

THE NUFFIELD COUNCIL ON BIOETHICS

GENETICALLY MODIFIED CROPS : THE SOCIAL AND ETHICAL ISSUES

Consultation Document : April 1998

Introduction

- 1 The Nuffield Council on Bioethics, an independent body, has begun an inquiry into the ethical issues raised by genetically modified crops. A Working Party has been established for this purpose (Annex A) and a report will be published early in 1999. We would very much welcome your comments on the development of genetically modified crops and their implications for consumers, the environment and the current regulatory framework. We would also value your views on the way in which ethical issues are being approached, now and in the future.
- 2 Genetic modification involves the *direct* introduction of desirable characteristics by the *artificial* transfer of foreign or synthetic DNA¹, into a plant. This new method of genetic improvement has obvious benefits for agriculture and most scientists believe that these modified crops are safe to grow and eat. But concerns about their environmental impact and safety remain.
- 3 This consultation paper describes the likely developments in genetically modified (GM) crops and sets out the principal ethical issues including those concerning food safety and consumer choice. The inquiry is concerned solely with those crops which have been genetically modified by the process of genetic engineering, rather than by traditional methods of plant breeding. It focuses on the issues surrounding the use of GM crops in the UK, but as their impact will be global, we are considering ethical issues raised by the use of technology elsewhere, particularly in developing countries.
- 4 It would be appreciated if your comments could be framed around the questions provided below:
 - 1 Do GM crops and food pose ethical questions about what is acceptable with regard to the manipulation of nature? If so what are the key ethical issues from your perspective?
 - 2 What are the principles by which we should control the development and application of GM crops? Do present regulatory systems reflect these principles?

¹ DNA (deoxyribonucleic acid) is the biochemical substance that genetic material is made of.

- 3 Is there an ethical obligation to ensure that non-GM foods continue to be available and distinguishable from GM foods?
- 4 How can consumer choice be adequately safeguarded?
- 5 How should we handle the uncertainty that exists in making predictions about the long-term environmental impact of crops?
- 6 Do people wish to be more involved in decision-making about the application of the technology? If so, how can this be achieved?
- 7 What benefits do you think that this technology might have for developing countries? Under what conditions could these benefits be realised?
- 8 What are the responsibilities of companies with regard to the development and commercialisation of GM crops?
- 9 What is the ethical acceptability of patents associated with novel GM crops?
- 10 Does the present regulatory structure provide adequate safeguards and is it transparent and accountable? How can it be improved?

Understanding the new technology

- 5 Before the advent of genetic modification of crops, genetic improvement was largely achieved through traditional plant breeding by selection of the best performing plants for breeding programmes. These methods have limitations: many species cannot be crossed with each other and this restricts the introduction of desirable characteristics from one type of crop to another.
- 6 Genetic modification allows the *direct* introduction of desirable characteristics through artificial gene transfer. Genes which confer disease and pest resistance, and improved storage may be incorporated in a wide range of crops. Many crops have now been genetically modified for a wide range of characteristics. It has taken scientists over ten years to develop these techniques and to ensure that the newly modified crops are stable and perform well in the field. The private sector has invested heavily in GM crops. Five major commercial companies control most of the basic technology world-wide.
- 7 Almost all food on sale in supermarkets, as well as animal feed, is made from traditionally bred crops. However, genetically modified soya, maize and cotton are being grown in the United States on an increasing scale. In Europe there has been considerable debate over the environmental impact and safety of GM crops. In some areas of the world, these crops

are being grown in the absence of a free press and with little public awareness of science.

- 8 Several different methods have been developed to produce GM crops. These include the fusion of cells from different species (protoplast fusion), the use of bacteria such as *Agrobacterium* to transfer DNA from one species to another and the transfer of DNA using 'biolistics'. GM crops may contain different kinds of inserted DNA, originating from bacteria, viruses or from other plants. In practice, the rate of successful gene transfer is low and scientists often use genetic markers to identify the few plant cells where effective genetic modification has taken place.

Current and Future Developments

- 9 Likely developments in GM crops include:
 - rapid methods to speed up traditional plant breeding;
 - the continued development of herbicide-resistant and pest-resistant crops;
 - further development of fruit and vegetables with extended shelf lives;
 - the modification of oils, fats and starches to improve processing or dietary characteristics;
 - the improvement of flavour, texture, bio-absorbability, nutritional content and the elimination of genes for toxic substances and allergens;
 - the identification of the many genes controlling salt tolerance, drought resistance, and response to day length, allowing the production of GM crops that can be grown in a wide range of habitats;
 - more quickly maturing crops;
 - the production of new therapeutic agents and vaccines in plants.
- 10 Twenty-three GM crop varieties have reached the stage where strict regulations are no longer required for field testing in the United States. In 1997 approximately 30 million acres worldwide were planted with GM crops. Nearly 15% of the 1997 US soya harvest was grown from GM seed and China is thought to be growing over 4 million acres of genetically modified tobacco and tomatoes.

