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Genetically modified crops: the ethical and social issues

NUFFIELD COUNCIL<sup>™</sup> BIOETHICS

# **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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### **Preface**

When the Working Party began work in January 1998 there was little visible public anxiety about genetically modified (GM) crops and almost no press interest in the subject. For politicians GM crops occasionally threatened difficulties with the World Trade Organisation or posed problems for European Union regulations, but the regulation of research and release into the environment of new plant strains was not politically contentious, and the subject of GM crops not seen as politically hazardous.

It need hardly be said that while we have been working, the safety of GM crops and their environmental impact have become hotly debated issues; the mass media, the scientific community, the agrochemical industry, environmental pressure groups and politicians have all had much to say.

As reports of previous working parties have had occasion to observe, heat and light are not the same thing. We have been struck by the extent to which hard-to-allay fears are aroused by almost any discussion of genetic science, not only in this context, but also in the contexts of cloning and the genetic components of physical and mental illness.

This, however, seems to the Working Party, as to the Nuffield Council itself, to be one reason why it is so important to undertake the dispassionate and apolitical investigation of the present state and future prospects of GM-based agriculture. The Working Party cannot dictate to the public nor to its political representatives, but we hope we can inform and assist the further development of policies that will secure the benefits of GM crops while most effectively avoiding any risks that they may pose. Conversely, we have ourselves been greatly helped and enlightened by the organisations and individual members of the public who responded to our consultation or came to see us and to give us information.

As chair of the Working Party, I have been deeply impressed by the energy, intelligence, patience and stamina of my colleagues; I have also been deeply impressed – as have all previous working parties – by the dedicated efforts of the Secretariat. Anyone who has worked with Sandy Thomas, Rachel Bartlett, her successor Susan Bull, and Julia Fox knows what a pleasure it is to be so well looked after – and how demanding the standards are that they set for themselves and the working parties they support. It is impossible to exaggerate my debt to them all.

Professor Alan Ryan

Alan Ryan

# Acknowledgements

The Working Party wishes to thank the many organisations and individuals who have assisted its work, particularly those who submitted consultation responses. It is also very grateful to Professor Gordon Conway, Dr Ed Dart, Professor Jonathan Glover, Professor John Hillman, Professor Paul Richards, Professor Andrew Watkinson, Dr Gary Toenneissen and Mr Tim Roberts, who all reviewed an earlier version of the report. Their comments, which contained both far-reaching and detailed criticisms to which we have sought to respond, were extremely helpful.

# Genetically modified crops: the ethical and social issues

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# Genetically modified crops: the ethical and social issues

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# Genetically modified crops: the ethical and social issues

#### Terms of reference

- 1 To briefly review the developments on the genetic modification of crops 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 of intellectual property issues
  - (g) the responsibilities of scientists in advising policy makers on these issues and to make recommendations.

### **Executive Summary**

The introduction of genetically modified (GM) crops has become highly controversial in the UK and some other parts of the world. The principal objections concern possible harm to human health, damage to the environment and unease about the 'unnatural' status of the technology. The Working Party has therefore examined the ethical issues which are raised by the development and application of GM plant technology in world agriculture and food security. Its perspective on GM crops has been 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 have been straightforward and broadly utilitarian. Others, stemming from the concern that GM crops are 'unnatural', have been more complex.

The Working Party accepts that some genetic modifications are truly novel but concludes that there is no clear dividing line which could prescribe what types of genetic modification are unacceptable because they are considered by some to be 'unnatural'. It takes 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. The Working Party concludes that it is now necessary to maintain and develop further a powerful public policy framework to guide and regulate the way GM technology is applied in the UK. It recommends that an over-arching, independent biotechnology advisory committee is established to consider within a broad remit, the scientific and ethical issues together with the public values associated with GM crops.

Recommendations about the needs for improved risk assessment methods, post-release monitoring and the evaluation of cumulative and indirect environmental impacts are made. The Working Party does not believe that there is enough evidence of actual or potential harm to justify a moratorium on either GM crop research, field trials or limited release into the environment at this stage. Public concern about the introduction of GM crops has led to calls for bans on GM food and moratoria on plantings. The Working Party concludes that all the GM food so far on the market in this country is safe for human consumption. A genuine choice of non-GM foods should remain available, with foods which contain identifiable GM material being appropriately labelled. The Working Party urges the Government and the scientific community to share their responsibilities in disseminating reliable information about the underlying science and to respond to public concerns.

The application of genetic modification to crops has the potential to bring about significant benefits, such as improved nutrition, enhanced pest resistance, increased yields and new products such as vaccines. The moral imperative for making GM crops readily and economically available to developing countries who want them is compelling. The Working Party recommends a major increase in financial support for GM crop research directed at the employment-intensive production of food staples together with the implementation of international safeguards.

# **Overview**

Genetically modified crops: the controversy The introduction of genetically modified (GM) crops into the environment and the food chain has become highly controversial in the United Kingdom (UK), parts of Europe and in other parts of the world. The possibility that GM crops will form a large proportion of the plants grown by farmers in the United States (US), and Europe within the next decade has aroused reactions ranging from outrage and unease to acceptance. By contrast, their introduction has been greeted with near-indifference by consumers in the US and Canada.

The genetic modification of plants involves transferring DNA (deoxyribonucleic acid), the genetic material, from a plant or bacterium, or even an animal, into a different plant species. Because we can increasingly identify which gene or genes determine particular characteristics, the appropriate genes can now be inserted directly into the plants we wish to modify. Although techniques required to create GM crops are recent and relatively sophisticated, genetic modification is in most respects an extension of what has been happening for ten thousand years. The primitive ancestors of almost all modern food crops are barely recognisable to the lay person; maize ears, for instance, were half an inch long rather than the eight or nine inches of their modern descendants.

The principle objections to GM crops and the food products made from them concern possible harm to human health, damage to the environment and unease about the 'unnatural' status of the technology. Many members of the UK public also object to what they perceive as an imposition of a new and uncertain technology which, in the case of GM soya, does not offer them obvious benefits. Where GM food has been cheaper or better-flavoured consumers have been more willing to purchase it.

Concerns over human health have arisen on several counts. The fact that GM crops can bring together new gene combinations which are not found in nature has led to unease about possible effects on health over the longer term. Alarmist media reports of negative health effects in animals fed with GM potatoes are likely to have reinforced such fears. The use of antibiotic-resistance marker genes in plant genetic modification has also focused attention onto the possible risk of increasing human resistance to antibiotics through the food chain. The possibility of increasing and unpredictable exposure to allergens through new gene combinations has also been raised. Recent failures on the part of UK government agencies and departments to deal adequately with the BSE (bovine spongiform encephalitis) outbreak have further undermined public confidence.

Environmental concerns have focused on the fear that GM herbicide-tolerant crops might encourage farmers to use more broad spectrum herbicides with a negative impact on insect and bird life. Genes conferring herbicide tolerance might also migrate from crop plants to their wild relatives resulting in herbicide-tolerant weeds. There are also fears about damage to non-target species by insect-resistant crops and the inadvertent creation of new viruses. Irrespective of their safety, GM crops are only one further step in the 'industrialisation' of agriculture. How much of a risk GM crops are to the environment is difficult to judge at this stage. They might damage it in some circumstances and enhance it in others. It could be that much of the dislike of GM crops stems from guilt by association: they are produced by agrochemical and seed companies and they are an element in 'non-organic' farming. They are also seen by some as 'unnatural'.

Obviously, GM crops should be marketed only when they meet appropriate safety and environmental standards. Although they offer the prospect of significant improvements in human welfare, there are risks which need to be guarded against. GM plant technology is at an early stage of development. So far, the genetic modifications made to food crops have mainly affected the plants' tolerance to herbicides and insect pests in crops grown in the developed world. Such crops may allow lower levels of agrochemical use and more efficient farm management. However, the scope of improvements offered by genetic modification in future is much wider and consumer benefits more evident. They include increased food micronutrient levels, removal of food allergens and the production of vaccines. More important is the expansion of the use of GM crops outside the developed world. Globally, the ability to engineer resistance to salty soil and in the longer-term

to modify cereal crops to use atmospheric nitrogen could considerably enhance the diet of the very poorest of the world's citizens. The application of genetic modification to crops extends well beyond foodstuffs. Cotton has already been modified to resist important pests such as the boll weevil. The blue colouring that jeans manufacturers use has even been introduced into some cotton varieties. The longer-term perspective suggests that industrial fuels and especially fuel for electricity generation could increasingly be based on GM plants rather than fossil fuels, and that construction materials could soon be grown in a tailor-made fashion.

A question raised by these arguments is whether the existing UK regulatory system achieves what it should. Regulation is there to protect public health, to protect the environment, to promote or enable consumer choice and to foster useful research. The long-term nature of many of the risks pointed to by critics of GM crops raises the question of whether existing and proposed regulatory schemes adequately monitor both field trials and commercial introductions. Public policy in the UK must properly accommodate the safety issues raised by GM crops and, in so doing, restore public confidence. We also attach great importance to the legitimacy of consumer choice and to ensuring so far as possible that consumers can avoid GM products if they so wish, whatever their reasons may be. The question of how to decide whether GM crops are 'unnatural' to an unacceptable degree is more difficult to address.

Concentrating exclusively on the safety and environmental impact of GM crops in the UK and Europe may distract both the public and governments from giving proper attention to the benefits they could bring. Proponents of GM crops argue that their introduction is necessary for the developing world. Such arguments have been greeted sceptically with claims that food security can be achieved by redistribution rather than increases in output. This argument raises hard political questions about how likely redistributive measures are, as compared with the introduction of GM crops. It has also been argued that as long as the development of GM crops is based in the US and Europe, there will be little research on their application to the developing world. The prospect of broad patents on basic GM technologies also presents particular and potentially serious difficulties for developing countries.

The possibility that GM crops could make a substantial contribution to providing sufficient food for an expanding world is, on its own, a solid reason for engaging in the research that underlies their development. Commercial incentives require that private companies that engage in the research can patent commercially useful results. But will such companies be willing in the future to grant licences on favourable terms for commercial research intended to benefit developing countries? How could governments help secure benefits of genetic modification for developing countries?

In the developed world the fact that the first GM foods have had no or little obvious benefits for consumers has contributed to the perception that they are unnecessary. Genetic modification could, however, be directed towards enhancing the flavour and quality of the food that reaches the tables of consumers in developed countries. At present it is more often used to enhance storage qualities and transportability. In economic terms, these are important qualities but have little impact on the consumer. If the public were given the opportunity to be better informed about GM crops, it might encourage supermarkets and farmers alike to produce food which offers more direct consumer benefits.

In this report, the Working Party sets out to examine the ethical and social issues associated with the introduction of GM technology. It aims to inform the public debate in the UK and elsewhere around the world. It also hopes to assist the further development of public policies that will secure the benefits of GM crops and lead to the development of a regulatory system which protects human health and the environment and at the same time commands public confidence. No ethical concerns can be all things to all people and we accept that some religious and other philosophical applications will have a different starting point to our own. This report is grounded in liberal, scientific values and takes a broadly utilitarian approach to ethics, a starting point which is shared by most people in the UK.

# Chapter 1

Genetic technologies: scientific possibilities and ethical principles

#### Introduction

- 1.1 The new technologies usually called 'genetic engineering' or 'genetic modification' (GM) promise to revolutionise medicine, animal husbandry and agriculture.¹ An optimistic view is that GM plants and foodstuffs will make a great, possibly indispensable, contribution to reducing mass hunger. Yet the development of GM crops has recently caused widespread unease in the United Kingdom (UK) and other European countries. The unease comes in diverse forms and in varying degrees of intensity. It is also based on a wide range of ethical beliefs. So it is worth setting out the perspective from which this report is written.
- 1.2 The development of GM plant technology raises two kinds of issues: the scientific and the ethical. Science is concerned with understanding the world in which we live and in particular the causal relationships that shape that world: for example, the association between genes as a molecular sequence and the characteristics, such as resistance to frost, that the genes express. Understanding such causal patterns is necessary if we are to alter or change the characteristics of plants in an informed way. Ethics, by contrast, is concerned with what we ought or ought not to do. Ethical principles provide standards for the evaluation of policies or practices, for example, indicating that it would be wrong to carry out a certain genetic modification because to do so would threaten human health or harm the environment. Although it may be scientifically possible to undertake a certain experiment or introduce a new type of crop for commercial planting, it does not follow that it would be ethically right to do so. Working out what it is right or permissible to do involves, therefore, bringing together our scientific understanding with our ethical principles to decide what we should do given the capacities for genetic modification that have been developed.
- 1.3 Few questions of practical reasoning about policy or practice can be dealt with in a simple form. Practical reasoning typically involves weighing up or balancing the benefits of a technology like genetic modification with its potential harms or disadvantages. Proponents claim that GM plant technology will raise agricultural productivity, assist the development of safer, more nutritious foods with a longer shelf-life, and contribute to the goal of increased food security for the poor in developing countries. Against these, we must set the claims of those who say that GM food technology is a threat to human health and/or the environment and that its introduction will raise the profits of private suppliers whilst at the same time depriving poor producers of primary commodities access to markets and to the new varieties of seed. Whether GM technology is morally acceptable is a matter of the plausibility of these factual claims and their importance in the light of moral principle.
- 1.4 There are three main types of principle that are relevant to the evaluation of policies or practices. The first principle is a principle of *general welfare* which enjoins governments (and other powerful institutions) to promote and protect the interests of citizens. The second is the maintenance of people's *rights*, for example their rights to freedom of choice as consumers. The third is the principle of *justice*, and it requires the burdens and benefits of policies and practices to be fairly shared among those who are affected by them. When we consider the introduction of a new technology, such as that related to GM crops, we can ask a series of questions in the light of these general principles. Will the technology promote the general welfare by making for improved food safety or reducing the use of chemical pesticides in agriculture? Or does the technology pose unknown risks for consumers and the environment that we would be wise not to run if we are concerned about the general welfare? What implications does the technology have for the rights of consumers, for example the right to be informed about the food one is eating? What implications does it have for the rights of

Genetic modification involves the direct introduction of desirable characteristics by artificial transfer of foreign or synthetic DNA (deoxyribonucleic acid, the genetic material) into an organism. A GM organism or GMO has therefore been altered in a way that does not involve mating and/or conventional genetic recombination. EC Directive 90/220/EEC (OJ L117) 8 May 1990, pp 15–27, Article 2.

scientists to be free to conduct their research in ways that protect their intellectual integrity? Finally, we can ask questions derived from a concern with the principle of justice. Who will be the principal beneficiaries from the introduction of the new technologies and what obligations do they have to compensate the losers?

- 1.5 This report discusses the social and ethical implications of GM crops. We do not intend to draw a sharp distinction between ethical concerns and social issues. On the one hand, ethical principles concern the social framework within which we live. On the other, we need to be aware of the social and technological background against which we discuss ethical issues. Scientific, ethical and social issues cannot be wholly separated from each other; nor should they be so. In particular, we accept the point made by many of the respondents to our consultation: it is, in a broad sense, an ethical choice to employ scientific knowledge in the hope of improving the human condition. Different societies have set different values on the acquisition and use of scientific information; trying to use scientific knowledge for what Francis Bacon called 'the relief of man's estate' may seem an obvious choice, but it is not an inevitable one.
- 1.6 It is the ethical basis of the regulation of commercial development and production of GM crops and the promotion of genuinely useful research by government action that mostly concerns us. For most individual consumers, the choice whether to consume or not consume GM food is not a matter of ethics. A consumer who thought GM food unsafe would be unwise but not wicked to eat it. Only if consuming GM food is thought to be intrinsically wrong, as eating non-kosher food is for orthodox Jews, is its consumption ethically wrong, and directly so. The consumption of GM food would be ethically problematic, but in an indirect fashion, if its production did harm, violated rights, or caused injustice. The claim that the production of GM crops does one or all of these things is frequently made by their critics.
- 1.7 In setting out the three main types of ethical considerations that we think are relevant to the evaluation of GM technology we have so far avoided one major issue, namely the ethical status of the natural world itself. GM crops do not raise questions about the rights of plants, in the way that animal experimentation raises questions about the rights of animals; nor do they raise questions about the welfare of plants. They do, however, provoke a reaction that is difficult to place within arguments about welfare, rights and justice. Some perceive GM crops as 'unnatural' and those who disapprove of their development and use for this reason are among the strongest critics of GM crops. Many individual respondents to our consultation expressed views of this kind. One said 'I grieve at what seems to me a violation of the fantastic and incredible world in which we live' and this was not an uncommon sentiment.<sup>2</sup> For all the decline in formal religion, there remains a deep-rooted belief that we 'tinker' with nature at our peril.
- 1.8 Others have argued that it is unethical to treat nature in an 'industrial' fashion, not simply because of the unfortunate consequences of so doing, but because they believe it is intrinsically wrong. Whereas the first of these concerns can be accommodated under the principle of the general welfare, the second makes 'the environment' an object of ethical concern, regardless of how the environment affects the interests of human and other animals. GM crops thus raise ethical issues about the rights and wrongs of the ways we affect the environment that are especially difficult to analyse and resolve.
- 1.9 The government of a modern democratic society is obliged not merely to accommodate the deeply held moral convictions of its citizens, but to treat them with respect. But these convictions on such vexed problems as euthanasia, for example are usually held by minorities no more numerous than those who hold the opposite conviction. The task of governments cannot be to legislate or regulate by making these convictions the basis of law, but it is rather to pursue policies that can command

- something close to a reflective consensus. This is why safety, health, economic well-being, and the avoidance of environmental degradation are commonly the goals of policy. To say this is not to ignore what some of our correspondents describe as 'intrinsic' ethical considerations, but it is to say that they must enter policy in more complicated ways than for example, considerations about safety and health.
- 1.10 Most people, and the majority of philosophers, believe that there is no single principle that should determine our conduct or the making of policy. We cannot assume that considerations either of welfare, or of rights, or even of justice taken on their own should be decisive in deciding what we are to do. Consequently, we need to consider the meaning and implications of each of these principles as part of our overall assessment. This is the task of the remainder of this chapter. However, even though we consider that the principles of welfare, rights and justice exhaust the principles that are relevant to the formation of public policy, we need to understand the concerns that lie behind the claim that GM technology is somehow unnatural or intrinsically wrong. We also seek to elucidate these concerns in this chapter, although we end by noting that the world into which GM crops are being introduced is one in which farming is already in many ways a decidedly 'unnatural' activity.

#### Welfare and the role of government regulation

- 1.11 One fundamental purpose of public policy is to protect and promote the welfare of citizens. In this context, the concept of welfare is normally understood in terms of a list of basic securities: access to safe and nutritious foodstuffs, protection from environmental harms, and enhancement of research and development (R&D) to provide the knowledge on which the provision of such securities can be built. A fundamental question about GM crops is whether and how they promise to increase human welfare and whether their introduction may damage human welfare directly, by injuring the consumer, or indirectly, by damaging other things we value, such as a diverse environment and wildlife. Arguments about human welfare are so familiar that they are sometimes dismissed as hardly ethical arguments at all. However, the impact of human behaviour on the welfare of others imposes stringent requirements on us. Endangering the health or safety of other people is morally wrong, and in severe cases almost invariably illegal. The health and safety of citizens are also at the heart of the greater part of government regulation. Since questions about human welfare frequently raise questions about the probability of the risks and benefits involved, the ethical issues are often obscured by the scientific problems of risk assessment. But it is always possible, in principle, to distinguish between the two distinct questions of 'how bad?' and 'how likely?' That is, we can and should separate the reasons for regarding an outcome as an evil from the likelihood of its occurrence.
- 1.12 The concern of government with the welfare of its citizens underlies much current regulatory practice. One of the duties of companies introducing GM crops, whether in experimental trials or for commercial use, is to ensure that they do no harm or that any harm is so slight as to be generally acceptable. The regulatory system for GM crops and their products in both the UK and the European Union (EU) is predicated on this simple proposition. The prevention of harm is sometimes extended to promote the adoption of the so-called 'precautionary principle'.<sup>3</sup> This puts the avoidance of harm to consumers and the environment at the head of the list of regulatory goals. The blanket adoption of the precautionary principle risks an imbalance between the avoidance of harm and the achievement of a positive good. This is because some interpretations of the precautionary principle require us to give an absolute priority to the first goal before we attend to the second.

The 'precautionary principle' is incorporated in the **Maastricht Treaty**. It is the rule that permits governments to impose restrictions on otherwise legitimate commercial activities, if there is a risk, even if not yet a scientifically demonstrated risk, of environmental damage. Its interpretation is disputed and we return to it in subsequent chapters.

- 1.13 The precautionary principle can be understood as a simple welfare-based principle. As such it raises familiar problems, of which the most important is to define the conditions under which the avoidance of harm should take priority over the attempt to do good. Ordinarily, we balance the good we hope for against the bad we would wish to avoid, a process which economists have elaborated into 'cost/benefit' analysis. Common sense suggests that the development of crops that substantially reduce hunger or improve nutrition in the developing world would justify running the risk of modest damage to the interests of well-off consumers or the environment. Conversely, critics argue that GM crops will bring benefits only to the producer or farmer, not to the consumer, and that any risk of harm cannot be justified. Both views imply that it is right to balance the good achieved against the harm imposed.
- 1.14 A stringent interpretation of the precautionary principle would preclude such balancing. It may, however, be best interpreted, not as part of our cost/benefit calculation, but as a principle governing how we should engage in such calculations. Consequently, it is treated sometimes as a rule of thumb that regulators should adopt a wary attitude to new technology and sometimes as a reminder that if the harm anticipated is very great, we should be attentive to very small risks of it occurring. As some of our respondents have suggested, the precautionary principle may also be understood as a reminder that human beings are all too easily carried away by excitement and novelty, and need to be warned against hubris. However, other respondents have treated the precautionary principle as a distinctively moral principle, which emphasises the intricacy of the natural world and which urges us to take that intricacy with proper seriousness. Understood in either of these ways, the principle does not yield very definite prescriptions, but does urge caution upon scientists, governments and farmers. We agree that a precautionary approach to so novel a technology as that of GM crops is justified, as we say below, but we would not wish concerns about very small risks to the inhabitants of developed countries to inhibit the R&D that can benefit the inhabitants of the poorer world.

#### Consumer choice and rights

- 1.15 One way of promoting welfare is to ensure that consumers have a choice, since we generally set out to choose what is good for us and avoid what is harmful. But for some consumers in the UK and the EU, the avoidance of GM foods is itself the good that they seek; their demand for 'choice' is primarily a demand to be allowed to avoid GM foods. For others, the provision of choice acknowledges a diversity of views. If consumers are to have a choice, they must of course know which foods are and are not GM. In the United States (US) farmers, food processors and the Government have all agreed on the need to avoid exposing consumers to danger. However, they have resisted requests, mostly from Europe, to accept mandatory labelling requirements which would allow consumers to avoid GM products, especially when the two alternatives are not substantially different. Such labelling requirements protect choice as a value independent of consumer safety, but at a cost. A demand for consumer choice not based on avoidance of harm needs to be justified in the context of regulation to politicians, regulators and food producers. US producers have viewed elaborate labelling requirements, imposed to allow consumers to choose not to consume GM foods, no matter what their reasons, as restraints on trade under another name.<sup>4</sup>
- 1.16 Choice thus raises issues of rights as well as issues of welfare. Considered as a matter of welfare, the 'balance' to be struck is that between the cost to producers of offering the choice and the cost to consumers of forgoing it. Considered as a matter of rights, the 'balance' to be struck is that between the expectation of commercial firms that they will be able to operate in a predictable environment and the right of the consumer to choose what she or he consumes.

- 1.17 It is sometimes said that consumers have an absolute right to choose what to consume and what not to. In one sense, this is undeniable. Nobody is obliged to shop in any particular store or to purchase any particular product. The right to reject goods that are offered to us, without giving any reason, is taken for granted. The right to choose presents difficulties only when it imposes costs on others and therefore diminishes their right to choose. It is, however, typical of rights that they impose costs. Even the seemingly modest right to know what we are eating will impose costs on others. To enforce a consumer's right to know what is in processed foods by requiring specific labelling imposes costs that initially fall on the producers. These costs may then be passed on to consumers in the form of higher prices or absorbed in lower returns for the producers or lower wages for their employees. There is no consensus to date on how substantial the costs of labelling GM ingredients might be or on whom they should fall. Such costs may be slight, or they may be considerable. This at least suggests that the argument for the consumer's 'right to know' through the imposition of labelling requirements on producers is less straightforward than many suggest.
- 1.18 A further question is the extent to which the consumer's right to choose implies duties on producers over and above the duty to label. If all brands of some processed foods now contain GM soya, the consumer of these foods is faced with Hobson's choice. The right not to consume GM foods has little meaning when there are no non-GM foods to be consumed in their place, or no way of knowing which is which. But does the consumer have the right to buy a range of non-GM products that other people would not otherwise have chosen to produce? To say the consumer has such a right seems extreme. Of course, if supplying such a demand is profitable, it is likely that the market would supply it anyway; but the assertion of a right to have such products available is more contentious than that suggests.
- 1.19 To claim a right is often contentious. The point of claiming rights is to limit other people's freedom. When we have a right, what other people may and must do is fixed by that right. Rights override, except in extreme cases, the preferences and even the well-being of those against whom the right exists. This means that the right to choose is unproblematic only when it is the right not to purchase a particular product. Claiming a right to have a product made available when the market would not otherwise have supplied it, presents grave difficulties. It is one thing to insist that suppliers guarantee not to poison the customer; it is another to insist that companies should supply any particular range of products. It is yet another to require that such measures should be accomplished at no cost to the consumer.

#### The principle of justice

1.20 Behind both the balancing of the welfare of different people and groups, and the balancing of their competing rights, lie ideas of justice. When considering the welfare interests or competing rights of individuals, groups, industry or the state, we try to strike a fair balance or seek a just outcome. For example, if protecting the rights of consumers by providing adequate labelling was very expensive and was generally agreed to do nothing to prevent harm, most people would say that upholding the right to know would not be worth the loss of value to producers, particularly if the producers were poor. Conversely, if informative but inexpensive labelling was desired by the majority of consumers, it would probably command wide public support. The principles at stake are not complex but their implementation is. Securing a consensus is complicated by the fact that producers have an interest in exaggerating the difficulty of complying with new regulations and pressure groups have an opposite interest in exaggerating the public demand for them. Such questions about where the balance of burden and benefit is to be struck are the subject of everyday political debate.

For example, if I owe you £30, I must pay it even if you need it much less than I. You may forgive me my debt, but I cannot forgive myself the debt I owe you.

- 1.21 A further issue of justice discussed in several parts of the report is whether the larger seed and agrochemical companies possess excessive market power in relation to new entrants to the market, researchers, consumers and the unorganised businesses and consumers of the developing world. The cost of developing new products may inevitably be such that only substantial enterprises will have the resources to undertake it. Large companies naturally carry out research that is in their interests and gives them an advantage over their competitors. They also acquire patents in order to protect their technology and products. There may also be clear advantage to a few large companies to pursue a degree of vertical integration so as to tie in both their customers and their own suppliers. The significance of these concerns is of course contingent on the extent to which such imbalances of power exist. If non-GM seeds continue to offer advantages to farmers that are unmatched by GM seeds, the problem may not be acute. However, in some parts of the world such as the US, it seems likely that almost all the best varieties of the major crops will be genetically modified within ten years. If poorer countries are excluded from adopting GM seeds, their cash crops may become uneconomic and their domestic food supplies may be deprived of potential improvements. The gap between rich and poor might grow.
- 1.22 Complex questions about justice are also raised by two generally neglected aspects of the problems posed by GM crops. The first is whether the benefits of GM-based farming will be directed towards those to whom they will do the most good. This is certainly a question to debate within developed societies but, more importantly, it is a question about fairness between the richer and poorer societies. So far, the initial benefits of GM crops have largely accrued to some of the seed and agrochemical companies, US farmers and US food producers. Farmers who use less herbicide and insecticide will benefit from reduced costs; and those companies who market both seeds and herbicides will increase their returns.
- 1.23 Benefits to consumers are harder to find. GM tomatoes that can be processed more efficiently to produce cheaper tomato paste have been readily accepted by UK consumers.<sup>6</sup> Apart from this example, however, little has happened to persuade the consumer that the quality of food will be enhanced in more sophisticated ways or that it will become cheaper. Since these are the two things that most affect consumers, GM crops are currently vulnerable to questions about their real usefulness and to questions about who benefits.
- 1.24 More important and yet frequently under-emphasised, is the disparity between the developed and the developing world in the effort they devote to agriculture. The prospect of a second Green Revolution, which extends the benefits of the first Green Revolution<sup>7</sup> to crops and areas so far unaffected, is an immensely attractive one. Improved crops in the developing world would create productive work and provide cheaper and more reliable food locally, reduce mortality and malnourishment, and perhaps assist development in other ways. Can these hopes be taken seriously while research, development and the commercial introduction of GM crops are focused almost exclusively on the needs of industrialised agriculture in the developed world? Failure to answer such questions would be a failure to take justice seriously.
- 1.25 If GM crops are developed to benefit less-developed areas, they will have an impact on the kind of farming practised. Many of those who responded to our consultation have suggested that farmers in the less-developed world practise viable ways of farming that it would be unethical to disrupt. If the impact were disruptive, it would raise the question whether the gains of future producers and consumers amounted to just recompense for whatever disruption occurs. There are two things to be said about such a question. The first is that any disruption would not stem from the fact that the new crops were genetically modified but from other features, such as altered farming patterns. As

The University of Reading National Centre for Biotechnology Education (http://www.ncbe.reading.ac.uk) has an account of the origins and introduction of the new tomato.

For a discussion of the Green Revolution, see paragraph 4.4.

we show in Chapter 4, GM crops would in fact tend to create more work, but innovation inevitably produces changes which some people find disruptive. The second point is that if the reality of farming in sub-Saharan Africa and elsewhere is that yields are declining and the present way of life is increasingly unsustainable, there is less to question about the morality of adopting better yielding GM crop varieties. If, however, GM crops are adopted but later found to be harmful or have consequences that can only be righted by substantial investment, poorer countries might be substantially disadvantaged.

- 1.26 The problem of justice needs to be considered in the context in which general agricultural productivity, and therefore general welfare, is raised but where some people benefit and others do not benefit or even lose. One idea here that has been popular among economists concerned with the ethical appraisal of technical change is that of Pareto optimality (named after its original formulator, Vilfredo Pareto, the Italian economist). A situation is defined as Pareto-optimal when nobody can be made better off without making someone else worse off. If a technical change, like the introduction of GM technology, can be introduced such that productivity can be raised so that everyone is better off, then from an economic viewpoint, it should be introduced. A Pareto-optimal improvement would have been achieved.
- 1.27 However, there are few cases of technical change which produce an unambiguous all-round improvement in the welfare of everyone who is affected, without making someone worse off. Usually technological innovation produces some gains and some losses, and there is no reason to think that GM technology is likely to be any different. How might the justice of the change be assessed in this common type of situation? Economists have extended the notion of Pareto optimality to develop the concept of the 'compensation test'. The new situation is better than the previous situation if the 'winners' can compensate the 'losers', and still have something left over. There is some tension between the economist and the ordinary person however. Most people think that the fact that the winners could compensate the losers is not decisive, and that a change is unequivocally an improvement only if the winners do compensate the losers. Where the winners gain greatly, but there is no way of compensating the losers, our intuitions about whether the situation is an improvement are affected by the relative prosperity and misery of the winners and losers. The terms of trade may change in such a way that a rich person can buy a second Rolls Royce while a hungry person in Zambia becomes hungrier. It is clear that if some of the rich person's gain could be transferred, the poor person would be very much better off; if it cannot, it is not obvious how we can compare the relative losses and gains. The relevance of this thought is that when we ask consumers in prosperous countries to suppress their doubts about GM crops so that research relevant to the developing world is continued and encouraged, we are asking them to agree that their losses are smaller than the gains of the poor, even though there is no obvious way in which that sum can be done. This may be right, but it relies on our everyday intuitions about justice, not on ideas about economic optimisation that economists can help us with.
- 1.28 A last question about rights and fairness concerns responsibility for the consequences of GM crop introduction. Consider the possibility that the introduction of GM oilseed rape alters the environment, as compared with current agricultural practice. Who is to be held responsible? If such crops were to be prohibited, who is to bear the burden of doing without them? Between the scientist's laboratory and the altered environment lie many steps. If the scientist had not done the research, no company could have applied it. If the company had not developed it, no trials could have been held; without trials, no plantings by farmers could have taken place, and so on. Yet it has generally been accepted that the scientist had the right to do the research because any remote effects were indeed remote. We normally take the view that it is not the originators of the technology who are responsible, but those who seek to develop and implement it.

- 1.29 Should responsibility be allocated differently? Who is most responsible? The scientist, the development company, the government committee that approves field trials, the commercial seed company or the purchasing farmer? The temptation to pass responsibility up or down the line to someone else is not always unreasonable. The producer is not usually held to account for the misuse of the product. The scientist would not, in general, be held responsible for the misbehaviour of farmers. However, a scientist or entrepreneur who put into circulation hazardous materials of whose dangers he was fully aware would be blamed for doing so. Where a product cannot be used 'properly', we blame the producer along with the user. There is no obvious solution to such problems about the allocation of responsibility, but their existence places another burden on governments and regulators.
- 1.30 The ethics of developing and growing GM crops has been our central concern. But we have also been led to reflect on the ethical standards that ought to govern the debate, in particular the need for participants in the debate to be careful about verifying facts and restrained about both optimistic and pessimistic speculation. The views expressed to us by many of the consultation respondents<sup>8</sup> and by those who talked to us directly<sup>9</sup> made it clear how hard it has been for ordinary people to obtain an agreed view of the facts about GM crops. Many respondents were concerned with the hypothetical condition of a world in which GM crops dominated agriculture. Others pointed out that despite the rapid uptake of soya, maize and cotton in the US, GM crops were not expected to make much headway in the UK for at least five years. The fact that Monsanto supplies only three percent of the world's seed<sup>10</sup> belies the image of a new industrial revolution sweeping through agriculture under the impetus of a few multinationals. A well-informed consensus on the facts would resolve some of the arguments and reduce some of the public unease.
- 1.31 Whose responsibility is it to secure such a consensus, and what are the ethics of public discussion? We say more in Chapter 8 about the need for an advisory committee to focus public discussion and enlighten policy. Meanwhile it is clearly deplorable, both on simple utilitarian grounds, and in terms of the violation of the public's right to be informed, for pressure groups, journalists, commercial concerns or others to put into circulation exaggerated accounts of what can be expected from GM crops. It would have been hard in recent months for anyone to discover from newspaper reports how GM crops were supposed to benefit or harm consumers or the environment. There are unknown dangers in all areas of human endeavour, but the debate on GM crops has too often appealed to hysteria and vested interests.

#### The natural/unnatural boundary

- 1.32 Issues involving general welfare, rights and justice, although complex, are unequivocally ethical issues. There are other issues that arouse great passion, which are 'ethical' in a different way. They arouse feelings, less of moral concern than of disgust and revulsion. The idea of genetic manipulation of human beings seems to provoke such reactions. Is it plausible to claim that some kinds of GM plants are also 'unnatural' in the same way?
- 1.33 If the 'unnaturalness' of genetic modification is to be admitted as a reason for disapproving of GM crops, even though health and environmental risks have been eliminated, the process must violate some important boundary. The cloning of Dolly in 1997 set off a wave of unease about the possibility of human cloning. Those who thought that if it worked, it might be a useful extension of

<sup>8</sup> Appendix 4 summarises the views expressed by respondents to the Working Party's Consultation.

<sup>9</sup> See Appendix 3.

Merritt C and Walters S (1999) Personal communication, Monsanto plc (CM) and Monsanto Europe SA (SW)

- ordinary human reproduction met with the charge that it would be an extension that simply went too far. Recent debates over GM crops have aroused exactly these sentiments.
- 1.34 Unease has been aroused by the thought of breaches of the 'species barrier', so that 'fish genes' may be put into strawberries, for instance. Many respondents to the Consultation thought that such breaches represent an improper tampering with nature. In what way is a gene that is found in a fish and which might be very similar in structure and function to one found in a micro-organism, plant or animal, a 'fish' gene? Some would say that it is no more than a defined stretch of DNA in a fish cell. But that does not seem to help. What lies behind such concerns?
- 1.35 It is unclear how widespread this sentiment is and it is not obvious what its source might be. The BSE epidemic is widely thought to have been caused by feeding meat products to cattle and by most definitions it is 'unnatural' to feed meat to herbivores. To take one example, when the UK food retailer, Iceland Frozen Foods, asked the general public whether they wished to purchase products containing GM ingredients, the response was broadly negative (paragraph 5.15). <sup>12</sup> Since consumers have a right to choose what not to purchase, Iceland had both a commercial and an ethical reason to accede to their wishes. However, Iceland also asked respondents how they viewed GM soya in their food. Interestingly, only a minority said that their main reason for disliking the idea was the feeling that GM foods were 'unnatural', and that this was 'interfering with nature'. The 23% who 'just didn't like the idea' may in fact hold similar views or may be worried about safety.
- 1.36 Indeed, most of the objections to GM foods in the Iceland Frozen Foods' study seemed to be on safety grounds. Although these consumers were not clear about how GM foods might add to existing risks, they did not wish to run additional risks without receiving any obvious benefit. Again, that raises no special ethical problems. Life cannot be risk-free, but consuming GM soya may not be a matter of substituting one risk for another but rather of possibly adding a new risk. The consumers made a prudent decision to avoid a new unknown risk. The ethical demand fell squarely on the company: to respect their choice, to acknowledge the right of the consumer to say no or to provide an obvious benefit, such as a conspicuous price reduction.
- 1.37 The more complex question concerns the minority of respondents in Iceland's survey who disliked 'unnatural' tampering with food. Some people claim to have no sentiments about nature and the unnatural at all. It is often said that it is only from a theological perspective that it makes sense to treat the naturalness of nature as a moral value. This is plainly not true, although people with religious beliefs may well derive their beliefs about the impermissibility of certain kinds of genetic modification from those beliefs, just as they would derive many of their other moral beliefs from the same source. From a Judaeo-Christian perspective, it is an important truth that God created nature for His own purposes, not merely for our use, and that these purposes are important, indeed that it is mandatory for us to respect nature as part of that creation.
- 1.38 Biblical premises yield positive duties as well as restrictions on what we may do with the world, however. We have been impressed by the emphasis placed by our Consultation respondents from the Church of Scotland, and the Office of the Chief Rabbi, among several others, on the duty laid on humanity to 'cultivate and reorder nature'. God's gift is a grant of sweeping authority to use the raw materials of nature wisely, i.e. the stewardship principle. Indeed, it would represent

<sup>11</sup> See Appendix 4.

The Gallup Organisation (1998) **Genetically Modified Food: Executive Summary Report (prepared for Iceland)** (unpublished). The research was carried out by the Gallup Organisation between 3 and 9 March 1998. Adults aged 16+ were interviewed randomly by telephone. There was a margin of error of ±3%.

In this study, of the 72% of respondents who were unlikely or very unlikely to purchase genetically modified food, 23% said they just did not like the idea, 24% said they didn't know enough to buy them and so were unsure, 29% said they didn't know enough about the long term effects and 30% said they did not like the interference with nature. Consumer opinions of GM foods are discussed further in Chapter 5.

<sup>14</sup> See Appendix 4, Appendix 5.

<sup>15</sup> **Genesis** 1.28.

ingratitude for God's bounty to neglect the materials placed before us. The parable of the talents is at home in both Jewish and Christian thinking, and God's injunction to 'be fruitful and multiply' is a moral injunction. <sup>16</sup> So far is orthodox Judaism, for instance, from restricting scientific inquiry that we were told during the consultation that orthodox Judaism has no problem with GM crops; being kosher is not a question of biochemistry.

- 1.39 The concern that GM crops transgress natural barriers raises a question: how does nature set boundaries and why is their transgression wrong? Anthropologists have explored this question in discussing ideas of pollution. Some critics of GM crops talk of cross-pollination from GM crops as 'pollution'. The concept of pollution has been said by some anthropologists to refer to illicit boundary-crossings, and they have thought that all cultures seem to have some conception of pollution because all cultures have some conception of 'things in the wrong place'. Sometimes the undesirability of pollution has a simple practical explanation. Grit in the oil will wreck the engine. Coal dust in the air will give us black lung. Not all sorts of wrongness have an easy explanation of that kind. Racism is an extreme, though widespread, symptom of the desire for purity. Indeed, many of the yearnings for 'natural purity' have little or no justification. Tribes that kill twins at birth appear to do so out of a sense that human beings are rightly born singletons and that only animals have multiple births, but they seem to take these drastic measures without much thought about exactly what would go wrong if they did not do so. Is it possible that some of the fear of GM crops is of the same sort?
- 1.40 The 'natural/unnatural' distinction is one of which few practising scientists can make much sense. Whatever occurs, whether in a field or a test tube, occurs as the result of natural processes, and can, in principle, be explained in terms of natural science. When human abilities to transform the world are limited, the distinction between nature and artifice seems fairly clear. It has often made better sense to accommodate ourselves to the forces of nature than to fight them. Is a plant acceptably natural or 'organic' if it has been successively bred to have a particular gene complement, but unnatural and not 'organic' if precisely the same gene complement has been arrived at through laboratory processes? We can see no reason in ethics to draw a distinction.

#### Taboos and moral conservatism

- 1.41 If the point of drawing a line between the natural and the unnatural is to provide a sort of comfort in our dealings with the world, what is the source of that comfort, and how far can we do without it? Two answers to that question may be borrowed, one from Mary Douglas, the other from Martin Heidegger. The anthropologist Mary Douglas is one of the few writers to treat pollution and taboos entirely seriously but from a secular point of view.<sup>17</sup> Her view of taboos is that they are reflections of attachments and cleavages in society. The Jewish prohibition on eating pork was a way of imposing order on a disordered world. Pigs have cloven hooves but do not ruminate; they were viewed as anomalous and therefore potentially dangerous.
- 1.42 This is, of course, speculative but, whatever the cause of taboos, the question then arises as to whether taboos should be given up whenever they are inconvenient. The 'defence' of taboo is complicated because it comes in two different layers which are not easy to separate. Societies with well-entrenched taboos are said to be happy, culturally coherent and religiously harmonious. Attempts to modernise such belief systems may cause more misery than good. This is the defence of moral conservatism in general. It infuriates rationalists and progressives, because it denies that

<sup>16</sup> Ibid.

Douglas M (1973) Natural Symbols, Barrie and Jenkins, London; her earlier Purity and Danger (1966), Routledge, London, is more 'intellectualist' in approach. Both are thought-provoking discussions of dietary and other forms of taboo.

there are overwhelming gains to be made by throwing out what progressives and rationalists regard as superstitions. Conservatives reply that they agree that we pay a price for conserving the moral environment. There are things we could do but do not do, and maybe some of them would have good effects. We need not deny that progress is progress when we decide not to pay the price of it, because that price is too high.

- 1.43 There is a further defence of a morally conservative view of the environment to be considered. It stems from the notoriously difficult philosopher, Heidegger, <sup>18</sup> but its appeal is wide. His idea is that the world possesses a meaning that we can only understand if we approach the world in a receptive mode, in the way the poet, the artist or the traditional peasant does, not in an 'industrial' way. On Heidegger's view, technology is a moral disaster. We become manipulators of things and lose touch with their sense. It does not follow that no use of the natural world is permissible or worthwhile, but many are not. All forms of industrialised agriculture are culturally impoverishing and GM crops would be another step further down an already disastrous road. This may be so, but there seems little justification in banning GM crops on these grounds when the rest of society travels so substantially in the direction Heidegger opposed.
- 1.44 The thought that animates many people when they object to the unnaturalness of one or another way of treating plants is that some relations with the world take the form of harmonious, satisfying, emotionally fulfilling interactions, and others amount to assaults on the world. Certainly, some of the case for organic farming seems to rest on that thought. Someone who holds that view can accept much of the sceptic's reminder that what we call 'nature' is for the most part the result of old technologies. The world bears many traces of what humanity has done to it in the past. The critic will think that some have gone with the grain of nature and some against it.
- 1.45 One view is that there is more to our interaction with the physical world than technical manipulation of it. That view does something to explain why some environmentalists would want an environmental audit to include a dimension that the most scrupulous and well-informed scientific inquest into the physical risks posed by the introduction of GM crops would lack. If new crops change the appearance of the environment, alter the wildlife in the terrain, demand new working habits and so on, they impose a kind of cost not easily captured by the usual cost/benefit analysis. We may doubt whether there is much prospect of living perfectly harmoniously with nature, no matter what form of agriculture we practice.
- 1.46 This report is largely concerned with the ethical implications of actual and potential government policy, and sees government policy as centrally concerned with human welfare, rights and justice. A government that puts in place regulations that enable innovation to prosper and commerce to flourish, encourages useful research, and which enables its citizens to do their duty by the poorest in the world as well as by their immediate neighbours, would be meeting high ethical standards as well as quite unusual standards of competence.
- 1.47 The world within which we are discussing these issues is already a world where human beings have transformed plants, animals and the soil itself. More narrowly, it is a world in which we have recently transformed farming from an occupation dependent on enormous quantities of animal muscle power into a sophisticated industrial activity. As with every other economic activity, this enhancement of productivity has brought many gains and many losses. It is necessary to remember that GM crops are, in the early stages of development in the developed world, a rather marginal addition to the scientific manipulation of nature over the past half-century.
- 1.48 Nor is it reasonable to blame GM crops for a tendency to industrialise agriculture. This is a process which owes its momentum to geopolitical and market forces. The industrialisation of agriculture was

Heidegger M (1977) **The Question Concerning Technology**, Harper and Row, New York, is the most notorious of his attacks on industrialised agriculture.

not something that farmers and scientists decided to 'do' for its own sake. Farming is the product of very many economic 'pulls and pushes'. On the one hand, the attractions of urban life and urban employment pulled workers off the land and made labour-saving farming more attractive. On the other, the low farm incomes of the first half of this century pushed workers off the land. War made agricultural self-sufficiency attractive; the availability of cheap food from the Commonwealth made it less so. Since the creation of the European Economic Community (EEC) and eventually the European Union (EU), an elaborate regime of subsidies has done at least as much to dictate what farmers are willing to produce as anything intrinsic to the soils and climates they worked on and in.

- 1.49 Modern food processing and the replacement of old-fashioned grocers and greengrocers with supermarket chains have had a great impact on what is produced. Consumers want and get uniformity and consistency of product, and a high value is placed not only on uniformity but also on storage qualities and those properties that make foodstuffs easy to warehouse and transport. It is these pressures that have accelerated crop monoculture. The dependence of the ultimate producer on both suppliers of seed and agricultural chemicals and on a monopoly purchaser in the shape of the modern supermarket chain does much to explain why the landscape is already one in which weeds have all but disappeared from cereal fields.
- 1.50 There is obviously a need to ensure that agriculture follows a sustainable path, so that the immense productivity gains that have been secured in the post-war period in the developed world are not purchased at the cost of loss of agricultural resources for the future. However, this is not the same as saying that it is possible to return to a previous, often highly romanticised, form of agriculture. Industrial methods, in some form or another, are here to stay. Concern for the poor and dispossessed in, say, Russia or sub-Saharan Africa, mean that the developed world must recognise that there are likely to be difficult choices to be made in the less developed world's search for the same productivity gains in agriculture that the developed world now enjoys.

#### **Conclusions**

1.51 We think that the general welfare of affected peoples largely determines the ethical acceptability of GM crops. In concrete terms, this means that their potential advantages are a matter of cheaper, more secure and less environmentally damaging food supplies, and their disadvantages, any risk to human health and environmental damage they may pose. GM foods raise issues of the right of consumers to choose what to consume and of the costs these rights may impose on producers and consumers alike. The way that the costs and benefits of agricultural technologies fall on the citizens of well-off and poor societies respectively raises questions of justice, as well as difficult issues of how policy makers can steer technological change so that it does good to those who most need it. We think that the decision about what is unnatural cannot be one for public policy, but that the freedom of choice of consumers must embrace the ability to refuse what they reject as 'unnatural' products. We do not believe GM crops will necessarily increase monoculture and conclude that there are no ethical objections to GM food other than any direct or indirect risk to human health or the environment.

