM crops. The views of farmers and other relevant stakeholders must also be taken into account** (paragraph 4.50).

Liability

It has been suggested by some that the use of GM crops by farmers in developing countries might be exploited by the multinational seed industry in such a way that seed of questionable quality were provided. We are not aware of any such instances. However, it is clear that the same standards of liability need to apply to both developing countries and developed countries. **Where there is clear evidence of damage attributable to the seed producer, compensation will need to be provided, regardless of whether the seed is GM or non-GM** (paragraph 5.36). We note that in previous instances of crop failures in developed countries, compensation has been negotiated successfully.

We recommend that possible scenarios, which include the principle of compensation, be considered by policymakers and the seed industry. Agreed standards should be published widely, taking into account in particular the situation of small-scale farmers in developing countries. Illiteracy and lack of adequate infrastructure for effective communication can present additional obstacles that need to be considered. Wherever possible, agreements should be established, to facilitate compensation of small-scale farmers who, in the event of loss or damage, are unlikely to be able to afford appropriate legal action (paragraphs 5.36 and 5.45-5.46).

The impact of European regulations on GM crops

The freedom of choice of farmers in developing countries is being severely challenged by the agricultural policy of the European Union (EU). Developing countries might well be reluctant to approve GM crop varieties because of fears of jeopardising their current and future export markets. They may also not be able to provide the necessary infrastructure to enable compliance with EU requirements for traceability and labelling (paragraphs 5.20-5.21).

One strategy which developing countries might choose could be to adopt GM crops for domestic use only. However, problems could arise if separation of GM crops and non-GM crops for export cannot be readily achieved. For example, small amounts of GM produce might become mixed with non-GM produce during storage. If current attitudes among EU policy makers and consumers prevail, countries which depend on exports to the European market might then be at considerable disadvantage (paragraphs 5.43-5.48).

A number of recent authoritative reviews have concluded that, based on current evidence, neither GM crops, nor food produced from GM crops, pose a significant risk to humans who consume them. However, complications could arise where risks for human health or the environment are exaggerated by the scepticism of some commentators from developed countries. Policy makers in developing countries would then be faced with very difficult choices. If a national policy that allowed the responsible domestic use of GM crops were adopted, it might well be perceived as promoting unsafe foods, and could lead to the loss of EU export markets. It is therefore important that policy makers in developing countries seek a range of advice about these issues.

There is a considerable imbalance between the hypothetical benefits afforded by the EU policy for its own citizens, and the probable and substantial benefits that could be afforded to developing countries. Current provisions of the revised *Directive 2001/18/EC, Regulation 1830/2003/EC on Traceability and Labelling* and of *Regulation 1829/2003/EC on Food and Feed* have not given sufficient consideration to the effects that these policies are likely to have on developing countries. **We recommend that the European Commission (EC), the UK Department for International Development (DFID) and appropriate non-governmental organisations which monitor the agricultural policies of developing countries examine the consequences of EU regulatory policies for the use of GM crops in developing countries. We recommend that the European Commission establish a procedure to report on the impact of its regulations accordingly (paragraph 5.50).**

The case of food aid

During the course of our investigation, we have repeatedly observed the extent to which complex issues are over-simplified. In a highly charged political atmosphere, the impact of public statements by influential bodies needs to be carefully considered, including the way in which those statements may be misinterpreted. In our view, there is a pressing obligation on all those who seek to be influential in policymaking to weigh carefully all the current and relevant evidence, and to consider the characteristics of specific uses of GM technology by comparison with other feasible systems. This obligation to base statements on an impartial consideration of the evidence applies as much to campaigning organisations as it does to any other public or professional body. We are sceptical about claims from individuals or organisations who found their arguments on political convictions rather than scientific evidence.

The issues raised by food aid are complex. We recognise that long-term reliance on food aid, whether provided in the form of GM or non-GM cereals, is highly undesirable. Clearly, assistance to developing countries should, where possible, be directed towards self sufficiency in food production. This is a complex task and GM crops could play a substantial role in improving agriculture. However, the question remains as to how developed countries can comply with their ethical obligations when emergencies arise. With regard to donations of GM crops as food aid, **we note that the preferences of developing countries dependent on emergency food aid must be taken seriously. A genuine choice between GM and non-GM food should be offered, where this is possible. It will therefore be necessary to provide full information about whether or not donated food is derived wholly or in part from GM crops (paragraph 5.41).**

Where developing countries prefer to receive non-GM food, the World Food Programme and other aid organisations should consider purchasing it. This is subject to its availability at reasonable financial and logistical costs. Where only donations of GM varieties are available and developing countries object to their import solely on the basis of environmental risks, we recommend that it be provided in milled form (paragraph 5.42). This is because seeds from food aid donations are likely to be planted in developing countries, and it would be unacceptable to introduce a GM crop into any country against its will by this means.