The environmental issues

- 11 There are concerns about the impact of GM crops on the environment. One important concern is the escape of introduced genes from crops to wild species. This can happen with any crop that has wild relatives with

which it can interbreed. In the UK this applies to oilseed rape and to sugar beet. It is difficult to say with certainty what effect these new genes will have in wild populations, particularly when trying to predict the effects several generations hence. Another concern is the effect of GM crops on the biological diversity of agricultural environments. For instance, growing large areas of insect-resistant crops could have an effect on insect populations, and in turn on the bird populations that feed on those insects. However, some argue that this effect will not be any worse than the current impact of chemical pesticides.

- 12 Environmental impacts are regulated in the UK through an EU Directive. Advice is given to the Government by a scientific committee, the Advisory Committee on Release to the Environment (ACRE). It evaluates the risk assessment put forward by the scientific institutions and companies as part of an application to make a release, and can insist on partial containment or monitoring of experimental releases. It also gives advice on applications for products to be put on the market. It is not part of ACRE's remit, however, to consider the broader environmental effects of GM crops. There may be a need for this general issue to be addressed elsewhere by government.

Consumer choice issues

- 13 Consumers have a right to know what they are eating and drinking. GM crops raise particular difficulties in this respect because of the potential absence of choice and this has been an issue in Europe. Because much of our food is imported, the ability to track genetic modification is beyond national control. US growers will not segregate GM soya from non-GM soya because of the costs involved causing difficulties when it enters the UK food supply. Moreover, the UK and EU cannot exclude GM imports as there are no safety grounds for doing so.² The National Farmer's Union has launched guidelines to ensure that GM food grown in the UK can be separated, and labelled accordingly.
- 14 There has also been concern over the possible transfer of antibiotic resistance genes to the gut of livestock fed a GM maize, and the possibility of eventual transfer to humans. Although the European Commission has approved the GM maize, Austria and Luxembourg have banned its import and the situation remains unresolved.
- 15 It is natural and proper to ask whether such genetic modification affects the safety of food derived from the modified crop. For example, is the product of the inserted gene at all toxic or could the introduction of a new gene into say, potato, increase the production of toxins that are normally present at very low levels in commercial cultivars? More generally, could the introduction of a new gene disturb the complex flow of substances involved in intermediary metabolism such that the proportions of their

² Since the recent World Trade Organisation (WTO) agreement, no country can exclude the export product of another signatory except on safety grounds.

major products (fats, carbohydrates etc) are altered? Often more than one gene is introduced, as for example, in the case of a marker gene which is present for selection after modification of the plant. Will such genes raise a safety problem? Finally, is there any likelihood of a new gene being lost or recombining with another gene? If so, would it matter?

- 16 Safety concerns of novel foods are the responsibility of the ACNFP³ an Advisory Committee that advises Ministers in the Department of Health and the Ministry of Agriculture, Food and Fisheries. It consists of 16 experts in such fields as genetic modification, plant biochemistry and genetics, nutrition, microbiology, toxicology and, for the last six years, a consumer representative and an ethical adviser. Initially the Committee worked on a case by case basis, subsequently formulating this process into a series of decisions which were the subject of wide consultation. The Committee also has consulted over such issues as the use of antibiotic genes as markers and has held workshops from time to time, for example on the fate of novel genes from GM plants in pollen and honey. It publishes an Annual Report, publishes its agenda before each meeting and a brief account of each meeting, and also after the Ministerial approval of each new product or process.
- 17 The introduction of novel foods and processes has undoubtedly produces some consumer uneasiness. There is a clear moral duty for those developing novel foods to test for their safety extremely carefully and it may be necessary at times to err on the side of caution where a risk may be apparent. Given this disquiet, is the public being sufficiently involved? The public are more suspicious of novel foods as a result of the BSE crisis and may be less willing to trust government regulatory bodies to make decisions on their behalf.

The UK regulatory framework

- 18 The environmental release and marketing of GM crops is governed in the UK by a European directive⁴ and Part IV of the UK Environmental Protection Act 1990. The purpose of the directive is to ensure that GM crops and other organisms cannot be released into the environment without the approval of a competent authority, acting on proper scientific advice and charged with ensuring that such releases do not cause harm to the environment or to human health or safety. The UK legislation provides more detailed rules and procedures for implementing the general purposes of the European directive.
- 19 The advisory committee ACRE⁵ assists the Secretary of State at the Department of Environment, Transport and the Regions (DETR) in deciding on the approval of proposed releases. There are requirements for a public register of releases and for releases to be publicised. To date about 134 trial releases of genetically modified organisms (GMOs) have been

³ Advisory Committee on Novel Foods and Processes

⁴ 19/220/EEC and various amendments.

⁵ Advisory Committee on Releases to the Environment

authorised in the UK and about six approved for marketing with about 12 more in the pipeline.