The scientific basis of genetic modification

#### Introduction

2.1 Genetically modified (GM) crops have come into prominence during the past decade. This is because plant breeders have learnt to apply GM technologies, first developed for plants in 1983, to a wide range of crop species. The first applications of genetic engineering, or genetic modification, as it came to be known, were in human medicine. The need to develop cheaper, safer and more plentiful sources of substances such as insulin and interferon drove developments from 1976 until the early 1980s, and led to the formation of a number of new, small, innovative biotechnology companies, often closely associated with universities. This, in turn, released new scientific knowledge and commercial opportunities which were taken up by leading members of the pharmaceutical industry and, more recently, by a number of agrichemical and seed companies. The initial commercial goals of plant biotechnology were directed at the markets of the developed world. There is, however, a growing realisation in the wider research community that this new set of technologies could make a valuable contribution to the increasingly urgent problem of the global food supply. In this chapter we set out the scientific basis for the genetic modification of plants.

#### Conventional plant breeding

- 2.2 Almost all of the crops that we cultivate today are much changed from their wild ancestors. Breeding by selection and saving the best seed for the next generation has been in progress for many thousands of years. In most crops, the incorporation of traits compatible with agriculture, such as free threshing in cereals, was achieved centuries ago. Scientific breeding, however, which followed the rediscovery of Mendel's Laws,<sup>2</sup> has been under way only for the last 90 years.
- 2.3 Progress has been dramatic, particularly for the cereal staples, wheat, maize and rice. New agricultural methods, particularly chemical fertilisers, herbicides, fungicides and mechanisation, have been developed alongside improved crop varieties to double world food production over the past 40 years. In view of some of the perceived problems associated with GM crops, it is worth pointing out that in conventional breeding, as with any new technology, some mistakes have been made and lessons learnt.
- 2.4 For example, in the 1950s, a type of maize was used for F1 hybrid<sup>3</sup> production in the US which was subsequently discovered to be associated with susceptibility to Southern corn leaf blight.<sup>4</sup> During the 1970s, wheat varieties with single major gene resistance to fungal diseases were released in the UK, one after another. The best varieties were usable, on average, for only 14 months as the fungus populations repeatedly overcame the disease-resistance genes. The supply of resistance genes became limiting and farmers increasingly had to rely on chemical fungicides to keep their crops free from disease.<sup>5</sup> These instances, although costly and apparently very serious at the time, did not produce significant, long-lasting effects.

Genetic modification involves the direct introduction of desirable characteristics by the artificial transfer of foreign or synthetic DNA into a plant. DNA (deoxyribonucleic acid) is the biochemical substance from which the genetic material is made.

Mendel's first law states that when a cell (containing two copies of each gene, arrayed on two matching chromosomes) divides to form two sex cells (such as eggs, sperm or pollen), each sex cell will only have one copy of each gene. The second law states that members of different pairs of genes will move into the sex cells independently of each other. Consequently, it cannot be predicted which one of the two copies of each gene will end up in a particular cell. However, the closer the genes are to each other on the chromosome, the more likely they are to be inherited together.

<sup>3</sup> F1 hybrid seed is produced by inter-crossing two predefined parental lines. F1 hybrids are favoured by producers because they display hybrid vigour or heterosis. F1 hybrids do not breed true and, therefore, farmers cannot save seed.

<sup>4</sup> Pring D and Lonsdale D (1989) Cytoplasmic male sterility and maternal inheritance of disease susceptibility in maize, **Annual Review of Phytopathology**, 27:483–502.

Johnson R (1992) Past, present and future opportunities in breeding for disease resistance, with examples from wheat, **Euphytica**, 63:3–22.

- 2.5 Many have therefore argued that the effects of the introduction of GM crops on the agricultural environment should, realistically, be assessed in the context of current intensive agricultural methods. These include not only the varieties produced by advanced plant breeding techniques, but also the use of more agrochemicals and water than before, and increased use of marginal lands. Others have argued that both conventional plant breeding and GM crops should be compared with a substantially increased use of organic farming methods. Some of the proposed benefits of GM crops are novel but, in general, the new technology offers only a more efficient or different way of solving old problems. For example, breeders have been using disease- and pest-resistance genes for decades. In effect, the new insect-resistance genes<sup>6</sup> are unlikely to be different from insect-resistance genes already in use, such as the leafhopper resistance used in rice or hessian fly resistance in wheat. 'Natural' tolerance to herbicides was used in maize in the late 1980s, and again, very recently, in Pioneer Hi-bred's 'Smart Canola'.<sup>7</sup> The new GM crops which are tolerant to Roundup<sup>8</sup> are unlikely to be different in their effects on the environment. Thus, although GM crops may pose novel pressures on the environment there is, as yet, no reason to consider GM varieties as qualitatively different from non-GM varieties.
- Over the past half-century the professional plant breeder has assimilated many new technologies. Examples include: 'doubled haploids', where lines can be made pure breeding in a single step; 'induced mutations', where new variation can be generated by irradiation or chemical treatments; 'F1 hybrids', where farmers can benefit from the expression of hybrid vigour, and 'molecular markers', where a breeder can select for a piece of DNA rather than a trait, thereby avoiding expensive and time-consuming tests in selecting the ideal parent or progeny. To the plant breeder, genetic modification is simply the latest technology which breeders hope to bring to bear in their quest for ever-improved crops.
- 2.7 At the current stage of its development, genetically modified or transgenic technology does not offer the means of targeting where transgenes are integrated into the chromosomes; integration into the plant chromosomes appears to be more or less random. However, conventional plant breeding is usually a matter of putting two sets of about 25,000 genes together, allowing them to segregate at random and then selecting the best. Indeed, entirely new species have been manufactured using this approach. An example is *Triticale*, a synthetic hybrid between wheat and rye grown extensively in Eastern Europe over this century, which is the result of combining 50,000 largely untested genes, 25,000 from each species.

#### Plant genetic transformation

2.8 'Transformation', 'genetic modification', 'genetic engineering' and 'transgenesis' are all synonyms for the transfer of isolated and cloned genes into the DNA, usually the chromosomal DNA, of another organism. Transformation of micro-organisms was first achieved in 1973 and this was followed by the development of GM technology for animals. Plants, due to the dense nature of the plant cell wall, were more difficult to transform. It was another ten years before the first successful experiments were reported. These first examples involved the use of the crown gall-inducing bacterium, Agrobacterium tumefaciens, to transfer genes for antibiotic resistance into tobacco plants (paragraphs 2.14–15).

Bt insect-resistance genes come from the bacterium *Bacillus thuringiensis*. These genes code for a variety of toxins, which vary in the extent to which they are toxic to different insects. Organic farmers spray Bt toxins on crops to control pests. In contrast, transgenic plants containing Bt genes produce Bt toxins within their cells, which are eaten by pests preying on the plants.

Concar D and Coghlan A (1999) A question of breeding, **New Scientist**, No. 2175:4–5.

<sup>8 &#</sup>x27;Roundup Ready' is the proprietary name given to crops which have been modified to contain resistance genes to the herbicide glyphosate (Roundup).

- 2.9 Since those early days, almost every significant crop species has been successfully transformed. The technology, initially in the hands of only a few advanced academic laboratories, has been established and refined in the laboratories of most major plant breeding companies. The international movement of research scientists between laboratories, the work of agencies such as the Department For International Development (DFID) in the UK, and initiatives such as the Rockefeller Rice Biotechnology Program<sup>9</sup> have ensured that effective transformation technology is now practised in all major plant breeding research centres in both developed and developing countries.
- 2.10 Initially, transformation was developed in model broad-leaved plants such as tobacco and tomato. Narrow-leaved plants, which include all the major cereal crops, were more difficult and the first successful transformations, in rice and maize, were not reported until the late 1980s.<sup>10</sup> Consistently successful transformations of the more recalcitrant cereals such as wheat and barley have only been achieved very recently.

#### The experimental components of successful transformation

- 2.11 First, for the novel gene to be transferred, the transgene, which will have been isolated as a stretch of DNA, must be linked or spliced to a suitable promoter.<sup>11</sup> The transgene will code for the production of a protein, often an enzyme, which in turn will catalyse a biochemical reaction in the plant. The promoter component of the DNA will determine where, when and to what degree the transgene is expressed in the plant. This engineered construct must then be introduced into the target plant's own chromosomes.
- 2.12 This is usually carried out on cultured cells which have to be subsequently regenerated into an intact plant. Since transformation can be very inefficient (in some situations only around one in a thousand cells may be transformed), most of the gene constructs used to date have incorporated a selectable marker gene as well as the transgene. Markers, such as antibiotic resistance or herbicide tolerance, allow the breeders to select only successfully transformed cells in culture media containing the antibiotic or plants grown in the presence of the herbicide. However, as transformation efficiencies have increased, the need for such markers has declined (see below).

#### **Transformation methods**

- 2.13 Although several methods of plant transformation have been used, only two are relevant today to the transformation of food crops. These are *Agrobacterium* and the 'gene gun'. Since both these methods have been patented, we can expect that other methods will continue to be developed in order to circumvent these patents. Both methods have advantages and disadvantages, depending on the application and the crop.
- 2.14 Agrobacterium: this bacterium has been called 'nature's own genetic engineer' because it naturally transfers DNA to its plant host. Of course, it also causes disease 'naturally' in plants. However, the attenuated strains used as carriers or vectors by plant genetic engineers have had their plant

The Rockefeller Rice Biotechnology Program began in 1984, focusing on Asia. It concentrated first on developing tools of rice biotechnology such as gene-mapping, gene-tagging and genetic transformation. As these tools have been developed, greater emphasis has been placed on training, technology transfer and capacity-building within individual countries.

Gordon-Kamm W, Spencer T, Mangano M, Adams T, Daines R, Start W et al. (1990) Transformation of maize cells and regeneration of fertile transgenic plants, **The Plant Cell**, 2:603–618 and Fromm M, Morrish F, Armstrong C, Williams R, Thomas J and Klein T (1990) Inheritance and expression of chimeric genes in the progeny of transgenic maize plants, **BioTechnology**, 8:833–839.

A promotor is a DNA sequence that regulates the expression of a gene. Each gene has its own promotor which receives specialised proteins that bind and activate a gene.

- gall-inducing ability removed. The modified vector is then transformed to carry the engineered gene constructs before being introduced into a host plant cell. The new genes then integrate into the host DNA of the plant. Initially this method was thought only to be applicable to broad-leaved plants, but carriers capable of infecting and transforming cereals have recently been developed.
- 2.15 This method has the advantage that it is relatively simple and can be applied by any laboratory with suitable tissue culture facilities. Occasionally, DNA from the bacteria may get transferred in addition to the transgene and it is possible that the carrier itself may persist in or on transformed plants for up to a year after transformation. These technical difficulties have been criticised as the inadvertent transfer of genetic material and the introduction of live-engineered bacteria into the environment.
- 2.16 The gene gun: in this method gold or tungsten micro-particles are coated with transgene constructs and fired into target cells or tissues. In the early experiments the guns were powered by gunpowder, but today the particles are accelerated with an electrical discharge or compressed helium gas. One or more copies of the transgene construct are integrated into the chromosomes of the target cells. Such methods initially required a sophisticated laboratory environment. However, portable hand-held guns have recently been developed to make the technology more widely available.
- 2.17 All plant transformation methods in use today suffer from the fact that the transgene(s) cannot be directed to any particular point on the host chromosomes. Incorporation into the host DNA is more or less at random. Since the location of the transgene in the host's DNA can affect the efficiency with which it is expressed, it is often necessary for the researcher to produce many individual transgenic plants to ensure that an effective breeding group or line with the desired characteristics can be selected from them. These plants will then be bred conventionally.

#### Selectable markers

- 2.18 Some of the debate about GM crops concerns the marker genes co-introduced with the transgenes. Several exotic markers have been used as research tools, for instance, GUS, a gene encoding β-glucuronidase, can be identified in stained material by a blue colour. However, in practical plant improvement programmes, markers have been largely restricted to proteins providing resistance to herbicides or antibiotics. Putative transformants can be sprayed with, or grown on, media containing the appropriate chemical. Transformed plants are identified as those that survive. Critics of GM technology argue that even if marker genes are avoided, the resulting lines are still likely to contain small segments of non-coding, non-native DNA, which initially flanked the construct in the vector. The presence, size and any possible function of such inserts are always considered in the UK regulatory approval process (see Chapter 7).
- 2.19 Markers are used only to make the detection of transgenic plants easier. Removal of marker genes from such plants is technically possible but extremely difficult, although methods are being developed to do just this. However, in situations where the presence of the transgene itself can be detected easily or when efficiencies in transgenic production become high enough, then the use of markers can be dispensed with. Efficiencies as high as 5% are now being obtained and, at these rates, it is feasible to screen directly for the unique DNA sequence that describes any gene. It is likely, therefore, that selectable markers (which include genes that confer antibiotic resistance) will cease to be an issue with the next generation of transgenic releases.

#### **Applications of plant transformation**

2.20 GM plants are used or will be used in a number of different ways. Research applications are increasingly important. For example, GM plants are developed to try to identify gene function by

simply seeing whether the introduced gene has any observable effects. Transformation is now so routine in some model species that it can be used as a tool to identify which fragment of a plant's DNA contains a gene of interest. When other experiments have narrowed the possibilities down to a stretch of DNA which contains, say, 100 genes, the critical gene may be identified by breaking the fragment into smaller pieces and firing these into the plant to see which have the desired effect. These sorts of applications are not considered here in detail.

- 2.21 The most important use of GM plants is to accelerate plant breeding: here, native genes and promoters, previously isolated from the target species, are placed directly into an otherwise ideal varietal background. Although this can also be achieved by repeated backcrossing, 12 it might take ten generations to meet the purity standards required by the Plant Breeders Rights legislation in the UK. The products of the transgenic strategy will be virtually indistinguishable from those of conventional breeding. However, the stringency of the DUS13 regulatory procedure means that varieties that have been developed elsewhere may take several years before they can be licensed in the UK, and this applies particularly to the new varieties of oilseed rape that are currently being developed. Quite apart from the issues that are specific to GM plants, these crops will not be available for commercial planting in the UK for several years because of the need, for example, to show that their yield is higher than that of current cultivars (see Box 3.1). One example of using genetic modification to accelerate plant breeding is the manipulation of storage-protein genes in wheat to improve bread-making quality. A further example, soon to be in agricultural use, is the transfer of a bacterial blight resistance gene, Xa21, from a wild relative to cultivated rice where it was found to confer resistance against most, if not all, races of the pathogen.
- 2.22 Antisense transformation: this technique eliminates the effects of unwanted genes. If a gene is inserted into a plant in reverse (antisense) sequence, the transcribed antisense RNA (ribonucleic acid) product will often interfere with the function of similar native genes. This property can be exploited to remove or suppress the effects of any gene or group of similar genes. In some situations a similar result can be achieved by mutating the target gene and rendering it functionless, but this conventional technique is much slower and requires considerable resources for the necessary screening. An example of the use of antisense transformation is the development of a transgenic tomato with delayed ripening and longer shelf life. In this case, the gene controlling production of an enzyme which promotes cell wall breakdown after ripening was knocked out by use of the tomato gene in an antisense sequence. As a result the tomatoes stay firmer for a longer period.
- 2.23 Transformation with beneficial genes isolated from other plants: this procedure, also called inter-specific transfer, provides a means of circumventing natural breeding barriers. This application is not in wide usage, simply because the identification and supply of useful genes from other plants is limited. However, the complete DNA sequences of the model plants Arabidopsis and rice will soon be available, so increasing the availability of a large number of plant genes (paragraph 3.41). One of the eventual goals of the plant breeder is transfer of the genes conferring apomixis (the ability to produce seed without going through normal sexual reproduction) to crop plants. Other examples include the use of plant genes to modify starches and oils.
- 2.24 Transformation using genes isolated from bacteria or viruses: at present this is a widely used approach because many genes have been identified from these sources. Examples include the insect-resistance genes and herbicide-tolerance genes, currently used in the US in the production of corn, cotton, soya and potato varieties. Although these genes are commonly spoken of as bacterial or viral in origin, the genes that are eventually used to transform crop plants are considerably

Backcrossing is the process by which an FI hybrid, made by crossing two parent plants, is crossed back to one of the parents.

DUS are the criteria needed for a new inbred variety to be approved for Plant Varieties Rights regulations in the UK. These are: distinctness – is it different from anything already available on the market? uniformity – are all the seeds exactly the same? and stability – is the variety stable over several generations?

modified. DNA is broadly similar in plants, bacteria and animals. However, even between narrow-leaved and broad-leaved plants, there are some differences between the preferred sequence of the DNA components. To accommodate this variation, transgenes are usually reconfigured, or 'optimised' and resynthesised. As a result, transgenes may bear as little as 60% identity to the original gene, although the differences will not often alter the amino acid sequence of the protein that is produced.<sup>14</sup>

#### New transformation technologies

- 2.25 Switch technology: as outlined in paragraph 2.11, the promoter or regulatory sequence at the beginning of a transgene construct determines where and when in the plant the gene will be turned on. Some promoters will respond to an externally applied stimulus, such as a chemical application. Developments in this area are known as 'switch technology' and offer the possibility of switching genes on only when they are needed, for example when a particular disease is prevalent, or when the weather is such that a decrease in crop quality can be expected. If the switch is a commercially available chemical then the same technology offers farmers the opportunity to use the technology only when needed. The seed producer can, in a similar way, restrict the use of farm-saved seed or the transfer of the gene to other varieties. These techniques have not yet been commercialised.
- 2.26 Gene use restriction technology (GURT): one extension of switch technology is the production of transgenic plants that make lethal proteins late in seed development. 15 This modification, dubbed 'Terminator' ensures that the seed cannot be germinated, at least not without application of a proprietary chemical stimulus. The advantages to the seed producer are obvious, as the farmer must then purchase new seed every year. The use of this or other similar technologies would prevent gene flow into other plants being grown near by, since they would produce no viable seed. GURT is still in the early stage of development (a patent is owned jointly by the USDA (US Department of Agriculture) and Delta and Pine Land Co., a US (United States) company currently under offer from Monsanto). It has been severely criticised as a technology which will disadvantage poor farmers, particularly those in developing countries, who will not be able to afford to buy new seed of this type and will have to rely on conventional sources. 16 A similar situation also arises from the current use of F1 hybrids which are sown in parts of the developing world. Tritics also argue that gene transfer to nearby 'non-Terminated' crops, particularly in outcrossing species such as maize, could lower the productivity of farm-raised seed. The risk of this happening will depend on the nature of the gene(s) in GURT. If the gene(s) are dominant, then any hybrid seed produced from low levels of cross pollination with nearby crops will not germinate. If the genes(s) are recessive, there is a possibility of low level accumulation in farm-saved seed from nearby fields. Any future application of GURT technology will need to be carefully monitored to avoid these potential problems.
- 2.27 The owners of the technology would argue that the protection offered by GURT technology might be the only means by which they could get proprietary genetic improvements incorporated into

Fujimoto H, Itoh K, Jamamoto M, Kyozuka J and Shimamoto K (1993) Insect-resistant rice generated by introduction of a modified delta-endotoxin gene of *Bacillus thuringiensis* (Bt), **BioTechnology**, 11:1151–1155. DNA is made up of base-pairs. Groups of three base-pairs code for individual amino acids. The amino acids are then linked together to form proteins

US Patent 5723765, Oliver *et al.* (1998) **Control of Plant Gene Expression**, Delta and Pine Land Co. and USDA.

Edwards R (1998) End of the germ line, **New Scientist**, No. 2127:22.

F1 hybrids have been developed for a range of crops and are used by farmers despite the fact that seed cannot be saved because such crops can offer multiple disease resistance, superior yields and improved yield ceilings. This is true in both developing countries such as India (where rice F1 hybrids developed by the International Rice Research Institute (IRRI) are proving popular) and developed countries like the US (where F1 hybrids have revolutionised corn production).

both developed and developing country agriculture without loss of their intellectual property. This type of technology could be protected by payment of an 'annual technology fee' in developed countries, a process which would be impractical in most developing countries. Moreover, while national programmes and the Consultative Group on International Agricultural Research centres (CGIAR)<sup>18</sup> continue to breed locally adapted varieties there will always be free choice for farmers, and the decision to grow or not to grow 'Terminated' crops will be a purely commercial one. The Working Party considers that it is very important for this and other reasons, that the CGIAR centres, which have already barred the use of GURT in their programmes, <sup>19</sup> and other national programmes continue to produce new varieties (see paras 4.39–42, 4.74–75, 8.54).

- 2.28 Multiple co-transformation: it is possible to introduce several genes simultaneously. Although the mechanism is not known, it has been observed that multiple groups of transgenes (up to 20), delivered at the same time tend to integrate in tandem at the same location on the chromosome.<sup>20</sup> This will increase the ability of the plant breeder to introduce more than one transgene at a time when multiple genes are needed to produce the desired result.
- 2.29 Chloroplast transformation: it is possible, although still technically difficult, to insert transgenes into chloroplasts and amyloplasts, plastids which are present in many copies in some plant cells, rather than into the nuclear genome. <sup>21</sup> Because of the large numbers of such plastids which would have to be transformed and the potential difficulties associated with controlling gene activity in a non-nuclear location in the cell, chloroplast transformation may not be appropriate for all transgenic applications. However, an advantage is that such transgenes are unlikely to be spread to wild relatives or other crops through the pollen, because pollen carries DNA from the nucleus, rather than from chloroplasts.

#### Potential problems with GM crops

- 2.30 Side-effects: when a genetic system is perturbed by the introduction of a transgene with a new or modified effect, it is possible that unexpected pleiotropic effects (side-effects) will be encountered. Yet, the situation with transgenes is no different from genes introduced by traditional varietal hybridisation and selection. Moreover, the several years of trials that are necessary prior to crop registration in the UK should allow any such side-effects to be identified and the new variety rejected.
- 2.31 *Gene silencing:* scientists have, as yet, no control over where in the plant's chromosomes a transgene will integrate. Some regions of the plant genome contain large domains of non-coding DNA, which will be highly methylated.<sup>22</sup> Transgenes inserted into this part of the DNA are prone to become methylated themselves, and eventually to cease to function, although this may take several generations. Gene silencing is effectively non-reversible and the GM plant will revert to the way it was before it was modified.
- 2.32 *Instability:* in practice, any set of genetic engineering experiments will yield a range of plants, some stable and some less so. The plant breeder will select on the basis of efficiency and stability and then, over several generations, breed the modified plant types into closely related varieties. Then,

The CGIAR system comprises sixteen international research institutions, with a principal mandate for increased, more robust and more sustainable agricultural production, especially of food staples in developing countries.

Anon (1998) CGIAR acts on 'terminator technology' **CGIAR News**, December, 3.

Hadi M, McMullen M and Finer J (1996) Transformation of 12 different plasmids into soybean via particle bombardment, **Plant Cell Reporter**, 15:500–505.

A plastid is an organelle which carries its own DNA and is contained in the cytoplasm of a plant cell.

Methylation is a natural mechanism by which many species, including humans, regulate when genes are turned on and off in particular cells, tissues or whole organisms. Some of the base pairs in DNA can have additional methyl groups added through the action of cellular enzymes. Such methylated stretches of DNA are then inactive.

before release, the new variety will be tested at many different locations over several years. It will only then be approved if it meets the UK DUS criteria (see paragraph 2.21). These controls alone would ensure that GM plants prone to being silenced would be identified and excluded early in the breeding process. However, it should also be noted that it is not in any company's interest to market an unstable product. To do so would involve them in lawsuits and compensation costs which would be prejudicial to their market share in future years.

- 2.33 Resistance breakdown: disease or pest resistance conferred by a transgene can become ineffective. Many plant disease resistance genes are specific to particular pathogen strains. This means that growing such crops becomes, effectively, an ideal environment for the rare mutant in the pathogen or pest population that can overcome the resistance gene and that such mutants would prosper. Strategies to avoid, or at least delay, this outcome include the use of multiple resistance genes or the cultivation of small areas of susceptible crop varieties to provide refuges in which the non-resistant pathogen or pest may persist. As a result, resistance to the genetic modification will develop more slowly. However, the conventional use of pesticides sprayed on crops encourages resistance in a similar fashion. GM sources of resistance are therefore likely to be no different from conventional resistance genes. Resistance genes derived from Bt, for example, are very specific in their ability to kill certain insect pests but are likely to be overcome by resistant insects in due course.
- 2.34 In summary, regulatory procedures, outlined in Chapter 7, take account of these problems which may arise during the development of GM crops. Specific concerns about human health are discussed in Chapter 5 while broader environmental concerns are discussed in Chapter 6.

### **Testing for transgenics**

- 2.35 The controversy concerning the segregation of GM from non-GM products has raised the question about whether reliable tests to identify such transgenic materials are available. For example, there might be a requirement for appropriate testing of plant materials, such as seeds, fruit or leaves, or of plant products, such as sugar or starch. There is no test for products which originate from GM plants, but which do not contain GM DNA or proteins, and are chemically identical to the product from the unmodified plant. For example, sugar produced from GM beet or cane plants cannot be distinguished from that produced by non-GM plants.
- 2.36 Yet DNA tests, similar to those used by researchers to identify GM plants, are simple to set up and will work on any plant material. These use the polymerase chain reaction (PCR) to amplify a fragment of unique and diagnostic transgene DNA. The test can be sensitive to a fraction of 1% and can be used to test mixtures of foodstuffs. The tests will also work on cooked material because, whilst high temperatures break down DNA, a few, often partially degraded molecules, always remain and are adequate for a PCR test. The key requirement is prior knowledge of the precise DNA sequence of at least part of the transgene.
- 2.37 This latter requirement is likely to provide a stumbling block as more and more gene constructs are used by commercial breeding companies. Where isolated genes are patented, the complete DNA sequence is published and therefore appropriate diagnostic tests can be devised, although the information may take some years to appear in the public domain. Where an isolated gene is kept and deployed as a trade secret, the sequence may never be in the public domain and a reliable test will not be obvious. Moreover, as more and more transgenes are incorporated into breeding programmes, they are likely to accumulate through the normal process of crossing and selection. The diversity of transgenes and promoters available is likely to make unequivocal testing for the presence of genetic modification impractical in the not too distant future.

# How far will the science progress?

- 2.38 In plants, the first genes to be manipulated were those for herbicide tolerance. There were several reasons for this, the first being that it was possible. The genes for herbicide tolerance are single genes and therefore much easier to isolate and manipulate than the multigene complexes responsible for such important traits as salt tolerance and drought resistance. Secondly, it made sense to the companies who were to finance the research and development (R&D), since herbicide tolerance is about creating a selective herbicide from a non-selective herbicide. Such herbicide-tolerant GM plants are examined for safety by regulatory authorities. Thirdly, although modern selective herbicides are very effective they are expensive and, unlike the broad-spectrum herbicide 'Roundup', can persist in the soil. A number of these GM herbicide-tolerant crops are now being grown, and soymeal from Monsanto's herbicide-tolerant 'Roundup ready' soybeans is already on the European market.
- 2.39 Biotechnology has the capability of producing many new plant products. A number of different types can be described:
  - application of a range of gene-inactivating techniques to reduce the activity of or switch off specific unwanted genes (paragraph 2.22). These might be fruit softening, toxin or allergen genes;
  - introduction of new plant genes or enhancement of existing gene action to improve starch or oil yield, modified oils or starches, enhance fruit flavour, colour or nutrition;
  - introduction of genes to confer resistance to herbicides, pests or pathogens, or to enhance resistance to environmental stresses like drought, heat or cold;
  - introduction of new plant genes to enhance the production of hybrid crops or to modify seed production by inducing apomixis, so that hybrid vigour can be effectively 'fixed' for harvest and resowing (paragraph 3.39).
- 2.40 It is very difficult to predict exactly when these new developments will become commercially available, but it is possible to arrange them in an approximate time sequence:
  - continued development of rapid genetic typing methods to speed conventional plant breeding systems, leading to the identification of genes responsible for desirable traits, and their transfer to other species, for example between cereals;
  - continued development of genetic manipulation, along the lines of herbicide tolerance, involving one or more genes, with the production of plants resistant to many herbicides, and a wide variety of pathogens, including viruses, bacteria and fungi, thus greatly reducing or eliminating the huge losses due to these agents;
  - continued development of novel fertility systems, leading to the production of new F1 hybrids, with increased yields;
  - continued development of fruits and vegetables with longer shelf-lives and better shipping characteristics;
  - modification of crops to produce oils with properties more suitable for industrial use, fats more suitable for the human diet and modification of starches and other carbohydrates for either dietary or industrial use;
  - isolation of genes that control development to manipulate flower shape and colour for the horticultural industry. Mauve carnations are already available. Other applications are possible such as blue roses, geraniums that smell of roses or lawns that (almost) never need mowing;

- genetic modification of fruits and vegetables with the aim of improving flavour, texture and nutritional content and, in particular, to ensure that levels of the micronutrients that appear to be increasingly important for health are either maintained or introduced at appropriate levels;
- elimination of genes for toxic or allergenic substances (peanuts can cause a fatal allergic reaction in some people); for example, by the use of antisense technology to block the activity of genes;
- isolation and utilisation of more complex genetic systems such as those controlling salt tolerance and drought resistance, making possible the production of plants which can be grown in a much wider range of environments;
- isolation and modification of genes that control plant development and differentiation; for example, the plant's flowering time, so that it may be possible to produce plants that come to maturity more quickly, or plants such as oilseed rape that could be grown further north in countries like Canada and Sweden, and aspen trees that are fertile within the first year. Conversely, it would be advantageous sometimes to delay flowering, in annual non-seed crops such as lettuce and potato;
- as timber and pulp increasingly come from cloned plantations they could be modified for pest and disease resistance, and have their juvenile period substantially reduced to aid breeding programmes;
- production of drugs and vaccines in plants;
- introduction of new genetic systems into the plant to increase yields by, for example, modifying photosynthesis or enabling crops such as wheat to fix nitrogen;
- application of GM technologies to bring orphan crops, particularly in tropical developing country agriculture, into commercial production.
- production of plants for cleaning up polluted areas.
- 2.41 To take a specific example, genetic modification of potatoes could:
  - increase the availability of UK varieties by extending the growing seasons through the introduction of stress tolerance characteristics;
  - improve flavour and mash texture through modification of starch and sugar content;
  - reduce the water content in potatoes and alter cell-wall composition to limit the fat retained in crisps and chips;
  - extend shelf-life by suppressing sprouting and reducing rot;
  - reduce chemical residues by introducing herbicide tolerance, disease- and pest-resistance traits.
- 2.42 During the period from 1986 to 1997, approximately 25,000 transgenic crop field trials were conducted on more than 60 crops with 10 traits in 45 countries. No adverse effects on food safety or the environment have been noted, relative to production in non-GM current varieties. Of this total of 25,000, 15,000 field trials were conducted during the first 10-year period and 10,000 in the last two-year period. Seventy-two per cent of all transgenic field trials were conducted in the US

Table 2.1

Traits already commercialised in field trials, and under development for selected crops in 1997

Crop	Traits already commercialised	Traits in field trials/development
Canola (oilseed rape)	Herbicide tolerance     Hybrid technology     Hybrid technology and herbicide tolerance     High lauric acid	1 Improved disease resistance 2 Other oil modifications
Corn	1 Control of Corn-borer 2 Herbicide tolerance 3 Insect protected/herbicide tolerance 4 Hybrid technology 5 Hybrid/herbicide tolerance	Control of Asian Corn-borer Control of Corn Rootworm Disease resistance Higher starch content Modified starch content High lysine Improved protein Resistance to storage grain pests Apomixis
Cotton	<ol> <li>Bollworm control with single genes</li> <li>Herbicide resistance</li> <li>Insect protected/herbicide tolerance</li> </ol>	1 Bollworm control with multiple genes 2 Control of Boll Weevil 3 Improved fibre/staple quality 4 Disease resistance
Potato	1 Resistance to Colorado Beetle	1 Resistance to Colorado Beetle + virus resistance 2 Multiple virus resistance (PVX, PVY, PLRV) 3 Fungal disease resistance 4 Higher starch/solids 5 Resistance to potato weevil/storage pests
Rice		1 Resistance to bacterial blight 2 Resistance to rice-borers 3 Fungal disease resistance 4 Improved hybrid technology 5 Resistance to storage pests 6 Herbicide tolerance
Soybean	Herbicide tolerance     High oleic acid	1 Modified oil 2 Insect resistance 3 Virus resistance
Tomato	1 Delayed/improved ripening	1 Virus resistance 2 Insect resistance 3 Disease resistance 4 Quality/high solids
Vegetables & Fruit	1 Virus resistance	1 Insect resistance 2 Delayed ripening

Source: James C. (1997) Global Status of Commercialised Transgenic Crops in 1997. ISAAA Briefs No.5, ISAAA, Ithaca.

and Canada. By the end of 1997, 48 transgenic crop products, involving 12 crops and six traits, were approved for commercialisation in at least one country by 22 owners of technology, of which 20 were private-sector operators.  $^{23}$  The crops include soybean, cotton, oilseed rape, potato, maize,

James C (1997) Global Status of Transgenic Crops in 1997, ISAAA Briefs No. 5, ISAAA, Ithaca, New York. ISAAA is the International Service for Acquisition of Agri-biotech Applications. It monitors and evaluates the availability of biotechnology for transfer to the developing world. In addition, work is being undertaken in the developing world to

- tomato and pumpkins, and the traits insect, virus and herbicide tolerance, delayed ripening, male sterility and changes in oil composition (Table 2.1).
- 2.43 There are several other crops where transformation could be agronomically valuable. Wheat has been technically difficult to transform, but GM wheat is expected to enter the market soon. Research on the genetic modification of rice, cassava, yam, pearl millet and sorghum is being undertaken in public-sector institutions.

# How far have GM crops entered agriculture?

2.44 The total area planted with GM crops in 1998 is shown in Table 2.2. In 1998 approximately 28 million hectares were planted with transgenic crops, mostly in the US, where 20.5 million hectares were sown, representing 74% of the global total of transgenic crop plantings. This figure was up from 11 million hectares in 1997 and 1.7 million hectares in 1996. These are extremely high adoption rates for a new technology by agricultural standards. Argentina grew 4.3 million hectares of GM crops in 1998, a three-fold increase from 1997.

Table 2.2

Global area of transgenic crops in 1998: by crop (millions of hectares)

Сгор	1998	%
Soybean	14.5	52
Soybean Corn/Maize	8.3	30
Cotton	2.5	9
Canola (oilseed rape)	2.4	9
Potato	<0.1	<1
Total	27.8	100

Source: James C. (1998) Global Review of Commercialized Transgenic Crops: 1998. ISAAA Briefs No.8, ISAAA, Ithaca.

- 2.45 The principal reported agricultural benefits of these GM crops include more flexibility in crop management, decreased dependency on conventional insecticides and herbicides, and higher yields and cleaner and higher grade of harvested product. In 1997, the economic benefit to US farmers was estimated at US\$133 million for Bt cotton, US\$119 million for Bt corn and US\$109 million for herbicide-tolerant soybean, with an overall total of US\$360 million, up from US\$159 million in 1996.
- 2.46 Why is the cultivation of GM crops growing so quickly? US farmers consider that herbicide-tolerant soya offers them real advantages. In the US, where springtime sowing is normal, the use of a post-emergent herbicide has meant some changes in agronomic practice, leading to retention of more soil moisture. This, together with the slightly longer growing season and the effectiveness of the herbicide, has resulted in significantly higher yields. Consequently, farmers in the US will soon be growing GM crops on a wider scale. These new crops will bring a much closer relationship between the farmer and the agrochemical company, which will sell both seed and herbicides, and also a similar closer relationship between the farmer and the retailer, as complete traceability will be essential. There may also be a need for a licensing system to monitor and, if necessary, deal with environmental issues.

assist national programmes, to identify priority needs for biotechnology applications, and to develop and implement priority proposals.

2.47 The situation is very different in Europe where there have been almost no commercial plantings. The EU's approval process for novel crops is slow, causing tensions with the US over the delay in permitting imports of GM food supplies.<sup>24</sup> There have also been difficulties in defining which products have to be labelled and how. These problems are discussed further in Chapter 7.

# Issues arising from the introduction of GM plants

- 2.48 Antibiotic resistance: this issue arose in connection with a GM-maize variety produced by Ciba-Geigy (now Novartis). The UK Advisory Committee for Novel Foods and Processes (ACNFP) recommended against authorisation of this product for animal feed, its only projected use. This was because of the perceived risk associated with the transfer of an antibiotic-resistance marker gene (paragraph 2.18) in the maize to the bacterial gut of livestock that had been given the feed. If the antibiotic in question (ampicillin) was present in the animal feed, there was perceived to be an eventual possibility of transfer of the resistance gene to humans through transfer of resistant bacteria to those in contact with the cattle, although this has not been observed. The widespread use of antibiotics in animal feed, coupled with their widespread clinical use has already led to an alarmingly high level of antibiotic resistance in bacteria which infect humans. The debate centred on whether that figure was already so high that a very small increased risk would be of little or no significance, or whether the high level meant that no increase, however marginal, should be permitted. The ACNFP took the latter view, influenced by the potential serious outcome of an event which although very unlikely, was not impossible. The Royal Society, in its recent statement on GM plants for food use, <sup>25</sup> reached a similar conclusion, as did a poll conducted through the Newsletter of the International Society of Chemotherapy<sup>26</sup> where 57% of the 198 Society members who responded opposed the use of this particular antibiotic marker gene, with a further 34% taking the view that the risk of resistance-gene spread was low but finite.
- 2.49 This recommendation was later overruled by the European Commission (EC) on a majority vote, since the maize was only to be used for animal food, and for production of starch for some processed food products, and such processing degrades the DNA so that it is no longer functional. The EC gave permission to allow marketing of the seed in January 1997, and 1000–2000 hectares were grown that year. However, in February 1998, Greenpeace applied to the French courts to overturn the issuing of the consent. The Conseil d'État issued an injunction preventing the marketing of the maize until the case put by Greenpeace had been resolved by consulting the European Court of Justice. This process is likely to delay the growing of this maize by at least a year, although 15,000 hectares of maize were grown in 1998 in Spain. GM tomatoes, which contain a kanamycin-resistance gene in a form which did not cause concern to regulators, are on trial in Spain, but a commercial permit has not yet been issued.<sup>27</sup>

# **GM DNA transfer in animals**

2.50 Concerns have been expressed that the DNA introduced by genetic modification might be transferred across the wall of the gut to the host, and lead to genetic alteration of that host, despite the fact that we eat large amounts of degraded and undegraded DNA in our everyday diet. Experiments have

The Royal Society (1998) **Genetically Modified Plants for Food Use**, p. 8. The Royal Society, London.

House of Lord's Select Committee on the European Communities (1999) **EC Regulation of Genetic Modification in Agriculture** (Session 1998–99 2<sup>nd</sup> Report), p. 46. The Stationery Office, London.

Pechére J-C (1997) A β-lactamase gene in a transgenic maize? **Antiobiotics Chemotherapy**, 1:9; Pechére J-C (1998) Concerns about the presence of a β-lactamase gene in a transgenic maize, **Antibiotics Chemotherapy**, 2:16.

House of Lords Select Committee on the European Communities, EC Regulation of Genetic Modification in Agriculture, p. 11.

shown that DNA consumed in the diet is very unlikely to survive intact beyond the stomach and into the gastrointestinal tract. That DNA which remains after digestion consists of very small fragments which do not contain whole genes. However, some experiments have shown that these fragments may enter the blood stream<sup>28</sup> and that small amounts may even enter cells and attach to cellular DNA.<sup>29</sup> Such DNA fragments would not function in the human or animal because of their small size. Furthermore, no evidence of active ingested genes, even those designed to work in human cells, has been found.<sup>30</sup>

- 2.51 Toxins: a number of plants produce toxins as a protection against insect and fungal pests and it is for this reason that we cook many foods such as potatoes. These are parts of their innate defence systems and, as such, are important to maintain. They are generally present at such low levels that humans and animals are able to tolerate them. Plant breeding, either with or without the aid of genetic modification, may be used to remove toxins or allergens in existing food crops. Such toxins are almost always bred out during development of commercial varieties.
- 2.52 It is always possible, however, that toxin levels could be increased by such breeding. For example, a hardy new potato variety called Lenape, produced by conventional breeding in the 1960s, owed its unusual burnt flavour to dangerous levels of toxins called glycoalkaloids, and was subsequently withdrawn.<sup>31</sup> Questions about toxins are always asked by UK regulatory committees in the consideration of submissions for entry into the human food chain.
- 2.53 Allergens: there is one documented case where genetic modification involving transfer of a gene from the Brazil nut to soybean also led to transfer of allergenicity.<sup>32</sup> Blood serum from people known to be allergic to Brazil nuts was tested for the appropriate antibody response to the transferred gene. Seven out of nine individuals showed a positive response. This adverse result alerted the company and the work was discontinued so the product was not even submitted to the regulatory authorities. The Working Party notes that the potential allergenicity of proteins expressed by novel genes is now a routine part of safety assessment procedures and that there are many databases of known allergens that could help identify proteins that may be problematic if inserted into food products. However, since the generation of new allergens can never be excluded, the Royal Society, in its report, sensibly recommends that this topic be given particular attention.<sup>33</sup>
- 2.54 When an application to market a GM variety for cultivation in the EU is submitted, information on likely toxic or allergenic effects must be included in the application. Continued care is needed in this area, and if there is any reason to suspect an allergenicity problem, then the appropriate health network can be alerted. It should be noted that the EU Novel Food Regulations specifically require that products must be clearly labelled if they contain genes that may result in toxicity or allergenicity, particularly if such genes would not normally be expected to occur in the
- 2.55 Feeding trials with foods from GM crops: some critics of the use of genetic modification in food production have argued that all such foods should be subjected to the same sort of safety assessment as new drugs. In particular, there have been calls for testing through long-term feeding trials. However, this is not easy and the difficulties have been well explained in a recent article.<sup>34</sup>

 $Schubbert\,R,\,Lettmann\,C\,and\,Doerfler\,W\,(1994)\,Ingested\,foreign\,(Phage\,M13)\,DNA\,survives\,transiently\,in\,the\,gastrointestinal$ tract and enters the blood-stream of mice, Molecular and General Genetics, 242:495-504.

Schubbert R, Renz D, Schmitz B and Doerfler W (1997) Foreign (M13) DNA ingested by mice reaches peripheral leukocytes, spleen, and liver via the intestinal wall mucosa and can be covalently linked to mouse DNA, Proceedings of the National Academy of Sciences, 94:961-966.

Cohen P (1998) Strange fruit, New Scientist, 2158:42-45. 30

Nordlee J., Taylor S., Townsend J., Thomas L and Bush R (1996) Identification of a Brazil nut allergen in transgenic soybeans,

The Royal Society, Genetically Modified Plants for Food Use.

For an example of a criticism of this argument see MacKenzie D (1999) Unpalatable truths, New Scientist, No. 2182:18–19.

The article reported that scientists from the 29 industrialised countries of the OECD concluded at a meeting in Paris in December 1998 that a whole new approach would be needed (if such a process were to be developed). For example, it is not possible to test foods at 100-1000 times the likely intake, as is done with new drugs, in order to ensure safety. This is because foods cannot be fed in such exaggerated doses without profound effects on the subject's physiology. The best that can be done is to replace the 'normal' component of the diet with the novel food and look for any adverse effects. Companies have done this a number of times during the regulatory assessment of novel foods by the ACNFP.

- 2.56 Because of these difficulties, the ACNFP's usual procedure for evaluating a novel food is to compare its composition with that of the conventional food it most closely resembles and which has been in the diet for many years. The question is then asked, 'Are there any differences between the two which might cause a problem?' This is the process called 'substantial equivalence' and is described in more detail in a recent report.<sup>35</sup> The report concluded, *inter alia*, that 'foods derived from GM sources should be assessed in a similar manner to those produced by conventional techniques'.
- 2.57 This conclusion has been questioned in a series of experiments conducted by Dr Arpad Pusztai at the Rowett Institute which are outlined in detail in Appendix 1. Initial press releases following the experiments suggested that potatoes which had been genetically modified to contain a lectin (a toxin) affected the growth rate and immune function of rats. The Rowett Institute subsequently withdrew the initial claims and apologised for releasing misleading information. At this stage the results of the experiments had not been submitted for peer review. An independent audit of the experimental results did not support the conclusion that the GM potatoes had an effect on growth, organ development or immune function. Dr Pusztai rejected some conclusions of the audit committee and 20 scientists from 14 countries announced their support for him. These events were accompanied by extensive media coverage, most of which highlighted the purported dangers of GM food and called for a moratorium.
- 2.58 A number of conclusions can be drawn from Dr Pusztai's work. First, the case for damage to rats in long-term feeding trials is, on published evidence to date, at the most 'non-proven'. Secondly, it is irresponsible to conduct science by press-release, rather than by the processes of peer review and criticism that ensure scientific integrity. Thirdly, the relative responsibilities of the scientist and their host institution are unclear in such a situation, in particular when and how scientists should express their own concerns. Fourthly, it is clear that the UK lacks a public forum in which such debates can be carried out and, as a result, issues that should be resolved by debate have instead resulted in parties talking past each other and directly to the public. Such a forum for debate is badly needed. The role of an overarching body in providing such a forum is discussed in paragraph 8.26.
- 2.59 The natural/unnatural boundary: critics of GM technology itself often state that this methodology provides the breeder with the opportunity to make unnatural combinations of genes. Presumably the perceived boundary between natural and unnatural lies at the limits of sexual compatibility, since the introduction of exotic genes from wild relatives of rice, wheat or Brassica crops has raised no difficulties in the past. What then when the technology is used to move native genes more efficiently through a breeding programme? Is this 'unnatural'? Such distinctions lie at the heart of the public debate, and we trust that what we have said elsewhere (paragraph 2.5) will be helpful, but we believe that there are no clear cut solutions, that such issues can only be settled on a case-by-case basis and that this falls within the remit of an overarching body.
- 2.60 *Environment:* the potential impact of GM crops on the environment has received much attention in recent years from the scientific community and is dealt with in Chapter 6.<sup>36</sup> In Chapter 6 we discuss

The Nutritional Assessment of Novel Foods and Processes (1993) HMSO, London.

<sup>36</sup> See also the discussion in The Royal Society, **Genetically Modified Plants for Food Use**.

studies on the effects of insect-resistant crops on non-target species, the possible development of pest resistance in insect-resistant GM crops, the risk of transfer of genes to wild relatives and non-GM crops and the assessment of risk where GM virus-resistant plants are being developed. In reaching a balanced perspective it is important that any negative effects are judged in relation to those of the conventional insecticides and herbicides which these crops are intended to replace.

### **Conclusions**

- 2.61 The Working Party concludes that the genetic modification of crop plants does not differ to such an extent from plant breeding as practised in the past as to make the process morally objectionable. GM technology is a new tool which plant breeders are using to achieve their breeding goals more accurately and rapidly. The Working Party accepts that combinations of, for example, bacterial and plant genes are being produced in GM crops which are very unlikely to be found or impossible to realise in nature. However, provided that caution is exercised with respect to potential side-effects such as allergenic reactions, we do not consider that the generation of such new combinations should be further restricted or even prohibited. Yet, the novelty of the technology together with broader public concerns leads us to conclude GM crops should be recognised as such and that specific GM regulations should be maintained for several years.
- 2.62 Most people lack the opportunity to gain an understanding about the science involved in the creation of GM crops and the differences between them and non-GM crops. They also lack a way of explaining their fears and concerns to those responsible for the development, production and sale of such crops. We suggest below some institutional arrangements that could deal with both these issues.
- 2.63 We also acknowledge that the credibility of the government information on food safety has been so badly impaired in recent years that it may be more expedient for non-governmental entities, supermarkets and food manufacturers to take on some of the task of informing the public. The public's distrust of information from those with vested interests, however, suggests that companies marketing GM crops carry little weight with them. In fact, companies' efforts to persuade people of the benefits of GM crops are probably counter-productive. This may also be true of attempts by food manufacturers that go far beyond the provision of simple and balanced information.
- 2.64 The Working Party considers that it is wrong to ignore public unease about GM crops, whatever its basis. We consider it very important that the Government take steps to acquire and disseminate reliable and up-to-date information about the underlying science, and also to respond to public concerns. So we welcome the formation of the Cabinet Ministerial Group on Biotechnology and Genetic Modification and the initiation of a review jointly by the Cabinet Office and the Office of Science and Technology (OST) of the framework for overseeing developments in biotechnology and genetic modification.
- 2.65 We next urge the scientific community to continue to bear its share of the responsibility for the task. Much has already been done through the OST programme called 'The Public Understanding of Science' initiative, but we believe that many such initiatives have been independent of each other, that they could be better co-ordinated, and that there has been little exchange of best practice. We also recommend that the Cabinet Ministerial Group on Biotechnology and Genetic Modification initiates a wide-ranging review of the scope, co-ordination and effectiveness of the several current 'public understanding of science' initiatives with a view to achieving the best use of the available resources.
- 2.66 But it also very important that the scientific community listens to and understands the concerns and fears of the consumer public, and in this the role of the social scientist is crucial. **The Working Party recommends that the UK Research Councils, COPUS, the Royal Society, the**

Institute of Biology, the UK Life Sciences Committee, and industrial bodies such as the Biolndustry Association and others, examine how they can work together to continue their development of both new and ongoing mechanisms in which scientists would be able to engage better with the public.