Micronutrient-enriched GM crops

The development of GM crops which can provide increased levels of crucially important micronutrients has been the focus of much public discussion. Strong claims with regard to the potential of Golden Rice have been made by both proponents and opponents, sometimes in the absence of validated empirical evidence. We conclude that Golden Rice could make a valuable contribution where rice is the principal staple crop and other means of obtaining sufficient levels of vitamin A are more difficult to provide. This is often the case in developing countries where extreme poverty is widespread. But full assessment of the effectiveness of Golden Rice is a

complex process which is not yet complete. It depends critically on the bioavailability of β -carotene, on which there are widely different claims and assumptions. It is thus premature to proclaim that the approach will fail. The need being addressed is an urgent one. **It is therefore essential that reliable empirical data from nutritional and bioavailability studies be obtained as a priority. At the same time, in endorsing continuing research on crops such as Golden Rice, we emphasise that evaluation of its cost-effectiveness, risk, and practicality in comparison to other means of addressing micronutrient deficiency is vital** (paragraph 4.25).

Gene flow and biodiversity

The possibility that genes from GM crops could be transferred by pollen to other cultivars or wild relatives has caused concern. Gene flow may require special attention where GM crops are used in developing countries. Whether or not it is acceptable depends primarily on its consequences. The introduction of GM crops in developing countries which are centres of diversity of specific crops may in some cases be problematic. **We recommend that in the case of sensitive areas such as centres of diversity, introgression of genetic material from GM crops in related species should be monitored. However, we are not persuaded that the possibility of gene flow should be sufficient to rule out the planting of GM crops in such areas, provided that regulatory requirements are met. Specific risks need to be assessed in particular contexts, and possibilities of safeguarding biodiversity must be considered carefully. The establishment and maintenance of comprehensive seed banks to conserve genetic resources of crop plants and their relatives is of crucial importance** (paragraph 4.34).

Intellectual property rights (IPRs)

In 1999 we noted that the agrochemical and seed industry was tightly consolidated around a small number of multinational companies. There has been continuing concentration in the number of companies that control between them the provision of seeds and important research technologies. There are concerns that growth of patents in both the private and public sectors could have an inhibiting effect on publicly funded research. The challenge for the public sector, especially where research is directed at agriculture in developing countries, is how to access GM technologies without infringing IPRs. New initiatives which recognise the potential of these constraints to inhibit research into crops relevant to developing countries are therefore very timely. However, we also note that the recent example of Golden Rice shows that patented technologies need not necessarily be a barrier.

Control of and access to genetic modification technologies

Access to plant genetic resources is critically important for the development of GM crops which are suited to the needs of developing countries. Usually, access to such resources is governed by Material Transfer Agreements (MTAs). The perception that the recent proliferation of MTAs is not necessarily in the public interest is widespread.

We welcome the decision by the UK Government to ratify the *International Treaty on Plant Genetic Resources for Food and Agriculture*. Access to resources falling under the Treaty is of crucial importance in the development of crops suited to developing countries. We recommend that in the negotiations regarding the standard Material Transfer Agreement (MTA), the UK Government aims for provisions that exempt users in developing countries from payments, where commercial applications arise from material covered by the MTA. Where exemptions are not appropriate, differentiation of payments should take into account the level of development of the country in question (paragraph 5.15).

Under patent law in the UK, it appears that a plant breeder does not have the clear right to use a patented GM plant variety for breeding purposes. To avoid possible litigation, he can either refrain

from using the variety or apply for a licence from the patent owner. Such requests may be refused or granted on less than favourable terms and the provision of compulsory licensing is often not straightforward. As we noted in our 1999 Report, this potential locking up of genetic variation would be contrary to the spirit and intent of plant variety rights (PVRs). We consider that there is a strong case for the principle of the breeders' research exemption, established for PVRs, to be applied to patented varieties. **We reaffirm our recommendation from that Report that the World Intellectual Property Organization (WIPO), the European Commission (EC), the Union for the Protection of the New Varieties of Plants (UPOV), the Consultative Group on International Agricultural Research (CGIAR) and the International Plant Genetic Resources Institute (IPGRI) together closely monitor the impact of patents on the availability of germplasm to plant breeders (paragraph 6.11 and paragraph 3.61 of the 1999 Report).**