- 20 The European regulatory regime has attracted criticism from two directions. Industry and agriculture are impatient at time it takes to get consent for testing and marketing new products. They fear that the delays will make Europe less competitive than the US. Environmentalists have feared that the uncertainties associated with GM release are not sufficiently taken into account either in the legislation or by those administering the case work under it.
- 21 A new directive has been proposed which provides for the division of applications for releases into two categories – well understood and relatively simple cases and difficult or novel cases. The new directive would restrict the period of approval to seven years, after which there is a review. It also proposes stronger monitoring and labelling requirements for any products that are released
- 22 The safety of GM crops is the responsibility of the ACNFP (see paragraph 16). The Food Advisory Committee has responsibility for food labelling decisions. Apart from preventing any harmful releases, a general objective of the present UK regulations is that people should know when GM crops enter the environment and the food chain, so that they can *choose* whether or not to consume products which contain GM crops. Given the difficulties over separating GM foods from traditional foods, labelling has become a major issue in Europe. Various categories of labelling to enable the consumer to have a choice have been proposed. It has been agreed that products containing, for example, GM soya should be labelled as such. If virtually all food becomes genetically modified over the course of the next few years, will labelling have any meaning if there are no affordable alternatives?

Developing countries

- 23 GM crops offer developing countries the prospect of substantial improvements. GM crops could greatly increase and stabilise yields and improve food consumption for the poor. It is likely, however, that GM technology will continue to be directed mainly to the needs of the rich countries with few improvements directed at crop staples which are important for developing countries. There is also a danger that new GM products will undermine the market for commodities from developing countries. Nor is it clear whether these countries will be able to access the technology other than by purchase of hybrid seed. So far, GM crops have had little effect on the rural poor of developing countries.

- 24 The United Nations Environmental Protection agency (UNEP) has adopted non-binding guidelines for the management of the release of GM organisms. The Biodiversity Convention has decided to negotiate a binding protocol on bio-safety issues which may incorporate these guidelines and give them more force. However, many developing countries cannot afford to implement what other countries see as essential safeguards when GM crops enter the environment or food chain and some have argued that lower safety standards are justified.

Property rights

- 25 Traditionally bred crops have been protected by plant variety protection, a form of intellectual property right. The development of GM plants has sparked an increasing trend to protect the underlying technology using patents. In the US, over 200 plant biotechnology patents have now been granted. In Europe, there has been long standing confusion over the validity of plant patents but there are now several patents protecting DNA in Europe and the US and elsewhere.
- 26 Some opposition to patents on crops and on plant DNA is concerned with ethical objections to do with the commercialisation of nature and stems from the view that nature is part of our common inheritance and should not be owned by individuals. Some is based on the restrictions that may follow the patenting. If particular genes or plants are owned by researchers or companies, will this stifle progress through the restriction of access?
- 27 The ownership of crop patents by industry has been a particular cause for concern. Would the need for confidentiality may deprive public sector researchers of the use of some plant material? The desire to patent is by no means confined to industry, however, and public sector scientists may also be reluctant to share information in their customary fashion.
- 28 The consolidation of the agro-chemical and seed industry may lead to some patents being licensed to very small numbers of users. Patents filed by multi-nationals relating to plant species with long established uses in developing countries have aroused opposition. There are views that such developments are unethical in that they exploit the resources of developing countries without adequate compensation. A further question is whether multi-nationals should be allowed to patent material which is freely available from international research centres?

Terms of reference of the Working Party on the Genetic Modification of Crops

- 1 To briefly review the developments on the genetic modification of plants and their impact on human food consumption and the environment.
- 2 To identify and consider the ethical and social implications of these developments including:
 - (a) issues of food safety and public health
 - (b) issues of environmental protection
 - (c) the public interest and the maintenance of consumer choice and public confidence
 - (d) the appropriateness of the criteria used at present by regulatory bodies in the UK and in the EU
 - (e) the implications for less developed countries
 - (f) the implications for farming practices and rural life
 - (g) the implications of intellectual property issues
 - (h) the responsibilities of scientists in advising policymakers on these issues

and to make recommendations.

Membership of the Working Party on the Genetic Modification of Crops

Professor Alan Ryan (Chairman) is Warden of New College, University of Oxford

Professor Derek Burke CBE is a former Vice Chancellor of the University of East Anglia, and was Chairman of the Advisory Committee for Novel Foods and Processes (1988-97)

Doctor Mike Gale FRS is Associate Research Director, The John Innes Centre, Norwich

Professor Brian Heap FRS CBE is Master of St Edmunds College, University of Cambridge. Senior Visiting Fellow, School of Clinical Medicine, University of Cambridge and a member of the Nuffield Council on Bioethics.

Miss Prue Leith OBE is Deputy Chairman of the Royal Society of Arts

Miss Julie Hill is Programme Advisor to the Green Alliance, an environmental charity and a member of ACRE (Advisory Committee on Releases to the Environment)

Professor Steve Hughes is the Unilever Research Professor at the Department of Biological Sciences, University of Exeter

Professor Michael Lipton is at the University of Sussex (formerly at the Institute of Development Studies and the School of African and Asian Studies)

Mr Derek Osborn CB is Chairman of the European Environment Agency and a member of the Nuffield Council on Bioethics.

The inquiry into **the Genetic Modification of Crops** follows the publication of the Nuffield Council's report **Animal-to-Human Transplants the ethics of xenotransplantation** in 1996. A report on **Mental Disorders and Genetics: the ethical context** will be published later in 1998.