2.67 We further recommend that the Government takes an initiative to bring relevant experts and consumer public together, possibly along the lines of the UK National Consensus Conference on Plant Biotechnology,<sup>37</sup> to seek to understand the underlying concerns and to propose a way forward. However, the most urgent need is to draw together, in a single decision-making process, three different strands: scientific assessment of risk, public perception of this risk and the ethical issues involved. We return to these points at paragraph 8.26.

Anon (1994) Final Report of the **UK National Consensus Conference on Plant Biotechnology**, The Science Museum,

Issues related to commercial implementation

### Introduction

- 3.1 The question of whether we should be concerned about the distribution of the potential benefits of genetically modified (GM) crops arises on two counts. The first count is that commercial considerations will lead agrochemical and seed businesses to concentrate R&D predominantly on markets in developed rather than developing countries. This is unlikely to encourage the prospect of using genetic modification for a significant improvement in food security for the world's poor. It may also undermine a powerful argument in support of continued R&D on GM crops. The second count is the fear that the commercial exploitation of GM crop research and development (R&D) will only promote the profitability of a small group of large companies rather than the wider public interests of consumers, farmers and researchers. In this chapter, we examine the ethical and social implications of commercial development of GM crops for both the developed and developing world.
- 3.2 The primary responsibility of the private sector in the agriculture/food supply chain is to provide safe and nutritious food in a culturally amenable form and at an acceptable price. It is obvious that in order to do this, the commercial company must be able to stay in business. It must therefore carefully manage not only its financial capital<sup>1</sup> and human resources but also the raw materials in the supply chain and the natural resources in the environment upon which it depends.
- 3.3 In the food sector, successful competition depends upon making products more attractive to customers, for example in both price and quality, or by achieving more effective distribution. Trading margins are relatively small in a market that is dominated by commodities and the trend is to divide the market by differentiating food products away from the standard commodity product. In the past, this trend has involved relatively basic agricultural and food technologies which have allowed a wide range of commercial organisations to thrive.

# Commercial investment in GM technologies

- 3.4 In recent years, however, large corporations have begun to introduce new, complex technologies into their products and processes. This has led the larger agrochemical and seed companies to acquire exclusive rights to new technologies which can be used in a variety of ways to establish a strong market position. For example, they might be used as negotiating tools in the formation of strategic alliances between firms, to maintain a high entry price to the markets, or to open up licensing opportunities. The development of technologies which underpin plant genetic modification has been timely for these industrial sectors. The scale of investment amongst leading members of the agrochemical and seed industry to secure exclusive access to the important technologies in this area amply illustrates their commercial confidence in its value, despite the costs of regulatory compliance and uncertainties over consumer acceptance.
- 3.5 Although competition coupled with financial capital growth is a primary motivation for the development and application of new GM technologies, corporate sustainability is also important. The security of the raw materials supply chain, the conservation of productive natural resources and ethical capital<sup>2</sup> in the duty of care to customers are all primary commercial considerations. Although there are differing opinions about the nature of the impact of the new GM technologies on sustainability, the agricultural and food industries have taken a proactive and collective stand

Accountability and care for financial capital are generally seen in terms of profit and loss accounting, the dividends returned to the investors and growth in the market capitalisation of the venture. Capitalisation value is a key indicator of company sustainability and underpins the motive for competition between companies.

<sup>2</sup> Ethical capital is invested in the quality control that supports the promotion of the brand in these terms. Such capital can now extend to 'GM-free' food products (Iceland Frozen Foods), non-use of slave labour in the manufacture of Asian carpets and sustainably-produced timber (B&Q).

- in spelling out the potential benefits through such trade organisations as the Green Industry Biotechnology Platform.<sup>3</sup> Many respondents to the public consultation commented on the ethical responsibility of companies to ensure the safety of their GM products for consumers and the environment. Some went further, suggesting that companies should be required to communicate clearly to the public and regulatory bodies any risks associated with GM products. Other respondents took the view that industry already accepted responsibility for their products in general.
- 3.6 Innovation, in the commercial world, broadly represents the process of producing a change in the market place through novel products. Innovation starts with discovery, an exploratory process which results in the acquisition of new knowledge. The agrochemical and seed industry has been highly dependent upon GM-related discoveries from publicly funded research, to the point where most universities and research institutes have established their own mechanisms for licensing inventions based on such knowledge to the private sector. The creation of new inventions can take the form of new methods, prototypes or new product designs. Inventions represent particular forms of knowledge known as intellectual property. Subject to meeting formal requirements in terms of novelty and utility (paragraph 3.23), intellectual property may be formalised as patents and thereafter traded as a commodity. The ability to protect and trade inventions in this way is a key factor in the selection and prioritisation of GM crop projects in commercial R&D programmes.

### The growth of the commercial sector

- 3.7 The growth of plant biotechnology start-up companies in the early 1980s was based on this approach. Their success, in terms of public flotation and continued investment, was measured by the competitive value of their patent portfolios. Larger companies and universities with an interest in the area were also drawn into the quest to apply for and license key patents. The competitive nature of these early developments led to the prioritisation of simple targets such as herbicide tolerance, which some critics now suggest to be relevant only to cost savings in large-scale agriculture (paragraph 6.22). However, at the time they represented what was realistically achievable within the limits and constraints of investment.
- 3.8 More recently, the leading agrochemical and seed companies have started the process of transferring these early technical achievements into products in the market place (Table 2.2). This has meant dealing with a range of national and international regulations and in some European countries, cultural hurdles. Even now, although herbicide-tolerant soybeans are being widely planted in mid-Western United States (US) agriculture, they are still very much a prototype in the international food-supply chain. This phase of introducing GM crops into developed markets has imposed increasing costs on the industry. The high costs of R&D and regulatory demands of implementation have been influential in the recent consolidation of the industry (paragraphs 3.19–20).
- 3.9 While this account might portray a world driven by expediency and technological opportunism, scarcely informed by agricultural needs or consumer awareness, it should be remembered that we are in an early phase of the development of a new technology. Furthermore, the range of products now reaching the market is based on the technical achievements of more than ten years ago. Despite views to the contrary, these developments do not suggest a reckless dash for profit. This phase has been important in providing practical examples of the significance of the technology, as well as something concrete and agriculturally relevant on which to perform practical tests of safety, efficacy and environmental impact.

The Green Industry Biotechnology Platform (GIBiP) represents the interests of 20 European member companies involved in plant biotechnology. The GIBiP focuses on issues which 'might pose hurdles to the introduction of seeds, plants and crops that have been genetically modified to achieve benefits for the farmer, the end-customer and the grower'.

3.10 The adoption of GM crops in Europe and the United Kingdom (UK) is likely to take several years. Of nearly 1200 agricultural, horticultural and ornamental crop varieties currently under evaluation for statutory registration in the UK, only 29 currently contain a transgenic modification. The GM varieties include forage maize, oilseed rape and sugar beet. If a variety is to be commercialised, it must either be on the UK National List or on the European Commission (EC) Common Catalogue following testing in another Member State. All varieties of all major agricultural crops are tested through a two-year trials programme to establish their value for cultivation and use. By the time any GM variety is registered it will have to compete with the best conventionally bred varieties and, if it is to be successfully adopted by farmers, it will need to offer additional benefits. At the current stage in the development of GM varieties, their yields, as tested through the UK National List trial series, are not superior to the best conventionally bred varieties and, taking all factors into account, current estimates suggest that GM herbicide-tolerant oilseed rape will take three to five years to compete effectively in the UK market. The technical development of GM cereals has been slower and more complex and it may take eight to ten years before such GM varieties are commercially significant.

# BOX 3.1 Seed registration in the UK

The process of developing new varieties is complex and takes time: from initial crossing it will take the breeder, depending on the crop, between seven and nine generations to select, stabilise and multiply sufficient uniform seed to enter a new variety into the registration process. All new varieties of the main agricultural and horticultural species must be on the UK National List or on the EC Common Catalogue before they can be commercialised and marketed. As part of National Listing new varieties are grown for two years to be assessed for DUS (Distinctness, Uniformity and Stability). Concurrently, all major agricultural crops undergo two years of field trials to measure performance in terms of yield, quality, resistance to pests and diseases (VCU, Value for Cultivation and Use). These processes are statutory requirements under UK and EC regulations and are funded by fees paid by the applicants.

In the UK, a further stage of non-statutory evaluation of varieties is carried out with industry funding and co-ordinated by the National Institute of Agricultural Botany (NIAB). These trials, over a further two or three years, result in Recommended or Descriptive Lists for all major crops: the criteria for recommendation is high and only varieties which are 'as good as, or better than, the best' are added. Over 90% of all crops are sown with these selected varieties tested for up to five years.

Source: NIAB Cambridge 1999

3.11 Uptake of GM soya and cotton has been much faster in the US because of the specific advantages offered by these new varieties. For example, Bt cotton offers cheaper and more efficient control of Boll Weevil which is a serious pest across much of the US.<sup>5</sup> GM soya has increased yields, lower costs and an absence of phytotoxic effects on the soya beans.<sup>6</sup> In addition, many US farmers are contracted to grow crops for large buyers and it is the buyers rather than the farmers who influence which crop variety is planted. This means that new varieties can be adopted very quickly if they offer significant advantages over existing ones. In the UK, only sugar beet, where the company British Sugar buys most of the UK crop, falls into this category. Given the time taken for evaluation of varieties and significant market penetration (see Box 3.1), it is clear that there is sufficient time to assess the implications of novel GM traits for best agricultural practice in the UK. This should help

<sup>4</sup> Ministry of Agriculture, Fisheries and Food (MAFF), Plant Varieties and Seeds Division, 1 March 1999.

Merritt C R (1998) The commercialisation of transgenic crops – the Bt experience. 1998 BCPC Symposium Proceeding No. 71. **Biotechnology in Crop Protection: facts and fallacies**, 79–86.

<sup>6</sup> MacLeod J (1999) Personal communication, NIAB.

- to reduce some of the immediate concerns about the pace of change and provide an opportunity for reflection.
- 3.12 The development of real products rather than 'potential' or 'predicted' innovations has sharpened the debate concerning the institutional reforms necessary to secure 'best practice'. As an example we can cite herbicide tolerance, which, while not threatening to the environment in itself, promises, in the opinion of some ecologists, to make weed control so effective that populations of farmland birds will be compromised (paragraphs 6.35–37). This has generated pressure for a re-examination of strategies for herbicide deployment in general.
- 3.13 The arrival of GM products in the market place has further alerted a wider set of stakeholders to the need for their participation in the process to identify 'best practice' for GM technologies. Wider consultation with stakeholders could make an important contribution towards the transparent, informed and responsible development and implementation of the technology. We recommend that the UK government departments, through their advisory committees, the agrochemical and seed industry and relevant trade associations, consult widely among consumers, farmers, environmental groups and the proposed stakeholder advisory group (see paragraph 8.24) to ensure that the future goals for the technology take account of the wider issues.<sup>7</sup>
- 3.14 Beyond this set of industry-centred issues lie a set of effects, consequences, threats and opportunities relevant to developing countries and other silent or invisible stakeholders. In this context it is relevant to ask questions about ownership and fairness in access to the technology and its benefits, as well as institutional and regulatory oversight. Although control of GM technology is concentrated in a few commercial organisations, implementation of GM crop technology involves complex networks of diverse organisations, some active and some passive, within the agriculture/food-supply chain.

# Where are the decisions taken regarding the goals for GM technology?

- 3.15 Historically, much of the plant breeding industry grew out of farmers' co-operatives which saw the benefits of sharing both the risks and the rewards of the continuous development of new varieties adapted to their needs. In fact, some plant breeding concerns are still owned in part by co-operatives. Decisions about crop development were very much in the hands of the breeders and farmers. The advent of F1 hybrid maize technology in the 1930s was the first break in the loop linking the two. This development produced a sharp and enduring division of labour, which shifted crop development increasingly towards breeders and their commercial framework.<sup>8</sup>
- 3.16 The new GM technologies have tended to move the decision-making processes even further away from farmer groups and to shift it to an interaction between technologists, market analysts and regulatory institutions. The general tendency is to contain decision making within a similarly informed set of individuals.<sup>9</sup> The rationale for this approach is probably partly explained by the difficulties

We recognise that the term 'stakeholder' in current usage tends to make the assumption of a dominant set of cultural norms which enable stakeholder involvement to be defined in terms of established practitioner groups (NGOs, regulators and the production chain). However we are obliged to accept that within a multicultural society like the UK, or within the broader international community, this represents an over-simplification, which could have the effect of maintaining and isolating the debate within the existing institutional framework. Ideally, stakeholder involvement should engage a deeper search for the diversity of cultural perceptions of problems, both the problems which the GM technologies are asked to address, and the problems related to the acceptance of technological and social change. This should then form the basis of our informed debate concerning the goals of technology. This approach was exemplified by the UK National Consensus Conference on Plant Biotechnology (Anon (1994) Final Report of the UK National Consensus Conference on Plant Biotechnology. The Science Museum London) and the preparation of this report

<sup>8</sup> Kloppenberg J (1998) **First the Seed**, Cambridge University Press, Cambridge.

<sup>9</sup> Douglas M (1986) **How Institutions Think**, Syracuse University Press, Syracuse, New York.

- of apportionment of accountability among members of more open, extended and transparent decision-making bodies. $^{10}$
- 3.17 Industrial organisations throughout the agriculture/food-supply chain are considering the questions of participatory and socially informed decision making as well as ethical accountability. In general, most are still in the phase of confidence building and seeking plausible models or methodologies to work with. Limited progress has been made in terms of accountability for environmental impacts where tools such as product life-cycle analysis and impact profiling are being developed. Furthermore, many companies are consulting with non-governmental organisations (NGOs) and interest groups about the practical processes of auditing their environmental accountability. This experience may help to build the confidence necessary for the extra step towards ethical accountability.
- 3.18 With the advent of technologies such as herbicide tolerance and insect resistance, where changes in agricultural practice are required, it is particularly important that farmers contribute to the debate concerning herbicide usage and the deployment of systems to avoid the emergence of resistant pest populations. Advances in both transgenic and conventional plant breeding are likely to continue this trend and bring about the need for further changes in agronomic practice. We welcome the role already being played by UK farmers and their representatives (as well as others in the agricultural/food supply industry) in the SCIMAC (Supply Chain Initiative on Modified Agricultural Crops) initiative to determine best practice for the introduction of GM crops. We recommend that the SCIMAC approach to best practice for the introduction of herbicide-tolerant crops be extended to the broader issues of transitions in agronomic practice raised by GM plant varieties which have significant potential environmental impact.

### Consolidation of the plant biotechnology industry

3.19 Over the last two years a major consolidation of the plant biotechnology industry has taken place. Many of the small discovery-driven plant biotechnology companies have been acquired by the major multinational agrochemical companies. This has concentrated ownership of most of the GM technologies and much of the corresponding intellectual property in the hands of the larger corporations. The question has been raised as to whether this consolidation is, in fact, part of the overall trend of corporate globalisation or whether it is a specific consequence of the novel nature and investment costs of GM technology and its need for regulatory oversight. Regulatory constraints and procedural hurdles have led to delays which have raised the costs of bringing GM products to market<sup>12</sup> and made it difficult for smaller companies to maintain an independent strategy. The implications of this concentration have yet to be evaluated. A central issue is whether access to the technologies held by these corporations will be granted to smaller organisations, particularly those in the developing world. Licensing strategy is a complex field influenced by

Accountability for remote outcomes such as the consequences arising from the flow of crop by-products into animal feed and into animal-derived food products.

The five member organisations of SCIMAC are the British Society of Plant Breeders, the National Farmers' Union, the British Agrochemicals Association, the United Kingdom Agricultural Supply Trade Association and the British Sugar Beet Seed Producers Association. These organisations believe that modern plant biotechnology (including GM crops) will bring advances to the agricultural industry and benefits to consumers, environment, farmers and industry. SCIMAC states that it is committed to ensuring that all sides of the GM debate are considered but feels that a delay in the commercial introduction of GM crops in the UK would be 'unscientific and unjustified'. Its overriding objective is to ensure that any introduction of GM crops is managed responsibly and openly and it has developed proposals for a controlled introduction of GM crops. At the time of going to press the proposals for joint stewardship are being considered by Government and are intended to complement regulatory controls in place to approve the commercial use of GM crops. The core aims of this initiative are to provide identity preservation for GM crops, so facilitating consumer choice, and to ensure effective integration of the technology onto UK farms through best practice guidelines. In addition, the proposals are designed to enable the longer-term implications of growing these crops on a larger scale to be monitored and assessed.

House of Lords Select Committee on the European Communities (1999) EC Regulation of Genetic Modification in Agriculture (Session 1998–99 2nd Report), p. 11. The Stationery Office, London.

- counter-currents of commercial risk and opportunism as well as the politics of international trade and protectionism. We discuss licensing in relation to patents and other forms of intellectual property below (paragraphs 3.53–56).
- 3.20 Ownership of the GM technologies has played a central role in shaping the structure of the industry and also the overall direction of research and investment. Researchers in the public sector play a significant role in making the discoveries on which the next phases of technological development are based. At the same time, it has been recognised that the UK has in the past been much more effective at scientific discovery than commercial development. This has led to much recent emphasis on wealth creation in the prioritisation of research targets. This has in turn been reinforced by the need to secure additional research funding from industry. Consequently, there is an increasing trend for commercial objectives to influence the priorities of publicly-funded research and this has increased awareness of the need to capture knowledge as intellectual property. Intellectual property rights are set to become critical to the future development and application of GM technology as the plant genomics field matures. In the next section we consider the ethical and social issues raised by the development of patents to protect GM crops and the associated technologies.

### The concept of property rights

- 3.21 Without property rights, economic life is impossible. Unless we know who owns what, we cannot expect to see goods produced or delivered and we cannot expect to be paid for what we do or produce. But property rights confer on their owners a power over both things and other people that raise wide-ranging moral questions about what can be owned and what rights ownership confers. For example, it is now agreed in all civilised countries that owners of historic buildings have duties of conservation to other members of society.
- 3.22 A special problem with property rights arises in the case of monopoly suppliers of goods and services. A monopolist's price is dependent on the alternatives available. Where a product is similar to existing products, consumers should have the benefits of price competition. Where a product is new, monopolists are able to raise prices above what would be charged in a competitive market. Without some element of monopoly, however, investors are less likely to finance the development costs of new inventions if competition prevents them from recovering start-up costs. In the case of GM crops, intellectual property is particularly important because the products, i.e. seeds, can easily be multiplied by farmers and growers. Without patent protection, farmers and growers would be able to freely multiply fertile seed of approved GM crops and start up costs would not be recoverable.
- 3.23 The overall aim of the patent system is to stimulate innovation for the public good. By rewarding the inventor with a monopoly on his invention for a fixed term, the system aims to provide investors with a means of recouping returns on investments in R&D. It also encourages disclosure of inventions so that others may benefit from the knowledge and further the field. To be granted a patent, an invention must meet three criteria of patentability. It must be novel, inventive and show utility or industrial application.
- 3.24 In the case of GM crops, two public concerns have been visible. One has been with the legitimacy of 'owning life'. Various interest groups have been campaigning, on ethical grounds, against the

Department of Trade and Industry and the Office of Science and Technology (1993) Realizing our Potential: A Strategy for Science, Engineering and Technology, Cm 2250, HMSO, London.

concept that property rights can exist in genetic material or activities associated with it. <sup>14,15</sup> While some of these objections can be attributed to deeply held beliefs (paragraphs 1.32–40), in others, a misunderstanding of the patent system may play a part. Owning a patent which includes a claim to a plant or plant DNA does not in fact allow the assignee ownership *per se*. It only allows the patent holder the right to defend his monopoly against infringement (i.e. the unlicensed competitive commercial exploitation of the invention by others). Moreover, the invention must allow for an inventive step and cannot be granted for naturally occurring species, nor simply genes alone. For example, a patent application which claimed the DNA sequence of a particular gene would also have to claim the use of that gene, such as conferring insect resistance on a plant.

3.25 The other concern, more amenable to the fine-tuning of legal arrangements, has been with the patenting of GMOs (GM organisms) and the research techniques associated with the development of GM crops. Patent-holders may be reluctant to license patents with broad claims to key technologies to their competitors or to public sector research institutions. Companies may seek patents that will not advance research or production, but which deter competitors and prevent research in areas that threaten their monopoly. We should be equally concerned about the implications of many public organisations being involved in the intensive patenting of plant technologies and research tools. Public laboratories are increasingly demanding a royalty on future commercial developments from their publicly funded colleagues in their terms for licensing access to research tools. Researchers tied to such agreements will find it difficult to secure industrial collaboration. The prospect of a complex web of licensing deals may deter some researchers and their potential industrial collaborators.

### The development of intellectual property in the life sciences

- 3.26 Advances in genetics and molecular biology over the past 20 years have brought intellectual property issues to the fore in the life sciences. Prior to these developments, protection of agrochemical and pharmaceutical inventions through patents was largely limited to chemical compounds, chemical processes and medical devices. In the case of plants, an alternative form of protection for plant varieties has been used by plant breeders (paragraph 3.59). The modification of living organisms though genetic engineering in the 1970s and 1980s opened up new possibilities for novel products and processes. By inserting foreign or synthetic genes directly into an organism, scientists were able to contemplate the creation of novel genetically engineered drugs based on human genes, crops with new or enhanced properties and GM animals for use in research and agriculture. These early developments led to a rapid appreciation of the commercial possibilities arising from genetic modification and the need for appropriate intellectual property protection.
- 3.27 Legal experts have sometimes used the 'purification' concept to allow patenting of a 'natural product'. Natural products cannot be patented because they are not new or inventive and an applicant could not describe how to make them. If the purification results in new qualities or a new substance, then it may meet the criteria for patentability. The more human intervention needed to produce the invention, the greater the chances of it being patentable. Applicants must be able to demonstrate that the invention is new, and describe how it can be made.

See Dworkin G (1997) Property rights in genes, **Philosophical Transactions of the Royal Society of London Series B (Biological Sciences)**, 352: 1077–1086.

A recent document, known as the Blue Mountain Declaration, sums up the set of concerns about the exploitation of indigenous people that have been articulated by a wide range of interest groups and religious bodies: 'Indigenous peoples, their knowledge and resources are the primary target for the commodification of genetic resources. We call upon individuals and organisations to recognise these people's sovereign rights to self-determination and territorial rights and to support their efforts to protect themselves, their lands and genetic resources from commodification and manipulation.' For text of the declaration see: http://www.web.net/~CSC/text/Bluemoun.htm.

# Patenting living organisms

- 3.28 Prior to the development of GM, patents on plants were not widely granted in the US or Europe. 16 In the US, the Patents Act defines the patent law. The broad classes of patentable matter which were framed in the eighteenth century to encourage a liberal approach to patentability remain in the Act.<sup>17</sup> According to the Product of Nature doctrine, any naturally occurring material or law of nature is excluded from patent protection. The patent applicant was only allowed to claim materials or processes which were novel and inventive. In Europe, the European Patent Convention (EPC) explicitly forbids patents on plant or animal varieties.
- 3.29 The development of techniques for the genetic modification of micro-organisms, animals and plants, has challenged the concepts of what is and is not patentable. In general, the US has been more responsive to these new developments and has led in the creation of legal precedents which have broadened the scope of patentable materials. In 1978, the Diamond v. Chakrabarty<sup>18</sup> case in the US allowed a patent on a novel genetically engineered micro-organism. This was widely interpreted as a signal to the nascent biotechnology industry that it could expect strong and broad intellectual property protection for inventions involving GM organisms. As a result of the Chakrabarty decision, the US Patent and Trademark Office (USPTO) received over 7000 patent applications for inventions involving biotechnology. Further legal precedents followed and in 1985, In re Hibberd resulted in a patent on maize plants which had raised levels of the amino acid tryptophan. 19 Over 200 US patents in the 'plant biotechnology' category have now been granted.<sup>20</sup> Many of these include claims for plants themselves, as well as for plant DNA, proteins or other biochemical compounds. In 1988, a patent was granted for a mouse which had been genetically engineered for a predisposition to develop cancer.<sup>21</sup>
- 3.30 In Europe the development of patents for living organisms has been slower.<sup>22</sup> The only means by which plant varieties can be protected in Europe has been under the UPOV Convention (Union for the Protection of New Varieties of Plants). Under UPOV, which was founded to provide international protection to the plant breeding industry, the breeder is awarded an exclusive right to sell the reproductive material for 20-25 years (paragraphs 3.58-62). There are two important exemptions to the plant variety protection afforded by UPOV. First, other breeders may use the variety to develop new varieties under the research exemption provision. Secondly, farmers may save seed for crop production though not for sale to other farmers, under the farmer's exemption provision.
- 3.31 Nevertheless, a number of plant patents have been allowed in Europe after protracted debate over whether the plants concerned were varieties or not. However, a decision in 1995 by the European Patent Office (EPO) somewhat reversed this emerging policy by refusing a patent on a GM crop, restricting instead the allowable claims to GM cells.<sup>23</sup> No further EPO patents on plants have since been issued although a test case under consideration should resolve the issue.<sup>24</sup> The recent European

Patents on living organisms are not unique to GM and biotechnology. Micro-organisms in particular have commonly been patented. As far back as the nineteenth century, Pasteur was granted a patent on a strain of yeast in both France and the US. Plant patents were occasionally granted prior to the first UPOV Convention in 1961 which specifically excluded the granting of both patents and plant variety rights for the same plant variety.

<sup>17</sup> The 1956 US Patent Act provides that 'Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore', S101 USC (1976). Diamond v Chakrabarty [447 U.S. 303, 206 USPQ 193 (1980)].

In 1987, the USPTO announced that 'the PTO now considers non-naturally occurring, non-human, multicellular living 19 organisms, including animals, to be patentable subject matter within the scope of 35 USC S.101'

USPTO, see http://www.uspto.gov/ The claims in the Harvard 'oncomouse' patent (USP 4736866) referred to 'non-human' mammals'.

Article 53(b) of the European Patent Convention states that patents shall not be granted in respect of 'plant or animal

<sup>23</sup> The applicant was Plant Genetic Systems.

A patent application from Novartis (G01/98) will be considered by the EPO Enlarged Board of Appeal.

Directive on the Protection of Biological Inventions allows patents on plants and animals if the invention is applicable to more than one variety. Generic inventions such as wheat modified with the Bt gene are not plant varieties eligible for protection under UPOV and are therefore patentable.

### **Patenting DNA**

- 3.32 The debate on patenting issues in biotechnology has not been confined to patentability of living organisms. Identifying, characterising and patenting biological molecules has been a central research activity, particularly in the commercial plant biotechnology sector. In terms of meeting existing criteria for eligibility, patenting biological molecules has not presented particular difficulties to the courts. These compounds are essentially chemical in nature and reliance has therefore been placed on the very extensive case law for chemical compounds which extends well back into the previous century. Despite the special status afforded to nucleic acids as the biological molecules which forms the basis for 'life', for the purposes of patentability they are, nevertheless, chemical entities.
- 3.33 Much of plant GM technology revolves around the identification and characterisation of particular genes. By understanding how a particular characteristic or process is controlled in genetic terms, scientists may gain the potential to modify that process or characteristic by modifying the gene itself. Such a gene, either in its modified or unmodified state, may then be introduced into other organisms to create GM (transgenic) organisms (see Chapter 2).
- 3.34 A substantial number of patents have been filed and granted for unmodified DNA sequences derived from humans, animals, plants and micro-organisms. <sup>25</sup> In a recent analysis, several hundred patent applications on plant DNA sequences covering over 50 species were filed between 1985 and 1995 worldwide. About half of these had been granted. Although most of these plant DNA patents cover crop species, model species, such as tobacco and *Arabidopsis* which are used in research, have also been important. <sup>26</sup> Both the public and private sector have been active in filing these patents. However, it is the companies which have the dominant position.

# Patents on basic technologies

- 3.35 The ownership of patents on GM technologies is a complex area. Several important patents are owned by more than 17 leading agrochemical and seed companies. There has been a tendency for these owners to respect each others' intellectual property and not to challenge these patents. There have, however, been four notable exceptions to this. These include the protracted litigation on antisense technology between the US companies Calgene (now Monsanto) and Enzo; the European opposition to the Lubrizol (Agrigenetics) broad claims on gene/promotor constructs used in plant transformation and the European opposition to Monsanto's broad claims on viral promotors and the kanamycin resistance marker gene. In these examples, common sense seems to have prevailed and unreasonable broad claims have not been upheld. In the fourth case, which concerns the broad claims in the Agracetus (now Monsanto) patent on cotton transformation, the USPTO reconsidered its judgement at the request of the US Department of Agriculture and restricted the breadth. The case is under appeal.
- 3.36 Consolidation in the agrochemical and seed industry continues to shorten the list of owners of the important 'enabling' intellectual property for plant genetic modification and plant molecular genetics.

Thomas SM, Brady M, Birtwistle NJ and Burke JF (1997) Public-sector patents on human DNA, **Nature**, 388: 709.

Thomas S, Birtwistle N, Brady M and Burke J unpublished data and Anon (1999), Nature, 392:525.
 Nuffield Council on Bioethics, unpublished data.

There are now six major industrial groups who between them control most of the technology which gives freedom to undertake commercial R&D in the area of GM crops. These are:

Agrevo/Plant Genetic Systems (PGS);

Du Pont / Pioneer;

ELM / DNAP / Asgrow / Seminis;

Monsanto / Calgene / Delkalb / Agracetus / PBI / Hybritech / Delta and Pine Lane Co.; 28

Novartis;

Zeneca / Mogen / Avanta.

They have made sufficient cross-licensing agreements to be able to supply a full technology 'package' to clients.<sup>29</sup> Below we discuss the implications of patent ownership for three key GM technologies: *Agrobacterium* transformation, GURT technology and apomixis.

- 3.37 The development of the *Agrobacterium* vector system provided the initial impetus for the genetic modification of plants (paragraphs 2.14–15). The system itself represents the concerted work over ten or more years of a number of laboratories in Europe, the US and Australia. The supporting initial research was exclusively in the public sector but the private sector became more heavily engaged as the system came closer to realisation. Ultimately the knowledge contained in the working system was protected by a small number of key patents now assigned to major corporations. These effectively control access to major sectors of plant GM technology. The parallel route to genetic modification known as particle bombardment or biolistics is similarly covered by patents owned by major corporations (paragraph 2.16). Antisense technology provides a means for the selective silencing of unwanted genes, such as those which cause post-harvest deterioration (paragraph 2.22). While the precise ownership of this technology is still under litigation, it still seems likely that this technology may also be used to maintain an entry barrier.
- 3.38 Gene use restriction technology (GURT), dubbed 'Terminator' refers to a set of genetic switches which may be activated to ensure that, as in F1 hybrid crops, the grain from GM varieties is of no use to the farmer as seed (paragraph 2.26). If effective in practice, this would ensure that farmers would be unable to save their own seed. It would also remove the need for monitoring patent infringements. Both GURT and novel F1 hybrids raise questions in relation to the ethical principles embodied in the UPOV Convention discussed below. However, it should be noted that the same technology could equally in principle be applied to the prevention of transgene escape into wild relatives of crop species.
- 3.39 Apomixis is a process which could prevent valuable combinations of genes being lost in the 50:50 redistribution of genes which happens through sexual reproduction. It could allow certain GM traits to be perpetuated even if farmers bred their own second generation crops rather than buying new GM seed each season. Apomixis occurs because the normal part of sexual reproduction where parental genomes are combined in gamete (egg and pollen) fusion is absent. Once established by the selection of desirable offspring from an initial cross or mating, the desirable maternal genotype is conserved. If apomixis technology can be developed in a form which is applicable to the major staple

Delta and Pine Land Co. is under offer from Monsanto.

The **Monsanto** group control an impressive combined intellectual property portfolio on several important technologies including *Agrobacterium* transformation, promotors (seed specific and CaMV35s), GURT (owned by Delta and Pine, currently under offer from Monsanto), biolistics, cotton transformation, selection markers, gametocide F1 hybrid and antisense. **Zeneca/Avanta** have intellectual property on antisense, *Agrobacterium* transformation and promotors, while **Du Pont/Pioneer** have patents on biolistics, herbicide tolerance and selection markers. The **ELM/DNAP/Seminis** group have patents on the sensum marker gene and herbicide tolerance. Other multinationals who do not appear to be part of these groups also have relevant intellectual property, for example, **Novartis** has patents on Bt (as does **Agrevo/PGS**) and cereal transformation and Japan Tobacco has patents on rice transformation and *Agrobacterium* transformation.

crops, it will be extremely valuable to local breeders and for the maintenance of within-crop genetic diversity. Under such circumstances, this technology would need to be widely available, particularly to breeders in developing countries. There is concern from some scientists that, once patented, access to the technology would be restricted to the major multinational organisations. At the same time, it is possible that the string of inventions and discoveries necessary to engineer such a complex trait as facultative apomixis, will be such that intellectual property will be distributed between several organisations. Provided that some of these are independent of the major corporations, there should be an opportunity for the negotiation of broad and equitable access to the technology.<sup>30</sup>

# Patenting and the impact of genomics

- 3.40 The definitive analysis of the genetic make up of organisms through the DNA sequencing of entire genomes is already having a major impact on research in the life sciences. The best known of these is the human genome which is currently being sequenced in both the public and the private sector. The entire complement of human genes is expected to be sequenced by 2000. This structural characterisation is already revealing many genes of unknown function and the next stage of the project will be functional analysis. The genome of yeast has already been completely sequenced and a large-scale collaborative research project to determine the function of unknown genes is in progress. The fact that many genes from a wide range of organisms show homology underlines the value of this approach where the genome of a model organism is sequenced. In other words, some of the genes identified and studied in the model organism can be matched with genes having the same or very similar structure in other organisms.
- 3.41 A large-scale global DNA sequencing effort is now also in progress in a model plant, *Arabidopsis*. This species has much more DNA than yeast and will be completed by the end of 2001. Functional analysis of the results will spread over the next 10–15 years. However, these estimates may well be reduced as DNA sequencing and microarray technologies improve. As particular genes are identified in the model species, so too will homologous genes be identified in a wide range of crop species. The fact that the genomes of some related species such as the cereals show extensive homology or synteny means that there will be further economies of scale through the Japanese public rice genome sequencing project.
- 3.42 In the human genome, two broadly opposing information strategies have been pursued. The large public sector sequencing programmes have viewed DNA sequence information as precompetitive and have accordingly released the data rapidly into the public domain. In contrast, the private sector, together with some public sector institutions, has instead been filing patents on partial and full length gene sequences. A similar pattern is emerging in plant genomics research programmes.
- 3.43 Recent private sector initiatives to apply more rapid 'shotgun' genome sequencing techniques to the human genome and the rice genome have met with a mixed reaction. The US company Celera plans to sequence the human genome by 2001, four to five years earlier than the publicly funded international collaborative project intended. It now intends to 'sequence the rice genome' in a few weeks, eight years ahead of the Japanese-led public sector US\$200 million rice project.<sup>31</sup> What are the implications of these developments? Celera's proposed method of analysis, while much quicker,

The Bellagio Apomixis Declaration was formulated on April 27–May 1 1998. The signatories shared a concern that the 'current trend towards consolidation of plant biotechnology ownership in a few hands may severely restrict access to affordable apomixis technology' especially for resource-poor farmers. Consequently they urged 'widespread adoption of the principle of broad and equitable access to plant biotechnologies, especially apomixis technology' and 'the development of novel approaches for technology generation, patenting, and licensing that can achieve this goal'. See **Bellagio Apomixis Declaration** http://billie.harvard.edu/apomixis.

Saegusa A (1999) US firm's bid to sequence rice genome causes stir in Japan, **Nature**, 398: 545.

is much less thorough in that it will yield partial rather than full gene sequences. Although it is too early to assess the impact of Celera's plans, the company intends to patent some of the human and rice DNA sequences and make most of them available in due course by database subscription. The leading public sector funding agencies for the human genome project have responded by providing a substantial increase in funding to bring forward their own completion date to the year 2000. The prospect of a similar response from the plant sequencing community would appear less likely as the funding agencies involved are more fragmented. This would make it difficult for potential sponsors to react quickly enough to match Celera's plans.

- 3.44 The large agrochemical and seed companies are also investing heavily in genome sequencing programmes. For example, the Du Pont-Pioneer sequencing project in maize, plans to sequence 200,000 partial gene sequences or ESTs (expressed sequence tags).<sup>32</sup> The prospects of patents being allowed for partial gene sequences of unknown function has alarmed many researchers. Although the USPTO rejected a patent application for human ESTs with no known genetic function in 1991, a similar patent has recently been granted in the US.33 The USPTO has indicated that EST patents are allowable in the context of inventions using partial DNA sequences as molecular markers or probes to identify specific sequences. The Working Party considers partial DNA sequences such as ESTs or SNPs (single nucleotide polymorphisms)<sup>34</sup> are research tools and as such should not be patented. The Working Party welcomes the recent initiative involving a consortium of ten pharmaceutical companies and the biomedical charity, the UK Wellcome Trust and the NIH, to pool efforts to create a public SNP map of the human genome. The non-profit SNP Consortium will accelerate the search for disease-associated genes by making the map available to all researchers. The initiative will also avoid duplication of effort and prevent those companies developing private maps from tying up large areas of the human genome with patent claims.<sup>35</sup> We consider that the extension of this approach to other genome projects may be worth pursuing.
- 3.45 There is concern over the extent to which patents on partial gene sequences may impose dependency or 'reach through' to subsequent patent applications with full-length DNA sequences and functional genetic data. A proliferation of patents on individual ESTs held by different owners would require costly future transactions to bundle licences together before a firm could acquire the rights to develop future commercial products. The 'reach-through' licence agreements essentially give the owner of a patented invention used in early (upstream) research, rights in subsequent (downstream) development. Although it has been suggested that benefits may accrue to patent holders, who gain licensees, and researchers, who gain access to the technology, there are fears that a patent 'stacking' effect may inhibit innovation downstream. Upstream owners risk stacking overlapping and inconsistent claims which may be difficult and expensive to resolve. We therefore recommend that national patent offices, the EPO and the World Intellectual Property Organisation (WIPO), limit patent claims for ESTs strictly to their specified uses to avoid dependency on subsequent patents which have overlapping DNA sequences. We further recommend that WIPO and the EC37 closely monitor the development of EST patents worldwide.

<sup>32</sup> ESTs are partial DNA sequences which represent genes that are turned on in a particular tissue type or organism.

The US company Incyte was granted a patent in 1999 for human kinase homologues based on 12 EST sequences for use as molecular probes (US patent US5817479).

SNPs are single DNA base pair mutations. In the human genome project they are being used as markers to locate disease genes. Most SNPs fall within the non-coding regions of human DNA and make no difference to the individual. A given set of SNPs is likely to be inherited with a particular gene and can be used to identify it.

Masood E (1999) Consortium plans free SNP map of human genome, **Nature**, 398: 545–546.

Heller M and Eisenberg R (1998) Can patents deter innovation? The anticommons in biomedical research, **Science**, 280:698–701.

The EC has a specific duty to report annually to the European Parliament on 'the development and implications of patent law in the field of biotechnology and genetic engineering' (Directive 98/44/EC Article 16 (c)).

#### Patents and commercialisation issues

- 3.46 The limitation of access to materials and processes by restriction of licensing is a major concern for organisations outside the main group of agrochemical multinational companies. We have already noted that most of the basic technologies of genetic modification are patented and that these patents are owned by the larger companies (paragraphs 3.35–39). Provided that these companies license their patents to each other (cross-license), the continued development of plant biotechnology should not be impeded by lack of access to patented technologies. However, not all companies are willing to cross-license all of their patents as some wish to retain a property advantage over their competitors and enjoy the benefits that patent monopoly brings. Fortunately, researchers have proved very able at circumventing the patents of others by creating similar but different inventions. It is precisely in this context that we have recommended in paragraph 3.57 the rejection of broad patents which prevent the development of second generation products.
- 3.47 To mitigate the potentially negative effects of monopolies on key plant technologies we recommend that public sector institutions which hold such patents serve the wider public interest by retaining their intellectual property and licensing it in a fair and equitable manner so that key technologies are not tied up in exclusive and inaccessible licence deals. By acting as a 'gatekeeper', the public institution is well placed to make the technology or product available and obtain a return on its investment. We further consider it highly undesirable that a single commercial organisation should have the intellectual property rights for several key technologies relating to one crop solely under its control. For example, Monsanto's (Agracetus) broad patent for technology to produce transgenic cotton has been twice challenged unsuccessfully. Furthermore, the fact that the company is apparently unwilling to license the patent illustrates the danger of broad patents for important crops. We therefore recommend that national patent offices, the EPO and WIPO discourage patent applications which allow extensive control over a single crop species. Rather, these offices should seek to restrict any such applications to the particular type of technology or products in the crop concerned.
- 3.48 There have also been fears that consumer choice could be limited if extensive vertical integration within the agriculture/food-supply chain becomes an objective for the large-scale breeders of the staple and commodity crops. In other words, the linkage of seed, agrochemical and food-processing companies through acquisition or joint ventures could reduce the diversity of food products which ultimately reach the supermarket shelves. The possible restriction of consumer choice may be interpreted as an infringement of consumer welfare or as a denial of a consumer right. However, it appears unlikely that most agrochemical companies will seek to become extensively vertically integrated.
- 3.49 Beyond this set of industrialised country issues lie a set of impacts and consequences relevant to developing countries. Many respondents to our consultation, while agreeing that GM crops would be beneficial to the developing world, expressed concern over the equitable sharing of intellectual property and revenues, especially where genetic resources from the developing world were involved. This issue is dealt with in Chapter 4 in relation to trade agreements and the Convention on Biological Diversity (CBD).

# Commercialisation and developing countries issues

3.50 The majority of developing countries are likely to be disadvantaged in negotiating licence terms. In terms of economic transactions, these are issues about fairness and justice between parties. The high prices paid for the acquisition of rights to GM technologies which control access to the field as a whole (often via the acquisition of whole companies) limit new entrants. It seems unlikely, therefore, that much consideration will be given to making the technology accessible to developing countries or

- to supporting an infrastructure which will allow resource-poor agriculturists in developing countries to pursue local goals for the technology.
- 3.51 It is vital that international agencies take up the challenge of providing access to the technology, both by supporting the development of appropriate derivatives of the technology for local application and by promotion of a climate for unrestrictive licensing (paragraphs 3.46–47). We therefore recommend a sustained programme supported by increased inputs from donors to support the International Agricultural Research Centres (IARC) system,<sup>38</sup> bilateral programmes and organisations such as International Service for The Acquisition of Agri-biotech Applications (ISAAA) and CAMBIA (Centre for the Application of Molecular Biology in International Agriculture) to develop and distribute enabling technologies in a form which is appropriate to the agricultural needs of the developing countries. This can be achieved more effectively in partnership with industry (paragraph 3.50).
- 3.52 Intellectual property and its ownership are essential drivers for the investment which will sustain the further development and support the implementation of new GM technologies. At the same time, it should be recognised that there are two main types of patent, those which enable the technology, and application patents which cover specific traits for improving plants but which are dependent on the enabling patents for their implementation. The possibility of very broad claims to large sectors of the enabling technology may lead to embarrassing and undesirable monopolies.

### Licensing

- 3.53 Developing countries are faced with serious potential difficulties over the patenting of key plant technologies, having few bargaining counters with which to negotiate. Under normal circumstances companies who own the rights to such patents are likely to be reluctant to license them to commercial developing country organisations at a cost they can afford. However, they are not obliged to license their competitors or any other commercial organisation. Where a technology is very powerful, companies will be keen to exploit its full potential. Experience with patenting and licensing of the polymerase chain reaction (PCR) shows that multinationals, in this case Hoffman la Roche, can be expected to be vigilant in pursuing patent infringement.
- 3.54 In the past, several developing countries such as India copied many patented pharmaceutical products and processes from overseas without paying licence fees. Since the TRIPS<sup>39</sup> agreement (see paragraph 4.71), such options are being phased out. Countries which are signatories to the TRIPS agreement will have trade sanctions applied to them by the World Trade Organisation (WTO) if they do not allow intellectual property rights to foreign patent holders. Although research is generally exempt from licence requirements, developing countries will not be able to export goods which have been produced with unlicensed patented technology regardless of whether the relevant patent rights have been granted in that country or not. While this may not restrict locally consumed and traded commodities, it does deny access to the international commodity market for occasional surpluses or by-products. International exhaustion of patent rights which allows for the unhindered trading of the products of licensed technologies, could provide a mechanism for relaxing this constraint. However, it is possible that such an imposition would have the counter-effect of making corporations more insistent on international patent coverage and less liberal in their licensing policies.

IARCs are international agricultural research centres run by the Consultative Group for International Agricultural Research (CGIAR).

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is currently the most comprehensive multilateral agreement on intellectual property. It came into effect on 1 January 1995.

3.55 We acknowledge that without the competitive investment which technology ownership has promoted, GM technology would either not be available at all or its development would be very much delayed. Some argue that its natural custodians are, therefore, the major agrochemical and seed multinational companies, since even the 'realistic' entry price is too high for the developing world. Others have argued that the costs of implementation of the technology, appropriately developed, are on the contrary, not too expensive for developing countries, and that the issue of access is governed simply by licensing. We conclude that there is an urgent need for a realistic assessment of the likely availability of licensed, patented technologies for developing countries. We recommend that those leading companies (and others) holding such patents work in collective partnership with a consortium of appropriate international organisations (such as the CGIAR, ISAAA and the Rockefeller Foundation) to identify and implement practical strategies for broad licensing terms for developing countries. While these should not restrict either the developing world for application to local crops and food security, or the smaller breeders in the developed world, they would, however, need to provide protection to the large corporations in their own competitive markets.

### Compulsory licensing

3.56 Where the non-availability of patented products or processes has gone against the public interest, governments have, from time to time, taken steps to force patent holders to share their inventions through compulsory licensing. Where international monopolies based on exclusive ownership of enabling technologies restrict further innovation, fair access and trade, compulsory licensing could, under some circumstances, be considered as an appropriate response. However, we do not recommend the wholesale imposition of compulsory licensing, since in this sector the outcome could be a decline in willingness to invest in research and development and to share knowledge with scientists in the public domain. Consistent with our recommendation in paragraph 3.55, we would prefer to see a set of intermediary negotiators willing to devise licensing arrangements. Compulsory licensing should be seen as a last resort in the creation of a climate for licensing this important technology.

# **Broad claims**

3.57 Broad claims are an issue in themselves in relation to the ethical intent of patent law. The intent of patent law is that the right to exploit should be set against the encouragement of further invention. Excessively broad claims could, because they can block the route to implementation, act contrary to this intent. Here, once again, welfare issues and issues of fairness in the marketplace are intertwined. We take the view that excessively broad patents will diminish useful research and so diminish welfare. We accept that they are the means whereby some economic users secure benefits they deny to others. The Working Party concludes that on balance broad claims within a patent are only justified where the invention is truly supported by correspondingly broad examples and deserves the reward of broad claims. We recommend that national patent offices, the EPO and the WIPO draw up new guidelines for patent offices to discourage the over-generous granting of patents with broad claims that have become a feature of both plant and other areas of biotechnology.

# Patented technologies which override the UPOV Convention

3.58 Plant breeders' rights under the UPOV Convention established in 1961, have played an important role in supporting the development of private plant-breeding companies and have the benefit of

- being non-exclusive and not favouring large-scale producers. This form of intellectual property protection, described below, could play an important role in the developing world in giving support to local breeding industries, especially in the context of approaches to breeding that are locally informed and culturally sensitive.
- 3.59 Plant varieties have been protected internationally under the UPOV Convention by a system of plant variety rights or plant breeder's rights, which are analogous to, and which did not anticipate, patents granted on living organisms. Plant breeders' rights differ from contemporary patent law since the right of ownership in the product (in this case the plant and its seed) is not exhausted when the product is sold. This enables the breeder to collect royalties from seedsmen and growers for each batch of seed multiplied or traded, the only exemption being the farmers' privilege of saving seed from their own crops for their own use. The duration of this protection depends on the individual crop and has a minimum of 20 years extending to 25 years for trees and vines. In order to be registered for plant breeders' rights the variety has to meet certain requirements for distinctness from other varieties, uniformity and stability (DUS). These requirements are analogous, although different, to the requirements under patent law for a full disclosure of the invention and the demonstration of originality and utility.
- 3.60 When a plant breeder exercises the monopoly granted by plant breeders' rights by placing a variety on the market, the variety automatically becomes available to other breeders. This ensures that the variety becomes available not only for cultivation but importantly, for further breeding. This obligation is viewed as an ethical quid pro quo to the granting of a temporary monopoly by way of royalty rights, which secures further breeding initiatives and encourages competition. Since the parental lines of F1 hybrids are not themselves placed on the market they need not become available for further development and can become effectively the equivalent of a trade secret. Newly-derived GM hybrid systems are beneficial to the breeder who can avoid the requirement to release the developed germplasm embodied in the parental lines. This provides the breeder with exclusivity.
- 3.61 New GM F1 hybrid systems and the recently publicised GURT technology offer to major breeders the possibility of ensuring that no fertile seeds can be collected by farmers from their varieties. We have noted further concern that the possibility of new varieties being presented for registration with the benefit of both plant variety rights and patent protection could limit the mechanism by which germplasm (and therefore, genetic diversity) is shared among breeders. This potential locking up of genetic variation would be contrary to the spirit and intent of plant variety rights. We are obliged to wait and see the extent to which a burgeoning influence of patents in the exploitation of plant varieties will restrict access to proven germplasm. We recommend, however, that WIPO, the EC, UPOV, CGIAR and International Plant Genetic Resources Institute (IPGRI) together closely monitor the impact of patents on the availability of germplasm to plant breeders.
- 3.62 At the same time we note that many conventionally-bred modern varieties are the products of substantial technical investment (for instance in the use of genomics and molecular marker technology in the introduction of disease resistances, see paragraphs 2.2–7). We conclude that it would be unfair to the breeder of such a variety for it to pass directly into the breeding programme of a competitor without some form of recompense. In this instance, patents could provide a basis for negotiating recompense provided that the intent of the UPOV Convention is respected.

These terms are specified in the 1991 revision of the UPOV Convention. In the UK, rights are now granted a term of 25 years for all species except tress, vines and potatoes which have a term of 30 years.

### Consequences of raw material substitution

- 3.63 Raw material substitution has been an historic fact of life in a technologically changing world. Examples include the switch from metals to recyclable plastics (composites) in the manufacture of automobiles or the replacement of plant-derived dyestuffs by synthetic chemicals. Although some of these instances have relieved pressure on finite resources, substitution has generally been a response to manufacturing changes or to changing consumer product demand.
- 3.64 Plant genetic modification will provide, in the longer term, the opportunity for acquiring the raw materials normally derived from a particular crop from the products of another modified crop. This kind of development can improve production efficiency and security of supply. An example would be the production of coconut oil (copra) with modified oil derived from oilseed rape. However, the original producers, who lose a market for a cash crop, potentially suffer economic loss when such a substitution is made. What are the ethical implications of such substitutions depriving developing world producers of their livelihoods and their ability to generate foreign exchange? These are especially difficult to assess where, for example, the new crop might be produced via more sustainable agricultural practices than the old.
- 3.65 It could be argued that there is an obligation on developed countries to buffer the developing world against the consequences of changes in trading patterns brought about by such changes in technology. Should accountability extend to the foreseeable consequences of substitutions, for example by providing the loser with an alternative cash crop? In practice these issues are very complex, and individual crops probably have to be considered on a case-by-case basis. Furthermore, not all of the consequences are likely to be predictable, nor is the party responsible for the introduction of a substitution crop likely to be qualified to assess or intervene in the economic or social networks of the affected party. In the context of this complexity, it is difficult to prescribe an institutional mechanism for ensuring justice in relation to substitution crops, and this issue is likely to remain contested.
- 3.66 In this context some respondents to the consultation suggested that companies have a duty to repair any damage caused by their crops, including the loss of income to other farmers as a consequence of GM crop introductions (for example, to organic farmers). It should be noted that the question of compensation for the negative economic and social consequences of the introduction of GMOs is very much on the agenda of the Conference of the Parties in the negotiation of the Biosafety Protocol of the CBD (paragraphs 4.63–65). However, the Working Party acknowledges that a major rationale for the implementation of genetic modification is to enhance the efficiency, effectiveness and competitiveness of farmers who plant such crops. Under normal circumstances it would be hard to justify recompense other than via higher prices for non-GM products in the market place for those farmers who elect not to do so.
- 3.67 With pressure on the developed world to develop and switch to renewable sources of feedstocks for manufacture, one could foresee a trend towards the engineering of specific crops for this purpose.<sup>41</sup> This could provide, on the one hand, the opportunity for new export cash-crops for the developing world. On the other, it might be seen as tempting farmers away from local food production. Nevertheless, there may be positive opportunities here for the constructive use of international aid, and we urge aid agencies to give support to this aspect of agricultural diversification. We conclude that international aid funds need to be allocated for valid projects aimed at diversification of cash crops and for the building of the technical capacity to achieve this.

#### **Globalisation and commodification**

3.68 Recent international trading agreements, intended to liberalise the movement of goods within and between the major trading blocks, have supported the so-called globalisation of the food chain as well as the trend towards commodification. Commodification means that crop products are traded on international markets on the basis of the expectation of future fluctuations in supply and demand, regardless of provenance or the local value systems of the farmers and societies that produced them. Despite this trend, we may expect to see an increased demand for GM crop products to be segregated or traceable. While segregation is required or desirable this may help to suspend the impact of commodification.

### Accountability in the international dimension

- 3.69 It has become a truism that the consequences of plant breeding do not respect national or local boundaries. The diffusion of social and economic consequences along the global food supply chain or the local wind dispersal of GM pollen are good examples of these effects. However, the majority of attempts at regulatory or ethical oversight are formulated on a national basis. In the international dimension, the field is highly polarised. From one perspective, the efforts of the Organisation for Economic Co-operation and Development (OECD) to harmonise regulatory frameworks might be interpreted as supporting the interests of the industrial base of developed trading nations. From another perspective, the codes of practice proposed within the framework of the FAO (Food and Agricultural Organisation of the United Nations) and the CBD appear to represent the agendas of campaigning groups such as Third World Network and Rural Advancement Foundation International (RAFI). This poses a complex operating environment for those industries involved in the international food trade. It leaves the issue of accountability across diverse national jurisdictions very much in the domain of individual corporate responsibilities and relies on their ability to define their own boundaries of accountability.
- 3.70 One specific aspect of international transgene deployment may merit special consideration. This relates to the planting of GM crops, modified for fitness traits, within the geographical centre of diversity of the crop itself (i.e. where there is an enhanced opportunity for out-crossing into wild species). These centres of diversity as defined by Vavilov<sup>43</sup> are of immeasurable global value as in situ germplasm collections for the future of plant breeding. We recommend that the IPGRI and others entrusted with stewardship of plant genetic resources consider the risk implications of introgression of genetically modified traits into the centres of diversity for the main temperate and tropical crop species and decide whether additional measures are needed to protect these genetic resources through ex situ and/or in situ conservation.

# **Conclusions**

3.71 The commercialisation of plant biotechnology has advanced rapidly over the past five years. It is now clear that intellectual property rights, mainly in the form of patents, are fundamental to the commercial development of the technology. Although patenting in biotechnology is now

This framework has its advantages and disadvantages. It does not provide a sound basis for the reform of agricultural practice or the means for persuading farmers to adopt attitudes which are more environmentally accountable or sustainable.

Nikolai Vavilov was a Russian botanist in the early twentieth century who took part in over 100 international plant-collecting missions. From the resulting collections he determined where each crop was most diverse and identified 12 centres of diversity in the world.

- generally widely practised by public and private sector researchers alike, excessively broad claims and restrictive licensing remain a potential threat to innovation. With regard to GM crops, the implications of patenting of important new technologies involving plant transformation, such as apomixis, will depend largely on the licensing strategies of the companies involved.
- 3.72 The agrochemical and seed industry is tightly consolidated around a small number of multinational companies. Although this structure has attracted a good deal of negative comment, we conclude that it is the *consequences* of that structure rather than the structure itself which should be scrutinised. If there is non-exclusive licensing on key patents and the needs of developing countries are addressed in an open and realistic dialogue with international agricultural organisations, the consolidated structure need not be a cause of concern. If, by contrast, the consolidation process continues further and the major companies acquire control of specific crops, then the contestability of developed and developing country markets could be compromised. The Working Party concludes that there is a need for the relevant competition authorities to keep this sector under close review. We consider the application of GM technology in the developing world in the next chapter.

Impact on developing countries:

implications for UK policy

#### Introduction

- 4.1 When deciding what to do, one major consideration, perhaps the overriding one, is to increase human well-being, or promote general welfare. Comparing the merits of different policies towards genetically modified (GM) crops is thus a question of discovering how many people are affected for the better or for the worse, and by how much. But 'how much' depends in turn on where people start off. Just as the loss of £50 is a disaster to a poor person and an inconvenience to a rich one, so small losses are disastrous to people already suffering low levels of well-being, and can amount to the difference between bare survival and death by starvation. At high levels of well-being, large losses seldom threaten survival or even health. This suggests that when choosing GM policies on the basis of their effect on human well-being, we should give more weight to the life-or-death concerns of the hungry, than to the less pressing concerns of the well fed. This principle in fact reflects a common idea of social justice: that we should distribute resources 'according to need'.
- 4.2 Although the principle of 'to each according to their needs' was adopted as a slogan by radicals in the nineteenth century, it is much less radical and much more generally accepted where the needs in question are the basic nutritional and health needs to which GM crops are relevant. There is general support in wealthy countries for famine relief and prevention. Beyond that, developing and developed nations (and the global food system) can go far to ensure basic nutritional needs are met world-wide, and yet leave a huge surplus to pay for 'rights-related', incentive-based or other inequalities as might be seen, by some, as necessary or desirable for justice, economic growth or political order. These considerations suggest that there need be no competition between giving full attention to the food needs of the poor and adopting policies for the promotion of GM crops that ensure the safety of people in developed countries and profitability for companies. The burden of this chapter is that policies to achieve this are ethically indicated and feasible, yet such policies are not in place.
- 4.3 If we value the ethic of 'to each according to need' (or in the alternative, believe that the poorest possess a 'right to survive', given feasible efforts on their own part and a global capacity to feed them), then the introduction of GM crops on a large scale would be a moral imperative. This is because GM crops are expected to produce more food, or more employment income for those who need it most urgently. 'More food for the hungry', unlike 'tomatoes with longer shelf-life', is a strong ethical counterweight to set against the concerns of the opponents of GM crops.
- 4.4 However, ordinary notions of justice or fairness are challenged by the present distribution of research effort, GM seed marketing and field trials which are dominated by a small group of leading agrochemical and seed multinational companies. In contrast, the Green Revolution<sup>2</sup> was largely due to public-sector research. Most of the companies' effort goes into reducing costs in capital-intensive farming in developed countries. Research on staples mostly involves varieties used for animal food. Only a small proportion of effort goes into what is most needed in less developed countries: cheap, labour-intensive, robust and high-yielding staples for human food. Inevitably, the companies respond mostly to the demands of the market. So it is unlikely that this state of affairs will change in the near future unless like-minded governments step in and act on explicitly market-correcting moral principles financing or stimulating an orientation of GM research towards the needs of the hungry.

It is accepted that some needs are 'socially constructed', see Douglas M and Ney S (1998) **Missing Persons: a critique**of the social sciences, University of California Press, California. But the level of calories and other nutrients required for functioning in particular circumstances can be determined (within probabilistic limits).

The Green Revolution is the popular term for the spread of high-yielding food staples in developing countries. This began with maize hybrids in the 1950s, but the main component was the semi-dwarf wheat and rice varieties, mainly in reliably watered parts of Asia and Central America, around 1962–85. See Lipton M and Longhurst R (1989) **New Seeds and Poor People**, London, Routledge.

# The need for increased food supply

- 4.5 Just as the world could not feed itself today with the farming methods of the 1940s, so farmers can hardly expect to meet the increased global demand for food in 20 years time using today's crop varieties and agricultural technologies. Many of the current needs of the developing world, in particular, arise from a mixture of economic and social problems. However, new agricultural approaches and new crop varieties will also be needed if the doubling of agricultural output necessary for food security is to be achieved for a projected world population of eight billion or more in 2020. In 1961 the amount of cultivated land supporting food production was 0.44 hectares per person; today it is about 0.26 hectares.<sup>3</sup> Based on population projections, by 2050 it will be approximately 0.15 hectares per person. The rate of expansion of arable land is now below 0.2% per year and it continues to fall. The growth rate of food staple yields since the mid-1980s has, moreover, slowed to less than half the pace of the 1970s.
- 4.6 Projections by the Food and Agriculture Organisation (FAO) indicate that 680 million people, 12% of the developing world's population, could still be 'food insecure' in 2010, down from 840 million in 1990–92. Food insecurity is expected to diminish in East Asia, South Asia and Latin America, but it could accelerate substantially in sub-Saharan Africa, West Asia and North Africa. Sub-Saharan Africa and South Asia, home to a projected 70% of the world's 'food insecure' people in 2010, are expected to remain the main locus of hunger in the developing world.
- 4.7 Since 1960, most people in the developing world have enjoyed huge increases in employment income and food access. This has been largely due to yield-enhancing progress in food farming and has brought big falls in under-nutrition. Yet the gaps (for example, most of Africa) and the unmet needs (of over 800 million underfed persons) remain vast. In addition, population growth is increasing these needs rapidly. Meanwhile, yield improvements are slowing, and with them the growth of employment and availability of cheap food staples needed to remedy world hunger. There are a number of fundamental reasons for the slowing of the Green Revolution (paragraphs 4.16–17). Conversely, renewed progress will require new routes to rapid yield enhancement, which will almost certainly involve developing new GM crop varieties. Other measures are also needed, but reliance on these *alone* is either not feasible, or environmentally unacceptable, or both (paragraphs 4.22–24).
- 4.8 As many respondents to the Working Party's consultation noted, better distribution might address some of today's problems of food shortages and deficiencies. Indeed, if the world's supply of food had been equally distributed in 1994, it would have provided an adequate diet for 6.4 billion people, more than the actual world population. However, such observations are very bad arguments against seeking employment-intensive technological progress in food farming. Political difficulties of redistribution within, let alone among, countries are huge. Logistical problems and costs of food distribution also militate against sole reliance on redistributing income (i.e. demand for food) to meet present, let alone future, needs arising from increasing populations in less-developed countries. Hence we must stress the importance of any new options that will secure higher direct and indirect employment and cheap food in labour-surplus developing countries.
- 4.9 GM crops have the potential to assist in alleviating world hunger. Some progress, indeed, has been made (paragraph 4.29) but significant inroads require radical changes in the current focus and structure of research and development (R&D) for such crops. The current focus is on non-staple

Pimentel D (1989) in **Food and Natural Resources**, Pimental D and Hall C (eds) Academic Press, San Diego pp. 2–32.

<sup>4</sup> FAO (1997) **Report of the World Food Summit November 1996**, Rome.

Response from the **British Medical Association** to the Working Party's Consultation, and others. Some respondents felt that more efficient redistribution of food would alleviate world hunger while others argued that steps to increase food production were needed in addition to improvements in distribution.

- crops, consumer quality, herbicide tolerance and other requirements of labour-saving production by large farms in industrialised countries for developed markets. The nature of GM crop development means that most R&D is undertaken by a relatively small number of large companies.
- 4.10 What is required is a major increase in support for GM crop research and outreach, directed at employment-intensive production of food staples within developing countries.<sup>6</sup> Much of this should involve public-sector scientists in developing countries and the Consultative Group on International Agricultural Research (CGIAR)<sup>7</sup> institutions. However, given the increasing concentration of GM funding and expertise in a group of large companies, it will also be necessary to involve the private sector, much more than at present, in the enterprise of 'feeding the world'. There are currently insufficient incentives or institutions to realise this goal.<sup>8</sup>
- 4.11 The resulting spread of GM food staples will probably be, on balance, highly beneficial to consumers' health and the environment in developing countries. However, safety concerns dictate a parallel improvement in regulation, both of field trials and of the use of GM crops in the food chain. Not only for GM crops does such regulation in developing countries frequently fall far short of the minimum standards taken for granted in the developed world.<sup>9</sup>
- 4.12 In the context of the new 'focus on poverty' in the UK Aid White Paper<sup>10</sup> and the fall in global funding for appropriate agricultural science, the UK is ideally placed to take the lead in addressing this situation. If it is not tackled, the world will be hungrier and more disease-prone. It will also be more unstable, ecologically threatened and politically dangerous, for rich and poor alike.

### Under-nutrition in the developing world

- 4.13 In 1990–92, 840 million people, one-fifth of the developing world, consumed so little food, relative to needs, that they suffered caloric under-nutrition.<sup>11</sup> About one-third of children less than five years old in developing countries were significantly underweight for their age, including most of the one in ten new-borns who would die before the age of five.<sup>12</sup> Severe anthropometric deficiency is associated with an increased risk of suffering from damaged human development as a result of more or longer illness, a shorter life-span, or reduced physical work capacity, mental functioning or immune response.<sup>13</sup>
- Despite the undoubted importance of labour-intensive processing and other industrialisation, its costs per job are such that most of the poor will continue to depend, for income growth, mainly on extra farmwork. This alone, moreover, can generate nearby, safe and affordable basic foods.
- The CGIAR system comprises sixteen international research institutions, with a principal mandate for increased, more robust and more sustainable agricultural production, especially of food staples in developing countries. Its annual budget in 1998 was US\$345 million. Member institutions specialise in particular geographical areas, farm systems, problems (such as irrigation management) or particular crops. Some of the latter institutions, such as the International Rice Research Institute in the Philippines and the International Centre for Maize and Wheat Research in Mexico, have developed many of the successive key high-yielding and robust varieties that together brought about the 'Green Revolution'. There is some world-class GM research capacity in these institutions, but due to the high fixed and variable cost of GM research, the CGIAR institutions remain relatively minor contributors.
- 8 **Horticulture Research International** and several other respondents to the Working Party's Consultation considered this to be a very important issue.
- The Foresight Health and Life Sciences Council and other respondents to the Consultation expressed fears that such shortfalls in regulation could lead to avoidable environmental and public health disasters. Concerns were also raised by Ken Collins (MEP for Strathclyde East) and others that lax regulation might lead to developing countries becoming testing grounds for GM crops.
- Department For International Development (1998) **Eliminating World Poverty**, Cm 3789, The Stationery Office, London.
- This rigorous definition of 'caloric under-nutrition' takes it to occur when dietary energy intake is less than 1.55 times the basal metabolic rate (BMR). BMR is the rate of energy breakdown by a warm, fasted (18 hour) person at complete rest. The caloric intake required to meet 1.55 BMR varies by country, partly because 'minimum calorie requirements take into account age and sex composition of the population' (FAO (1995) **Food Agriculture and Food Security** WFS 96/Tech/1, Rome). For example, 1.55BMR averages 1790 kcals/man/day in Asia but 2000 in Latin America.
- United Nations (UN) (1997) **Human Development Report**, Oxford University Press, New York.
- Payne P and Lipton M (1994) How Third World Rural Households Adapt to Dietary Energy Stress, **Food Policy Review** no. 2, International Food Policy Research Institute, Washington D.C. The association between mild to moderate

- 4.14 There have been very substantial recent gains in calorie consumption, causing corresponding falls in under-nutrition. The average calorie supplies per person in the developing world rose by 18% between 1969–71 and 1990–92, while the proportion of persons in developing countries with a daily calorie consumption below 1.55 BMR fell from 35% in 1970 to 20% in 1990. Such gains were absent only in sub-Saharan Africa. Small-scale surveys of children under five for 1976–95<sup>14</sup> confirm the big improvements, but also reveal serious gaps.<sup>15</sup>
- 4.15 Where under-nutrition is a problem, its levels and trends, and those in average dietary energy supply (DES), are linked to (and often caused by) levels and trends in national production of staple foods. 16 Such trends, in turn, have been improved mainly by yield-enhancing technical progress, through the Green Revolution. Yet cereals production growth slowed from 3% per year in the 1970s to 1.3% in 1983–93. It is projected to grow at 1.5% per year to 2020 'if investments in agricultural research and infrastructure do not fall below the already reduced levels of the 1980s'. 17

# The global slowdown in yield

- 4.16 This global slowdown in the growth of yields is only in part a response to attenuated farm subsidies in the developed world. It is observed in most of Asia, including India and China. It is especially worrying that yield growth has slowed right down in many of the previously most dynamic areas, such as parts of the Punjab. The underlying causes, such as groundwater exhaustion, micronutrient depletion and low-level pest build-up, have proved very hard to manage using conventional plant breeding. As will be shown, further reduction of under-nutrition among the world's poor depends mainly on growth in employment income from producing local food staples. This, in turn, depends increasingly on re-igniting growth in yield potentials, which has been very slow since the late 1960s.
- 4.17 The general fall in under-nutrition has exposed other problems. Some large groups (for example, girls in South Asia) and regions lag behind. A shift to monocultures, to intensive animal products, and in marginal lands from pasture (for animal grazing) to arable (growing crops), may threaten both the provision of staples for the poor and the environment. These major continuing problems could, in principle, be addressed through spreading growth in yields to areas such as Africa and most of the semi-arid world. But this continues to prove very difficult with the present range of methods. Ultimately, a sustainable increase in the field performance of food staples depends on higher and more robust yield potentials. GM crops offer one way to achieve this, while potentially also encouraging (i.e. making more economic) reduced use of water and agrochemicals.
- 4.18 Apart from under-nutrition, it could well prove feasible to greatly reduce malnutrition through the development of micronutrient-rich GM crops (such as the Vitamin A-enriched rice developed by the

anthropometric deficiency (especially stunting) and bad subsequent outcomes is, however, weak and probably not causal. Mild to moderate stunting is (a) a 'marker' of an economic and physical environment leading to troubles later, rather than a direct cause of such troubles; (b) often a sign of biological adaptation to an environment that imposes severe strain: a population that cannot acquire much food is under genetic pressure to adapt by selecting genes for low energy requirements (smallness).

FAO (1996) Sixth World Food Survey, FAO, Rome.

Sachdev H (1997) Nutritional Status of Children and Women in India: Recent Trends **Nutrition Foundation of India** 18, 3:1–5. In successive nation-wide surveys in sub-Saharan Africa, the proportion of under-fives underweight rose in ten countries and fell in three (substantially only in Zimbabwe). In the Near East and North Africa three countries showed improvements. In Latin America and the Caribbean, the favourable balance was 14 to three. In Asia, only Laos showed deterioration; ten countries showed improvements, which were especially big and steady in India and Pakistan. Regions such as Tibet and the 'Bimaru States' in India have remained little touched by the improvements, Drèze J and Sen A (eds) (1997) **Indian Development: Selected Regional Perspectives**, Clarendon, Oxford; Bhargava A and Osmani S (1997) 'Health and nutrition in emerging Asia', Background Paper for **Emerging Asia: Changes and Challenges**, Manila: ADB.

To see how a nation's DES per person reflected under-nutrition, see Lipton M (1998) **Food Consumption**, Background Paper, UNDP Human Development Report, OUP, New York.

Pinstrup-Andersen P and Pandya-Lorch R (1996), Food for all in 2020: can the world be fed without damaging the environment? **Environmental Conservation** 233:228.

- Rockefeller Rice Biotechnology Programme). Vitamin A deficiency affects over 200 million people and over 14 million children have consequent eye damage. Iron deficiency affects some two billion (2100 million) people, impairing physical and mental work and increasing risks in pregnancy. Iodine deficiency affects some 1100-1500 million people, of whom over 600 million are goitrous.  $^{18}$
- 4.19 To evaluate the potential of GM crops for alleviating under-nutrition and malnutrition, it is essential to grasp the connection between more food and less hunger. This is not simply the 'balance between food requirements and food availability'. Hunger and famine happen mainly because, even where food is available, the poor cannot afford it. They depend largely on income from employment, including self-employment, to obtain cheap food staples; hunger happens when such employment, in wealth-creating and hence rewarded work, is too scarce to buy the requisite staple foods. It will remain overwhelmingly staples production that can provide such employment income at capital costs (per workplace) that poor countries can afford. So the fact that most hunger is due to lack of employment income strengthens the case for raising food productivity on small farms in developing countries.

# The impact of the Green Revolution

- 4.20 The growth in yields achieved through the Green Revolution greatly reduced hunger in the 1970s and 1980s for two reasons. First, as new arable lands become scarcer, it provided much the most affordable route to productive employment at low capital cost. Secondly, it supported a combination of events of particular benefit for the poor: a steady downtrend in the price of food staples relative to manufactures, so that the poor in urban areas could afford more food with their wages. Yet in areas benefiting from the Green Revolution, food production increased faster than food prices fell<sup>19</sup> so that small surplus farmers there were also better off and had more incentives to employ the poor.
- 4.21 The need to revive the faltering momentum of yield increases in food staples in developing countries, and to extend it to arid lands and to Africa, is emphasised by three factors. First, although the rate of population growth in developing countries is falling, populations are still increasing rapidly. Workforces, and hence the numbers of people needing employment income, are increasing faster still, even as fertility declines. Secondly, to produce an equal number of calories for human consumption, up to seven times as much grain is needed if this is consumed via animal products instead of being consumed directly. Yet global economic growth and increased prosperity increasingly swell demand for animal products. As these pressures lead to a shift of land and grains away from human food, towards animal feed, even higher grain yields are required if staples for human consumption are to be produced sustainably and affordably. Thirdly, paths to increased food output other than through higher yields from GM crops, while needed, will not be sufficient to revive world crop growth, or to achieve much nutritional improvement, without unacceptable side-effects.

# Increasing yields: alternatives to GM crop varieties

- 4.22 What might such alternative paths be?
  - Area expansion: this slowed to very low rates during 1960–98. Pushing crops further into marginal lands decreases returns and increases environmental hazards. One estimate suggests

Graham R and Welch R (1996) Breeding for staple crops with high micronutrient density. Agricultural strategies for micronutrients: **Working Paper No. 3**, **International Food Policy Research Institute**, Washington, D.C.

Food staples prices have been falling (relative to manufacturers' prices) by about 0.5% yearly for the past 35–40 years. But in Green Revolution areas of South and East Asia and Central America, total factor productivity in food farming has been rising by over 2% a year.

The world population is projected to rise in 1998–2050 from 749m to 1766m in Africa, from 504m to 809m in Latin America and the Caribbean, and from 3585m to 5268m in Asia. United Nations (1998) **Briefing Packet: 1998 Revision, World Population Estimates and Projections**, United Nations, Population Division, New York.

that, if world crop yields had not been tripled between 1960 and 1992, we would have ploughed 10-12 million square miles of additional uncultivated land for low-yield crops. To avoid this happening in the next 20 years, 'we must be able to triple the yields from the world's existing farmland again'. <sup>21</sup>

- Irrigation: like land expansion, this has contributed enormously to past food production growth but now faces sharply diminishing returns, increasing marginal costs and hazards. Irrigation covers approximately one-third of the cropped area in Asia, barely 5% in sub-Saharan Africa, and 16% globally. Irrigation increases land productivity over 2.5-fold on average, but both expansion and improvement of irrigation efficiency are limited by growing urban competition for water and by serious environmental problems. Hence it is critical to know whether GM crops with 'increase[d] resistance to drought . . . [are] likely to be as valuable. . . for the lower-potential lands as for the high-potential'. Drought resistance and salinity tolerance are not the current priorities of GM crop research or funding, but could become so.
- Increased fertiliser and pesticide inputs: especially in Africa, these can do much to enhance yields, but, like agrochemicals for pests, diseases and weeds, are expensive for poor farmers. Fertilisers and pesticides may also cause environmental and health problems, which are compounded by weak regulatory controls in developing countries. GM crops could raise the efficiency of fertilisers and can help to control pests and diseases with fewer chemicals.
- Conventional plant breeding: supported by agrochemicals and irrigation, this has been associated with huge falls in food poverty incidence since the mid-1960s, from 30–35% to below 10% in China and Latin America and from 55% to 32% in India. Hese falls are, to a considerable extent, due to semi-dwarf rice and wheat and hybrid maize. Continually modified to meet evolving pests and new soil and water conditions, such varieties have spread to cover 70–80% of areas planted with these crops in developing countries. Conventional plant breeding still has much to offer, and still has high returns; but its increasingly 'defensive' orientation means that it has shown steadily decreasing yield impact since the dramatic spread of such semi-dwarfs as IR8 and IR20 rice and 7094 wheat in the 1960s. Conventional plant breeding aims to produce ever-improving crop varieties but faces continually evolving varieties of pests; and has to extend gains to ever more recalcitrant areas and crops. Without major increases in yield potential, such breeding will become increasingly defensive, at best maintaining results rather than improving on them.
- Alternative approaches: conventional plant breeding, and other means to food output enhancement, may benefit from alternative approaches. Integrated pest management, by manual and biological controls, together with tolerant or horizontally moderate-resistant<sup>25</sup> crop varieties and modest pesticide use, reduces chemical pollution. It also reduces the evolution of new virulent pests which can overcome pesticides and/or strongly resistant crop varieties. Inter-alley and relay cropping present promising alternatives to the monocultures typical of conventional research. Participatory research goes beyond 'farming systems analysis' to integrate farmers' priorities and experimentation. This includes the introduction of land-races and other populations of plants, such as beans in Rwanda, into conventional formal

Avery D (1997) Saving the planet with pesticides, biotechnology and European farm reform, Bawden Lecture, Brighton Conference, British Crop Protection Council.

Kendall HW, Beachy R, Eisner T, Gould F, Herdt R, Raven PH et al. (1997) The Bioengineering of Crops, report of the World Bank Panel on Transgenic Crops, World Bank and CGIAR, Washington D.C.

<sup>23</sup> Conway G (1997) **The Doubly Green Revolution**, Penguin, London.

Lipton M and Ravallion M (1995) Poverty and Policy, in Behrman J and Srinivasan T (eds), **Handbook of Development Economics**, Vol. IIIB, North Holland, Amsterdam.

A moderate-resistant plant kills less than 100% of the pathogen that it is resistant to. If, for example, only 95% of the targeted pathogen is killed, the plant absorbs some damage but there is not such a strong selection pressure for the pest to evolve a new and virulent biotype.

research systems.<sup>26</sup> Such methods were central to smallholders' strategies in centuries of slow or zero growth of population and demand. But the very slow food output growth in those times shows that, in coming decades, such strategies cannot suffice to revive the faltering pace of staples yield, productivity and, above all, productive employment to the level required.

# Field yields and incentives for farmers: why 'yield potential' matters

- 4.23 It is sometimes argued that, because farmers' yields in developing countries fall far short of 'yield potential', there is no urgency to increase it, by GM crops or other technical means. It is claimed that the need for more food can be more readily met by action from farmers or governments to raise field yields towards their full potential. GM crops, it is argued, are therefore not a priority for developing countries. We believe that this claim is misguided because the alternatives to raising yield potential via GM crops are either running out of steam or themselves rest on renewed success with GM crops.
- 4.24 'Yield potential' is the maximum attainable crop yield from a given soil-water regime under experimental conditions, with no limits to the addition or adjustment of inputs such as irrigation, fertilisers, farm labour and machinery, or of agronomic conditions, for example by staking individual plants. On a real farm, it hardly ever pays farmers to reach more than 20–40% of this yield potential.<sup>27</sup> Rises beyond that level involve extra costs that outstrip the declining value of the extra crop returns. If it is uneconomic for a farmer to expand yield above, say, 25% of potential in given conditions, and that percentage has been reached, then field yields can, in principle, be expanded towards the full yield potential by four sorts of actions:
  - Farmers can, in principle, 'farm better' with the resources they have. However, researchers
    agree that most smallholders, even if illiterate, use scarce resources well, seeking profit and
    avoiding risk.
  - Service providers, such as agronomists and extension workers, can increase the farmers' knowledge or provide innovations that are more responsive to local needs and conditions, so making it safer or more profitable for farmers to raise yields towards their potential. However, this approach alone, over large areas, has hardly ever raised yields by more than 0.5–0.7% per annum. Moreover, agronomic innovation, by farmers or service providers, is much more likely to be rapid when more attractive plant yields make it more profitable.
  - Policy makers can improve farm incentives by investments such as irrigation extension, credit
    and transport. This should make it safer or more profitable to raise field yields towards the
    yield potential. Progress has been made along these lines, but often with diminishing returns
    or with strong resistance from urban interests. Such policy changes have more effect on
    farmers' responses, and hence on output, and are therefore politically more affordable if yield
    potentials and field yields are rising.
  - Breeders can improve resistance to pests or moisture stress, enabling field yields to rise, even with a static yield potential. However, the great progress here since the mid-1960s increasingly involves 'running to stay in the same place'. Falling water-tables, new pest strains and micronutrient exhaustion, themselves the results of that progress, reduce potential gains. Improved plant varieties are the path to better responses to these constraints, as well as to higher yield potential. Such varietal improvement has been slowing down. Furthermore, if

McGuire SJ, Manicad G and Sperling LJ (1999) **Technical and Institutional Issues in Participatory Plant Breeding Done from the Perspective of Farmer Plant Breeding: A global analysis of issues and of current experience**,
Systemwide Program for Participatory Research and Gender Analysis, CIAT, Colombia.

The best farmers in 'lead' areas, such as the Indian Punjab, obtain only 30-40% of yield potential for rice and wheat. In Malawi, good field yields of maize are usually below 10% of yield potential.

GM plants are not used, it is in many cases not clear where new basic resources are to be found to revive the flagging pace of improvement. For example, almost all the dwarfing of rice relies on a single gene; the huge genetic range of maize has not provided answers to the search for better tolerance of rainfall delays (paragraph 4.45); the non-GM search for a means to allow cereals to fix significantly more natural nitrogen has been disappointing; and so, to some extent, have F1 rice and wheat hybrids.

4.25 Hence, unless GM research is directed towards improving the yield potential of food staples, farmers' field yields in non-temperate areas will be sluggish. Since the major progress of the 1960s, it has become increasingly difficult and costly to raise field yields without a renewal of that rate of progress. Typically, the physical, price, service and policy environments make it profitable for farmers to attain only x% of yield potential – and x itself rises, if at all, only very slowly. However, if yield potential is increased, so is 'x% of it'.<sup>28</sup>

# The potential of GM crops to raise field yields

- 4.26 As a seed variety is adopted, learning takes place. Farmers gradually raise their field yields to the proportion of 'potential' that is most profitable (allowing for risk). Unless the plant, and hence the next new variety, shows increasing yield potentials, the growth of field yields must eventually slow down. GM crops may offer the best route both to higher yield potentials and resistance to stresses which have proved hardest to tackle by conventional plant breeding techniques alone. These recalcitrant problems include some biotic stresses such as viruses and fungi (in addition to birds, weeds and some insects, nematodes and bacteria); and abiotic stresses such as moisture and temperature stress (and in some conditions salt, iron and aluminium).
- 4.27 GM research should not, however, divert resources from conventional plant breeders where these efforts offer better promise of success. New conventionally bred varieties continue to seek improved crop robustness against pests and to increase yield potentials of food staples, for example through F1 rice and wheat hybrids, or biological nitrogen fixation. That these latter examples have proved disappointing is probably due in part to the greater concentration of GM crop research in developed countries. This indicates that the main risk at present is that without adequate GM inputs, conventional plant breeding will not greatly increase the growth of yield potentials in the main tropical food staples, so that field yields will be increasingly sluggish. This will seriously imperil employment, income and food access for the world's poorest people.

# GM crop research on tropical staples

4.28 Despite the urgent need and the lack of adequate alternatives, well below 10% of the 25,000 GM crop field trials in 1997 were in developing countries.<sup>29</sup> Of the 27.8 million hectares of GM crops commercially grown in 1998, approximately 16% were grown in developing countries.<sup>30</sup> This is not surprising: 'total agricultural biotechnology research expenditure in the entire developing world may not exceed US\$50 million annually' as compared to US\$190 million for government-financed research<sup>31</sup> and well over ten times that sum in US private-sector research alone.

This is not to say that better yield potential alone, in the absence of improved policies, outreach or transport, is *sufficient* to transform, say, semi-arid African field yields – only that it may well prove *necessary*.

<sup>29</sup> Kendall HW et al. **The Bioengineering of Crops**, p13.

James C (1998) **Global Review of Commercialised Transgenic Crops**, 1998, ISAAA Briefs No. 8, ISAAA, Ithaca, p4. Much recent growth is of herbicide-tolerant (and thus labour-displacing) soya on large Latin American farms for export as animal food to the US – a low priority for the poor.

<sup>31</sup> Kendall HW *et al.* **The Bioengineering of Crops**, p14, 16.

- 4.29 Despite the small amount of GM research resources devoted to developing-country agriculture, there is ample evidence that GM crops could significantly improve nutrition in developing countries. For example, researchers in Mexico have inserted a gene which enables crop plants to secrete citric acid from their roots. This increases their tolerance to aluminium toxicity, which affects a significant proportion of arable land, and which often reduces yields by over 30% and sometimes by as much as 80%. In GM rice, inserting genes from two wild rice relatives into the best performing Chinese rice hybrids has raised yields by 20–40%. Research funded by the Rockefeller Foundation has produced a GM rice variety resistant to the tungro virus; very promising GM vitamin A-enriched rice varieties, and a tissue which is giving up to 25% higher yields in China. The GM crop examples relevant to developing countries include potato varieties bred in Peru with stable multigene resistance to late blight, a wild wheat cross yielding 18 tonnes/ha and virus-resistant sweet potatoes in Kenya, conservatively estimated to raise yields by 15%. Sa, and a virus-resistant sweet potatoes in Kenya, conservatively estimated to raise yields by 15%.
- 4.30 As for the future, probable contributions to increased rice yields from biotechnology in Asia have been estimated at 10–25% over the next ten years.<sup>37</sup> Evenson<sup>38</sup> uses the best scientific and economic information to assess the probable impact of a ten-year halt in public-sector GM crop development on developing countries in 2020. Because cereal prices would rise by about 12%, mostly for want of the extra supply of GM rice, the numbers of undernourished children aged up to six years would increase by 1.2 million, more than half of them in sub-Saharan Africa. Of course, the impact would be larger if private GM research were also halted, and much larger (but positive) if it were more relevant to developing country staple production.

### The implications of GM crops for developing country trade

- 4.31 The implications of GM crops and food products for trade are seldom considered.<sup>39</sup> The main developing country exports are tea, coffee, cocoa, cotton and sugar, while Africa and China are big cereals importers.<sup>40</sup> If GM crops (or substitutes), grown in developed countries, raised the supply of a beverage crop by 20%, a price fall of about 60% would be needed to clear the market.<sup>41</sup> Such a development would threaten to devastate low-income exporters of beverage crops such as Ghana and Sri Lanka (see paragraphs 3.63–67). Conversely, failure to achieve rapid cereal output increases in Africa or Asia would, in view of the pending growth of demand and population, mean explosive rises in food import needs and some rise in the price at which such imports would be available. We consider that such trade effects, while seldom quantified, are potentially very damaging. They justify a major effort by international agricultural research centres to offset the emphasis of commercial GM crop research on the consumption, crops and conditions of developed countries.
- 4.32 As GM crop research is organised at present, the following worst case scenario is all too likely:
  - slow progress in those GM crops that enable poor countries to be self-sufficient in food;
- 32 Conway G, The Doubly Green Revolution.
- 33 Kleiner K (1998) Save our spuds, **New Scientist**, No. 2136:24.
- 34 C Holden (ed.) (1998) Wonder Wheat, **Science**, 280:527.
- 35 Kendall HW et al. The Bioengineering of Crops, p18.
- Wambugu F (1998) Benefits and risks of genetically modified crops: gathering important insights on research into the benefits and risks of genetically modified crops for man and his environment, CERES Forum on Food Products from Plant Biotechnology II, 8–9 June 1998, Berlin.
- 37 Kendall HW *et al.* **The Bioengineering of Crops**, p17.
- 38 Evenson R (1998), Personal communication, Yale University.
- Thus minor crop issues received the main emphasis: 'Bio-engineered sources of vanilla could compete against producers of vanilla beans in some developing countries'. Galvin T (1998) Agriculture trade implications, **Ceres**, p. 36.
- 40 Hardly any important, low-income cereal net exporters now remain.
- The large price fall happens because consumers expand demand only slightly in response to each price cut.

- advances directed at crop quality or management rather than at drought tolerance or yield enhancement;
- emphasis on innovations that save labour-costs (for example, herbicide tolerance), rather than those which create productive employment;
- major yield-enhancing progress in developed countries to produce, or substitute for, GM crops now imported in conventional (non-GM) form from poor countries.

# GM crops and the poor: getting the debate back on the rails

- 4.33 GM crops offer developing countries:
  - positive prospects: for sustainably resuming and spreading the benefits of the Green Revolution and hence for rapid rises in the welfare of the food-poor;
  - positive dangers: regulatory or political arrangements may lead to significantly lower foodsafety and environmental standards than in industrialised countries. In addition, breeders may try to incorporate plant genetic resources in patent applications which are indigenous to developing countries;
  - negative risks: GM crop technology may concentrate unduly on the crops and farm systems of industrialised countries, so that farm exports in developing countries may become uncompetitive, and there may be opportunity-costs of lost food production and employment. For example, research may be directed towards Roundup Ready yellow maize for poultry, rather than drought-tolerant white maize for people.
- 4.34 All three issues have implications for United Kingdom (UK) policy nationally, and also in the United Nations (UN), the European Commission (EC), the World Bank and the CGIAR. So far, proponents of GM crops have made too much of the first issue (claiming that they will lead to big gains for the world's poor, even with the present structure of GM research). Opponents have overplayed the second issue (emphasising possible dangers, mainly in developed countries). The ensuing debate has neglected the third and most serious issue: the risk that the gains from GM crops will pass the poor by.
- 4.35 To correct the imbalance in the GM crop debate, we should recall the debate about the Green Revolution. Its early advocates stressed the mass benefits of higher food production. Critics stressed the proneness of the new varieties to drought and pests, and the increased risks for poorer, risk-averse farmers. The main problem proved to be different. Where the Green Revolution spread, mainly in irrigated Asian and Latin American rice and wheat monocultures, the potential dangers were largely avoided (partly because the breeders listened to critics) and the poor benefited. The main drawback of the Green Revolution was the exclusion of huge areas, notably in Africa, from the potential benefits.
- 4.36 This was due to inadequate or misdirected research into the farming systems (and crops) of semi-arid, ill-drained and inter-cropped areas.

Africa, though relatively informed, is wanting, waiting and hoping that the biotechnology revolution will not pass them by, as the Green Revolution did, due to a lack of resources and unrealistic controversial arguments from the North based on imagined risks.  $^{42}$ 

- 4.37 This is something of an overstatement, as some of the risks are not 'imagined' and the developing countries largely lack a biosafety infrastructure. Nevertheless, Africans, facing continued expansion of population and workforce after forty years of static or worsening hunger, and slow technical progress in food production and hence employment, naturally stress 'risks' of GM plants less than well-fed Europeans do. The Director of the International Service for the Acquisition of Agri-biotech Applications (ISAAA) centre for technology transfer in Nairobi, herself a former researcher on GM crops, has provided a welcome corrective to the self-righteous.
- 4.38 In planning science policy for a second Green Revolution through GM crops, we believe that the main issue is not the danger to the developed world, which faces real but well-regulated environmental (and very small, if any, food safety) risks. It is the developing countries, with their far greater needs, prospects and risks, cash-starved science, and sometimes weak or corrupt regulation, which face greater dangers. These dangers may conceivably come from carelessly introduced GM plants or foods, but are more likely to be due to neglect. Since the mid-1980s, funds for developing-country agricultural research have stagnated, while those for private GM crop research in developed countries have rapidly expanded.
- 4.39 In the longer term, GM crops will probably transform farming in developed countries. However, unless something is done, this will be achieved largely to suit the needs of the food industry in supplying the market demands of adequately-fed people in developed countries, while passing the poor by. What can be done to encourage a more equitable outcome? In contrast to the situation with plant breeding for the Green Revolution in the 1960s, public-sector systems will not be able to carry out most of the work on their own. A very small and dwindling proportion of research money and GM expertise is in public-sector systems, both international (CGIAR) and national (Brazil, China, India, Mexico and South Africa), which are relevant for developing countries. Sole reliance on these public-sector systems will not be sufficient.
- 4.40 The costs of identifying and isolating a desired gene from an organism and transferring it to a target crop plant, in addition to field-testing and obtaining regulatory approval, will be extremely difficult to meet without the involvement of the private sector. However, the 'non-market' concerns of the poor and the hungry are likely to continue to be undervalued, unless the international public sector and the leading research institutions and scientists in developing countries retain some influence over GM research choices. One solution, although costly, might be for them (via the CGIAR) to set a research agenda and then to reward or finance private companies or researchers either for attaining specific monitored outcomes, or for research directed towards plants and activities that will mainly benefit the poor in developing countries.
- 4.41 Just as the CGIAR institutions attracted the scientific capacity that enabled the spread of the first Green Revolution, so the second, especially if it is to benefit those by-passed by the first, will require new incentives and new, or adapted, institutions for agricultural research. We conclude that developing countries and multilateral agencies need to devote much larger shares of effort to agricultural research that not only develops new GM crops, but derives criteria for such development from the stated requirements of small farmers in staples-based systems. These should take into account farmers from rainfed and intercropped areas, and the needs of poor countries for employment-intensive production and processing of cheap food staples.
- 4.42 The Working Party recommends that the UK Government and EC, preferably working through the CGIAR,<sup>43</sup> invite those developing countries willing and able to commit genuinely additional resources, to enter a joint initiative. In view of the proven high

There are two administrative bodies: the Technical Advisory Committee (TAC, located in Rome at the FAO) and the CGIAR (located at the World Bank in Washington DC), concerned with obtaining donor commitments, setting priorities on the basis of TAC recommendations, and obtaining consensual allocation of funding among CGIAR institutions.

returns to and impact on poverty of appropriate agricultural research, and the new salience of fundamental and applied GM research,<sup>44</sup> there should be a funded and major expansion of research:

- (i) into higher, more stable and sustainable production of tropical and sub-tropical food staples;
- (ii) seeking gains for poor farmworkers, food consumers and smallholders;
- (iii) by mainly CGIAR institutes and developing-country national agricultural research systems (NARS), working with private sector researchers in the developing and developed world where desirable;

devising alongside locally appropriate:

- (i) research planning;
- (ii) regulatory/implementation mechanisms for environmental review of GM crop experiments (paragraph 4.62);
- (iii) food-safety clearance of GM releases to farmers.

The Working Party further recommends that the Department For International Development (DFID) and the Ministry of Agriculture, Fisheries and Food (MAFF) should jointly help UK researchers to contribute to developing this initiative. We endorse the recommendation by the House of Commons Environmental Audit Committee that a Minister from DFID be appointed to the Cabinet Ministerial Group on Biotechnology and Genetic Modification. 45

# Prospects for environmentally-friendly GM crop growth in poorer countries and the UK role

- 4.43 With appropriate emphasis and incentives in GM crop research, and with luck, GM crops could raise calorie or economic yields per hectare and per worker-hour by improving efficiency through:
  - (i) conversion of inputs of nutrients, water or sunlight into dry harvest;
  - (ii) partition of harvest between edible (or otherwise useful) and other dry matter;
  - (iii) extraction of soil nutrients and water (if sustainable).

The conventional Green Revolution approach to the first two points, through shorter-strawed, more fertiliser-responsive wheat and rice, has been less successful for other crops, intercropped systems, uplands, and marginal or uncertain rainfall areas. GM crops are believed to have the potential for particularly significant impact here $^{46}$  and to:

- improve bio-absorbable and acceptable micronutrients per calorie of food crops;
- stabilise yields in the face of pests and water stress, by improved resistance, tolerance, or crop timing for avoidance of pests and water stress. (This often also enhances conversion efficiency.)

In the NARSs, most research would be screening or adaptive. A few, however, have capacity at breeding and fundamental levels, for example India, China, Brazil, Mexico and Kenya.

<sup>45</sup> House of Commons Environmental Audit Committee (1999) GMOs and the Environment: Coordination of Government Policy, Fifth Report, The Stationery Office, London.

<sup>46</sup> Conway G, The Doubly Green Revolution.

- 4.44 Conventional plant breeding has usually been relatively successful when breeding for yield and for single-gene pest resistance. The latter, like pesticides, induces emergence of adapted and virulent pest strains (see paragraph 2.5). Pest tolerance (which allows plants to live with and survive pest attack), and multigene resistance, are more stable and better at reducing risks for remote, poor and small farmers and communities. Multigene resistance is harder to achieve, partly because it is associated with many genes, as is a plant's capacity to use water more efficiently and to avoid moisture stress. GM crop research, however, allows specific groups of genes to be integrated into the host plant genome, unlike conventional plant breeding.<sup>47</sup>
- 4.45 GM research into smallholder food staples will not be adequately addressed with the current balance of research incentives and institutions. For example, if white maize, Africa's main food crop, could be engineered to have prolonged latency, 48 this could make a major contribution to the fight against hunger. This unattained goal of conventional breeding is a key challenge to GM maize researchers. But the extent of gains for the poor will depend on the emphasis given to GM crop research that gives priority to employment-intensive methods and crops, especially cheap staples, not just to 'more output' or even 'more food'.
- 4.46 In planning for research strategies to realise the potential of GM crops for the world's poor, in the context of UK policy we must consider two objections. First, research into crops or farming systems, however targeted towards poor people's needs, is useless if prospects of success are also poor. To some extent, however, this is often a self-confirming argument. Yams are little researched because they are thought to be unpromising and therefore remain so. When the Rockefeller Foundation initiated GM rice research it was thought a recalcitrant crop; today it is a 'model' for other cereals.
- 4.47 Secondly, researchers need freedom to follow their intuition about which gene transfers are worth exploring and which farming systems can benefit. The best innovative research is seldom locked wholly into a policy-driven agenda. However, the direction of those intuitions may be affected not only by objective perceptions of what lines of work are the most promising but by peer-group incentives, promotion prospects, publication priorities of journals, and other aspects of the social setting. Policy makers seeking to transform GM crop research into an effective weapon against poverty must consult not only with researchers, but also with the poor. Often poor farmers' and workers' own perceptions of their needs and prospects need to be incorporated early on, if they are to gain the most benefit from the required substantial changes in the incentives and institutions that help fix scientific agendas.
- 4.48 The Working Party welcomes the aim of the March 1998 White Paper on overseas aid to underpin the agreed Organisation for Economic Co-operation and Development (OECD) effort, following the UN Copenhagen Summit on social policy and development, to construct 'aid partnerships' with developing countries to halve world poverty<sup>49</sup> by 2015. To help to achieve this we recommend that alongside consultations with the developing countries concerned about their own agricultural research priorities, the UK Government should pre-commit a substantial amount of the rise in UK aid announced in July 1998 to additional spending on the R&D of GM food staples grown in developing countries. A part of this sum should be for consultative work with those countries on the design of appropriate regulatory regimes (see paragraph 4.62). We further recommend that this contribution should be used to leverage

For example, GM potatoes in Peru have been planted with stable multigene (horizontal) resistance to late blight: (Kleiner K, Save our spuds). However, it is important to avoid the danger that early GM research, undertaken before the functions of all the genes in a plant are fully understood, may further shift the emphasis towards single-gene resistance. This underlines the importance of maintaining public-sector capacity and influence alongside commercial GM research. See Conway G, **The Doubly Green Revolution**.

The capacity to defer flowering if late rains mean that soil moisture is scarce.

Incidence of absolute poverty is defined as consumption per person worth less than US\$1 per day at internationally standardised prices of 1985.

**extra funds from other donors (including the EU) for developing-country NARS and for the CGIAR institutes.** The funds should be focused on those developing countries eager to support the initiative with extra domestic financing for public-sector agricultural research.<sup>50</sup>

# Regulation of GM crops in developing countries

- 4.49 The proposal above needs to be balanced with measures to help developing countries create an infrastructure to evaluate and regulate GM crop variety trials, initial distribution to farmers, and releases into the food chain. Structures for assessing environmental impact, food safety and socio-economic effects will be needed. This is partly because GM crops may carry additional risks. Most scientists agree that these dangers are not significantly different from those associated with conventional plant breeding, or indeed with natural outcrossing. However, 'Green' groups in some developing countries, like part of the UK public, are sceptical. Whether due to error, self-deception or incentives, regulators, and even the scientists who advise them, have sometimes been mistaken about health risks or risks to the environment.
- 4.50 Although approved GM crops are considered as safe by designated government advisory committees, if one or two high-profile accidents were plausibly linked to GM crops there would be a public outcry. Such accidents, which could discredit potentially valuable food innovations, are far more likely to occur in developing countries. In developed countries, public information is more readily available, there is more oversight and regulation and GM crop field trials and commercial releases are surrounded by well-developed infrastructures for assessing environmental and human biosafety.
- 4.51 GM plants raise issues of public concern, as discussed in Chapter 5. These are addressed in developed countries by infrastructures for regulation and overview. Developing countries also need to assess and to act on, actual or potential GM crop-linked environmental risks, especially from the unwanted spread to weeds of herbicide tolerance; from Bt-gene poisoning of untargeted insects; and from undesired food-chain or pathogen damage to life-forms.<sup>51</sup>
- 4.52 Without an effective and open-access regulatory infrastructure, there is a subtler danger. Commercial pressures may induce (or transfer from the North) GM crop introductions, decisions and outcomes that are manageable in developed countries, but that in most developing countries require:
  - different regulatory measures, usually incentives rather than compulsion, because there are too many small seed distributors and far too many small farmers to supervise;
  - special care (and methods) for communication to the public, given inadequacies of the 'open' civil society, and/or of public scientific literacy, education and media.
- 4.53 These problems are familiar in the UK, but need different solutions in many developing countries. Other issues, special to developing countries, include the need to:
  - avoid 'biopiracy' (the unauthorised and/or uncompensated gathering, for commercial advantage, of developing-country and international biological resources) and yet retain incentives for properly compensated and beneficial exploitation;
  - develop farmers' broad and equitable access to apomixis technology when this becomes available (see paragraphs 2.42, 3.39 and 4.72);

The African scenario of 1980–95, in which increasing aid funds for NARS were offset by declining national funding, must not be repeated.

Risks to human health from GM crops are probably much smaller than these potential environmental hazards. Such hazards might arise from insecticides and herbicides themselves – with or without GM crops. Indeed, GM crops embody more knowledge about what genes do, and so should be better at avoiding unwanted targets.

- consider and implement appropriate responses, both directly and via 'the international system', to the increasing concentration of GM crop research in a group of multinational companies (see paragraph 3.19).
- 4.54 The regulatory experiences, both good and bad, and global contacts throughout the European Union (EU), mean that the UK is well placed to assist developing countries. What environmental or biosafety concerns may require special regulatory or other solutions there? These need a strong scientific basis, public representation, monitored enforcement and open access. The appropriate means to achieve these ends will differ in, and between, developing countries.
- 4.55 The concern that plant pathogens will be induced to develop new and virulent strains has been focused largely on virus-resistant GM varieties (paragraph 6.31).<sup>52</sup> Rather than seeking to prevent the testing and release of such crops, it might well be more feasible to steer research towards forms of resistance that pose less risk. An example is countering the main virus of cassava (tobacco mosaic virus) through safe forms of coat protein-mediated resistance.<sup>53</sup> Strategies to avoid the emergence of new types of pathogens by selective cycling and deployment of particular types of crop have been developed with success in maize in the United States (US) against the build-up of virulent races of *H. maydis*. However, this approach is less feasible in most developing countries, where there are large numbers of very small farms, often with poor communications and controls.
- 4.56 Another risk is that herbicide-tolerant crops will hybridise with weed relatives. This has already happened in experimental plots between oilseed rape and the related wild radish (see paragraphs 6.22–26). The problem is also relevant for out-crossing food staples such as maize and sorghum, crops of major food interest to the poor. Even inbreeders such as rice outbreed occasionally, so that the problem could be important, especially for rice, where, as in some African uplands, it grows adjacent to wild rice and weed species in conditions where good weed control is costly and trying. The danger is not to the majority of poor smallholders who use no herbicides for them, herbicide-tolerant weed varieties do not matter but for the few smallholders, and the larger food producers, who do.<sup>54</sup> On family farms in many developing countries, weeds, especially wild rices and barnyard grasses, are probably the most serious single cause of crop loss, especially for upland farmers, and increase the need for deep ploughing which in turn leads to soil erosion.
- 4.57 Of the various traits under consideration in GM crops, it should be noted that herbicide tolerance may be associated with special socio-economic effects when utilised in varieties for use in developing country agricultures. For example, the use of herbicides replaces hand weeding. Notwithstanding the fact that some of the most striking applications of herbicide tolerance are in developing countries (such as the introduction of direct seeded rice in the Philippines), the same use of herbicide-tolerance varieties may work against poverty reduction programmes which require raising, not lowering, demand for labour. We recommend that the CGIAR should carefully assess both socio-economic and agricultural needs before introducing crop varieties with novel traits into developing country agricultures and should co-ordinate careful assessment of the potential risks of hybridisation of GM crop plants with weed relatives. The Working Party notes that the centres of diversity of the wild populations of some main modern agricultural crops lie in developing countries, for example wild potatoes in the Andes, wild wheats in the Middle East and wild rices in South East Asia. Although there is no indication of widespread transfer of genes from conventional cultivated varieties to close wild relatives, it may nevertheless be prudent to co-ordinate careful assessment of any potential risks of transfer in these regions.

Coghlan, A (1998) The devil we don't know, **New Scientist**, No. 2151:21.

Beachy R (1998) **Strategies that minimize real and perceived risks of pathogen derived resistance in transgenic plants**, CERES Forum on Food Products from Plant Biotechnology II, 8–9 June 1998, Berlin. Cassava is a main food staple produced and consumed by Africa's poor. Tobacco mosaic virus also affects other plants of interest to developing countries.

Recent work provides a route to reduce, but not eliminate, this risk: Gray A and Raybould A (1998) Reducing transgene escape routes, **Nature**, 392:653–4.

- 4.58 Other conceivable consequences of GM crops are even harder for developing countries to control in practice. One wonders how India, let alone Angola, could deal with the remote prospect that weed control through herbicide-tolerant varieties becomes so efficient that beneficent insects and birds, dependent on the weed seeds, are seriously harmed.
- 4.59 Several concerns have been voiced about the gene that expresses the Bt toxin (see paragraph 2.33). First, pest resistance may develop, limiting the use of directly applied Bt pesticides as well as the GM crop. Some leading US experts believe that 'Bt resistance management plans should be enforceable by the Environmental Protection Agency (EPA) and that Bt-engineered crops should be grown with "large" refuges of 25–50% of affected acreage. Secondly, untargeted organisms are threatened (paragraph 6.29).
- 4.60 The UK Advisory Committee on Novel Foods and Processes (ACNFP)<sup>56</sup> argues that the complaints cited in Greenpeace's report entitled *Genetic Engineering: Too Good to go Wrong*? 'indirectly highlight the strength of the existing European regulatory framework in being able to ensure that activities involving [GM crops] do not cause harm to human health or the environment in Europe'. Similar remarks probably apply to the US. However, it is unlikely that any developing country can afford to implement the sort of regulation of trials that is taken for granted in Britain. If field trials indicate some small risk and a GM crop is released on certain conditions, it is most unlikely that these could be enforced by developing counties for millions of smallholders, tiny retailers or semi-subsistence food consumers. Nor, in most cases, is there a 'civil society' of media and non-governmental organisations sufficiently active to induce effective regulation. India is ahead of most developing countries in such respects, yet every year many die by poisoning from unregulated liquor; until the mid-1970s many new cases of lathyrism arose from the 'prohibited' semi-staple lentil *Lathyrus sativus*;<sup>57</sup> and laws for the iodisation of salt remain unenforced.
- 4.61 The probable costs of the (mostly remote) environmental risks from GM crops to developing countries, even with no controls, do not approach the probable gains of GM crops concentrated on the local and labour-intensive production of food staples. Are lower safety standards justified because, by producing more and better food and more jobs for the undernourished, or by reducing agrochemical use, GM crops save many more lives than they cost and improve more lives than they worsen?
- 4.62 There are two objections to this argument. Ethically,innocent victims of GM crop side-effects will not often, in practice, be compensated out of the gains of others. Politically, frightened farmers and consumers will react to adverse side-effects by rejecting GM crops altogether, deferring any gains for many years. Consequently, it is important to ask how risks to environmental and human health can be minimised, given the limited regulatory capacity of many developing countries. The costs and risks can almost certainly be much reduced, and the risk of a backlash thus avoided, by ensuring appropriate public awareness, and by insisting on transparent arrangements for overview and enforcement. However, this will have to depend far more on incentives, and probably on co-operation with commercially employed scientists and companies, and less on commandand-control, than is feasible or necessary in the developed world. Nevertheless, we conclude that transfer of experience and know-how from advisory and regulatory bodies in developed countries to the developing world, with suitable adaptation to its socio-political as well as physical environments, is urgently needed. The Working Party recommends that part of new UK aid funds recommended to be earmarked for GM in and for developing countries

<sup>55</sup> Fox J (1998) UCS says EPA Bts around the bush, **Nature Biotechnology**, 16:324.

See ACNFP Consideration of Greenpeace Report on Genetic Modification, May 1998, http://www.maff.gov.uk/food/novel/gpeace.htm

This crop is grown mainly in Bihar. It has long been known to induce lathyrism, but is a robust calorie source on very poor soils. It declined as wheat became high-yielding and cheaper (and as poverty fell somewhat) – not because of laws; any cheap staple, even if 'risky', is almost uncontrollable among the poor (indeed *Lathyrus sativus* has recently been *introduced* into Northern Ethiopia). The development of GM varieties which have lost the toxic effect, rather than prohibition, is a possible way ahead for developing countries.

(see paragraph 4.48) should be used to help such countries in devising appropriate incentive and regulatory regimes against possible environmental and biosafety hazards. While consultation with regulatory bodies in the US, EU and elsewhere is essential, developing countries have different (and varied) farming systems, food chains and environments, and so need different biosafety and environmental procedures. We therefore recommend that this part of the new GM funding be guided by leading researchers via appropriate international bodies with strong developing-country representation such as the FAO, the International Food Policy Research Institute, and/or the Institute for the Support of National Agricultural Research.

# Developing countries' regulatory requirements: international aspects

### (A) The Biosafety Protocol

- 4.63 Developing countries need appropriate GM crops to enhance their crop yields and food security. At the same time they need the ability to regulate the management of GM plants in their countries to protect their environments and their food safety just as developed countries do.
- 4.64 In many ways their dilemmas are more acute on this matter than those of the developed world. Their need for increased yields from crops that may be grown in inhospitable or deteriorating environments is more pressing. But at the same time some of the developing countries have particularly rich natural biodiversity which needs to be conserved. As and when GM crops suitable for their conditions are developed they are likely to be subject to very strong commercial and international pressures to grow these. But so far they have less well-developed regulatory structures and expertise to manage these introductions appropriately.
- 4.65 The Biosafety Protocol being considered by the parties to the Convention on Biological Diversity (CBD) is intended to provide a first line of defence in this area, principally for the benefit of developing countries. It enshrines the basic principles of requiring information to be given about imports of GM material, and informed agreement obtained in advance. So far, however, the negotiation of the Protocol has been blocked by the US acting with a few other countries which have already started extensive commercial planting of GM crops in their countries. The Working Party considers the Protocol to be an essential safeguard to enable the desirable development of appropriate GM crops for developing countries to take place safely, and recommends the UK Government and its European partners redouble efforts to reopen the stalled negotiations on this subject and to bring them to a successful conclusion.

# (B) Controlling 'biopiracy' or stopping seed development?

4.66 The international infrastructure for seed movement has gaps and distortions that carry some risks<sup>58</sup> of harming developing countries by discouraging commercially fair bioprospecting, and by facilitating so-called 'biopiracy' instead. There are two distinct issues: legal field crop transfer and the unauthorised and uncompensated removal from developing to developed countries for experimental

Potatoes genetically modified with the Bt gene, legally introduced by Monsanto to Georgia, 'may have crossed into Russia and Azerbaijan' where priorities and risks may differ, and where tests have not been done, see Anon (1998) Environmentalists fear uncontrolled movements of GMOs, **Nature Biotechnology**, 16: 892. Gains from reduced risk of hunger may well outweigh the risk of collateral damage from the Bt gene. However, states, consumers and farmers want to be involved, and must feel in such cases that decisions are taken over their heads.

use with a view to commercial development. Neither approach necessarily involves GM crops. In addition, neither approach is necessarily confined to private companies. In a recent controversy, Australia's public-sector scientists claimed plant breeders' rights on CGIAR genetic resources, including chickpeas grown in India and Iran.<sup>59</sup> However, the increasing privatisation of GM crop research, in the context of the TRIPS agreement,<sup>60</sup> has increased the incidence, complexity and urgency of ownership issues.

- 4.67 It is widely agreed that obtaining crops from small farmers in developing countries, patenting genes of agronomic interest and attempting to restrict the use of such crops, is unethical. All inventors depend on predecessors; the special claim of small farmers is that they have almost always invested their own intellectual capital in selecting, developing and often informally researching their land-races or varieties. Fortunately, the principle of compensation has been explicitly recognised by Monsanto and some other companies. These companies have responded to requests from non-governmental organisations and others for the sharing of profits from such ventures, with funds to assist the farmers from whom the germplasm came. This seems to be the right approach but will be hard to enforce. Indian legislation restricting the export of biological samples<sup>61</sup> should make it less so but risks reducing the opportunities for international collaboration. However, any attempt to restrict subsequent use seems impossible to implement.
- 4.68 Patenting by individuals or agencies of varieties from an International Agricultural Research Centre (IARC) or NARS, especially F1 hybrids or other plants that do not reproduce true from retained seeds, raises a special problem. For a NARS, seed release and control is an important tool, not only for R&D, but also as an incentive and to ensure political salience. For the CGIAR system, open access has been a central principle exemplified by permitting the free exchange of plant material. Yet the NARS loses access (and conceivably even legal power to distribute) when there is a patent involving its resources. At least one IARC has felt obliged to include its own materials in patent applications, one reason being to protect the material from being patented by others. Even so, such patenting may threaten open access to the IARC material. ICARDA (International Centre for Agricultural Research in the Dry Areas) has admitted to signing agreements with Australian research institutes allowing them to claim rights over seeds developed by ICARDA 'as long as they gain approval from the countries of origin'. This has aroused wide opposition from developing countries and scientific organisations.<sup>62</sup>
- 4.69 Patents may be the best way for IARCs and NARSs to assert their intellectual property rights. A strong argument is that an IARC or NARS should raise as much funding as it can from a private organisation (or industrialised country public agency) that uses its seeds. Indeed, the CGIAR has just reversed its long-standing position on open access by allowing member institutes to file patents applications. Their capacity to continue to supply seeds to farmers in developing countries, as the seeds increasingly come to contain GM progeny, will partly depend on whether seed companies are much concerned about competing seeds in developing countries.
- 4.70 If, as seems the case, they are generally not, biopiracy may be transformed into bioprospecting through appropriate institutions. Existing national policies on medicinal plants are inadequate and do not promote local development of processes and technologies. This inadequacy also extends to food and fibre plants. The Indian Agricultural Research Institute has confirmed that Australian researchers seeking to work with seeds of its toxin-free variety of the pulse *Lathyrus sativus* (kesari

Anon (1998) Lest we starve, **New Scientist**, No. 2121:3; Anon (1988) Breeders' rights row leads to UN action, **GenEthics News** 22:9

The agreement for Trade Related Aspects of Intellectual Property Rights (TRIPS), which developing countries are under great pressure to ratify, has been modified by the World Trade Organisation (WTO) to exclude payment of fees for traditionally developed technical knowledge (including genetic materials) collected or otherwise obtained from indigenous communities.

Anon (1997) China and India move to control gene export, **GenEthics News**, 20:5.

<sup>62</sup> Edwards R and Anderson I (1998) Seeds of wrath, **New Scientist**, No. 2121:14–15.

dal) must negotiate a deal.<sup>63</sup> However, Indian legislation, revoking open access to its gene banks, could be used to undermine this intelligent approach by 'nationalist' prevention of seed transfer, even if fairly recompensed. More probably, the law will be used to reinforce the 'deal' approach, which will encourage plant development by sharing its rewards in a more accurate proportion to intellectual inputs, corresponding precisely to the Monsanto-NGO (non-governmental organisation) approach to community-developed crops. Recent Chinese legislation is similarly double-edged: it could be used to ensure that bioprospectors pay for the materials and research (formal or indigenous) that they use, or to prevent access to and use of such research.

# Intellectual property rights and the TRIPS agreement

- 4.71 The legal framework for regulating the ownership, access and exploitation of genetic resources has been substantially changed since the recent adoption of two international legal instruments: the 1992 CBD and the 1994 TRIPS agreement of the WTO.<sup>64,65</sup> The CBD is focused mainly on providing rules related to tangible property rights of access to, and exploitation of, genetic resources as phenotypes. The TRIPS agreement is concerned with mandatory standards for intellectual property rights, including those which cover genetic information.<sup>66</sup> These standards constitute the international law to be observed under the CBD (Article 16) whenever access to, and transfer of, patented or other intellectual property rights-protected technology is under consideration.<sup>67</sup>
- 4.72 The TRIPS agreement sets the minimum standards for certain existing rights. It has 'no requirement on applicants to involve or consult with local communities or governments about patenting a compound based on a natural product from that country [or] sharing the benefits or including the prior contributions of indigenous peoples'. 68 The CBD, on the other hand, requires host government consent and 'approval and involvement' of traditional communities. There have been attempts to amend patent law so that the CBD objectives would be better supported by taking into account the access legislation. For example, it has been suggested that provisions are included which require the patent applicant to disclose the country of origin of plant materials, any traditional knowledge in the application and whether explicit consent for use of the materials was obtained.<sup>69</sup> The European Parliament also tried to amend the EC proposal for a directive on the legal protection of biotechnological inventions<sup>70</sup> in 1997 in a similar way.
- 4.73 The proposed amendments were rejected, although EU Members States are required to give particular weight to the intentions of the CBD when enacting the necessary laws and regulations to comply with the Directive. 71 To 'help a common appreciation of the relationship between intellectual property rights and the relevant provisions of the TRIPS agreement and the CBD' it encourages the patent applicant to include information on geographical origin. 72 If patent laws need to be amended to better support the achievement of the CBD objectives for the benefit of all parties involved, it must be done within the framework of the WTO and the TRIPS agreement. The UK, occupying an intermediate position on GM crops between the liberal regulatory position of the US Government

Jayaraman K (1998) India seeks tighter controls on germplasm, Nature, 392:536.

As Annex IC to the Marrakesh Agreement establishing the World Trade Organisation. Strauss, J (1998) Biodiversity and intellectual property, AIPPI Yearbook 1998/1X, p99. 65

<sup>66</sup> Ibid. p. 102.

Ibid. p. 108 67

Masood E (1998) Social equity versus private property: striking the right balance, Nature, 392:537.

Watal, cited in Strauss J, Biodiversity and intellectual property, p.99.

Official Journal of the European Commission (1988) 98/44/E Directive on the Legal Protection of Biotechnological 70 Inventions of July 6, 1998, 213/13, July 30 1988.

Strauss J, Biodiversity and intellectual property, p.99. 71

Recital 27 of the Directive states 'if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material,

and the hostile view of some European governments and NGOs, is well placed to broker progress on this matter via the WTO and the CGIAR. The Working Party recommends that the UK, in consultation with like-minded developing countries and other member states of the EU, propose that the WTO explore and report on the extent to which the international and national legal framework currently frustrates the objectives of the CBD on providing fair and equitable access to genetic resources and how this conflict might be addressed. There is an overriding need to respect the property rights of developing country researchers, public agencies and indigenous communities regarding plant materials developed by them.

### **Apomixis or termination?**

- 4.74 The role of appropriate national and international infrastructures in supporting the world's poor is well illustrated by the controversy over apomixis genes. It may soon be possible to develop plant varieties that can produce seeds without sexual fertilisation, by apomixis, resulting in offspring that are genetically identical to the mother plant (paragraphs 2.39, 3.39). This would revolutionise plant breeding by allowing any desired variety, including hybrids, to breed true, thus permitting plant breeders to more readily develop locally adapted and genetically diverse varieties. Moreover, resource-poor farmers would be able to replant the seed every year. Such a strategy is not possible with today's commercial hybrid varieties (paragraph 2.4). However, the current trend towards the consolidation of plant GM technology ownership into a relatively small number of companies may severely restrict access to affordable apomixis technology (at least for the duration of the patent rights). Moreover, agricultural products of the developing world cannot be sold in global markets if they infringe technologies patented in the developed world, denying resource-poor farmers access to the global marketplace.<sup>73</sup> (paragraph 3.54.)
- 4.75 Almost the opposite problem could be created by GURT (gene use restriction technology) ('Terminator') patented in the US by the Delta and Pine Land Company and the United States Department of Agriculture (USDA) (paragraphs 2.26–27, 3.38). This not only has the potential to compel annual seed purchase by users of varieties with GURT, but also to prevent the farm-to-farm spread of new varieties. The USDA's<sup>74</sup> Melvin Oliver sees this as 'a way of self-policing the unauthorised use of American technology'. To others, GURT technology sounds like an assault on farmers' rights. 76 Indeed, the CGIAR, meeting in Washington DC in November 1998, agreed to ban the use of the technology because of its consequences for poor farmers, for genetic diversity, and for other plants denied cross-pollination.<sup>77</sup> This is despite the fact that the technology has not yet been demonstrated in practice and no decision has yet been taken on its development.<sup>78</sup> Yet GURT technology is only the latest in a long line of more or less efficient ways of compelling farmers to buy seeds from the companies that have developed them, which is thought perfectly reasonable for most researched products. The monopoly control, or non-release to poor farmers, of plants with apomixis could be similarly defended. It is right that seed developers should be able to obtain normal, market profit on their full investment, including R&D, and also some reward for risk-taking and for special scientific skill or business judgement. However, this right cannot apply without restraint to monopolies operating in non-contestable markets.

<sup>73</sup> See **Bellagio Apomixis Declaration** at http://billie.harvard.edu/apomixis and paragraph 3.39.

Anon (1998) Company aims to block seed saving, **GenEthics News**, 22:1–2.

<sup>75</sup> Edwards R (1998) End of the germ line, **New Scientist**, No. 2127:22.

Respondents to the Working Party's Consultation, such as the **Farm and Food Society** and others, considered that the use of GURT would be unethical because it would threaten the food security and independence of farmers in the developing world.

Anon (1998) Labs to terminate use of 'Terminator' gene, **Nature**, 396:11.

Waters S and Merritt C (1999) Personal communication, Monsanto (Europe SA) and Monsanto plc.

4.76 Despite the fact that most individual seed companies sell only a small proportion (below 3%) of all seeds in farm use, there is considerable and increasing market power over the supply of seeds for some crops, and for the best varieties for an increasing range of crops and conditions. Monsanto has recently acquired a significant stake in seed markets through acquiring Cargill, DeKalb Genetics, Plant Breeding International, and possibly Delta and Pine Land Co. (paragraphs 3.19, 3.38). Monsanto has so far used this power reasonably in many ways, appears to be more open than some large companies<sup>79</sup> and contains scientists of high ethical as well scientific quality. But this in no way guarantees future policies. Even if it did, there is a danger, especially if uncorrected by an adequately financed, open-access public research infrastructure and supervisory systems such as in the NARS and in the CGIAR, of exposing the feeding and farming of the world's poorest people to the R&D (and pricing) consequences of the business decisions of a few market-dominant multinational companies.

# The need for public sector research

- 4.77 At present the agricultural research balances between private and public, research and regulation, and developed and developing world could well tie in more and more desirable plant types with patents on GM technology or other controls, perhaps including GURT technology and to fail to develop or even to actively prevent development of apomixis genes. This could be inefficient as well as inequitable. The UK should use its position in the World Bank, EU, CGIAR, WTO and other bodies to reverse this trend through improving the infrastructures and remedying the underfunding and biases of public-sector research in developing countries.
- 4.78 There seems little doubt that the multinational companies will operate increasingly in developing countries, particularly in Asia and South America. There is every probability that these companies will wish to deploy the same sorts of intellectual property in developing country agriculture which have been successful in the North. While it is likely that farmers may benefit from these new technologies, it is most important that they retain the choice to grow either new improved, and probably more expensive, seed from the companies or grow the new improved seed from national breeding programmes or the CGIAR centres. We consider that it is vital, therefore, that these centres maintain proficiency in the latest technologies and continue to deploy the best technology available in the public sector. We strongly recommend that the UK continue to support the CGIAR system to this end. At the same time we recommend that the CGIAR seeks to protect proactively its own technology through patenting and use it to access other protected technology on behalf of their clients, the developing world.

# Hidden risks of neglecting poor people's GM crops

4.79 The most serious of the 'positive dangers' for the developing world may arise from not developing the capacity to screen, breed and safety-test GM crops, and to manage their release and use. If no such capacities are developed, the best scientists in the developing countries, who are badly needed not only in genetic modification but also for the improvement of existing national conventional plant breeding, will continue to drain to commercial organisations in industrialised countries. The danger then is that yield increases and employment income from food staples will remain sluggish. Many

Fig. 2138.3

Even if much of this is primarily a public relations exercise, it still requires some real openness. For example, the website http://www.monsanto.co.uk has access to a searchable database containing a wide range of reports, articles and data, including those provided by opponents such as Greenpeace. See also Anon (1998) You, the jury, **New Scientist**, No. 2138.3

- respondents to the Consultation expressed concern that the narrowing of the commercial base could have the consequence of restricting availability of diverse crop varieties, particularly non-GM varieties.
- 4.80 Furthermore, attractive GM crops will spread and may cross, without effective controls, into ecologies quite different from those for which they were bred. Large-scale GM crop trials in China, a country with non-transparent regulatory procedures, are a cause for concern. The opposite situation may occur in other developing countries. By legislating restrictively but unenforceably, they may push GM crops into illegal channels where scientific and safety standards cannot operate.
- 4.81 If developing countries stimulate appropriate, regulated, open GM crop research and selective release, they can steer it towards activities that are safer, more employment-intensive and better directed towards availability, quality and stability of food for the poor. But such hopes would be thwarted, not just by a 'genetic Bhopal' (which is a negligible risk, not obviously much increased by GM crops), but even by a much smaller but well-publicised accident. That is much more likely without an appropriate regulatory regime. Hence the regulatory and research aspects of the recommendations set out in paragraphs 4.42,4.48, and 4.62 above are aspects of a single package.

### **Conclusions**

4.82 So far, GM crops have had little effect, good or bad, on food-poor consumers in developing countries, or the farmers and farmworkers who mainly supply them. Millet, sorghum and yams, the main staples of Africa's food-poor, are largely untouched by GM technology although work on cassava has begun. Wheat is relatively unaffected and the impact on rice is only just beginning. Maize, the food-poor's main staple in Latin America and parts of Africa, is already being grown as genetically modified, but largely as feed crops grown by large commercial farmers in developed countries. So far, 'the market' has not directed major private-sector scientific resources towards breakthroughs in conventional Green Revolution type plant breeding, or into GM crops of main food staples (or tropical export crops)<sup>80</sup> for employment-intensive production in poor countries. Serious prospects for such shifts will require new market incentives, combining the work of private-sector scientists with that of national and international public-sector research institutions. To forgo such efforts would not protect the poor from the unregulated risks of genetic modification and other agricultural innovations, but would sacrifice the prospects of major GM crop-based advances in food and agricultural output and employment for the food-poor.

<sup>80</sup> Cotton may prove an exception, but the gains seem likely to accrue mainly to developed-country producers, at the cost of developing-country competitiveness.

# Chapter 5

Consumer choice and food quality

- 5.1 The part played by food in human life is much larger than its role as fuel for physical activity. Food features prominently in religious rituals and in the small rituals of everyday life; we welcome friends with food; and our credentials as good parents rest partly on what we feed our children and under what circumstances. Although the overriding interests of consumers in the developed world are, first, safety and, second, informed choice, we are very conscious that the cultural meanings of food are more elaborate. Any parent will remember teaching children to 'eat properly', and recall their children's adamant refusal to eat even the most nutritious food if it was declared to be 'yucky'. Powerful adult emotions are aroused when age and infirmity makes it harder for us to 'eat properly'. The public's concerns about the introduction of genetically modified (GM) foods into their diet is therefore not surprising, even to those who think GM foods pose little risk to health.
- 5.2 The majority of concerns about the possible consequences of GM crops are of two kinds: the effects of such crops on human health, and environmental effects. This chapter discusses consumer attitudes to food containing ingredients made from GM crops. The majority of our evidence to date comes from the developed world, but consumer attitudes in the developing world are also important. The environmental effects of GM crops are discussed in Chapter 6.
- 5.3 There is much greater public concern about GM foods in the United Kingdom (UK) and some other European countries than in the United States (US). Most Americans appear to accept the Food and Drug Agency's (FDA) positive stance on GM soya and maize without concern. On the face of it this is surprising, since North American society is a highly litigious one. It may be, however, that the high regard in which the FDA is held by the US public, and their more entrepreneurial, innovative and less risk-averse culture may in part account for the more relaxed acceptance of genetic modification and the comparative lack of debate on the subject in the US. Alternatively, as GM ingredients do not have to be labelled in the US, perhaps the public is unaware of the extent to which GM ingredients have entered their food chain and the question of GM crops may not appear as pressing as it does to Europeans.
- 5.4 Consumers in the UK and much of Europe appear to be increasingly concerned about the safety and impact of GM food. This is almost certainly linked to two major factors: first, the high-profile campaigns of environmental and other pressure groups and secondly, the development of intensive farming, which, although it has delivered high quality food at ever decreasing prices, has been accompanied by:
  - well-publicised food scares, particularly BSE (bovine spongiform encephalitis);
  - a rise in food-poisoning statistics;
  - overcrowding of animals and a concomitant need for antibiotics to ward off disease.
- 5.5 These have combined to make the public suspicious of what the food they buy might contain. It is not surprising, therefore, that the idea of genetic modification has not been widely welcomed. This attitude may be caused in part by natural conservatism, a resistance to the new and a feeling that the old ways were the best ways, particularly if the new ways do not appear to offer many direct benefits. It is also possible that genetic modification is a 'lightning-rod' upon which the public's general uneasiness about the modern world is focused.
- 5.6 Consumers have expressed fears and anxieties about the impact of GM foods on human health. However, it should be remembered that eating *any* food carries some dangers, such as the risk of food poisoning or an allergic reaction. This chapter considers the consumer's perception of

A study for the National Science Foundation concluded that North Americans' confidence in science was based the country's 'string of successes in science'. The strong support for science found in the US study is also present in Canada and European countries. However, far greater reservations about science are expressed in Europe than in the US (Macilwain C (1998) US public puts faith in science, but still lacks understanding, **Nature**, 394:107).

- additional risks that GM foods might carry, over and above those carried by their non-GM equivalents.
- 5.7 There is often a conflict between the consumers' desire for attractive, nutritious and affordable food and food that has been grown in a conventional or environmentally-friendly manner. This conflict makes it difficult to predict the attitude consumers would have to any GM food that offers demonstrable benefits, for instance by being cheaper, better-tasting or more nutritious than its conventional alternative.
- 5.8 An example is the general acceptance of the addition of preservatives to food to make it safer or to prolong its shelf-life. Would GM food which eliminates the need to add these chemicals also be acceptable, or even preferable? Rather, it seems that public unease is focused on the stage at which the plant breeder intervenes. It seems to be considered acceptable to add vitamins to bread flour but not, one suspects, to modify the wheat plant genes to enable the plant to produce the vitamins itself. Why might it be acceptable to 'put back' nutrients lost in processing, but not to modify the plant?
- 5.9 What, for example, would the public regard as the right response, if any, to the dramatic decline in household intake of vitamins among the poorest fifth of families in the UK? Since 1980, beta carotene (a vitamin A precursor) intake has dropped by 47% and vitamin C intake by 23%. Nutritionists in the UK would understandably argue that it would be better for children if they ate fresh carrots (a source of beta carotene) but this ignores the fact that exhorting young people to do what is good for them seldom appeals. In these circumstances, is ensuring beta carotene intake from the foods that they are determined to eat, such as chips, justifiable? In the developing world, millions of children could be saved from eye defects if they had more vitamin A in their diet. One way to achieve this would be by introducing the genes coding for beta carotene (which the body uses to make vitamin A) into their rice (see paragraph 4.18). Should such GM developments be encouraged? Will developments such as this result in one set of ethics for children from the developing world and another set for our own?

# **UK consumer attitudes**

- 5.10 In examining existing patterns of public attitudes towards GM food, there is not a large body of evidence to go on. Table 5.1 provides a list of five important surveys to date. The sources fall into two main groups. On the one side there are large-scale statistically representative surveys, like the European-wide Eurobarometer<sup>3</sup> poll, or Iceland Frozen Foods' poll as conducted in a nationally representative telephone survey by the Gallup organisation (paragraphs 1.35–1.37). The second group comprises the small-scale qualitative studies, which take a small group of people and create a context in which they receive evidence on a question, can deliberate about it and come to a group conclusion. These latter sorts of studies cover a variety of methods, including focus groups and more experimental procedures, like citizen panels, which resemble a more formalised procedure.
- 5.11 Each method has its strengths and its weaknesses in judging public opinion. The small-scale qualitative studies enable evidence to be presented to participants and discussed by them, thus allowing a more subtle appreciation of underlying reasoning and ambivalence of feeling, but they suffer from the obvious disadvantage of being statistically unrepresentative and therefore forming a poor basis for generalisation. Statistically representative polls, by contrast, are prone to 'off the

Leather S and Dowler E (1997) Intake of micronutrients in Britain's poorest fifth has declined, **British Medical Journal**, 314: 1412 and Government data, Ministry of Agriculture, Fisheries and Food (MAFF) National Food Survey 1980 and

<sup>3</sup> European Commission (1997) **The Europeans and Modern Biotechnology: Eurobarometer 46.1**, European Commission Directorate General XII. Science, Research and Development, Brussels.

Table 5.1
Summary of Main Surveys of Public Opinion

Name	Date	Туре	Commissioner	Main Results
UK National Consensus Conference <sup>1</sup>	1994	Consensus Conference	Science Museum	There were benefits and risks. Product labelling and freedom of choice were very important.
Eurobarometer <sup>2</sup>	1997	Representative Sample (EU)	European Commission	Genetic modification less well endorsed than other new technologies. Variation in support by country. Moderate level of objective knowledge of genetics. Increased support correlated mildly with knowledge. Stronger support for genetic techniques for medicines than for foods. Importance of clear labels.
Consumer Attitudes <sup>3</sup>	1997	Focus Group	IDG	Low awareness and understanding. Importance of clear information.
Uncertain World $^4$	1997	Focus Group	Unilever <i>et al.</i>	Doubts about GM as proxy for more general uncertainties.
Genetically Modified Food <sup>5</sup>	1998	Representative Sample (UK)	Iceland	High levels of concern about GM. Considerable uncertainty about what it involved. High level of concern about labelling.

<sup>&</sup>lt;sup>1</sup>Anon (1994) Final Report of the **UK National Consensus Conference on Plant Biotechnology**, The Science Museum, London.

top of the head' answers and a sensitivity to question wording that can make estimates of opinion problematic.  $^4$ 

5.12 Despite these drawbacks, the surveys of public opinion are thought-provoking. In all forms of sampling, a desire for clear and informative labelling is a strong theme. This was a feature of the earliest study, the 1994 UK National Consensus Conference (paragraph 2.67) and also came through very markedly in the Iceland Frozen Foods survey of 1998, where 81% of respondents favoured clear labelling. A similar proportion of respondents to the Working Party's consultation attached great importance to labelling. Another common theme in all the surveys is a sense of uncertainty in the face of complex issues and a desire for caution when dealing with potentially important technical innovations. This may be interpreted as a proxy for a wider unease about the

 $<sup>^2 \</sup>hbox{European Commission, {\it Eurobarometer~46.1}}.$ 

<sup>&</sup>lt;sup>3</sup> Policy Issues Council, Institute of Grocery Distribution (1997) **Consumer attitudes to genetically modified crops: results of qualitative research**, Institute of Grocery Distribution, Watford.

<sup>&</sup>lt;sup>4</sup> Grove-White R, Macnaghten P, Mayer S and Wynne B (1997) **Uncertain World: Genetically Modified Organisms, Food and Public Attitudes in Britain**, Lancaster University, Lancaster.

<sup>&</sup>lt;sup>5</sup>The Gallup Organisation (1998) **Genetically Modified Food: Executive Summary Report** (prepared for Iceland) (unpublished). The research was carried out by the Gallup Organisation 3–9 March 1998. Adults 16+ were interviewed randomly by telephone. There is a margin of error of ±3%.

Some scepticism about the validity of survey findings is understandable: if asked whether we would like 'strawberries that could, on account of being genetically modified, be frozen without becoming mushy when thawed', the answer is more likely to be positive than if the question is phrased as 'Would you like fish genes in your strawberries?'.

'unnatural' implications of innovative technology,5 or it may be more specific worries about GM techniques compared to other technologies. This was implied by the Eurobarometer results, in which GM techniques were thought to have less promise of human benefit than, say, telecommunications or solar energy.

- 5.13 Even so, it is possible for members of the public to make important distinctions. For example, the UK National Consensus Conference panel drew attention to the potential for medicines and vaccines to be derived from GM crops, and Eurobarometer respondents also showed a clear preference for genetic modification for medical purposes over that of plants or organ transplants, even though there was a net balance of opinion that was favourable to all applications.<sup>6</sup>
- 5.14 One interesting aspect of public opinion is the relationship between levels of information and attitude towards GM applications. The Eurobarometer poll<sup>7</sup> shows a positive link between knowledge of genetics, as measured objectively by a ten-question test, and optimism regarding biotechnology. Yet we cannot infer from this that as people become more knowledgeable so they will readily accept biotechnology. In Iceland Frozen Foods' poll, the proportion of respondents with reservations about GM technology increased as it was explained to them. The focus group results also showed a pattern in which increased awareness and discussion inclined respondents to be more cautious. There is no reason to think that we can predict attitudinal developments as public knowledge increases. Consumer knowledge about GM crops is discussed in more detail in paragraphs 5.29–33.
- 5.15 It is, in any case, difficult to infer behaviour from opinions. An example of the difference between expressed opinions and actual purchases is provided by comparing the sales of GM tomato purée at two UK supermarkets and the answers given in a survey by a third. Tomato purée produced from GM plants developed by Zeneca can be processed at lower temperatures than conventionally bred alternatives. The lower temperature of processing ensures that no caramelisation takes place, which provides an apparently 'fresher' flavour. The tomato purée has been sold under the 'own brand' label at selected Safeway and Sainsbury's<sup>8</sup> supermarkets and clearly labelled as genetically modified. It has also been cheaper than the traditional 'own brand' purée. Between February 1996 and November 1998, approximately 1.7 million cans of the GM purée were sold. In Safeway supermarkets, GM purée outsold traditional purée by 60:40 where they were sold side by side, and in Sainsbury's supermarkets sales of GM purée were only 30% less than the traditional purée. <sup>10</sup> In contrast, in the Iceland Frozen Foods' poll examining consumer attitudes towards GM foods, 11 8% of respondents reported that they were likely or 'very likely' to buy GM food, 15% might purchase it and 77% reported that they were unlikely or 'not at all likely' to buy GM food.
- 5.16 The silent majority may well buy GM food without qualm, and accept the growth of genetic modification without question, or they may feel a deep latent unease about the technology but feel powerless to influence its development.<sup>12</sup> And, as implied above, they may state an objection and buy the product anyway. The Uncertain World study<sup>13</sup> suggests that purchasing GM foods does not necessarily indicate approval of them. The focus groups showed an 'apparent paradox that

<sup>5</sup> This was the interpretation of the Lancaster Group that conducted a study commissioned by Unilever (Grove-White R et al.,

European Commission, Eurobarometer 46.1, p 32-37.

Following Sainsbury's decision on 16 March 1999 to remove GM products from their 'own brand' labels, stocks of the tomato purée will not be renewed and are expected to run out by June 1999 In November 1998 Zeneca GM tomato purée was priced at 29p for 170g as opposed to 29p for 142g of the conventional

product. Sainsbury's and Safeway determined the price at which they would sell the GM puree.

GM tomato purée is hit with consumers, Financial Times Food Business, September 1998 Issue 2 page 22; Gittus K (1999) personal communication, Zeneca.

The Gallup Organisation, Genetically Modified Food: Executive Summary Report. 11

One study, based on nine tocus group discussions, noted a 'sense of "inevitability" and fatalism, reflecting perceptions of the possible future persuasiveness of GMOs in foods'. Grove-White R, et al., Uncertain World.

- people may purchase particular GMO products, whilst also harbouring significant unease about the technology as a whole, and about potential implications of its trajectories'.
- 5.17 Respondents to the Working Party's Consultation expressed concerns that GM food would be introduced against their wishes. It was thought that GM crops would provide benefits to growers and producers rather than consumers, and that for this reason the crops would be grown, irrespective of consumers' wishes. Consequently, consumers would have to buy GM food and face any attendant risks, without receiving any benefit. Particular frustration was expressed at the proposition that GM foods might not have to be labelled, so that consumers would not be able to avoid them if they wished. The question of labelling is discussed in more detail later in this chapter and in Chapter 7.
- 5.18 When consumers who have stated that they do not wish to buy food are asked why, a range of reasons are offered. In Iceland Frozen Foods' poll, of those who were unlikely or very unlikely to purchase GM foods, reasons included that they 'just didn't like the idea', 'didn't know enough and were unsure', 'didn't know enough about the long term effects' or 'didn't like the fact that GM foods were produced by 'interfering with nature''. Two Consumer Association surveys<sup>14</sup> have reported that reasons for a reluctance to buy GM food include: a lack of awareness/interest; caution; insufficient information; a dislike of tampering with nature/food; a preference for fresh/natural food; concerns about long term consequences to the food chain and environment; and that GM food is wrong.
- 5.19 In addition to these views, respondents to the Working Party's public consultation have expressed the following specific concerns about GM food:
  - some consumers, including vegans, vegetarians and some religious groups are concerned about the possible introduction of genes of animal origin into other animals or crops;
  - there is concern that farmers, manufacturers and retailers will not pass on savings gained through genetic modification to the consumer;
  - the suspicion exists that research is more likely to be focused on genetic modifications that help the farmer, manufacturer or retailer, such as herbicide tolerance or longer shelf-life, than on those that might benefit the consumer, such as improvements in nutrition or a reduction in allergens;
  - some people believe that humans might absorb and be affected by DNA transferred to them through the cell walls during digestion (see paragraph 2.50);<sup>15</sup>
  - the risk that allergenicity could be transferred from one food plant to another with the transfer of genes has concerned some scientists and others;<sup>16</sup>
  - there is also a more general unease that there may be long-term risks to human health from this technology. Because the nature of such risks is unknown, questions were raised about whether they would necessarily be picked up by the safety tests that GM foods undergo (see paragraph 2.55).

<sup>14 1994</sup> Consumers' Association Survey. The Consumers' Association held face-to-face interviews with a nationally representative sample of 176 adults. In April 1996, the Consumer Association carried out face-to-face interviews with a representative sample of 506 UK men and women.

<sup>15</sup> In the Eurobarometer survey 29% of respondents thought that their genes could become genetically modified as a result of eating GM fruit.

Only one example of this has been reported: experiments on the introduction of a Brazil nut gene into soya beans were halted by the company when they found that people allergic to nuts could have an allergic reaction to the GM soya, the allergenicity having been transferred with the transferred gene (see paragraphs 2.53–2.54). The production of allergenic GM soya is of particular concern because GM soya is used in a wide variety of processed foods. Nordlee J A, Taylor S L, Townsend J A, Thomas L A and Bush R K (1996) Identification of a Brazil nut allergen in transgenic soybeans, **New England Journal of Medicine**, 334: 688–692.

5.20 So there is a wide range of public concerns in the UK about the merits and risks of GM food. It is possible that some concerns about the consequences of genetic modification may be alleviated if more information becomes available to the public and as further research is carried out, but the evidence is conflicting. The next section considers to what extent consumer concerns in Britain are present throughout the European Union.

# **European attitudes**

- 5.21 The Eurobarometer survey published in 1997 examined the attitudes of 16,246 Europeans<sup>17</sup> to six applications of biotechnology. Respondents were asked to consider whether the applications were morally acceptable, would benefit society, would involve risks for society, and whether or not they should be encouraged. There was a strong correlation between applications of biotechnology expected to benefit society and those that were considered to be morally acceptable. When asked about the use of biotechnology to genetically modify crops to make them more resistant to insects, <sup>19</sup> 62% of European Union (EU) respondents and a similar number of UK respondents considered this morally acceptable. When asked about changing food characteristics such as taste and nutritional content about half of EU and UK respondents thought this was morally acceptable.
- 5.22 When asked whether these biotechnological applications would benefit society, about three-quarters of UK and EU respondents thought that creating GM insect-resistant crops would be beneficial and close to half thought that changing food characteristics would benefit society. UK respondents were slightly more optimistic than the EU as a whole. Of EU respondents, nearly two-thirds thought that GM food posed a risk to society while just under half thought that GM insect-resistant crops posed such a risk. A higher number of respondents answered 'don't know' to the question about risk compared to previous questions about benefits, suggesting that respondents found it easier to assess the benefits than the risks offered by biotechnology. Figures for the UK were slightly higher than the EU average. However, of EU respondents, 28% (rising to 40% of respondents in the UK) agreed with the statement 'We should accept some degree of risk from modern biotechnology if it enhances economic competitiveness in Europe'.
- 5.23 The Eurobarometer survey demonstrates the public is aware of the benefits offered by GM foods and crops as well as its perceived dangers. Where forms of genetic modification are seen to be useful, they tend to be perceived as acceptable, even if they are also thought to carry risk. The European public appears to be ambivalent about the role of GM, both in food and crops.

# Potential benefits of genetic modification

5.24 Interviews with supermarket shoppers and focus group discussions present a picture of suspicion and nervousness about GM technology. When asked to what extent they supported the development and introduction of GM food, a quarter of respondents to the 1998 MORI poll for GeneWatch supported GM food to a slight or great extent while over half opposed it.<sup>20</sup> When asked if they

In each EU country, a number of sampling points were drawn in relation to population size and density. The figures for the EU as a whole are a weighted mean of national figures. Results for each country are weighted according to the country's population aged fifteen and over within the total Community population of the same age.

Pearson correlation coefficient=0.71

The phrase used in the survey was 'Taking genes from plant species and transferring them into plants, to make them more resistant to insect pests'. Much current research into insect resistance involves the transfer of genes originating from bacteria (Bacillus thuringiensis) into plants, which some consumers find less acceptable than the transfer of genes between plant species.

The MORI poll for GeneWatch involved the face-to-face interviewing of 950 adults aged 15 and over. Data have been weighted to reflect the national profile.

would be 'happy to eat GM food', approximately a quarter of respondents were willing to and about two-thirds were slightly or greatly unwilling to eat such food. Much of the public debate has centred on the safety or otherwise of genetic modification, without as much consideration being given to any potential benefits. Quite apart from the question of improved global food security discussed in Chapter 4, and the environmental benefits discussed in Chapter 6, it is theoretically possible that genetic modification could improve the flavour, texture, appearance, price, and nutritional content of a number of plant foods (see paragraphs 2.39–2.41, 4.18). It is likely that if the public could see, smell, feel and taste improvement to their food, their attitudes would become less hostile. At this early stage of GM crop development, current field trials in the UK focus on herbicide tolerance and insect resistance, matters of no direct benefit to the ultimate consumer.

- 5.25 Price: Zeneca's tomato purée is cheaper, has sold well and is rated more highly in blind taste tests than conventional tomato purée. This suggests that the purchaser's confidence in the safety of GM foods, or his or her ethical stance about such foods, can be swayed by price. A similar phenomenon was observed during the BSE crisis. Beef sales fell until desperate retailers halved prices, whereupon supermarkets rapidly sold out of beef. There would appear to be a balance reached between price and the amount of perceived risk or ethical discomfort that consumers are prepared to tolerate. However, in the 1996 Consumers' Association Survey there was not a significant increase in the number of respondents who said they would buy GM food if it was cheaper. But, if GM foods are substantially cheaper than non-GM foods, and taste and look better, it is reasonable to suppose that some people may not feel that they can justify, to themselves or others, the higher price of non-GM foods, even if they would prefer to purchase such a product.
- 5.26 Flavour: There is little evidence about how consumers would respond to food with an 'improved' flavour. In the Eurobarometer survey, 29% of EU respondents (37% of UK respondents) agreed that they would 'buy GM fruit if it tasted better'. Of the respondents to the Iceland Frozen Foods' poll who were likely or very likely to purchase GM foods, a better flavour was the second most popular reason for doing so (cited by 15% of respondents). In contrast, in the Uncertain World study and responses to the Working Party's Consultation, concerns were raised that changing the flavour of foods was a trivial reason for 'meddling'. Some respondents mentioned that they would not wish flavours of their favourite foods to be altered. It was also proposed that flavours only need to be 'improved' because foods had lost flavour as a result of modern agricultural practices.
- 5.27 Nutrition: The use of genetic modification to improve the nutritional values of developing world crops is discussed in Chapter 4. Some respondents to the Working Party's Consultation questioned whether there was a similar need to alter the nutritional profiles of foods in the developed world, given that such consumers have access to a more varied and complete diet. It has been pointed out that conventional plant breeding has reduced the levels of such protective substances as sinigrin and sulphoraphane in sprouts and broccoli, and it has been claimed that increasing the levels of these substances would improve protection against cancer of the gut.<sup>21</sup> However, foods modified to have high levels of particular nutrients such as high-lycopene tomatoes may not be as beneficial as expected.<sup>22</sup> Some forms of genetic modification of nutrient values, such as altering fatty acid profiles of particular oil seeds, might even have a deleterious effect on a nutritional profile, in addition to the positive effects. On a larger scale, it was proposed that public health messages about nutritious values of certain foods will become increasingly complicated and confusing as the nutrient profile of foods are modified.
- 5.28 As discussed above, the *Eurobarometer* results suggest that consumers are more prepared to tolerate risks if some benefit is offered. Apart from the cheaper price of Zeneca's tomato purée,

Institute of Food Research (IFR) (1997) **Why your best friend could be a Brassica**, IFR, Norwich.

The British Dietetic Association's response to the Working Party's Consultation.

consumers in the UK have experienced no direct benefit from the introduction of GM foods. At this stage it is uncertain whether or not consumers will welcome GM foods offering them direct benefits, and, as discussed in Chapter 3, it will be some time before such products appear in UK supermarkets.

# Public awareness of GM technology

- 5.29 In a 1994 Consumers' Association Survey following the release of Co-op's 'vegetarian cheese'<sup>23</sup> about one-fifth of respondents had heard of gene technology and only 17% had some comprehension of what it meant. In their April 1996 survey, following the release of Zeneca's tomato purée,<sup>24</sup> approximately two-fifths of consumers had some understanding of the terms 'biotechnology', 'gene technology' or 'genetic modification'. The term 'genetically modified tomatoes' was most widely understood. A similar number of respondents realised that 'made using genetic modification' and 'produced using gene technology' meant the same thing.
- 5.30 In the 1998 Iceland Frozen Foods' survey, around two-thirds of the population had heard of the terms 'genetically modified foods' or 'genetically engineered foods'. When asked what these terms meant, the seven most common responses were 'changing the nature of food', 'changing genes', 'something to do with science', 'human involvement in changing food', 'playing around with genes', 'playing around with nature' and 'something to do with longer lasting qualities'.
- 5.31 In the Eurobarometer survey,<sup>25</sup> respondents were asked whether statements were true or false to test their 'objective' knowledge of biotechnology:
  - 'ordinary tomatoes do not contain genes, whereas genetically engineered tomatoes do'
    (approximately equal numbers of respondents correctly thought this statement was false,
    incorrectly thought it was true, or did not know);
  - 'if people eat genetically modified fruit, their genes could also become modified' (half the respondents correctly thought this was false, but about a quarter thought it was true and a similar number did not know);
  - 'it is impossible to transfer animal genes to plants' (one quarter of respondents correctly stated this statement was false, another quarter answered incorrectly and about half did not know).
- 5.32 Levels of knowledge about aspects of genetic engineering will often affect opinions about GM food. This survey suggests that one-third of the EU population believe that eating genetically modified fruit could alter their genes. Information about such fundamental misapprehensions from trusted sources may alleviate much consumer concern about the effects of GM foods on the food chain.
- 5.33 When considering the necessity of using genetic modification in plants and animals, 56% of EU respondents agreed that 'only traditional breeding methods should be used, rather than changing the hereditary characteristics of plants and animals through modern biotechnology'. However, 43% of EU respondents also agreed that 'traditional breeding methods can be as effective as modern biotechnology in changing the hereditary characteristics of plants and animals'. Consumers may increase their support of GM foods as they realise that genetic modification has the potential to make changes to food that are not possible through conventional plant breeding.

Co-op's vegetarian cheese carried the label 'produced using gene technology'.

The Sainsbury's GM tomato purée is labelled as 'made with genetically modified tomatoes' and Safeway's produce carries the label 'produced from genetically modified tomatoes'.

# **Public information**

- 5.34 As discussed above, whether or not further information about the process of developing GM crops and their consequences will be reassuring is uncertain. Increased anxiety as a result of more information may have more to do with how people get information, than the quality of that information. In the first months of 1999, the UK media had what one journalist called a 'feeding frenzy' regarding risks associated with GM foods. Stories were published with eye-catching headlines such as 'MP links genetic food to 37 deaths' and were later contradicted in articles with titles like 'Gene foods scare rooted in confusion'. Inaccurate assertions, an example being the claim that GM foods were not tested to see if they cause allergic reactions, were made and rebutted within days. One of the most prominent stories over this time regarded Dr Arpad Pusztai's research (see paragraphs 2.57–2.58 and Appendix 1). Numerous newspaper articles appeared supporting his research into the effects of GM potatoes on rats, and alleged a cover-up of unfavourable results. Later newspaper reports presented a contrary view to earlier articles and a wide variety of contradictory 'expert' opinions were aired. It is extremely difficult to see how this abundance of partisan or confused reporting could aid the public understanding of GM crops. The problem of prejudicial reporting is not restricted to arguments about genetic modification, and cannot, in a society with a free press, be avoided. There is no way of ensuring that either side in a debate must present information in an ethical and fair way, however regrettable this may be.
- 5.35 Press coverage aside, most people lack the opportunity to gain an understanding about the science involved in the creation of GM crops and the differences between GM and non-GM crops. However, public information is needed: people should know, if they are interested, what their food is made of. Carefully written leaflets from official or semi-official bodies such as the Science Museum, or interested parties such as the Food and Drink Federation (FDF) or the National Farmers' Union or even official government public information documents are not widely read by the general public. Often such documents are intended primarily for professionals and opinion formers and are frequently much more detailed than the general public wants. The question therefore becomes how to make this information available to consumers to answer the questions that they have and in a form that they are able to access. It is also important to understand whether calls for 'more information' are in fact calls for something else, for instance, reassurance about the efficacy of regulation.<sup>26</sup>
- 5.36 Consumers also lack a way of explaining their fears and concerns to those responsible for the development, production and sale of GM crops. Some respondents to our public consultation expressed frustration that information about decision making regarding GM crops was difficult for them to access and that they could see no way to express their concerns and influence decisions. We suggest below some institutional arrangements that could improve the dissemination of information and allow people's concerns to be taken into account.
- 5.37 In the Eurobarometer survey, respondents were asked which organisation they would trust most to tell them the truth with regard to modern biotechnology in general and, in particular, about GM food crops grown in fields. With regard to GM crops, environmental organisations commanded the support of around one-quarter of respondents, followed by consumer organisations and farmers' organisations. Industry, religious organisations and political parties received the least amount of support (0–1% of respondents). In February 1999, a poll for the Cabinet Office suggested that the public trusts independent scientists and pressure groups more than politicians for advice on scientific matters.<sup>27</sup>

This view was echoed by some respondents to the Working Party's Consultation, including **BTG plc** which stated 'People expect official bodies and NGOs to deal with [GM crops] on their behalf, objectively and free from ideological opposition to biotechnology in industry'.

Public scorns advice over food safety, **The Times**, 8 February 1999.

- 5.38 Furthermore, incidents such as the BSE crisis, have led to some public mistrust of scientists. An additional reason for such mistrust may be because of the difference in the perception of risk between scientists and the public. Scientists and technologists often see novel applications of new discoveries as logical and reasonable, and may characterise opposition as unreasonable. They are more used to an uncertain world, where knowledge is always flawed, can handle risk judgements more easily, and can be impatient with those who differ from them. The public's reaction can be quite different, and could be described as 'outrage' how dare they do this to us, 'dread' the way we all would regard a nuclear power station explosion, or 'stigma' the way the public regards food irradiation.<sup>28</sup>
- 5.39 We acknowledge that the credibility of the government information on food safety has been so badly impaired in recent years that it may be more fruitful for non-governmental entities, supermarkets and food manufacturers to take on some of the task of informing their customers. All of these organisations have, however, vested interests of some kind. The public's distrust of information from such organisations suggests that advice from companies marketing GM crops would also carry little weight with the public. In fact their efforts to persuade people of the benefits of GM crops are probably counter-productive. Consequently, information about GM plants needs to come from an impeccable source. This disinterested and authoritative information can then be disseminated by supermarkets, libraries, the media and others.
- 5.40 Independent information from a trusted source will not allay all fears, but such information will at least allow the public to make a better informed choice about what food they will buy, and what risks they are prepared to take. We recommend that the proposed Food Standards Agency (FSA) should be the main source of independent information. But perhaps the onus on communicating this information in an accessible form for consumers should fall on organisations that they are more likely to trust. The major retailers such as Marks & Spencer, Sainsbury's and Tesco, have a far higher 'trust' rating than the Government, and should be encouraged to disseminate impartial information in a readable and user-friendly form from the FSA, as long as the agency is constructed in such a way that it is able to command widespread confidence.

# **Consumer choice**

- 5.41 Many people fear that genetic modification will lead to less choice for the consumer.<sup>29</sup> Even if choice does exist, there is the risk that it will not be a 'real' choice for everyone. Someone at the bottom of the income table, struggling to feed a family, cannot be said to have much choice if he or she has to pay a premium for the 'natural' product. The same argument has been made about organic produce which, because of its expense, is more readily affordable by the middle classes.
- 5.42 In addition, there is the practical problem of whether or not a choice of GM and non-GM foods will be achievable as more foods become genetically modified. The questions of provenance or traceability of foodstuffs, the feasibility of guaranteeing that plants have not inherited modified DNA from a GM parent and the practicalities of a dual path from farm to table of segregated GM and non-GM foods raises concerns that non-GM food at a realistic price may be unattainable in a few years' time. If, however, there is enough demand for non-GM food, it is more likely that the market will segregate GM and non-GM crops, and choice will be preserved. Retailer responses to consumer demand for non-GM foods are discussed below.

<sup>28</sup> Burke D (1999) Making British food safe, **Food Science and Technology Today**, 13:12–18.

In the 1996 Eurobarometer survey over a quarter of British respondents thought that over the next 10 years genetic modification would lead to a reduction in the varieties of fruit and vegetables available. Some respondents to the Working Party's consultation expressed similar concerns.

5.43 Labelling is meaningless unless the public know what genetic modification is. If foods are to be labelled, readily available information about genetic modification should be available at the point of sale in all shops carrying GM products. The situation has been unsatisfactory, with most supermarkets relying on their telephone help-lines to answer customers' questions, but with the employees on the help lines ill-equipped to give accurate information. The current position on labelling is that while some GM products in the UK are clearly labelled, such as GM tomato purée and Co-op 'vegetarian' cheese, 30 not all are. One well-known example results from the non-segregation of GM and non-GM soya grown in the US. In 1998, GM soya accounted for about 40% of the US soya harvest and US soya is used in approximately 60% of processed food in the UK. While some soya products need to be labelled, not all do. In addition, ingredients such as hydrogenated vegetable oil do not contain material which allows a test to prove whether it has come from a GM plant or not (see paragraph 2.37). Consequently, manufacturers and retailers wanting to label these substances accurately will have to trace the non-GM plants from the farm gate, and label products which are indistinguishable by any known test differently. This is difficult to do, especially across national boundaries, and the problem of potential fraud, such as representing a product as GM-free when there is no test available to distinguish products, is a serious one.

# Responses to consumer concerns

- 5.44 For the reasons discussed above, it is difficult to determine with any precision what the attitude of UK consumers would be to a gradual introduction of GM foods, especially if such foods provided some benefit to the consumer, such as being cheaper or nutritionally superior to a non-GM equivalent. In contrast, consumer's opinions about the labelling of GM products appear to be more unified (paragraph 5.12) and appropriate labelling of GM ingredients is sought, in some cases, even when the ingredient from a GM plant is chemically identical to the same ingredient from a non-GM plant.
- 5.45 Retailers and food manufacturers must build suitable relationships with both consumers and suppliers to remain profitable. GM crops thus provide a dilemma. On the one hand, GM crops appear to be cheaper to grow and the crop of choice for many farmers (especially in the US), and such savings could ultimately benefit the consumer. In future, GM crops could offer the additional benefits to consumers such as 'improved' flavours or nutritional profiles (paragraphs 2.39–41). On the other hand, many consumers would like accurate labelling of GM ingredients (despite research showing that on average in the UK only 10% of consumers read labels) and may wish to avoid food containing GM ingredients altogether. Manufacturers may end up supplying what they consider to be a superior product, containing GM ingredients, for which there will be little demand. A similar situation happened in the early 1990s when food irradiation was proposed. In the 1980s factories were built to carry out irradiation but, because of public disapproval, such foods were never marketed widely in the UK.
- 5.46 Current regulations for the labelling of GM ingredients have been criticised as having too many loopholes, so that additives, processing aids and products from which DNA or protein are removed during processing, need not be labelled as genetically modified, despite coming from GM crops<sup>31</sup> (see paragraphs 2.37, 7.54, 8.22). In response to these perceived concerns, many manufacturers have agreed to label their GM produce beyond the level currently required by regulation. Such labelling can be unreliable because of the difficulty of testing for some GM ingredients (see paragraph 5.43). Indeed, many manufacturers have recently received adverse publicity for failing to label their products

The vast majority of hard cheeses in the UK are made by using chymosin produced using genetic modification.

<sup>31</sup> An example of recent criticism is in Anon (1999) Gene cuisine Which? March: 8–11.

- as containing GM ingredients. In some of these cases manufacturers were unaware that their foods contained GM material or had specifically sought to make their products GM-free.  $^{32}$
- 5.47 As a result of the level of public concern and the difficulty with labelling some forms of GM ingredients, many supermarkets have decided to remove any GM ingredients from their 'own brand' products. 33 As discussed above, to enable supermarkets to ensure that ingredients such as hydrogenated vegetable oil have not come from GM sources, such supplies will need to be segregated and traced from the farm gate. Consequently, a consortium of European supermarkets has formed, including Sainsbury's and Marks & Spencer in the UK, to provide enough buying power to guarantee the provision of non-GM crops, particularly soya. Growers are beginning to recognise the European demand for non-GM plants and countries such as Brazil and Canada are considering the prospect of providing soya that has not been genetically modified, possibly at a premium price. However, the soya component of many processed foods is so small that the increase in cost to the consumer will be minimal. Fast-food chains such as Pizza Express and Burger King have followed the trend and announced that their food is, or is in the process of becoming, GM-free. Large food manufacturers, such as Nestlé and Unilever have made similar statements. 34
- 5.48 The Government has also recognised consumer concerns about labelling GM foods to the extent that it announced regulations in February 1999 requiring restaurants to label GM food. In March the controversial regulations were extended so that restaurants, fast-food outlets and waiters were required to inform customers if meals contained GM ingredients. Fines of up to £5000 would be imposed on organisations failing to comply with the regulations<sup>35</sup>.
- 5.49 Just 20% of Eurobarometer respondents thought that the regulation of modern biotechnology could be left mainly to industry. However, over half of EU respondents agreed with the statement 'irrespective of the regulations, biotechnologists will do whatever they like'. When considering current regulation, about a quarter of EU respondents agreed that 'current regulations are sufficient to protect people from any risks linked to modern biotechnology'. Of organisations administering regulation of modern biotechnology, international organisations such as the United Nations or World Health Organization were most popular, followed by scientific organisations. The remaining organisations in order of popularity were: public authorities, ethics committees, the EU and parliament. The question of regulation of GM crops is considered in detail in Chapter 7.

# Implications for public policy

5.50 It is clear that the public wants choice as to whether to eat these new foods or not, and choice requires labelling, and labelling requires segregation of supplies. So to quote a recent editorial in the journal *Nature*:

Finally, broad public concerns, however 'irrational' they may appear to some, must be taken into account in food safety regulations if they are to maintain their credibility. Industry complains that the public has lost trust in its scientific experts, but it will only make matters worse by declaring its own loss of trust in the judgement of the consumer. If labelling all foods

<sup>32</sup> The reverse situation has occurred in the US where 'BST-free milk' was sold at a premium price but was, in fact, regular

<sup>33</sup> Iceland was the first supermarket to take this step in 1998 and has been followed in 1999 by Safeway, Sainsbury's, Co-op, Asda and others, most recently Tesco. For some supermarkets this was a gradual decision: Sainsbury's first announced that they would label all GM ingredients in their own products and then announced that all GM products would be removed from their 'own brand' labels.

Nestle remains committed however, to using GM ingredients in food products to be sold outside the UK. The decision to stop using GM ingredients in UK foodstuffs is in response to public concerns but Nestlé hopes that this halt will be temporary. Nestlé remains confident that GM ingredients offer benefits. **Nestlé UK Ltd Position on Gene Technology**, 28 April 1999

<sup>35</sup> **GM labelling - Rooker puts new powers on the menu**. MAFF News Release, 18 March 1999.

produced by GM techniques, as many argue, turns out to be a necessary step in regaining trust on both sides, it could be a small price to pay. $^{36}$ 

# **Conclusions**

- 5.51 Consumer opinion about GM foods in the UK and much of Europe is complex and appears to be primarily focused on ecological issues and health concerns. It is difficult to gauge the concerns of the silent majority of the public. However, focus groups and surveys suggest that there is considerable unease about GM products entering the food chain. Although sales of some clearly labelled GM products have been robust, focus groups suggest that people may purchase particular products while 'harbouring significant unease about the technology as a whole'. A large amount of public concern is focused on the issue of choice and there is widespread demand for the labelling of GM foodstuffs. We return to the issue of labelling in Chapter 7. It is unclear how consumer opinion will change if, as predicted, the benefits of GM foods become more established over the next few years.
- 5.52 The public has now become even more sensitised to GM foods following extensive public debate in the media, but, because of the misleading and inaccurate information, are unlikely to be much better informed. More research is required to learn what information the public want to know about GM food. Although some may want information about risks and benefits from a reliable and trusted source, others may prefer more information about regulatory processes so that they know a trusted group is making the decisions for them. People have mixed feelings about whether government regulation is adequate and impartial. Many official sources of information are mistrusted, particularly concerning science and the limits of current scientific knowledge. We recommend that further research is undertaken to determine what information the public would like about GM food and how best to provide such information. Such research could build on the public consultation exercise being undertaken by the Office of Science and Technology, due to report in May 1999. In addition, there is a need for public concerns to be integrated into regulatory regimes. Means for doing this are discussed in Chapter 7.

# Chapter 6

The environmental impact of genetically modified plants

# **Ethical considerations**

- 6.1 Public concern about the environment has been increasing in the developed world since the 1960s and is now growing rapidly in the developing world. In the UK (United Kingdom) all the main political parties have well-developed environmental agendas. Most of these concerns about the environment are ethically based and the majority centre on welfare, both the welfare of people living now and the welfare of future generations. Obviously, if the resource base provided by our environment became so depleted or damaged that it could not sustain human life, the loss of welfare would be infinite and the moral responsibility of those who bring about such ecological disasters undeniable.
- 6.2 Less tangibly, another component of welfare takes the form of the pleasure that is derived from living alongside elements of the natural world, or perhaps even the pleasure of knowing that they still exist somewhere and could be visited. Issues of rights are also at stake. One particular conflict of rights is between the rights of some people to exploit the environment in pursuit of a livelihood, as against the rights of others who want to preserve the environment as an amenity.
- 6.3 Some people argue that the environment, or perhaps the living organisms that comprise it, have rights of their own. This is a difficult argument. Entities that possess rights usually, although not always, possess the ability to waive their rights and to make choices about how they exercise them. Plants and animals certainly cannot pass that test. At another level, rights are often thought to protect the vital interests of creatures that cannot make choices for themselves: babies and unconscious people have rights even when they cannot make choices. It is a stretch of the imagination to think that plants have vital interests, as distinct from human beings having vital interests in what happens to plants, although many people feel that non-human animals can be said to have vital interests.
- 6.4 Some of those who argue that genetic modification (GM) is intrinsically wrong, or 'unnatural', do so from a position that the environment has rights, including the right not to have species boundaries violated. Such views may come from either a religious or secular perspective. Whether we accept the idea of rights for the environment or not, this could be taken as a way of saying that human beings have no right to act in a way that violates such boundaries. Such views have something of an 'unarguable' quality, inasmuch as no amount of information, explanation or rationalisation would move a person with such views from their position. In addition, they present the problem of how, democratically, such views can be taken into account when it is uncertain whether they are in the minority or majority.
- 6.5 Others raise issues of 'naturalness' as a way of expressing uneasiness about what genetic modification means for our relationship with the natural world. Although they are prepared to accept that we already live with considerable human intervention in the environment, particularly in the high intensity agriculture involved in modern food production, genetic modification seems like a 'step too far'. Indeed, the advent of genetic technology may have prompted some people to reflect on just how far we have come in terms of our interventions, in gradual steps, and to question these interventions from a fresh perspective. Such reflections have been an important contributor to the rise in interest in organic farming. The problem with taking account of such views is that, in the absence of detailed knowledge about the technology, people may not be able to say precisely what boundary is being breached, and feelings about those boundaries will differ from person to person. For some the limit might be the introduction of human genes into crops. For others it may be the presence of animal genes or of even any gene that could not have reached its destination through 'conventional' breeding techniques.<sup>1</sup>

As yet only copies of plant genes and modified copies of bacterial genes have been used in commercially released crop plant varieties. For some the fact that these modifications transcend the range of transfers allowed by 'conventional' breeding means this limit is already crossed.

- 6.6 These reactions raise important public policy issues. One is the difficulty in assessing just how far these concerns might be traded off against the perceived benefits of the technology, such as the price of food, or the self-sufficiency of a country's food supplies. None the less, it should be an objective of public policy to understand these concerns more fully and to take them into account when regulatory guidelines or legislation are being drawn up. The articulation of an ethical framework for the development and control of genetic technology, particularly a framework that requires a statement of what is considered acceptable and unacceptable by society, would help to draw out consensus on the dominant ethical questions.
- 6.7 Other ethical considerations to do with the environmental impact of GM crops are based on welfare in a more straightforward way. They are concerned with the consequences, rather than the intrinsic rightness or wrongness of manipulating genes. Having said this, it must be recognised that, as a recent Church of Scotland study of the ethics of genetic engineering<sup>2</sup> points out, people bring their intrinsic values and judgements to bear on their arguments about likely consequences, whether they are comfortable with the use of or against the technology. Thus, proponents of the technology citing practical benefits may have an intrinsic value system that views science and progress as good things in themselves, and opponents may be analysing risks from a world-view that questions the rightness of technological progress.
- 6.8 The dominant welfare-based concern is that genetic modification, like some other technological advances, will not be an unqualified success and that we risk damaging the economic and amenity resources of the environment. Such concerns are more amenable to the traditional role of public policy in ensuring safety. They are not completely amenable, however, because of the difficulties in determining the nature and extent of any hazard. For example, we do not even have an agreed measure of the relative seriousness of different kinds of environmental harm. Such concerns also point strongly to the need to find ways of weighing risks against benefits, for without such a calculation it is impossible to judge the contribution either of GM technology as a whole, or individual applications of the technology, to the sum of human welfare.
- 6.9 The genetic modification of plants also raises questions of rights in relation to environmental impact. For example, do seed companies, farmers and the food industry have a right to pose environmental risks, however small, in pursuit of benefits, whether these are profits, consumer benefits, or both? On most understandings of rights, individuals and others have a right to risk their own well-being, but not to risk that of others. Conversely, it may be that those who wish to protect the environment might have the right to forgo their own rights, to avoid limiting other people's economic benefits. It is the responsibility of governments, acting on wider considerations than safety assessments alone, to balance these interests. A balance needs to be struck between the legitimate desire of farmers to provide a livelihood for themselves and their families, the reasonable demands of the food producers, retailers and the consumers, and the continuing need to maintain a sustainable environment for future generations.
- 6.10 There has been much emphasis in the public debate on the negative ways in which the genetic modification of plants could affect the environment. These do, however, need to be examined in the context of fluctuation in ecosystems, and we have therefore attempted to set such concerns alongside potential advantages. We discuss in Chapter 7 how far these possible negative impacts might be amenable to risk assessment, risk/benefit analysis, and control within an ethical framework. But first we pick up some general issues.

Bruce A and Bruce D (eds) (1998) Engineering Genesis: The Ethics of Genetic Engineering in Non-Human Species, Earthscan, London.

# How does genetic modification differ from 'conventional' plant breeding?

- 6.11 We have seen in Chapter 2 that conventional plant breeding techniques rely on the repeated crossing of closely related plants and the selection of those showing the most desirable characteristics. Genetic modification enables more rapid introduction of desired characteristics. Once the genes for the desired traits have been identified, they can be spliced directly into plant cells. However, as pointed out in that chapter, the immediate products of such plant transformations go through a series of extensive breeding trials. They are grown initially in closed greenhouses, then in isolated field plots, before further testing in a variety of crops and climates, in exactly the same way as the products of conventional plant breeding. All novel crops, whether obtained by genetic modification or by conventional cross-breeding, have to satisfy certain standards before they can be released. GM crops do not have a short-cut to the market.
- 6.12 However, genetic modification differs from conventional plant breeding because it expands the range of genetic material available to the plant breeder beyond that of related plants. Genes from bacteria, fungi, viruses and animals, as well as unrelated plant species, have already been successfully introduced into crop plants. One example is the Bt gene which is derived from bacteria and inserted into plants to provide protection against insects (see paragraph 2.33).

# The analogy between genetically modified crops and plant 'exotics'

- 6.13 Political decisions to regulate GM plants were taken largely on the basis of experience with 'alien' or 'exotic' organisms. In most countries there are many thousands of plants and some animals which are not native, but have been introduced either deliberately or accidentally. Our gardens and parks are full of plants that have been introduced, over a period of about five hundred years, from all over the world. The Victorian plant hunters were particularly active. Exotics have flourished in the new environment and are to be found in every garden centre. A few flourish to the extent that they become pests, to the detriment of native species and, possibly, to economic activity. The mussels that clog up Canada's lakes, rabbits in Australia and the grey squirrels that have nearly pushed out the UK's native red squirrels are well-known examples. Plants get less attention, but rhododendrons, Japanese knot-weed and giant hogweed are all considered serious pests in some UK environments.
- 6.14 So just how exotic are GM plants? Clearly the answer must depend on the nature of the new genes. Although all are exotic in the sense that the particular genetic combination achieved will not have been released into the environment before, few are likely to cause problems, just as few exotic introductions cause problems. Critics of the analogy with exotic organisms argue that conventional introductions that cause problems are more likely to be radically different from anything present in that environment before. In the case of GM plants, a familiar crop with a few, often very few, genetic changes is involved.
- 6.15 It is not generally realised that crop plants are usually uncompetitive outside their normal agricultural environments, since they have been bred for characteristics that humans want, at the expense of traits that enable them to flourish in wild conditions. One such crop is wheat. However, if the genes inserted were to increase the plant's competitive ability in any way, there may be potential to disrupt natural eco-systems. The finding from the GM plants studied to date is, on the one hand, that introduction of the foreign gene does not increase the plants competitiveness in the wild, and if there is no selection pressure for maintenance of the transgene, then the transgene itself may be lost

in a few generations. $^3$  On the other hand, a recent research report suggests that GM insect-resistant rapeseed survives better in a wild environment than non-GM oilseed rape, so caution is required and further research is vital. $^4$ 

- 6.16 Accordingly, it is the traits that increase competitive behaviour that are of primary concern. These traits involve genes that increase general vigour and growth, genes which increase a crop's ability to survive outside the normal agricultural environment or genes which affect 'fitness' in any way. A plant's ability to spread its genes to near relatives is also a concern, in case the near relatives take on competitive characteristics. Some crop plants are effectively 'biologically isolated'. They have no near relatives with which they can interbreed and there is therefore no risk of genetic transfer. For example, maize and potatoes have been developed from plants endemic to South America and have no European relatives with which they can hybridise.<sup>5</sup>
- 6.17 Oilseed rape and sugar beet, however, have been developed from European native plants and both have been shown to be capable of transferring genes to related wild species. Thus, the risk of 'transgene escape' is related to the environment in which the crops are being grown. GM potatoes in South America would raise more concerns about genetic transfer than would the same crops in Europe. We consider that the analogy with exotics has been a helpful one in regulating the release of GM crops.
- 6.18 Research is currently being carried out into ways to limit interspecies hybridisation. The pollen dispersal and gene flow of transgenic crops has been studied<sup>8</sup> and is being compared to data about similar, non-transgenic crops.<sup>9</sup> This allows assessments to be made about the distances GM crops must be planted from wild relatives and other plants to reduce risks of hybridisation. Research is also being carried out into ways to prevent pollen-mediated transmission of transgenes by ensuring that transgenic DNA (deoxyribonucleic acid) is not incorporated into pollen (see paragraph 2.29).<sup>10</sup>

# What benefits and risks do GM crops bring to the environment?

6.19 A considerable amount has been said and written already about both the potential benefits and risks to the environment of GM plants, but we are only beginning to accumulate the data that will enable us to evaluate precisely the pros and cons of these issues, or more correctly, series of issues. This is an argument for continued, controlled research. If further research indicates that some particular applications of GM technology pose such risks to the environment that they should not go into commercial production, they should be withdrawn. The most difficult aspect of the discussion of risks and benefits is whether to develop a mechanism for weighing them up against each other. This is not an explicit part of our current policy and regulatory approaches. The arguments for and against doing so are explored further in Chapter 7.

See, for example, Brookes M (1998) Running Wild, **New Scientist**, No. 2158:38–41 and the discussion reported in Masood E (1999) UK gets the green light on modified crops, **Nature**, 397: 286.

Stewart C, All J, Raymer P and Ramachandran S (1997) Increased fitness of transgenic insecticidal rapeseed under insect selection pressure, Molecular Ecology, 6: 773–779.

Raybould A and Gray A (1993) Genetically modified crops and hybridisation with wild relatives: a UK perspective, **Journal** of **Applied Ecology**, 30: 199–219.

Mikkelsen T, Andersen B and Jorgensen R (1996) The risk of crop transgene spread **Nature**, 380:31; Timmons A, O'Brien E, Charters Y, Dubbels S and Wilkinson M (1995) Assessing the risks of wind pollination from fields of genetically modified *Brassica napus ssp. olifera*, **Euphytica**, 85:417–23.

<sup>7</sup> Brookes M, Running Wild, p. 38–41.

For example Scheffler J (1993) Frequency and distance of pollen dispersal from transgenic oilseed rape (*Brassica napus*), **Transgenic Research**, 2:356–364; van Raamsdonk L and Schouten H (1997) Gene flow and establishment of transgenes in natural plant populations, **Acta Botanica Neerlandica**, 46:69–84.

<sup>9</sup> Hokanson S, Hancick J and Grumet R (1997) Direct comparison of pollen-mediated movement of native and engineered genes, **Euphytica**, 96:397–403.

Daniell H, Datta R, Varma S, Gray S and Lee S (1998) Containment of herbicide resistance through genetic engineering of the chloroplast genome, **Nature Biotechnology**, 16:345–348; Gray A and Raybould A (1998) Reducing transgene escape routes, **Nature**, 392: 653–654.

# Potential benefits to the environment as a consequence of using GM technology

- 6.20 Reductions of inputs: widespread use of GM crops, particularly herbicide-tolerant crops, in the United States (US) and Canada is producing data about changes to herbicide regimes. The most immediate benefit is an increase in yield due to the introduction of herbicide-tolerant or insect-resistant crops. It may be for this reason that the planting of GM soya has spread so quickly in the US, growing from 2% to 15% to 40% of the annual crop in three successive years. Zeneca, which produces tomatoes with improved shelf life, has data about energy and water savings as a consequence of the tomatoes being easier to process. There are also figures for pesticide reduction as a consequence of the in-built pest-resistance strategies beginning to be used on a commercial scale. A valuable summary of the data that are currently available is to be found in the recent House of Lords report on the regulation of GM crops. 11
- 6.21 Improved agronomic practice: besides the reductions in inputs of chemicals, energy and water, other possible benefits may accrue from changes in agronomic practice. 12 For example, experience in the US and Canada shows that the more efficient weed control gained by use of herbicide-tolerant crops allows the farmer to sow directly into unploughed land. This leads to a reduction in soil moisture loss and a small increase in the length of the growing season. The use of herbicide-tolerant crops may also be beneficial where soils are prone to erosion, or where they have become damaged, for example through increased salinity after inappropriate irrigation.

# Concerns about possible environmental changes as a consequence of using GM technology

- 6.22 Concerns about the introduction of herbicide-tolerant crops: one of the first developments in this new field has been the introduction of herbicide-tolerant crops, where the crop is engineered to be tolerant to a broad-spectrum herbicide (see Chapter 2). The fact that the crop can be sprayed and be unaffected means that farmers can control a wide variety of weeds and control them early in the growing cycle. The alternative is repeated spraying of herbicides specific to certain weeds. Also, it is argued, the broad-spectrum herbicides are less persistent in the soil than alternatives and are therefore less environmentally damaging.
- 6.23 Critics argue that the development of GM crops is perpetuating chemical use, when the goal should be to move away from it. Much of the difficulty of these discussions is to decide what kind of agriculture should be used as a basis of comparison; either conventional high-intensity agriculture, or integrated pest management, or organic farming. On the one hand, critics of GM crops are unconvinced that the broad-spectrum herbicides can be termed 'environmentally friendly', citing evidence of damage to aquatic life. They are also concerned that use of broad spectrum herbicides will leave even fewer weeds in fields than in intensive agriculture, and this will further threaten the already diminishing farmland wildlife, particularly insects and the birds that rely on them for food. On the other hand, if yield increases meant that marginal land could be taken out of cultivation and returned to the wild, then the use of GM crops might tip the balance the other way. This may be more of an option in some countries than in others.
- 6.24 Critics of the introduction of herbicide-tolerant crops also argue that if unwanted herbicide-tolerant crop plants were to become a problem in the following season's crops, a less acceptable herbicide

House of Lords Select Committee on the European Communities (1999) **EC Regulation of Genetic Modification in Agriculture** (Session 1998–99 2nd Report), The Stationery Office, London, p 21.

James C (1998) Global Review of Commercialized Transgenic Crops, 1998. ISAAA Briefs No 8, ISAAA, Ithaca, pp 12–16.

might have to be used to control them although this might only mean reverting to current agricultural practice. The example of herbicide-tolerant crops illustrates for many the need to consider the cumulative environmental impacts of GM crops, that is, in terms of the agricultural context in which they will be used. Research is being carried out by the UK Ministry of Agriculture, Fisheries and Food (MAFF) and the Department of the Environment, Transport and the Regions (DETR) into the environmental effects of, and biodiversity surrounding, farm-scale plantings of herbicide-tolerant crops which took place in Spring 1999. Research into the biological diversity of areas surrounding herbicide-tolerant crops is currently being carried out.

- 6.25 Several accounts of such work have appeared in 1999. A recent press report entitled 'Bees "spread genes from GM crops'"13 described work with oilseed rape from the Scottish Crop Research Institute in Dundee. 14 The scientists measured the amount of gene flow through pollen dispersal in an agricultural context, and found that although the density of pollen declined rapidly with distance from the source, as would be expected, pollination occurred up to four kilometres from test sites, much further than expected, probably carried by bees. They concluded that 'farm to farm spread of OSR (oilseed rape) transgene will be widespread'. A second paper described a modelling approach to the long-distance pollen movement. 15 A third paper at the same conference also described research using oilseed rape. It found that 7% of seed set on male sterile plants placed at 400 metres from a GM crop were herbicide-tolerant. 16 While this use of male sterile 'bait' plants is a deliberate worst case scenario, <sup>17</sup> these results are pertinent to current discussions on protocols for GM crops: and particularly for organic farmers wishing to prevent cross pollination. But there are also implications for cross-farm boundary pollen spread for conventional agriculture. This cross pollination in oilseed rape has already been recognised as a problem when edible oilseed rape crops are grown in close proximity to industrial (non-edible) oilseed rape crops, and indeed, there is already a standard isolation requirement for industrial crops to maintain the quality of the product.<sup>18</sup> This approach will need to be extended in order to ensure that any spread of transgenes into organic or non-GM crops remains below agreed thresholds. The implications of cross-pollination between GM and non-GM or organic crops for labelling of food products is discussed in paragraph 7.53.
- 6.26 There is no suggestion that the pollen from GM plants behaves differently in any way from that from non-GM plants, so presumably such cross pollination has been occurring for several years. It should also be borne in mind that farmers have alternate strategies available: thus, if 'volunteers' 19 become resistant to one particular herbicide, the farmer can still use a number of other herbicides or crop rotation to control the problem. The transfer of herbicide-tolerance would only be relevant to areas where herbicides are used.
- 6.27 Concerns about the introduction of insect-resistant crops: plants that are modified to carry integral pesticide genes, such as the gene for Bt toxin, poison target insects as soon as they start eating the plant (paragraphs 2.5, 2.33). The advantage of this approach is that it may be seen as a more environmentally friendly option than spraying crops with chemical pesticides. As an example, a recent report suggests that the use of Bt-cotton has decreased the amount of insecticide sprayed

Nuttall N (1999) Bees 'spread genes from GM crops', The Times, 15 April 1999.

Thompson C, Squire G, Mackay G, Bradshaw J, Crawford J and Ramsay G (1999) 'Regional patterns of geneflow and its consequence for GM oilseed rape' a paper presented at a conference titled Gene Flow for Transgenic Crops, University of Keele, 12-14 April 1999

Squire G, Crawford J, Ramsay G, Thompson C and Bown J (1999) 'Gene flow at the landscape level' a paper presented at a conference titled Gene Flow for Transgenic Crops, University of Keele, 12–14 April 1999.

Research by Sweet J and Simpson E was cited in: Coqlan A (1999) Gone with the wind, New Scientist, No 2182: 25.

Male sterile 'bait' plants are the worst case scenario because they do not produce any pollen of their own and can therefore 17 be described as 'hungry for pollen'.

oilseed rape crops.

<sup>19</sup> A 'volunteer' is an unwanted crop plant self-propagated from previous year's crop.

- in the US by 250,000 gallons in  $1996.^{20}$  Yield increases averaged 7%, and insecticide savings were US\$140 to US\$280 per hectare, while the farmers paid a 'technology fee' of US\$75 per hectare, resulting in an overall saving of US\$77 per hectare.
- 6.28 However, there are concerns on three fronts. First, such crops might achieve a more efficient and comprehensive kill of pests than spraying (which inevitably misses a certain number of insects). This would result in less food for birds and other animals further up the food chain. Secondly, a high level of killing would exert strong selection pressure on any resistant insects, so that the pest resistance might quickly become ineffective. This might force farmers to go back to spraying. Thirdly, inbuilt pest resistance might affect non-target species, including susceptible beneficial insects which feed on pest species.
- 6.29 Preliminary research into insect predators which prey on crop pests suggests that the consumption of pests which have eaten Bt crops does not harm the predators. However, a recent laboratory study on lacewings suggested that effects on non-target species were possible, but there are as yet no corroborative field data. A similar result has been reported for a system involving transgenic potatoes expressing the snowdrop lectin gene for aphid resistance, aphids and predatory ladybirds. The authors found that the expression of the lectin gene could cause an adverse effect on the predatory ladybirds via aphids in its food chain. These scenarios are possible under conventional spraying regimes, but environmentalists argue that if inbuilt pest resistance is to be presented as environmentally preferable to current chemical treatment, it should have less impact on non-target species. This comment is a good illustration of the different perspectives that are brought to the debate about GM crops. Those generally in favour of the technology concentrate on the reduction in chemical use; while those against concentrate on the failure of this approach to achieve their goal, that of a transition to an environmentally-friendly agriculture.
- 6.30 Such research raises important questions about how extensive non-target effects might be. Further research over several generations of pest predators will be required to determine whether crops with insect-resistance genes such as Bt have any long-term effect on them. An additional issue is whether, in a field of GM plants, some fraction (and 20% has been suggested for Bt corn), should be sown with a conventionally bred equivalent, in order to reduce the development of pest resistance.<sup>24</sup>
- 6.31 Concerns about creating new viruses: viruses cause extensive damage to a wide variety of important agronomic crops, costing several million pounds per annum in the UK alone.<sup>25</sup> Virus resistance was one of the first targets for genetic modification of crops, as plant viruses have a relatively simple genetic make-up, the function of which is reasonably well understood. One strategy involves taking just part of the genetic material of a plant virus and inserting it into its host plant. The viral genes act in a similar way to a vaccine, conferring on the plant some resistance to the virus. However, the use of virus particles in plants in this way has raised some concerns.<sup>26</sup> The concern is whether different
- James C (1997) **Global Status of Transgenic Crops in 1997**, ISAAA Briefs No. 5. ISAAA, Ithaca, New York, p 13.
- Riddick E and Barbosa P (1998) Impact of Cry3A-intoxicated Leptinotarsa decemlineata (Coleoptera: Chrysomelidae) and pollen on consumption, development, and fecundity of Coleomegilla maculata (Coleoptera: Coccinellidae), Annals of the Entomological Society of America, 91: 303–307; Pilcher C, Obrycki J, Rice M and Lewis L (1997) Preimaginal development, survival, and abundance of insect predators on transgenic Bacillus thuringiensis corn, Environmental Entomology, 26:446–454.
- Hilbeck A, Baumgartner M, Fried P and Bigler F (1998) Effects of transgenic *Bacillus thuringiensis* corn-fed prey on mortality and development time of immature *Chrysoperla carnea* (Neuroptera: Chrysopidae), **Environmental Entomology**, 27.480–487
- Birch A, Geoghegan I, Majerus M, McNicol J, Hackett C, Gatehouse A and Gatehouse J (1999) Tri-trophic interactions involving pest aphids, predatory 2-spot ladybirds and transgenic potatoes expressing snowdrop lectin for aphid resistance, **Molecular Breeding**, 5: 75–83.
- Anon (1999) Monsanto concession on engineered corn, **Nature**, 397:98.
- 25 It is difficult to obtain accurate figures for viral damage to crops. One report suggests that four viruses in four crops cause 50–100 million damage per year. Wilson TMA and Davies J (1994) New roads to crop protection against viruses, **Outlook on Agriculture**, 23: 33–39.
- Robinson D (1996) Environmental risk assessment of releases of transgenic plants containing virus-derived inserts, Transgenic Research, 5:359–362.

viruses subsequently infecting the plant might incorporate some of the original viral DNA, giving rise to a new hybrid virus. The new virus might retain the outer coat and capacity to raise antibodies of the original viral DNA in the plant but retain other properties too. For example, the recombined virus might also retain the range of the original viral material. Experts differ considerably as to how likely this is to be a problem.<sup>27</sup>

- 6.32 Another new technique, still at the research stage, is to use a modified plant virus system to produce high value/low volume substances such as pharmaceutical drugs or antigens for vaccines. The coat protein of a plant virus is first wrapped around a viral genome modified to include the genes coding for the drug in question. The viruses are allowed to infect the host plants under strict biological containment, multiplying and producing the pharmaceutical as they do so. The plant material with its virus/pharmaceutical product is then harvested and the substance purified. Since yields of the drug would be high, it would not be necessary to infect very large numbers of plants, and the products would, of course, have to be processed completely separately. This work, which is still in its early stages, has raised some concerns about the widespread introduction of GM viruses into the environment, although the scale and the degree of containment that would be appropriate have not been settled.
- 6.33 Concerns about possible changes in land use: another concern is whether GM crops would radically change land-use patterns. If the modification of a crop were to make it much more profitable than many other crops, farmers might switch to it on a large scale. Certainly planting patterns can change quickly, for example, the planting of oilseed rape and linseed have greatly increased in popularity in recent years due to changes in the subsidies from the CAP (Common Agricultural Policy). <sup>28</sup> It is impossible to predict whether commercial advantage, and hence the effect on planting patterns, will be changed as much by genetic modification as by the CAP, which is now overdue for reform.
- 6.34 So it could be argued that, in a time of falling farm incomes, farmers should not be lightly prevented from attempting to maintain their incomes. However, it is also possible that the introduction of crops that could grow on previously unusable land, such as arid or salty areas, might mean that marginal land, which may be of ecological interest, is taken for agriculture.

# Loss of biodiversity

6.35 Loss of biodiversity: the proposed introduction of GM herbicide-tolerant and insect-resistant crops into UK agriculture has led to a range of concerns about the potential impact on wildlife. The intensification of agriculture has already led to a serious decline in the populations of several farmland birds in the UK. Over the past 25 years several species, including the skylark, reed bunting and grey partridge have declined in numbers by more than 50%. Many aspects of intensified farming are making survival more difficult for farmland birds by reducing the amount of food available, including the removal of field margins and hedgerows, harvesting crops early and planting cereals in the autumn rather than the spring. The harmful effects of pesticides and herbicides have been demonstrated by case study research on the grey partridge.<sup>29</sup> The UK government has committed itself to higher population targets for recovery of these declining farm birds. The Royal

Royal Society (1998) **Genetically Modified Plants for Food Use**, Royal Society, London, p 11.

MAFF, SOAEFD, DANI and the Welsh Office (1998) Agriculture in the United Kingdom 1998 The Stationery Office, London.

Harm was caused by damaging the food chain of the grey partridge. The reduction of weeds through the use of herbicides resulted in fewer insects, the staple diet of the grey partridge chicks. Chick survival increased dramatically if the outer edges of wheat crops were not treated with herbicides or pesticides (Campbell L H, Avery, ML, Donald P, Evans A D, Green R E and Wilson J D (1997) A Review of the Indirect Effects of Pesticides on Birds. JNCC Report No 227, The Joint Nature Conservation Committee (JNCC), Peterborough.

- Society for the Protection of Birds (RSPB) fears that the commercial introduction of some types of GM crops could prejudice the recovery of these bird populations.<sup>30</sup>
- 6.36 The RSPB and other organisations such as English Nature<sup>31</sup> are most concerned about the introduction of herbicide-tolerant and insect-resistant crops as they may further reduce the food supply available for farmland birds. Inbuilt pest resistance might also affect non-target species (paragraph 6.29). Currently, broad spectrum herbicides cannot be used for most broad leaved crops although they are widely used in cereals. Use of broad spectrum herbicides such as Roundup will further reduce the weed populations in a wide range of GM Roundup-resistant crops. However, the degree of reduction and its impact on bird populations in a given environment is uncertain.
- 6.37 The weeds of most use to birds are located around the edge of fields. Although increasing field margins in GM plantings might appear to offer a means of redress for the weed loss in the fields, such an approach might lead to crops which have unacceptably high levels of weed seed.<sup>32</sup> The use of refuges on farmland may well have more potential to enable farmland bird populations to recover from the decline caused by the intensification of agriculture and any additional pressures created by the introduction of GM crops. Research to assess the cumulative impact of GM crops on the biodiversity and potential value of refuges on farmland is urgently needed to be establish best practice.
- 6.38 Loss of genetic diversity: another concern that has been raised is that the introduction of these new technologies will lead to a loss of genetic diversity within our crops. The argument is that the practical and infrastructural costs of using the technology will be such that breeders will be motivated to develop and aggressively market only a small number of highly bred varieties, which will not be representative of genetic variation within the species. But this is not very different from the situation in modern high input agriculture. In the 1970s, as noted in paragraph 2.4, it was necessary to introduce a string of wheat varieties with new resistance genes as the prevalent pathogens, particularly yellow rust (*Puccinia striiformis*) repeatedly overcame the disease resistance genes.
- 6.39 The same outcome might have been predicted from the implementation of F1 hybrid technology in maize breeding. The extra costs and infrastructure for the production of hybrid seed might have been expected to focus breeders' efforts on the promotion of a limited range of germplasm. But this did not happen, and the outcome for the introduction of GM crops might be the same. For example, it is certain that there will be a number of alternative herbicide-tolerant soya varieties on the market in the US quite soon. However, the possible reduction of available crop varieties does underline the need to ensure that plant breeding is supported in the public sector so that a sufficient number of varieties are kept in circulation (see paragraph 4.77).
- 6.40 Concerns about extensification versus intensification: critics of GM technology often assert that it will lead to greater intensification of agriculture, and hence to greater environmental damage, including the indirect effects on wildlife of all sorts. However, extensive agriculture is not necessarily environmentally benign, since it could mean extending agriculture into valued natural habitats and thus losing biological diversity. In the longer term, extensification could result in erosion of productive resources if the marginal lands annexed for agriculture are ecologically and agriculturally fragile. Changes in intensive farming, with the introduction of GM crops leading to environmentally sensitive land being taken out of agriculture and restored to its previous state, although expensive, would tip the balance the other way.

Avery, M (1998) Personal communication, the Royal Society for the Protection of Birds, UK.

**English Nature**, response to the Working Party's Consultation and Johnson, B (1998) Personal communication, English Nature, UK.

<sup>32</sup> Barber V (1999) Personal communication, National Farmers' Union.

For example see English Nature Clarifies its Position on Genetically Modified Crops, English Nature Press Release, 12 February 1999.

- 6.41 Concerns about 'genetic pollution': some critics of the technology see the transfer of genes to places that they could not have reached naturally as a form of 'genetic pollution', even if that transfer has no immediate or imaginable deleterious consequences. For them, it is an extra form of 'loading' on the environment which is already under enough stress from man's activities. This kind of position, which revolves around the presence of new genes rather than their effects, is more problematic than the kinds of concerns outlined above, although it is still in essence a 'welfare-based' concern. It is strongly linked to the idea that, owing to the complexity of the environment, risk assessment will always be fraught with uncertainties and it is therefore impossible to fully predict or evaluate the long-term environmental consequences of releases fully.
- 6.42 Concerns about the nature of GM technology: plant breeders using GM techniques often make the point that the technology is more precise than conventional plant breeding. The claim to precision is fair in the sense that once the desired gene is identified, it can be introduced into the crop plant in fewer steps than would have been required by conventional techniques, if indeed it could have been achieved by conventional techniques at all. Moreover, in conventional plant breeding unidentified genes in novel combinations will always be present in any new variety. However, critics say that plant scientists cannot always know the effects of the gene once it is inserted. Such unexpected consequences do not necessarily mean that the technology is unsafe, as most side-effects are likely to be recognised well before a plant is released, but they do point to the need for vigilance in the regulatory procedure.
- 6.43 As to the 'smallness' of genetic changes, this may be an unhelpful way to describe them. In humans, sickle cell anaemia is caused by only a single base-pair change in the beta globin gene.<sup>34</sup> Similarly, a very limited change can make a plant sterile, make it flower early or late, or change its colour. Thus the scale of the genetic change in terms of base pairs is not always related to the scale or impact of the consequence. Of much more importance is how the functioning of a plant's genes has been changed and whether the change will be stable and predictable if inherited by wild relatives.
- 6.44 So, although proponents of genetic engineering often present GM technology as no more than a simple extension of conventional plant breeding, it is an extension that involves considerable extra power, and some greater uncertainties about long-term impacts. Researchers have uncovered some unexpected properties of transferred genes, including different effects depending on where or how many copies of the gene have been inserted. However, the effects described, although unexpected, have not led to the production of 'genetic monsters'. They do, nevertheless, argue for a careful, thorough regulatory process, on a case-by-case basis. The need for a large-scale assessment of the cumulative effects of GM crops is discussed in Chapter 7.

# Conclusions

6.45 There is a complex set of possible environmental impacts, both positive and negative, and an equally complex set of ethical considerations covering both the intrinsic (is this wrong in principle?) and the consequentialist (are we creating problems for ourselves?) issues. Ways in which a balance might be struck between these concerns are discussed in Chapter 7.

From principles to policy

### **Principles: recapitulation**

- 7.1 The introduction of genetic modification (GM) technology needs to be assessed by the principles according to which we would judge any policy or practice, the principles of welfare, rights and justice. So much is a matter of general agreement. However, there are also those who argue from religious or other fundamental beliefs that genetic modification is inherently unnatural and should be forbidden; or as a fall-back position, that they should be protected from having any such modification in their own food and environment. This argument is in conflict with the view that public policy on the use of genetic modification in plants should be guided by the same kind of risk assessment and cost–benefit analyses that are applicable in many other areas of public policy. There are also many intermediate strands of opinion. Some people find some types of genetic modification unobjectionable, but regard others as going 'too far'. This is, however, slippery territory as there do not appear to be any clear dividing lines in the science that would provide a generally acceptable a priori boundary to what constitutes going 'too far'. Therefore, those who are prepared to accept any genetic modification at all are effectively driven into the second camp of examining each case or type of case on its merits, using risk assessment and weighing up costs and benefits.
- 7.2 Modification of existing stock to breed new plant varieties and combinations has been practised successfully for centuries, and techniques have evolved for creating, selecting and promoting successful variations and eliminating unsuccessful ones. Such conventional breeding methods have themselves over time produced large modifications in the genetic inheritance of all cultivated plant varieties. Changes brought about by the new techniques for modifying genes directly, rather than through selective breeding, do not appear to us to be so fundamentally different in kind that they should all be banned outright as a matter of basic principle.
- 7.3 We also recognise the theoretical potential of the genetic modification of plants to bring substantial benefits to the world. Crops of many kinds could be improved so as to increase yields and quality in various ways. Properly managed increased yields could, in turn, help to lessen food shortages and malnutrition in the poorer parts of the world, as discussed in Chapter 4. There are, however, some risks which need to be guarded against carefully. But, in our view, it would a mistake to allow fear of the possible risks to rule out the potential benefits of a well-managed development and introduction of the new crops.
- 7.4 This does not, however, mean that we consider the concerns about genetic modification to be misplaced. There may indeed be no fundamental ethical difference between the new GM technologies and all the other ways in which humans have modified plants and their environment over time. But the introduction of GM technologies is clearly one of the most far-reaching technological changes in agriculture of our generation. This change needs careful handling so as to minimise risks and optimise benefits.
- 7.5 GM techniques have the potential to bring about novel changes to plants and crops more easily and more quickly than conventional breeding methods. This is the source both of potential economic benefits and of concerns. Special features include:
  - the novelty and power of the techniques employed;
  - the extent of cross-species genetic transfers that are made possible by genetic modification;
  - the potential irreversibility of some modifications to the environment and the food-chain;
  - the speed with which modifications will become possible, and once possible, may become universal in parts of agricultural practice, if seen to have an economic advantage;
  - the completeness of control of agronomic aspects of plant cultivation which GM techniques

- the extensive scientific and economic control of GM technology which major multinational companies appear to be establishing.
- 7.6 The economic effects also need to be considered. There is concern that some GM plant varieties may be so commercially successful that they rapidly become dominant or universal in the market place, and marginalise unmodified competitors. Although this is unlikely to occur in the United Kingdom (UK) (paragraph 3.10), adoption of GM soybean and cotton varieties in the United States (US) has increased substantially over the past two years. There are fears that introduction of GM material in foods might reduce consumer choice. Yet, this has been the normal way in which food production has developed, and the continuing fall in food prices that development has brought has been of great benefit to the consumer.
- 7.7 To respond to these concerns, as well as to take advantage of the opportunities that this new technology offers, there must clearly continue to be strong and effective regulatory controls. These controls must ensure that the introduction of GM plants and crops is only allowed after careful risk assessment, and under conditions which allow appropriate levels of monitoring of their impact on health and the environment. There must also be the possibility of appropriate sanctions such as revocation or modification of consent if problems were to emerge. The introduction of GM crops is being led by a group of major multinational companies who have the potential to bring about very significant changes in agricultural practices and in the economic and social structures of agriculture, initially in the developed world. It will be important to try to ensure that the benefits are spread widely, and that the risks are not discounted because of commercial pressures.
- 7.8 Some of the present level of concern appears to stem from a lack of information about genetic modification and its possible consequences (paragraphs 5.34–37). There needs to be a much greater effort to spread knowledge and understanding about the processes of genetic modification, what it can and cannot achieve, what risks there are and how they are being guarded against. If it is to be handled successfully, it is important that there should be full public knowledge of the developments that are taking place. In addition, the public should so far as possible be consulted.
- 7.9 It is quite possible that fears will diminish as knowledge spreads and familiarity with these technologies becomes more widespread. The use of GM technologies under proper controls and safeguards would then become more generally acceptable. The Working Party considers it important, however, that this should not be regarded as a foregone conclusion that will eventually be arrived at, even if nothing were to be done. It is likely that, with proper controls, the kinds of GM introductions that are currently being contemplated have very small risks. But the risks are not zero, and the possibility cannot be excluded that new or more remote adverse consequences may only be discovered after a longer time.
- 7.10 The BSE (bovine spongiform encephalitis) debacle is still very much in everyone's mind. It shows that what initially seemed to be a very small risk can sometimes have devastating consequences in the longer term. It underlines the importance of open and rigorous regulation, free of political control and rigorous implementation of such controls. The BSE case also underlines the importance of listening to the public and the different groups within it, as well as disseminating knowledge. It has been impressed on the public that one cannot always rely on government departments to get the right balance of risk assessment by themselves alone, especially if they are perceived as being too much influenced by producers' interests. This indicates the importance of consulting wider groups about the operation of the regimes controlling the new techniques and practices which may affect everyone's food or environment.
- 7.11 Even with such strengthening of the regulatory regimes and spread of public understanding and involvement, there are many people who would at present prefer not to have genetic modification affect their own food or environment, either as a consequence of their beliefs or because of their

- scepticism about the adequacy of the safeguards put in place against risks. It is not clear what their response would be if they were brought into consultation; some would undoubtedly remain opposed, but some, having listened to the arguments and made a contribution, might then be content for the changes to go ahead.
- 7.12 We do not think the views of those who strongly oppose the new technology are so widespread or based on such a well-founded risk assessment that they should themselves be a ground for a policy of banning outright the use of genetic modification in plants, or for a moratorium on their further introduction. A ban would stifle innovation, and frustrate those other groups who want to make legitimate use of the improved or cheaper products which genetic modification potentially offers. Given the existence of such fundamental doubts by some about the use of GM plants, and a degree of continuing uncertainty about their possible long-term effects, the protection of diversity and of choice is itself an important objective. We consider that there is a strong case for policies to preserve as much choice as possible. To enable such choices to be exercised effectively, some food products and environments that do not contain GM material would have to be maintained.
- 7.13 How far is this judgement consistent with acceptance of the precautionary principle? We noted in Chapter 1 that on a stringent definition of the precautionary principle there could be no balancing of the risk of harms with the benefits of innovation, since even a suspicion of possible harm, no matter how ill-founded, would be sufficient to prohibit a new technology. However, we do not hold that the precautionary principle is plausible in this stringent form. Its adoption would preclude almost any innovation, since there can be unknown or hidden risks associated with any technical change. There are no good reasons, deriving from a concern with the general welfare, to apply a more stringent test of acceptability to GM food technology than to any other innovation that carries health risks. Moreover, there is sufficient experience from field trials and commercial planting for us to say that some of the worst fears are exaggerated. In a less stringent sense of taking steps to guard against unlikely or remote harm, we believe that our recommendations are consistent with the precautionary principle.
- 7.14 The denial of a licence to a GM maize variety carrying an antibiotic resistant marker gene (paragraph 2.48) shows that regulations can be cautious in the face of risks that, though very unlikely, cannot be ruled out entirely. In such cases, the principle of precaution is properly invoked to guard against the low probability that harm will be caused. Similarly our recommendation for post-licence monitoring (paragraph 7.40) is in the spirit of the precautionary principle. Although pre-release tests provide good grounds for thinking that products are safe, the principle of precaution requires us to monitor to ensure that the assumptions on which risk estimates are made are borne out in practice.

### The objectives of public policy bearing on the use of GM plants

- 7.15 Public policies have already been developed around the world to deal with some of these concerns and objectives. The release of GM plants into the environment and of GM material into the human food chain is subject to regulatory regimes, so that products and releases are carefully assessed before consents are given. In the light of the above analysis, the Working Party considers that a broader view of the objectives of public policy in this area now needs to be taken. We suggest a reformulation of the principal objectives of public policy in relation to GM plants along the following lines:
  - to continue to ensure that new introductions are subject to rigorous risk assessment procedures
    designed to identify from the outset, and minimise as far as possible, all risks both to the
    environment and to food;

- to continue to monitor the impact of the introduction of GM crops so as to ensure that both the individual and the cumulative effects of the introduction of GM plants on food production and on the environment are kept under review and that corrective action can be taken if any problems emerge;
- to maximise consumer choice, so that consumers are informed when GM material is included in food products and can exercise choice accordingly;
- to try to ensure that the introduction of GM crops into the developing world is handled in a way that brings true net benefits to the citizens of those countries and minimises adverse social impacts;
- to maximise the dissemination of reliable information;
- to determine ethical desirability.
- 7.16 Many groups and sectors of society are concerned with these issues and have a legitimate interest in the outcome. Some groups have doubts about the adequacy of the present regulatory regimes to handle all their concerns, and have varying degrees of mistrust about the ability of the regulatory bodies and those who advise them to deal with all the issues or to bring a wide enough perspective to bear. The Working Party concludes that it is important that a wider range of stakeholders in society should be consulted about the introduction of GM crops and the monitoring of impacts.
- 7.17 So far, regulatory controls have focused primarily on the assessment of each new GM crop and its proposed use under the legislation covering the first two items above. Environmental impacts are assessed both within the field or area where the plants are used and for potential for any wider spread from the area of planting. Impacts of the use of such plants in the food chain are assessed separately from a food safety perspective. There are also European measures concerning the labelling of food containing GM material.
- 7.18 We believe that such types of control were quite appropriate in the early stages of GM plant development, when criteria were being established, when every case needed individual attention, and when GM material was still only being used in a few cases in agriculture and in food. The controls are now in danger of giving us the worst of both worlds by slowing down the introduction of potentially beneficial new varieties, thus leaving the commercial advantage to countries, such as the US, which have streamlined procedures; and at the same time failing to adequately safeguard our environment. Moreover, by concentrating on the impact of the individual GM crop introductions, we may not focus properly on the combined impact of several GM crops on the environment and the food chain. There is a risk that the broader picture is not perceived.
- 7.19 We therefore recommend consideration of a more integrated policy stance. We suggest that wider policy measures to address the broader consequences of the spread of the use of GM plants in the environment and of GM material in food should be considered. In particular, we recommend consideration of:
  - a broadly-based environmental audit of the likely cumulative impact of GM crops on agricultural practices and the environment;
  - measures to ensure appropriate labelling of GM and non-GM food and to encourage food producers to produce lines of non-GM food, and retailers to stock them.
- 7.20 Currently, in relation to food supply, there is clearly public demand for food that does not contain GM plants (see paragraphs 5.11–20) and also for organic foods. In the longer term demand may not be strong enough to support significantly higher prices, especially if GM foods become more acceptable to consumers. Maintenance of a viable non-GM sector in the shops and in the supporting

- supply chain might therefore eventually require more explicit support from Government through agricultural subsidies and other means if it is not simply to be overwhelmed. Maintaining areas or regions of non-GM planting could be of some help here as a source of non-GM foods for those who wish to avoid them.
- 7.21 Some people are arguing for a moratorium on any further GM planting or use of GM material in food in the UK or Europe until additional research and monitoring has provided further reassurance that some of the risks are illusory or can be managed safely. We do not consider that such a moratorium would be the right stance. The Working Party recommends that the next step should be to allow some commercial planting of the most promising GM crops, on a limited and closely monitored basis, designed to identify and contain any adverse environmental and safety effects. At the same time we recommend that steps are taken to ensure that appropriate amounts of non-GM planting continue with a segregated production chain to support the availability of non-GM foods in the shops to satisfy that demand. In the next section we review the present regulatory regimes in the light of the above objectives and consider other policy instruments which could contribute to achieving the general objectives.

#### The regulatory regimes

- 7.22 The release and marketing of GM organisms (GMOs) into the environment is governed in the UK by European Directive 90/220/EEC with various subsequent amendments, Part VI of the Environment Protection Act 1990 and regulations made under that Act. The use of GM material in food is governed by EC Regulation 258/97 on novel foods and novel food ingredients and by UK regulations detailing how the European regulation is to be applied in the UK.<sup>1</sup>
- 7.23 The central purpose of the directive is to ensure that GMOs should not cause harm to the environment. It provides that such organisms cannot be released into the environment without the approval of a competent authority acting on proper scientific advice. The UK legislation contains more detailed rules and procedures for implementing the general purposes of the European directive. Similarly, the purpose of the novel food regulation is to ensure that GM foods should not present a danger or be nutritionally disadvantageous for the consumer, and should not mislead him or her.
- 7.24 The essential elements of the UK regime for release of GMOs include:
  - definitions of GMOs;
  - a brief definition of damage to the environment or harm which is to be avoided;
  - a general duty of care;
  - requirements for persons proposing to release or market any GMO to conduct comprehensive risk assessments first and report them to the Secretary of State;
  - a consent procedure for the Secretary of State to allow release in appropriate circumstances and on appropriate conditions;
  - a requirement to report to the Secretary of State the effect of such releases;
  - an Advisory Committee to assist the Secretary of State in deciding on such consents;

For a more detailed description of the regulatory regimes and comments on them see: House of Lords Select Committee on the European Communities (1999) **EC Regulation of Genetic Modification in Agriculture** (Session 1998–99 2nd Report), The Stationery Office, London.

- requirements for a register and publicity for releases, and for consents and conditions to be made available to the public;
- the normal procedures for inspections, prosecutions and enforcement.
- 7.25 In the UK there are three competent authorities, the Department of the Environment, Transport and Regions (DETR), the Health and Safety Executive (HSE) and Department of the Environment (DoE) (Northern Ireland), but DETR takes the lead in dealing with applications (see Appendix 2). They are advised in doing this by the Advisory Committee on Releases to the Environment (ACRE). To date 373 trial releases of GMOs have been authorised in the UK, some 12 products have been approved for regular use (primarily processing) with some 15 in the pipeline.
- 7.26 The Novel Food regulations have similar consent procedures, but are administered by the Ministry of Agriculture, Fisheries and Food (MAFF), and the Department of Health (DH), and a separate advisory body, the Advisory Committee on Novel Foods and Processes (ACNFP). A new GM variety intended to be planted as an agricultural crop for production of human food needs consents under both regimes and arrangements are in place for appropriate consultation between the relevant competent authorities in such cases.

### Weaknesses of the present regulatory regime

- 7.27 The present regulatory regimes have ensured that systematic checks are carried out before any new GM plant releases or any introduction of GM material into food. Having regard to the objectives identified above, the present regimes can, however, be criticised on a number of grounds. The way in which risks and benefits within the regulatory regime are weighed up is not explicit. Neither advisory committee has been charged with the responsibility for monitoring impacts, although consents can be withdrawn if adverse effects are detected. Nor is ACRE required to take account of the cumulative impact of multiple releases of many different GM plants. Although it has recently been asked to consider the environmental impact of changes in agricultural practices that GM plants may bring about, ACRE does not have any responsibility for safeguarding any areas of non-GM farming or environments. The ACNFP has, underpinning its decisions, the very considerable powers of the 1990 Food Safety Act. This Act provides the authority to maintain the safety of all foods that are sold to the public, and through this power, authority over the processing and manufacturing of food. The Food Advisory Committee (FAC), a committee which, like the ACNFP, has consumer representation, carries the responsibility for food labelling, an important way to preserve choice, but labelling decisions are controlled by EU legislation.
- 7.28 The legislation controlling the release of GMOs has been criticised for not taking such concerns sufficiently into account, either in the legislation or in the administration of the case work. Similar criticisms have been made that GM food products are being introduced into the food chain without giving people sufficient information or choice of alternatives to enable them to choose non-GM food if they wish. There is also the view that there are some aspects of the judgements that need to be made which are not purely scientific, but involve value judgements in which consumers will wish to be involved.
- 7.29 It is fair to ask how far it may be possible to address these problems by modification of the existing regulatory regimes and how far it may be necessary to consider solutions going wider than the scope of the present regulation. We consider that it should be possible to amend the current regimes to strengthen the risk assessment process in ACRE and to introduce extended monitoring of effects. It might also be possible to widen the acceptability of the processes by involving a more broadly based group of stakeholders in reviewing consents for releases by ACRE. Managing the cumulative or

indirect effects of GM plants on the environment, or ensuring the continued availability of non-GM food in the longer term requires quite different types of measures which we have not explored.

#### A broader basis for risk assessment

7.30 Risk assessment of the environmental and food health impacts of GM plants is the central core of the regulatory regimes. The current Advisory Committees already ask such questions as: 'What do we know about the host plant and its behaviour in the environment, and in the food chain?' and 'What do we know about the function of the genes that are being inserted, and the organism from which they been derived?' On the environmental side, the questions are: 'Are these genes likely to alter the competitive ability of the crop?', 'Can they be passed to close relatives?', 'Do they involve viruses, and if so, is there a risk of their escape?', 'What is the nature of the environment in which the crop is being grown?' and 'Is the crop being managed in any special way that makes a difference to the risks, for instance by not being allowed to flower?' With regard to food, questions include, 'Could the modifications harm humans in any way, or their resistance to disease?'

#### Risk assessment for the environment

- 7.31 Risk assessment involves identifying possible hazards and then ascribing a probability to each of them. For GM crops, this raises two immediate problems: defining the hazard, and ascribing a probability. On the face of it, the dominant environmental hazard is clear: ecological disruption. But what exactly does this mean? Loss of a whole species? Loss of a large number of individuals in a species? Or loss of just a few individuals? The answer will depend on the situation and on the attitudes and values of the individuals involved. Ecosystems are rarely static in any case. If a GM introduction might have an effect on butterflies, and there are rare butterflies in the locality, then just a few individuals might matter. Alternatively, whole populations of beetles or mites might be wiped out before anyone notices. The habitat of rare orchids is likely to be considered more valuable and more vulnerable than the home of several species of grasses. Our notion of 'harm' or 'hazard' may therefore be dependent on the value attached to particular parts of the natural world. The difficulty of finding adequate articulations of harm is demonstrated by the fact that in the Environment Protection Act, it is more or less equated to 'change' leaving more detailed interpretations to be evolved through court cases.<sup>2</sup>
- 7.32 The probability of gene transfer in open fields is not easy to measure and requires carefully planned experiments, possibly extending over several years. For example, in order to determine just what is the probability that oilseed rape will pass its genes to near relatives, both laboratory and field tests are necessary, and since such transfer is a rare event, quite large areas have to be used. In recent work scientists using a nine-hectare plot and male sterile 'bait' plants placed 400 metres away from the GM crop to detect pollen transfer.<sup>3</sup> They found that, at 400 metres, up to 7% of the seeds were herbicide-tolerant the trait that was being assessed. It should be stressed that the use of male sterile 'bait' plants will maximise the risk of cross pollination and that with normal, fully fertile, field crops of oilseed rape the incidence of cross pollination is much lower. At 400 metres separation with normal, fully fertile, oilseed rape, extensive Seed Certification data shows that cross pollination is less that 0.1%. So it is possible, although not easy, to measure such probabilities.
- 7.33 Judgements about the likelihood of an introduced gene persisting in the environment rely on assumptions based on what we know about natural selection. If the introduced gene is for a trait

<sup>2</sup> Environment Protection Act 1990, section 107.

Coglan A (1999) Gone with the wind, **New Scientist**, No 2182: 25 describes research carried out by Sweet J and Simpson E.

- that is assumed to be 'selectively neutral', i.e. confers no competitive advantage, then it is judged that it will either persist at a low level in natural populations or die out. Such assumptions can now be tested in the ways described in the preceding paragraph and paragraph 6.25.
- 7.34 Critics have argued that the regulatory system takes a relatively narrow interpretation of the risks of GM plants, and is fragmented in its approach, because it relies on narrowly defined scientific considerations and leaves out broader views of risk that take account of a number of different issues together. Risk assessment, it is suggested, would be more robust if it were able to take more of an 'overview', or strategic view, of the technology. Many of the disputes that have taken place in the UK and elsewhere in Europe have been about how much scientific uncertainty in the assessment of risk is acceptable, and what should be done to mitigate that uncertainty. Those who see advantages in the introduction of the technology may be comfortable with a greater degree of uncertainty than those who see little benefit in it.
- 7.35 Some commentators argue that risks and benefits should be evaluated together. This would imply requiring a statement from an applicant about what benefit it will bring, and would help to make clearer to consumers or to those concerned with the environment why they are being asked to accept possibly novel risks. Many of the GM crops that have so far been developed are intended to enable the crops to be managed in a different way on the farm. Herbicide-tolerant crops may enable weeds to be controlled by reduced amounts of well-known broad-spectrum herbicides. Insect-resistant crops facilitate pest control with less use of pesticides. Such introductions must therefore include an assessment of the effects of these changes in farm management practices from a baseline of present agricultural practices. Until recently these effects were outside the scope of ACRE, and the assessments were to that extent limited. The Government has recently asked ACRE to review these wider impacts, and to consider how to take them into account in considering applications for approval of commercial plantings.
- 7.36 The idea of weighing up risks and benefits for a technology that has a wide range of applications and implications seems intuitively right to many people. It is extremely difficult to do this comprehensively, since it almost impossible to assess all the future benefits or risks of a new technology at an early stage. Who could have predicted the scope of the World Wide Web at the time of its genesis by a group of theoretical physicists? But as technology develops both benefits and risks become clearer. GM crops will change some agricultural management practices, and any potential indirect impact of these changes on the wider environment and on wild life is one of the particular points of concern, at least in the UK. Therefore, we consider it is desirable that those proposing to introduce new GM crops should spell out those benefits and risks that are assessable for that particular application at the time, so that the advisory and regulatory bodies can take account of this information in making judgements.
- 7.37 We recommend accordingly that all applications for GM crops to be approved for commercial planting should be accompanied by a statement of the way in which the planting is expected to be managed in the field, and an analysis and assessment of the wider environmental impact that is anticipated. The advisory bodies should take these impacts into account in considering their recommendations. We further recommend that the regulators and the advisory committees should also explore the pros and cons of adopting a more explicit risk/ benefit assessment in advising on cases. Such assessments are likely to involve judgements that are not purely scientific, and involve issues on which different people may legitimately take different views. The Working Party therefore considers that a more broadly-based group of advisers representing a wider range of interests should form part of the regulatory structure giving advice on the balance to be struck before decisions are taken. From this perspective we regret the lack of consultation about the recent Government proposal to exclude industry and environmental group representatives from membership of ACRE when new appointments to it are made. We return to this point in Chapter 8.

### Risk assessment for food safety

7.38 In relation to the safety of GM food, the professional methodology for assessing risks and the probability of harm is better developed. But because food is of such intimate importance to all of us there may be a similar reluctance to accept official reassurance at face value. Here too, a more broadly-based advisory body with a wider range of stakeholders could help to restore public confidence in the decision-making process. But since the Advisory Committees still have to carry out a rigorous science-based evaluation of each case, membership of the Committee will have to balance these requirements.

#### The case for monitoring

- 7.39 Environmental concerns of the kinds discussed above have given rise to arguments for post-commercialisation monitoring. At present, the system implies that once consent has been given, the release is safe and needs no further monitoring, or consent should not have been given. But since the initial risk assessment is inevitably based more on basic assumptions and deductive logic than it is on empirical evidence, this is not a wholly satisfactory position. Once releases have been conducted on a large scale, monitoring is needed to check that the original assumptions are borne out in the field.
- 7.40 The recognition that there are environmental concerns about the introduction of GM crops has led the National Farmers' Union, SCIMAC (paragraph 3.18) and others to develop proposals for post-release monitoring. The EC has stated that it has now adopted the principle of post-release monitoring to 'verify the non-appearance of any harmful effects on human health and the environment' by modifications to EC Directive 90/220 on deliberate releases of GMOs into the environment. Details of how this is to be done have not been decided. The Working Party strongly endorses these developments and recommends that the Government should plan to make regular post-commercialisation monitoring of the impact of GM releases a general condition for all releases, with inspection of the results by regulators, public access to the monitoring results and provision for modification or revocation of consents if the monitoring results show that this is necessary. This monitoring should include impacts on biodiversity.

### Cumulative and indirect impacts on the environment

- 7.41 The present regulatory system reviews applications for consent for release of GM crops on a case-by-case basis. It has not been asked, nor is it well suited, to take into account and regulate the cumulative impact of a succession of releases of the same or different GM plants. This potential problem, which of course did not exist until a number of releases had taken place, cannot be solved by modification of the regulatory regime alone. It needs a broader policy approach.
- 7.42 The 'case-by-case' approach assesses the possible impacts of each application to release a GM crop, whether experimentally or commercially. Each application is unlikely, alone, to have much effect but once the majority of crops are pest resistant and/or herbicide tolerant, and grown on a large scale, there may be cumulative effects. Such effects may be, for example, on the insect populations of the crop itself or indirectly on the environment. The regulatory system in the UK is beginning to consider how to assess such cumulative and indirect effects but its case-by-case structure is not well suited to dealing with such considerations. Are the first two applications to commercialise an in-built

- pest resistance all right, but the third not? In how many different types of crop should herbicide tolerance be allowed? Can farmers be stopped from growing GM crops if their area is felt to have too great a concentration of such crops? Should they be required to have 'GM-free' areas? No answers have yet been given to these questions.
- 7.43 These problems might be tackled both through processes of consents and management that is, some GM crops might not be allowed at all and others might be subject to strict conditions of use. One of the difficulties in imposing such conditions is that we need to be much clearer what it is we are trying to prevent, that is, what do we mean by environmental harm? This has never been clearly spelt out in regulation and is a value judgement which may be assessed very differently by diverse interest groups and individuals. How much farmland biological diversity is enough? Which species are we most concerned about? Are concerns specific to particular areas? We need some consensus on the answers to these questions before any judgements can be made about the cumulative and indirect effects of GM crops.
- 7.44 The introduction of GM crops on a large scale could have impacts on the environment either through escapes or gene flow from such crops into the natural environment or other crops, or through changes in agricultural practice which GM crops would permit. Discussion about the environmental impact of GM crops has outlined ways in which such crops may both benefit and harm the environment (Chapter 6). The Working Party welcomes recent announcements that DETR is commissioning further research into the impact of GM crops on wildlife. The Working Party recommends that the comprehensive and ongoing research into the environmental impact of GM crops should continue to be carried forward, with the specific objectives of obtaining sufficient information from such trials to control the effects from possible interaction of the GM crops with both native plant species and other agricultural crops, including organic crops.
- 7.45 In the UK, most people have always attached value to the diversity of our landscape and the natural environment and biodiversity which it supports. There is corresponding concern about the progressive intensification of agriculture, and the move towards cultivation of crops in larger and larger fields. These trends were already well established long before any GM plantings were planned. Some people fear that the introduction of GM plantings on a large scale may take these trends further, and that the consequent changes in agricultural practice may cause further loss or disturbance of habitat, wildlife and biodiversity. Others believe that GM planting could, on the contrary, enable land and farming to be managed in ways which would be better for habitat and biodiversity.
- 7.46 This raises the broader issue of how we assess and manage the overall effect of GM technology on agriculture. In what direction will GM crops take agriculture? In particular, will the widespread use of GM crops result in a further move towards intensive agriculture or the reverse? Will it lead to a decrease or an increase in the use of pesticides? Will it lead to the less suitable land being taken out of cultivation as yields elsewhere increase, or will this poorer land still be in use? Will water use fall? The multiplicity of possible effects and different GM/chemical scenarios that could result from introduction of the technology, point to the need for long-term careful monitoring as part of an ongoing 'environmental audit' of GM crops.
- 7.47 This would be consistent with emerging ideas about 'sustainable agriculture' where there is general consensus about the need to minimise inputs, particularly non-renewable ones, and minimise waste and pollution. There are already some data on how GM and conventional crops compare in these respects. There is less consensus as to whether agriculture should be more intensive or more extensive or which would count as being more sustainable. Should we produce crops even more intensively than at present from a smaller amount of land, risking this land being less hospitable for biological diversity but leaving land free on which greater diversity can be encouraged? Or should

- we produce the same amount of crop from a larger area of land and allow biological diversity (to farmers this means weeds and pests) to flourish in conjunction with it?
- 7.48 The Working Party believes that it is first necessary for the Government to establish a broader policy on these wider issues. They cannot be answered by regulators dealing with individual applications for the release of GM plants on a case-by-case basis. But, once established, a broader policy could provide a framework within which individual applications could be considered. Thus, to take but one example, if a general policy were established to limit the use of GM crops in some parts of the country, individual applications could be assessed in the light of that policy. Incentive payments would be necessary to implement such a policy.
- 7.49 The Working Party accordingly recommends that the Government should first undertake a broad environmental audit of the general implications of widespread use of GM crops and their impact on farming practices and the rural environment, using current agricultural practice as a base-line. We suggest that the initial environmental audit study might include the six main elements outlined below.
  - Step one is to agree what are the right parameters of environmental impact;
  - step two is to agree what kind of information and expertise is needed to evaluate these impacts;
  - step three is to agree what levels and kinds of uncertainty are acceptable in relation to any given parameter;
  - step four is to agree, in relation to the agreed parameters, what kinds of harm should be judged 'significant';
  - step five is to agree a set of conditions for management of the GM crop and surrounding land, that will minimise adverse effects on biological diversity and maximise benefits, and that could be applied in full or in part to any consent to grow a GM crop;
  - step six is to agree parameters for post-commercialisation environmental monitoring of GM crops, taking into account all the factors in the original environmental audit.
- 7.50 The study should also consider the desirability and feasibility of measures that might limit any adverse overall environmental impact of large-scale GM planting and optimise any potential benefits. We suggest that special consideration be given to measures which encourage the maintenance of biodiversity alongside all crops (including GM crops) such as 'set aside' and through the timing of planting and cropping. The voluntary arrangements of this kind which are being developed by SCIMAC are a useful starting point, but would need to be developed further to include explicit measures aimed at encouraging greater biological diversity within GM crops. The study might also consider whether it would be desirable or feasible to seek to exclude GM plantings from environmentally sensitive parts of the country if this seemed a practicable way of protecting the environmental status of such areas. We believe there is already some interest in the farming and environmental communities in investigating action along these lines.

### Food and consumer choice

7.51 The Working Party have carefully examined all the evidence that we have been able to assemble about possible risks to food safety from GM food. We have not been able to find any evidence of harm. We are satisfied that all products currently on the market have been rigorously screened by the regulatory authorities, that they continue to be monitored, and that no evidence of harm has been detected. We have concluded that all the GM food as yet on the market in this country is safe

for consumption. There is nevertheless widespread public concern about GM food safety. Some people do not want to eat food containing or derived from GM material either because they do not trust the regulatory process or because they dislike or object to food produced in this way or because they feel that they do not have enough information about the processes or consequences of genetic modification. We believe that four conclusions flow from this.

- 7.52 First, continuing vigilance is necessary for all GM food just as for other novel foods. Some of the recommendations we have made above for strengthening or broadening the regulatory machinery in respect of environmental impacts could be relevant to the machinery for assessing novel foods.

  In particular we recommend consideration of:
  - the possible value of a more explicit risk/benefit analysis in assessing GM foods being applied by regulatory bodies;
  - a more extensive monitoring programme over a longer time of any effects of the introduction of GM foods;
  - the involvement of a broader base of stakeholders in the consideration of GM cases, and the monitoring of impact.
- 7.53 Secondly, nobody should be obliged to eat what they do not wish to. So it is important to ensure that a genuine choice of non-GM foods remains available, and that GM foods are properly labelled so that choice can be exercised. Thirdly, more efforts should be made to disseminate accurate and accessible information about GM food products and what is being done to test and monitor their safety. Fourthly, if effective choices are to be made it will also be necessary for food producers to segregate food from GM and non-GM sources and to label it appropriately. Segregation and labelling bristle with practical difficulties, as the current discussions on the European labelling directive reveal. For example, there needs to be an agreed threshold whereby GM presence below the threshold would not require the ingredient to be labelled. The threshold for the presence of non-organic materials in organic food is 5%. The detectable limit for genetic modification is currently 0.1%. It has been suggested that a practical threshold for GM foods might be 2%.4 However, an unlabelled product containing a large amount of an ingredient below the threshold might actually contain more GM material than a labelled product containing only a little of the GM ingredient.5
- 7.54 The case for continuing the quest for a viable labelling system is overwhelming given the level of public interest and demand. In response to consumer pressure, several of the major retailers as well as the organic sector are themselves taking steps to identify the sources of all their food products, and to indicate which contain GM materials and which are GM free. Other retailers are going further and removing GM ingredients from their products. This market-driven solution is one way of securing an appropriate degree of choice for the public. But in our view, however, it will continue to need to be reinforced by statutory regulations requiring GM content to be specified in labels. We recommend that labelling of GM products should only be statutorily required for foods and products that contain identifiable GM materials (DNA and proteins) above an agreed threshold. We recognise that some people want to avoid GM foods because of how they are grown, not just because of what they contain. However, where products derived from GM sources are chemically indistinguishable from non-GM products we do not think it necessary nor practical to make universal labelling a statutory requirement (paragraphs 2.35–2.37).

<sup>4</sup> House of Lords Select Committee on the European Communities, **EC Regulation of Genetic Modification in Agriculture**.

<sup>5</sup> Ibid. p. 41–42.

Conclusions and recommendations

### Introduction: the present state of genetic modification of plants

- 8.1 Humans have been modifying plants for thousands of years. Selective breeding and many other techniques have evolved into powerful tools for developing innumerable varieties of cultivated plants. The new techniques of genetic modification that have been developed during the last twenty years by research scientists and the biotechnology industry differ in the methods used, and the extent and speed of the changes that can be produced. But, to date, they do not differ fundamentally in their broad objectives.
- 8.2 The science of genetically modified (GM) plants is still at a comparatively early stage. The detailed function and significance of most plant genes is still to be determined. The technologies so far developed for modifying particular genes are also at an early stage, as are the methods for assessing the probable and actual results of such modifications. However, an immense amount of research and development effort around the world is being directed to this area both in the public and private sectors. In 1998, 27.8 million hectares of GM crops were cultivated, mainly in the United States (US) (74% of the total GM crop area), Argentina (15%) and Canada (10%). The pace of discovery and potential applications must be expected to increase further in the next few years.
- 8.3 It is already clear that genetic modification will enable specific desired characteristics to be achieved more quickly and precisely and will speed up the process of developing new crop varieties significantly. This is expected to lead to increased crop yields, greater efficiency of farm management practices and improved product quality, assisting market penetration in much of world agriculture. It is therefore essential that appropriate safety and environmental regulations are implemented.
- 8.4 So far, the commercial introduction of GM crops in the US has been largely driven by a small number of major multinational companies which have the skills and resources to undertake the necessary development, rigorous testing and marketing. There is now pressure for the commercial introduction of GM food and seed into the United Kingdom (UK) and parts of the European Union (EU). Plant breeders have concentrated mainly on those modifications which enable farmers to manage pest and weed control more efficiently and which extend the shelf-life of food products derived from the crops. The principal crops so far to have been modified in this way are soybean, yellow maize (for animal feed), cotton, oilseed rape and tobacco. Modifications under test which may be of more benefit to the consumer include the improvement of food quality, flavour and processing characteristics. Other modifications which increase yields through increased uptake of nutrients or by making plants more resilient to drought or other harsh conditions might soon become possible. If properly managed, these developments could be particularly important for the undernourished people of poorer developing countries.
- 8.5 The Working Party notes that none of the companies and farming interests concerned has plans to introduce widespread commercial planting in the UK in the immediate future. We understand that the first commercial UK plantings of GM herbicide-tolerant crops will only be allowed if environmental data from the Government-run trial plantings on a farm scale pose no new or unacceptable risks. More extensive planting is unlikely for one or two years thereafter. Although the introduction of commercial plantings of GM soya and cotton has been rapid in the US, it is unlikely that this will be the case in the UK. Slow market penetration and superior non-GM varieties will probably delay the significant uptake of GM crops for 3–5 years (paragraphs 3.7–12). This interval is therefore available for further research and policy development to be undertaken. This should be regarded as an opportunity to strengthen the structure of regulatory controls and to put other policy measures in place.

### **Ethical considerations**

- 8.6 The Working Party has reviewed the ethical considerations which should guide the development of this new technology and its application in world agriculture and food production. In some ways these considerations are very straightforward, and in others more complicated. The straightforward considerations have been broadly utilitarian. We have been concerned with the need to ensure that basic nutritional needs can be met world-wide for both present and future generations. We have considered the safety of consumers, care of the environment and the avoidance of environmental degradation. We have also examined the role of the intellectual property regimes on the one hand and the regulatory regimes on the other that are necessary to foster research and development of genuinely useful plants without encouraging monopolies which act against the public interest. We have been much concerned with the global distributional issue: how to ensure that the potential benefits of GM technology address the pressing food needs of the developing world, while at the same time meet market demands of the developed countries.
- 8.7 The rights at stake are many. They include the right of consumers not to be involuntarily subjected to possible risks posed by the developers and growers of GM crops; the right of consumers to choose not to consume GM foods, and perhaps to have non-GM foods kept available in spite of market pressures tending in the opposite direction. Yet it is in the interests of all to maintain employment and thus prosperity, and so governments have a responsibility to enable companies to trade in an environment of reasonable stability. Rights at stake also include the right of citizens of developing countries to have their interests considered in the policy decisions of the regulators, researchers and agrochemical companies in the developed world. We have not taken sides on the question of whether we have a right to live in an environment of any particular sort. This is because we take the view that there are such powerful utilitarian and welfare-based arguments for treating the environment carefully that no purpose is served by straying into philosophically contentious territory to bolster this case.
- 8.8 The most complicated ethical considerations have been those implicated in the concern that genetic engineering is 'unnatural'. Since most human behaviour is in various senses 'unnatural', and does not arouse moral comment, the line between those unnatural activities that do not cause unease and those that do is hard to draw. Maize is everywhere very different from its wild ancestor; is Bt maize unnatural in a different and morally deplorable way? It is, of course, true that the presence of Bt will have some tendency to encourage immunities in insects that would not otherwise have developed them. But using Bt insecticides as sprays will also have that effect, and such sprays are used by organic farmers. Breeding insect resistance in crops by conventional means will also encourage the development of immunities in insect pests. In short, it is the deleterious consequences of our farming techniques to our environment and human health, not their 'unnatural' character that should preoccupy us.
- 8.9 'Naturalness' and 'unnaturalness' are part of a spectrum. At one end of the scale, some modifications of the plants that are now being achieved by genetic modification might also have been achieved over time by conventional means of plant breeding; indeed, this has recently occurred. It would be hard to object to such a modification as a matter of principle as being 'unnatural', since it would only be using a new and presumably more efficient means of achieving a result that could have been achieved by conventional, more 'natural' means. Other plant modifications currently being developed probably could not have been achieved by more conventional means, but their effects in terms of increased yield or improved pest or herbicide tolerance are still not very dissimilar to the kind of changes that have been achieved over time by conventional methods. At the farther end of the spectrum are possible modifications such as putting copies of animal genes into plants. Some of these would be truly novel and unachievable by conventional breeding. Such modifications

- are felt by some to be 'unnatural'. We ourselves, however, can find no clear dividing line on the spectrum which would provide in advance a generally agreed barrier for defining what types of genetic modification of plants are unacceptable because they are unnatural.
- 8.10 After examining all the scientific evidence in the light of these ethical considerations, the Working Party takes the view that the genetic modification of crop plants, as so far developed, does not differ to such an extent from conventional plant breeding or other human interventions with the natural world as to make the process morally objectionable in itself. GM technology is a new tool which plant breeders are using to achieve their breeding goals more accurately and rapidly. The Working Party accepts that combinations of, for example, bacterial and plant genes in GM crops are very unlikely to be found or impossible to realise in nature. However, provided that potential side effects are thoroughly assessed, we do not consider that the generation of such new combinations should be prohibited. In our view there is no alternative to assessing individual cases or types of case for their effects on human health and the environment. At the same time, we also need to monitor the cumulative effects of modified crops, since it may sometimes be the cumulative impact that produces results that are perceived to be unacceptable, rather than the specific impact of the individual cases.
- 8.11 The Working Party concludes that the novelty of the technology, and the speed of its introduction into the agricultural environment and the food supply, along with broader public concerns make it both necessary and desirable to develop and maintain a powerful public policy framework to guide and regulate the way in which this technology is applied. We believe that there is a need for public policy to:
  - minimise any risks both to our food and to our environment that might arise from the use of GM plants in agriculture;
  - maximise consumer choice, so that consumers are informed when GM material is included in food products and are able to choose whether or not to buy such foods;
  - maximise the potential benefits of GM technology for people throughout the world, and particularly to encourage a fair distribution of such benefits;
  - determine the ethical desirability of particular types of genetic modification and their cumulative impact on the environment and society at large;
  - maximise the dissemination of clear information about GM technology from trusted sources, its potential benefits and potential risks, and what is being done to increase knowledge about these matters.
- 8.12 In each of these areas elements of the framework are already in place. But we believe that each needs strengthening to guard more securely against the risks, to encourage the fair distribution of the potential benefits, and to improve the quality and reliability of information available to the public. It is clear that some consumers wish to have the choice not to consume food containing GM ingredients for personal reasons and because of concerns about safety.

### Minimising risk: the role of regulation

8.13 In the UK, the release of GM plants into the environment and food chain is subject to regulatory regimes so that products and releases are carefully assessed before approval is given. The existing regulatory controls, which have concentrated on the impact of individual cases, have been quite appropriate for the early stages of GM development. Now that GM crops and food materials are reaching the marketplace, the Working Party considers that a broader view of the objectives of public policy needs to be taken. By using the case-by-case approach for approval of

individual crop introductions, we may not assess the combined impact of several GM crops on the environment and the food chain properly. We therefore recommend consideration of a more integrated policy stance. We suggest that wider policy measures to address the broader consequences of the spread of the use of GM plants in the environment and of GM material in food should be considered. In particular, we recommend consideration of:

- a broadly-based environmental audit of the likely cumulative impact of GM crops on agricultural practices and the environment;
- measures to ensure appropriate labelling of GM and non-GM food and to encourage food producers to produce lines of non-GM food, and retailers to stock them (paragraph 7.19).
- 8.14 There are separate regulatory regimes in the UK for controlling safety aspects of release of genetically modified organisms to the environment, and of their incorporation into food products. Having examined the regulatory regimes and the criticisms of them in some detail the Working Party concludes that there are four principal areas which need to be addressed in the regulatory regimes:
  - to consult with a broader base of stakeholders in the consideration of GM cases and the monitoring of impacts;
  - to broaden the scope of the risk assessments of GM plantings to take account of effects on agricultural practice and the wider environment and to bring potential benefits as well as risks into consideration;
  - to require more extensive monitoring over time of the effects of GM introductions;
  - to introduce environmental audit analysis on an ongoing basis to ensure that any longer-term cumulative or indirect effects of introduction are being assessed.

# Risk assessment methodology

8.15 Many of the GM crops under development will change the way crops are managed on the farm. There may be benefits to the environment and wildlife but there may also be risks. The Working Party considers that a full environmental assessment of the direct and indirect effects of such introductions should be undertaken so that the risks and benefits can be weighed against a baseline of present agricultural practices. We welcome the UK Government's recent request to Advisory Committee on Releases to the Environment (ACRE) to review these wider impacts and to consider how to take them into account in considering applications for commercial plantings. We recommend accordingly that all applications for GM crops to be approved for commercial planting should be accompanied by a statement of the way in which the planting is expected to be managed in the field, and an analysis and assessment of the wider environmental impact that is anticipated (paragraph 7.37). The advisory bodies should take this impact into account in formulating their recommendations. We further recommend that the regulators and the government advisory committees should also explore the pros and cons of adopting a more explicit risk/benefit assessment in advising on individual cases (paragraph 7.37).

### **Monitoring**

8.16 It may not be possible to assess all risks of GM plantings adequately in advance. It is highly desirable to monitor the release of commercial GM crops for a number of years, together with

the possibility of modifying or withdrawing consents if problems are revealed by the monitoring. We therefore welcome the modifications to EC Directive 90/220 to 'verify the non-appearance of any harmful effects on human health and the environment' and the proposals for post-release monitoring recently developed by the National Farmers' Union and others. The Working Party strongly endorses these developments and recommends that the Government should plan to make regular post-commercialisation monitoring of the impact of GM releases a general condition for all releases, with inspection of the results by regulators, public access to the monitoring results and provision for modification or revocation of consents if the monitoring results show that this is necessary (paragraph 7.40). This monitoring should include any impact on biodiversity.

### **Cumulative and indirect impacts**

- 8.17 Although the scientific evidence suggests that the potential risks posed to the environment from individual GM crop varieties are very low, the introduction of these crops on a large-scale could have an impact on the environment through changes in agricultural practice or through gene flow into the wild or into other crops. Our discussion about the environmental impact of GM crops in Chapter 6 has outlined ways in which such crops may both benefit and harm the environment. The Working Party welcomes recent announcements that Department of the Environment, Transport and the Regions (DETR) is commissioning further research into the impact of GM crops on wildlife. The Working Party recommends that the comprehensive and ongoing research into the environmental impact of GM crops should continue to be carried forward, with the specific objectives of obtaining sufficient information from such trials to control the effects from possible interaction of the GM crops with both native plant species and other agricultural crops, including organic crops (paragraph 7.44).
- 8.18 In the UK, there has been concern about the progressive intensification of agriculture, and the move towards cultivation of crops in larger fields. Although these trends have been established for over four decades, there have been fears that the introduction of GM plantings on a large scale may do more damage to existing habitats, and wildlife. Others believe that GM planting could improve land and farm management in ways which would be better for habitats and biodiversity. We consider that any introductions of commercial GM plantings should be handled in a way that contributes so far as possible both to improvements in agricultural practice and to wider national objectives for the countryside and biodiversity. The Working Party accordingly recommends that the Government should first undertake a broad environmental audit of the general implications of widespread use of GM crops and their impact on farming practices and the rural environment, using current agricultural practice as a base-line (paragraph 7.49). The audit should also consider the desirability and feasibility of measures that might limit any adverse overall environmental impact of large-scale GM planting and optimise any potential benefits. The study might also consider whether it would be desirable or feasible to seek to exclude GM plantings from environmentally sensitive parts of the country. We believe there is already some interest in the farming and environmental groups in investigating action along these lines.

## Food and consumer choice

8.19 The Working Party has carefully examined all the evidence that we have been able to assemble about possible risks to food safety from GM food. We have not been able to find any evidence of harm. We are satisfied that all products currently on the market have been rigorously screened by

- the regulatory authorities, that they continue to be monitored, and that no evidence of harm has been detected. We have concluded that all the GM food so far on the market in this country is safe for consumption.
- 8.20 There is nevertheless widespread public concern about GM food safety. Some people do not want to eat food containing or derived from GM material either because they do not trust the regulatory process or because they dislike or object to food produced in this way or because they feel that they do not have enough information about the processes or consequences of GM. The Working Party concludes that continuing vigilance is necessary for all GM food just as for other novel foods. In particular we recommend consideration of:
  - the possible value of a more explicit risk/benefit analysis in assessing GM foods being applied by regulatory bodies;
  - a more extensive monitoring programme over a longer time of any effects of the introduction of GM foods:
  - the involvement of a broader base of stakeholders in the consideration of GM cases, and the monitoring of impact (paragraph 7.52).
- 8.21 A genuine choice of non-GM foods should remain available with foods containing GM material being properly labelled so that choice can be exercised. More efforts should also be made to disseminate accurate and accessible information about GM food products and what is being done to test and monitor their safety. If effective choices are to be offered it will also be necessary for food producers to segregate food from GM and non-GM sources and to label it appropriately.
- 8.22 We conclude that the case for a viable labelling system is overwhelming given the level of public interest and demand. In response to consumer pressure, several of the major retailers as well as the organic sector are themselves taking steps to indicate which of their food products contain GM materials and which are GM free. Others are removing GM ingredients from their products. This market-driven solution will need to be reinforced by statutory regulations requiring GM content to be specified in labels. We recognise that some people want to avoid GM foods because of how they are grown, not just because of what they contain. However, where products derived from GM sources are chemically indistinguishable from non-GM products we do not think it necessary nor practical to make universal labelling a statutory requirement (paragraphs 2.35–37). We recommend that labelling of GM products should only be statutorily required for foods and products that contain identifiable GM material (DNA and proteins) above an agreed threshold (paragraph 7.54).

# External advice and advisory bodies

- 8.23 There is clearly a continuing need for expert bodies to advise the regulatory authorities on individual applications for approval of plantings or novel foods. The crucial requirement for such bodies is that they are expert and independent and have the means and authority to obtain thorough analysis of any question which they think needs deeper investigation. Some of our own members have been involved with the work of ACRE and Advisory Committee on Novel Foods and Processes (ACNFP) and we have also received consultation responses on the working of these bodies from a number of respondents. We believe that they have discharged their functions well, and ensured that safety and environmental considerations have been very thoroughly assessed.
- 8.24 It may be desirable to separate purely scientific assessment of issues about the safety and environmental impacts of GM planting and foods from some of the broader assessment suggested

above. Such broader assessments are likely to involve judgements that are not purely scientific, and involve issues on which different people may legitimately take different views. The Working Party therefore also recommends that a more broadly based group of advisers representing a wider range of stakeholder interests should form part of the regulatory structure giving advice on the balance to be struck before decisions are taken. This group should report to the overarching body (paragraph 8.26) with its chair as a member of that body. From this perspective we regret the lack of consultation about the recent Government proposal to exclude industry and environmental group representatives from membership of ACRE when new appointments to it are made.

- 8.25 The difficulty of policy making with regard to GM food is greatly exacerbated by the current climate of public distrust. Our consultation brought home to us the interconnection between ethical unease and factual uncertainty. We believe that it is particularly important that the government advisory committees continue to have consumers and advisers on ethics as full members, involved in the scrutiny and evaluation of all applications. Any change to this well-proven procedure would, in our judgement, be a retrograde step and would be perceived adversely by the public. A public that does not know what to believe or whom to trust is even more likely to fear that 'unnatural' things are being done to food, that the results may be unsafe, and that the environment may suffer damage of an unspecified kind.
- 8.26 We therefore recommend as an over-arching body the creation of a biotechnology advisory committee that would report to the Cabinet Ministerial Group on Biotechnology and Genetic Modification, both upon request and on its own initiative. We propose that this body would provide a locus for the discussion of scientific, ethical and general policy issues, and would have as part of its remit the duty to consider the wide variety of moral concerns as well as the factual uncertainties surrounding the treatment of GM crops. It would determine the ethical desirability of particular types of genetic modification and their cumulative impact on the environment and society at large. Its advice would be published.

### 8.27 Such a committee would:

- be an independent advisory committee whose members would be appointed by Ministers in consultation with learned societies, industry, commercial, consumer and environmental organisations and other appropriate bodies, in such a way as to command public confidence;
- draw its members from a wide range of backgrounds, including the scientific, philosophical, religious, public policy, environmental and health communities;
- report directly to the Cabinet Ministerial Group on Biotechnology and Genetic Modification
  with a remit to anticipate potential issues as well as to make recommendations on the
  scientific, commercial, environmental, consumer and ethical issues arising from applications
  to the advisory committees;
- be responsible for the integration of advice from the relevant advisory committees, and operate under terms of reference similar to those recommended by the Royal Society in the summary of its Report entitled *Genetically Modified Plants for Food Use*.
- 8.28 We think it important that such a committee explore public attitudes and views in depth, and the way in which these are affected by different types of information and knowledge, perhaps through the medium of 'citizen juries' of the kind used in policy discussions in the US and the UK 'consensus conferences'. It would need to give careful consideration to the views of all groups that have strong opinions on the issues, including religious groups, consumer and environmental groups as well as the commercial and scientific community and the public at large.

## **Disseminating information**

- 8.29 Most people lack the opportunity to gain an understanding about the scientific differences between genetically modified and conventional crops or how they are regulated. Nor do they have the means of explaining any fears or concerns to those responsible for the development, production and sale of GM crops. We have therefore suggested below the adoption of new institutional arrangements that could improve the dissemination of information and allow people's concerns to be taken into account.
- 8.30 We conclude that there is an urgent need to rebuild public confidence and that the recent credibility of government information on food safety has been so badly damaged that it may be more helpful for other organisations to take on some of the task. Although independent information from a trusted source will not allay all fears, such information will allow the public to make a more informed choice. We recommend that the proposed Food Standards Agency (FSA) should be the main source of independent information (paragraph 5.40). The major food retailers should also be encouraged to disseminate impartial information from the FSA in a readable and user-friendly form.
- 8.31 It is difficult to gauge the concerns of the 'silent majority' of the public. However, focus groups and surveys suggest that there is considerable unease about GM products entering the food chain. The public has become even more sensitised to GM foods following extensive coverage of this topic in the media, and because of the publication in the press of misleading and inaccurate information. We recommend that further research is undertaken to determine what information the public would like about GM food and how best to provide such information (paragraph 5.52). We also recommend that the Cabinet Ministerial Group on Biotechnology and Genetic Modification initiates a wide-ranging review of the scope, co-ordination and effectiveness of the several current 'public understanding of science' initiatives with a view to achieving the best use of the available resources (paragraph 2.65).
- 8.32 We urge the scientific community to continue to bear its share of responsibility for disseminating information. We believe that many of the 'public understanding of science' initiatives have been independent from each other, that they could be better co-ordinated, and that there has been little exchange of best practice. The Working Party recommends that the UK Research Councils, COPUS, the Royal Society, the Institute of Biology, the UK Life Sciences Committee, and industrial bodies such as the Biolndustry Association and others, examine how they can work together to continue their development of both new and ongoing mechanisms in which scientists would be able to engage better with the public (paragraph 2.66). We further recommend that the Government takes an initiative to bring relevant experts and the consumer public together, possibly along the lines of the UK National Consensus Conference on Plant Biotechnology, to seek to understand the underlying concerns and to propose a way forward (paragraph 2.67).

### Commercialisation

8.33 The Working Party considers that in the developed world, the present mix of public sector research and commercial research and development is well structured to provide the motive power to develop the new GM technology appropriately as determined by the market. Although GM crops such as herbicide-tolerant soybeans and insect-resistant cotton are now being widely planted in the US, the Working Party concludes that the technology is still very much at an early stage. The adoption of GM crops in Europe and the UK is likely to take several years. Current estimates suggest that GM crops will take 3–10 years to become significant in the UK. This means that there is sufficient

- time to assess the implications of novel GM traits and should help reduce some of the immediate concerns about the pace of change.
- 8.34 The arrival of GM products in the marketplace has sharpened the debate concerning the institutional reforms necessary to secure 'best practice'. Wider consultation with stakeholders could make an important contribution towards the transparent, informed and responsible development and implementation of the technology. We recommend that the UK government departments, through their advisory committees, the agrochemical and seed industry and relevant trade associations, consult widely among consumers, farmers, environmental groups and the proposed stakeholder advisory group (see paragraph 8.24) to ensure that the future goals for the technology take account of the wider issues (paragraph 3.13).
- 8.35 The new GM technologies have tended to move the decisions about breeding even further away from farmer groups. The Working Party concludes that it is particularly important that farmers contribute to the debate concerning herbicide usage and the deployment of systems to avoid the emergence of insect populations resistant to pest control measures. Advances in both transgenic and conventional plant breeding are likely to bring about the need for further changes in agronomic practice. We recognise the role being played by farmers and their representatives (as well as others in the agricultural supply industry) in the Supply Chain Initiative on Modified Agricultural Crops (SCIMAC). We recommend that the SCIMAC approach to best practice for the introduction of herbicide-tolerant crops be extended to the broader issues of transitions in agronomic practice raised by GM plant varieties which have significant potential environmental impact (paragraph 3.18).
- 8.36 Although market power is mainly concentrated in a group of multinational firms the Working Party believes that there is currently effective competition between them in most areas, and that the pace of innovation and development to the market is rapid. Market development has concentrated so far mainly on modifications that improve the efficiency of farm management, but modifications that aim to improve the quality of consumer products are likely to become common before long. However, if the consolidation process continues further, and major companies acquire control of specific crops, then the contestibility of developed and developing country markets could be compromised. The Working Party concludes that there is a need for the relevant competition authorities to keep this sector under close review. This is not only a matter of preserving the ability of the end-user, i.e. the farmer, to choose between suppliers. It is also a matter of protecting the capacity of the research environment to innovate.

## Commercialisation and intellectual property rights

- 8.37 The commercialisation of plant biotechnology has advanced rapidly over the past five years. Intellectual property rights, mainly in the form of patents, have been fundamental to the commercial development of the technology. Several hundred patents on plant genes, techniques for genetic modification and transgenic plants have now been granted and many more have been filed. Although patenting in biotechnology generally is now widely practised by public and private sector researchers alike, excessively broad claims and restrictive licensing remain a potential threat to innovation. In the GM crop area, the implications of patents on important new technologies such as apomixis will depend largely on the licensing strategy of the companies involved.
- 8.38 Plant genome sequencing programmes will accelerate the development of GM crops. The identification of a wide range of genes in model species will allow the rapid identification of

genes of economic importance in crop species. The large agrochemical and seed companies are also investing heavily in genome sequencing programmes. The prospects of patents being allowed for partial gene sequences of unknown function has alarmed many researchers. The Working Party considers partial DNA sequences such as ESTs (expressed sequence tags) or SNPs (single nucleotide polymorphisms) to be research tools and as such they should not be patented. The Working Party welcomes the recent initiative involving a consortium of ten pharmaceutical companies and the biomedical charity, the UK Wellcome Trust to pool efforts to create a public SNP map of the human genome. The initiative will also avoid duplication of effort and prevent those companies which are developing private maps from tying up large areas of the human genome with patent claims. We consider that the extension of the consortium's approach to other genome projects such as rice and *Arabidopsis* may be worth pursuing.

- 8.39 Many plant genes will be patented and the Working Party has noted the concern about the extent to which patents on partial gene sequences may 'reach through' to patent claims on full length DNA sequences. We therefore recommend that national patent offices, the European Patent Office and the World Intellectual Property Organisation (WIPO), limit patent claims for ESTs strictly to their specified uses to avoid dependency on subsequent patents which have overlapping DNA sequences. We further recommend that WIPO and the EC closely monitor the development of EST patents worldwide (paragraph 3.45).
- 8.40 The Working Party is also concerned that some of the current practices of the major firms concerning patenting and licensing in this area may restrict competition and in particular make it difficult for developing countries to gain access to the new technologies on fair terms. To mitigate the potentially negative effects of monopolies on key plant technologies we recommend that public sector institutions which hold such patents serve the wider public interest by retaining their intellectual property and licensing it in a fair and equitable manner so that key technologies are not tied up in exclusive and inaccessible licence deals (paragraph 3.47).
- 8.41 The Working Party also takes the view that the situation where a single commercial organisation has broadly based intellectual property rights for one crop technology under its sole control is highly undesirable. We therefore recommend that national patent offices, the European Patent Office and WIPO discourage patent applications which allow extensive control over a single crop species. Rather, these offices should seek to restrict any such applications to the particular type of technology or products in the crop concerned (paragraph 3.47).

### Commercialisation and developing country issues

8.42 The majority of developing countries are likely to be disadvantaged in negotiating licence terms. It seems unlikely, therefore, that much consideration will be given to making the proprietary technology accessible to developing countries or to supporting an infrastructure which will allow resource-poor agriculturists in developing countries to pursue local goals for the technology. In terms of economic transactions, these are issues about fairness and justice between parties. It is vital that international agencies vigorously address the challenge of providing access to the technology, both by supporting the development of appropriate derivatives of the technology for local application and by promotion of a climate for unrestrictive licensing (paragraphs 3.50–55). We therefore recommend a sustained programme supported by increased inputs from donors to support the International Agricultural Research Centres (IARC) system, bilateral programmes

- and organisations such as International Service for the Acquisition of Agri-biotech Applications (ISAAA) and CAMBIA (Centre for the Application of Molecular Biology in International Agriculture) to develop and distribute enabling technologies in a form which is appropriate to the agricultural needs of the developing countries (paragraph 3.51). This can be achieved more effectively in partnership with industry.
- 8.43 The Working Party concludes that the possibility of new plant varieties being presented for registration with the benefit of both plant variety rights and patent protection could limit the mechanism by which germplasm (and therefore, genetic diversity) is shared among breeders. This potential locking up of genetic variation would be contrary to the spirit and intent of plant variety rights. We must wait and see the extent to which the growing influence of patents in the exploitation of plant varieties will restrict access to proven germplasm. We recommend, however, that WIPO, the EC, Union for the Protection of New Varieties of Plants (UPOV), the Consultative Group on International Agricultural Research (CGIAR) and International Plant Genetic Resources Institute (IPGRI) together closely monitor the impact of patents on the availability of germplasm to plant breeders (paragraph 3.61).
- 8.44 Developing countries are faced with serious potential difficulty over the patenting of key plant technologies, having few patents of their own with which to negotiate favourable cross-licensing terms. Under normal circumstances companies which own the rights to such patents are likely to be reluctant to licence them to commercial organisations in developing countries at a cost these countries can afford. Countries which are signatories to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement will have trade sanctions applied to them by the World Trade Organisation (WTO) if they do not allow intellectual property rights to foreign patent holders. Although research is generally exempt from licence requirements, developing countries will not be able to export goods which have been produced with unlicensed patented technology regardless of whether the relevant patent rights has been granted in that country or not. While this may not restrict locally consumed and traded commodities, it does deny access to the international commodity market for occasional surpluses or by-products.
- 8.45 We acknowledge that without the competitive investment which ownership of technology has promoted, GM technology would either not be available at all or its development would be very much delayed. Some argue that its natural custodians are therefore the major multinational agrochemical and seed companies, since even the 'realistic' entry price is too high for the developing world. Others have argued that the costs of implementation of the technology, appropriately developed, are, on the contrary, not too expensive for developing countries, and that the issue of access is governed simply by licensing. We conclude that there is an urgent need for a realistic assessment of the likely availability of licensed, patented technologies for developing countries. We recommend that those leading companies (and others) holding such patents work in collective partnership with a consortium of appropriate international organisations (such as the CGIAR, ISAAA and the Rockefeller Foundation) to identify and implement practical strategies for broad licensing terms for developing countries (paragraph 3.55). While these should not restrict either the developed world for application to local crops and food security, or to the smaller breeders in the developed world, they would, however, need to provide protection to the large corporations in their own competitive markets.
- 8.46 Where international monopolies based on exclusive ownership of enabling technologies restrict further innovation, fair access and trade, compulsory licensing, could under some circumstances, be considered as an appropriate response. However, we do not recommend the wholesale imposition of compulsory licensing, since in this sector the outcome could be a decline in willingness to invest in research and development and to share knowledge with scientists in the public domain (paragraph 3.56).

### **Broad claims**

8.47 Excessively broad claims clearly act counter to the intent of the patent system. The Working Party concludes that on balance broad claims within a patent are only justified where the invention is truly supported by correspondingly broad examples and deserves the reward of broad claims. We recommend that national patent offices, the European Patent Office and the WIPO draw up new guidelines for patent offices to discourage the over-generous granting of patents with broad claims that have become a feature of both plant and other areas of biotechnology (paragraph 3.57).

### Impact on developing countries: implications for UK policy

- 8.48 The most serious of the dangers for the developing world may arise from *not* developing the capacity to screen, breed and safety-test GM crops, and to manage their release and use. If no such capacities are developed, the best scientists in the developing countries and the CGIAR system will be tempted to migrate to commercial organisations in industrialised countries. The danger is then that yield increases and employment income from food staples will remain sluggish.
- 8.49 So far, GM crops have had little effect, good or bad, on food-poor consumers in developing countries, or the farmers and farmworkers who mainly supply them. 'The market' has not directed any major private-sector scientific resources at breakthroughs into conventional Green Revolution-type plant breeding or into GM crops or main food staples (or tropical export crops) for employment-intensive production in poor countries. Serious prospects for such shifts will require new market incentives and/or new public resources for non-commercial research. To forego such efforts would not protect the poor from any unregulated risks of genetic modification and other agricultural innovations, but would sacrifice the prospects of major GM crop-based advances in food and agricultural output and employment for the food-poor.
- 8.50 At present the balance of agricultural research between the developed and developing world could well limit the use of increasing numbers of desirable plant types. This would occur because desirable GM plants could be subject to patents on GM technology or other controls, perhaps including GURT (Gene use Restriction technology or 'Terminator' technology). In addition, in the private sector, there may be a failure to develop or even attempts to actively prevent development of apomixis genes. This could be inefficient as well as inequitable. The UK should use its position in the World Bank, EU, CGIAR, WTO and other bodies to reverse this trend through improving the infrastructures and remedying the underfunding and biases of public-sector research in developing countries.
- 8.51 Multinational companies are likely to operate increasingly in developing countries, particularly in Asia and South America. These companies will probably wish to deploy intellectual property measures which have been successful in developed countries. While farmers may well benefit from these new technologies, it is most important that they retain the choice to grow either the new improved seed from the companies or the new improved seed from national breeding programmes or the CGIAR Centres. We consider that it is vital, therefore, that these centres maintain proficiency in the latest technologies and continue to deploy the best technology available in the public sector. We strongly recommend that the UK continue to support the CGIAR system to this end. At the same time we recommend that the CGIAR seeks to protect proactively its own technology through patenting and use it to access other protected technology on behalf of their clients, the developing world (paragraph 4.78).
- 8.52 The TRIPS agreement has 'no requirement on patent applicants to involve or consult with local communities or governments about patenting a compound based on a natural product from that

- country, or sharing the benefits or including the prior contributions of indigenous peoples'. The Convention on Biological Diversity (CBD), on the other hand, requires host government consent and 'approval and involvement' of traditional communities. There have been attempts to amend patent law so that the CBD objectives would be better supported by taking into account the access legislation.
- 8.53 The UK, occupying an intermediate position on GM crops between the liberal regulatory position of the US Government and the hostile view of some European governments and non-governmental organisations, is well placed to broker progress on this matter via the WTO and the CGIAR. The Working Party recommends that the UK, in consultation with like-minded developing countries and other member states of the EU, propose that the WTO explore and report on the extent to which the international and national legal framework currently frustrates the objectives of the CBD on providing fair and equitable access to genetic resources and how this conflict might be addressed (paragraph 4.73). There is an overriding need to respect the property rights of developing country researchers, public agencies and indigenous communities regarding plant materials developed by them.
- 8.54 The Working Party recommends that the UK Government and EC, preferably working through the CGIAR, invite those developing countries willing and able to commit genuinely additional resources, to enter a joint initiative. In view of the proven high returns to and impact on poverty of appropriate agricultural research, and the new salience of fundamental and applied GM research, there should be a funded major expansion of research:
  - (i) into higher, more stable and sustainable production of tropical and sub-tropical food staples;
  - (ii) seeking gains for poor farmworkers, food consumers and smallholders;
  - (iii) by mainly CGIAR institutes and developing-country national agricultural research systems (NARS), working with private sector researchers in the developing and developed world where desirable;

devising alongside locally appropriate:

- (i) research planning;
- (ii) regulatory/implementation mechanisms for environmental review of GM crop experiments (paragraph 4.62);
- (iii) food-safety clearance of GM releases to farmers.
- The Working Party further recommends that the Department For International Development (DFID) and the Ministry of Agriculture, Fisheries and Food (MAFF) should jointly help UK researchers to contribute to developing this initiative (paragraph 4.42). We endorse the recommendation by the House of Commons Environmental Audit Committee that a Minister from DFID be appointed to the Cabinet Ministerial Group on Biotechnology and Genetic Modification.
- 8.55 The Working Party welcomes the aim of the March 1998 White Paper on overseas aid to underpin the agreed Organisation for Economic Co-operation and Development (OECD) effort to construct 'aid partnerships' with developing countries to halve world poverty by 2015. To help to achieve this we recommend that alongside consultations with the developing countries concerned about their own agricultural research priorities, the UK Government should pre-commit a substantial amount of the rise in UK aid announced in July 1998 to additional spending on the research and development of GM food staples grown in

developing countries (paragraph 4.48). A part of this sum should be for consultative work with those countries on the design of appropriate regulatory regimes (see paragraph 4.62). We further recommend that this contribution should be used to leverage extra funds from other donors (including the EU) for developing country NARS and for the CGIAR institutes (paragraph 4.48). The funds should be focused on those developing countries eager to support the initiative with extra domestic financing for public-sector agricultural research.

- 8.56 Of the various traits under consideration in GM crops, it should be noted that herbicide-tolerance may be associated with special socio-economic effects when utilised in varieties for use in developing country agricultures. For example, the use of herbicides replaces hand weeding. Notwithstanding the fact that some of the most striking applications of herbicide-tolerance are in developing countries (such as the introduction of direct seeding rice in the Philippines), the same use of herbicide-tolerant varieties may work against poverty reduction programmes which requires raising, not lowering, the demand for labour. We recommend that the CGIAR should carefully assess both socio-economic and agricultural needs before introducing crop varieties with novel traits into developing country agricultures and should co-ordinate careful assessment of the potential risks of hybridisation of GM crop plants with weed relatives (paragraph 4.57).
- 8.57 It is important to ask how risks to environmental and human health can be minimised, given the limited regulatory capacity of many developing countries. The costs and risks can almost certainly be much reduced by ensuring appropriate public awareness and by insisting on transparent arrangements for overview and enforcement. However, this will have to depend far more on incentives, and co-operation with scientists and companies, and less on command-and-control, than is feasible or necessary in the developed world. Nevertheless, we conclude that transfer of experience and know-how from advisory and regulatory bodies in developed countries to the developing world, with suitable adaptation to its socio-political as well as physical environments, is urgently needed. The Working Party recommends that part of new UK aid funds recommended to be earmarked for GM research and development in and for developing countries (see paragraph 4.48) should be used to help such countries in devising appropriate incentive and regulatory regimes against possible environmental and biosafety hazards (paragraph 4.62). While consultation with regulatory bodies in the US, EU and elsewhere is essential, developing countries have different (and varied) farming systems, food chains, and environments, and so need different biosafety and environmental procedures. We therefore recommend that this part of the new GM funding be guided by leading researchers via appropriate international bodies with strong developing-country representation such as the Food and Agriculture Organisation, the International Food Policy Research Institute, and/or the Institute for the Support of National Agricultural Research (paragraph 4.62).
- 8.58 We are unable to recommend a single ethically based solution to the broad and complex issue of substitution crops. This issue is often cited by those who oppose GM technology, but the problems are by no means restricted to genetic modification or to agriculture. Nevertheless, given the need for increased reliance on renewable raw materials, we conclude that international aid funds need to be allocated for valid projects aimed at diversification of cash crops and for the building of the technical capacity to achieve this (paragraph 3.67).
- 8.59 The Working Party notes that the centres of diversity of the wild populations of some of our modern day agricultural crops are in developing countries. We recommend that the IPGRI and others entrusted with stewardship of plant genetic resources consider the risk implications of introgression of genetically modified traits into the centres of diversity for the main temperate and tropical crop species and decide whether additional measures are needed to protect these genetic resources through ex situ and/or in situ conservation (paragraph 3.70).

8.60 The need of developing countries for increased yields from crops that can be grown in inhospitable or deteriorating environments may contrast with their desire to care for their particularly rich natural biodiversity. To date, developing countries have less well-developed regulatory structures and expertise to manage the introduction of GM crops appropriately. The Biosafety Protocol being considered by the parties to the CBD is intended to provide a first line of defence in this area, particularly for developing countries. However the negotiation of the Protocol has been blocked by countries which have already started extensive commercial planting of GM crops. The Working Party considers the Protocol to be an essential safeguard to enable the desirable development of appropriate GM crops for developing countries to take place safely, and recommends the UK Government and its European partners redouble efforts to reopen the stalled negotiations on this subject and to bring them to a successful conclusion (paragraph 4.65).

#### **Conclusion**

- 8.61 In conclusion, we reaffirm our view that GM crops represent an important new technology which 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 recognise and accept a very 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.
- 8.62 The introduction of GM crops is at present only at an experimental field trial stage in the UK. But the pace of development of new crops is accelerating, and it is timely to review the considerations that should guide public policy in this area and to strengthen the framework in certain respects. At the present time public concern about the introduction of GM crops and food is running at a high level. The principal objections concern possible harm to human health, damage to the environment and unease about the 'unnatural' state of the technology. There are calls for bans on GM food and moratoria on GM plantings. We do not believe there is evidence of harm to justify such action.
- 8.63 Many groups and sectors of society are concerned with the implications of GM crops and have a legitimate interest in the outcome of decisions about them. Some groups have doubts about the adequacy of the present regulatory regimes to meet all of their concerns. They also have varying degrees of mistrust in the ability of the regulatory bodies and those who advise them to deal with all the issues or to bring a wide enough perspective to bear. We do not, however, advocate a moratorium on either research, field trials, or limited release into the environment, irrespective of the likelihood that such a moratorium could be legally challenged. We do not see any grounds for it that cannot be better dealt with in other ways. Nor, if these trials proceed successfully, should there be a longer-term blanket moratorium on commercial growing. We do, however, believe that energetic action by the Government is needed before any commercial plantings are undertaken in the UK in order to protect the wider environment, to ensure that choice is available for those who do not wish to consume GM foods, and to allay public concern. The Working Party recommends that the next step should be to allow some commercial planting of the most promising GM crops, on a limited and closely monitored basis, designed to identify and contain any adverse environmental and safety effects. At the same time we recommend that steps are taken to ensure that appropriate amounts of non-GM planting continue with

# a segregated production chain to support the availability of non-GM foods in the shops to satisfy that demand (paragraph 7.21).

- 8.64 The EU has put in place a regulatory framework that has provided a reasonable set of controls for the experimental stage of the technology. But we consider that the UK government now needs to take further steps to determine the desirability of particular types of genetic modification, to strengthen the safeguards against specific risks, to enable broader impacts to be better evaluated and managed, to strengthen consumer choice, to secure better dissemination of information and to understand more fully the ethical basis of concern.
- 8.65 The scope of improvements offered by genetic modification in the future is much wider and consumer benefits much more evident. However, concentrating exclusively on the safety and environmental impact of GM crops in the UK and Europe may distract both the public and governments from giving proper attention to the benefits they could bring to developing and developed countries. Industry must play its part in making the technology available to developing countries. The research investment in plant genetic modification by the private sector has already greatly accelerated the development of the technology. The need for concerted action to assist in the safe application of plant genetic modification by industry in partnership with governments, charitable foundations and international research organisations to food staples of the developing world is urgent.

# Appendix 1

Rats and potatoes at the Rowett Institute The following chronological sequence outlines the events which led to an extensive media debate about the dangers of genetically modified (GM) foods. The conclusions that can be drawn from the research are discussed in paragraph 2.58.

#### 10 August 1998

- Press releases described Dr Arpad Pusztai's experiments. The experiments were designed to determine whether or not GM potatoes which had been engineered to produce concanavilin A (Con A) (a lectin and a known toxin) would have any effect on the growth and immune functions of rats when fed over a long period. The first press release said that when rats were fed GM potatoes containing the gene for Con A there was no immediate effect. However, there was a reported effect on growth rate and immune function.<sup>1</sup>
- A second press release from the Chairman of the Institute's governing body asked for an assurance from the European Commission (EC) 'that any GMOs [GM organisms] be adequately tested for any effects that might be triggered by their consumption in animals or humans'. In addition, 'The testing of modified products with implanted genes needs to be thoroughly carried out in the gut of animals if unknown disasters are to be avoided'.
- A television programme was shown the same day which made much of this finding and had been previously filmed at the Institute. It did not mention what lectin was involved; it transpired that two different lectins had been used.

#### 11 August 1998

A second press release said: 'Dr Pusztai's work ... is being collated for transmission to MAFF (Ministry of Agriculture, Fisheries and Food) where it will be scrutinised by their Novel Foods Committee ... A range of carefully controlled studies underlie the basis of Dr Pusztai's concerns; the approach being adopted and the question of which lectins to use in transgenic plants have been published but the results on which the World in Action programme was based are new and need appraisal. The Rowett will be working with UK and European experts and officials to ensure that appropriate screening procedures are maintained and developed for monitoring the impact, if any, of genetically modified plants used in human and animal feeding.'

# 12 August 1998

• A press release announced that the long-term feeding data had been obtained by feeding potatoes to which Con A had been added, not from GM potatoes. The only feeding trials that had been carried out with GM potatoes were with potatoes that had been transformed with a second lectin, termed GNA, from snowdrops, which is much less toxic that Con A. The initial claims were withdrawn. Dr Pusztai was suspended and the Institute said that it regretted 'the release of misleading information about issues of such importance to the public and the scientific community'. None of this information had been submitted for publication in scientific journals. The press release commented: 'This morning it would be premature to conclude whether or not there are data of concern to those assessing the safety of foods with transgenic lectins.'

The exact words were 'the rats had slightly stunted growth when tested after 110 days of feeding and the response of their lymphocytes to mitogenic stimuli was about half that of controls'. It has been suggested that during the experiments the rats had a protein deficient diet and that this may have caused some of the effects on their growth and the immune systems.

#### 28 October 1998

- The report of an independent audit committee reviewing Dr Pusztai's results was published on the Rowett website. The report concluded that:
  - 'Addition of Con A to diets of rats at  $800\,\mu\text{g/g}$  diet does cause a small but significant reduction in growth over 110 days. However, the concentration used was some 5000-times greater than was measured in tubers of Con A4, the experimental line expressing this lectin.'
  - 'GNA ... did not have any deleterious effects on the growth of rats in three short-term and one long-term feeding experiments even when added at 100-times the concentration expressed in the tubers of the transgenic products.'
  - 'The significant effect on digetsa retention of feeding raw transgenic GNA line 74/T2 to rats in one short-term experiment remains unexplained, but was not observed in a second experiment involving line 71.'
  - 'Given the known mitogenic effects of some lectins, the intention to examine whether consumption of transgenic constructs expressing lectins has any effect on the immune response of higher animals was entirely valid. However the results obtained were, in most cases, far too variable to reach statistical significance and too inconsistent to draw any meaningful conclusions. Therefore, the audit committee is of the opinion that the existing data do not support any suggestion that the consumption by rats of transgenic potatoes expressing GNA has an effect on growth, organ development or immune function.'
- So, in contrast to the statements made in the August TV programme:
  - Feeding studies were made with only one type of GM potato, that expressing the gene for the lectin GNA.
  - There was no statistical difference in the growth of rats fed transgenic GNA potato over the 110 days when compared with the parental controls. Also, rats fed cooked potatoes spiked with added GNA and lactalbumin diet similarly spiked with GNA grew at the same rate as rats fed the same diet without the lectin.
  - No test of immune function in rats fed cooked GNA transgenic potato for 110 days had been made at the time of filming or broadcast.
- Dr Pusztai rejected some of the conclusions of the audit committee, in particular their conclusion that feeding the GNA potatoes had no effect on growth, organ development or immune function. The Audit committee were not persuaded by Dr Pusztai's response to alter their conclusion.<sup>2</sup>

# 12 February 1999

Twenty scientists from 14 countries announced their support for Dr Pusztai. In an attached Greenpeace press release, the possibility was raised that the damage claimed by Dr Pusztai might not be due to the lectin but to the 'virus' that was used as a source of the promoter in the transgenic construct. This is a serious confusion, for although the virus in question is not toxic (it is widely present in the broccoli in our diet), and it was only the promoter (see paragraph 2.11) that had been transferred from the virus, it raised the possibility that the damage claimed by Dr Pusztai might be a general response to other GM foods.

• The media ran such front page headlines as 'Alarm over "Frankenstein" foods' and 'Food scandals exposed'. The story quickly became a major news item on radio and television, and in all the newspapers, but the Government remained unmoved by calls for a moratorium.

#### **19 February 1999**

• Professor Tom Sanders, a professor of nutrition in the University of London published a thoughtful critical review in *The Independent* in which he said about Dr Pusztai's report:<sup>3</sup>

The document has not been carefully prepared and is not up to the standard required for publication in a good scientific journal. The tables are not clear, and the captions do not make it clear whether the results are expressed as mean with SEM or SD [two statistical ways of expressing the possible error in calculating an average]. The food intakes are not adequately described - this data is essential for interpretation of the data. The dietary design of the first three studies is fundamentally flawed, as the diets did not contain adequate amounts of protein and the intake of nutrients and anti-nutrients differed between the transgenic and control animals . . . The level [of protein in the diet] was not adequate to sustain normal growth and development in the rats. The transgenic potatoes contained 20% less protein than the parent variety but it appears that no attempt was made to ensure that the protein content of the diets was similar. Thus differences between the parent variety and the transgenic animals could be attributed to differences in protein intake. It is unclear why a diet of raw potatoes was used, given that they are renowned for containing high levels of natural toxins. The study generalises conclusions made from the use of raw potatoes to the use of cooked potatoes. It is well documented that protein malnutrition in rats leads to decreased growth rate, changes in gut morphology and hepatic atrophy features that were observed in these studies.'

He concluded: 'I would not recommend this paper be accepted for publication in its current form.' He then went on to make a series of detailed points to which the author would need to respond before acceptance for publication.

• A full review by the Royal Society was announced.

# 20 February 1999

• The Prime Minister wrote personally in the *Daily Telegraph* under the headline 'GM foods: we stand firm', rejecting calls for a moratorium. Other scientists voiced criticisms, calling for appropriate control experiments and speculating that the process of inserting the lectin had 'disrupted the behaviour of the potatoes' other genes'. Several companies pointed out that their own toxicity tests would have picked up the sort of effects claimed by Dr Pusztai.<sup>4</sup>

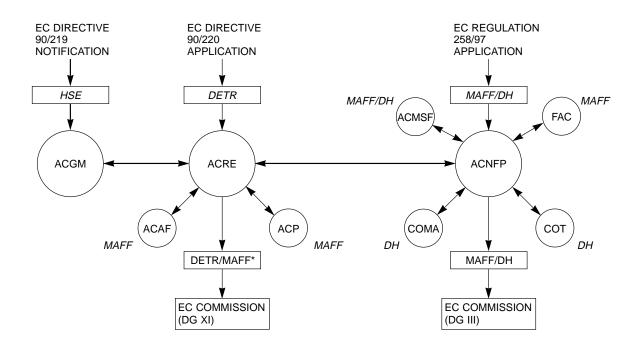
# Late February 1999 / March 1999

• Some of the original 20 scientists explained that they were supporting Dr Pusztai because they thought he had been poorly treated, not because they were necessarily against genetic modification and one said specifically that he was 'not acting as a referee'.<sup>5</sup>

<sup>3</sup> Sanders T (1999) Pusztai: the verdict, **The Independent**, 19 February 1999

Coghan A, Concar D and Mackenzie D (1999) Frankenfears, **New Scientist**, 2174:4–5.
Concar D, Mackenzie D and Coglan A (1999) Mashed potatoes, **New Scientist**, 2176:13.

Advisory Committees



#### Sponsoring Department

There is cross membership between all Advisory Committees except ACRE/ACP and ACGM/ACNFP where the link is through Departmental officials.

\*Where appropriate DETR/MAFF acts together with the Secretaries of State for Scotland, Wales and Northern Ireland.

MAFF Ministry of Agriculture, Fisheries and Food

DH Department of Health

ACNFP Advisory Committee on Novel Foods and Processes

FAC Food Advisory Committee

ACRE Advisory Committee on Releases to the Environment

COT Committee on Toxicity

COMA Committee on Medical Aspects of Food Policy

ACP Advisory Committee on Pesticides

ACGM Advisory Committee on Genetic Modification

(ACAF) Proposed Advisory Committee on Animal Feedingstuffs

HSE Health and Safety Executive

DETR Department of the Environment Transport and the Regions ACMSF Advisory Committee on Microbiological Safety of Food

Source: MAFF

# Appendix 3

Fact-finding meetings

The Working Party wishes to thank the following individuals and their organisations for providing helpful information and insight into the subject of GM crops:

The British Society of Plant Breeders Ltd (BSPB), Dr Penny Maplestone, Technical Liaison Manager Department For International Development (DFID), Mr Andrew Bennett, Director, Natural Research Division

English Nature, Dr Brian Johnson

European Commission DG III, Mr Gwenole Cozigou

European Commission DG IV, Ms Dorothee Andre-Schoboboda

European Commission DG XII, Mr Etienne Magnien

European Commission DG XII, Mrs Laurence Cordier

European Commission DG XXIV, Ms Patricia Brunko

European Commission DGI, Mr Ramiro Cibrian

European Commission SG, Mr Lars Mitek-Pedersen

Institute of Virology & Environmental Microbiology, Dr Ian Cooper

The Institute of Terrestrial Ecology, Professor Alan Gray

Ministry of Agriculture, Fisheries and Food (MAFF), Dr John Bell, Joint Food Safety and Standards Group

MAFF, Mr Nick Tomlinson, Joint Food Safety and Standards Group

Monsanto Europe SA, Agricultural Sector, Dr Stephen Waters, Regulatory Affairs Manager

Monsanto plc, Agricultural Sector, Dr Colin Merritt, Technical Manager

National Farmers' Union (NFU), Dr Vernon Barber, Food Science Adviser

NFU, Mr Archie Montgomery, Chairman of Biotechnology Working Group, NFU representative to SCIMAC, Council member

NFU, Mr Bob Fiddaman, Member of Biotechnology Working Group, NFU representative to SCIMAC, Council member

National Institute of Agricultural Botany (NIAB), Mr John MacLeod, Director

Pioneer, Mr Tim Stockton, Director of Government Affairs: Europe

The Royal Society for the Protection of Birds (RSPB), Dr Mark Avery, Head of Conservation

Sainsbury's, Ms Alison Austin, Senior Manager

Science Museum, Professor John Durant, Assistant Director

Supply Chain Initiative on Modified Agricultural Crops (SCIMAC), Mr Daniel Pearsall, Secretary

University of Cambridge, Department of Biochemistry, Dr David Ellar and Dr Paul Davis

The Wellcome Trust, Dr Susan King, Head of Consultation and Education

Yale University, Professor Robert Evenson, Centre for Economic Growth

Zeneca Plant Sciences, Dr David Lawrence, Head of Crop Research

# Appendix 4

Method of working and consultation

The Working Party met nine times between January 1998 and March 1999. The inquiry was announced in the press in January 1998 and interested organisations and individuals were invited to obtain a consultation pack (also placed on the Web) and comment on the issues raised by the introduction of GM crops. One hundred and eighteen responses were received from a variety of organisations and individuals including 55 sixth-form pupils from one school, 75 individuals, 16 academics or academic organisations, ten agricultural and industrial organisations, eight environmental organisations, seven organisations concerned with food and consumers, eight religious groups, five health organisations, three governmental or regulatory bodies and six organisations or groups of organisations, with a broad remit. Those who responded are listed in Appendix 5 and the Working Party is grateful to them all. Some of the main themes to emerge from the consultation responses are set out below.

# Ethical questions about the acceptability of genetic modification of nature

- Respondents varied widely in their views about whether or not GM crops and food posed ethical questions about what was acceptable with regard to the manipulation of nature. Less than one-tenth of respondents believed that no new ethical issues were involved. A similar number pointed to the centuries of selective plant breeding that have already been carried out in agricultural systems and the fact that genes are exchanged between different species and genera in nature. A few respondents noted the extent to which plants were currently altered by means other than genetic modification. Some respondents questioned whether moral reactions to genetic modification were affected by an individual's knowledge about the science of genetic modification.
- Almost one-third of respondents believed that new issues were being raised and suggested that genetic modification was fundamentally different to selective breeding because it involved breaching the natural integrity of an organism by introducing 'foreign' genes, thus transgressing species barriers. More than half the respondents raised consequentialist concerns about harm to ecosystems and the plant and animal kingdoms. Over one-tenth of respondents asked in addition what right we had to manipulate creation in this way and whether or not the process of GM itself was impermissible and tantamount to 'playing God'.
- Some respondents expressed the concern that limitations in our current scientific levels of understanding meant that genetic modification amounted to attacking a complex natural organism with a 'blunt instrument' and that it would be impossible to predict the consequences of such manipulations. Such changes might have unacceptable consequences because they are carried out on a large scale as opposed to the case-by-case spontaneous changes which occur in nature. Most respondents expressed concern about the harm we may do to ourselves and our environment and expressed a wide range of views about the extent and degree of damage which may result from GM crops. Questions were raised about the permissibility of causing such harm to ourselves and our environment for improvements in crops that many perceived to be 'unnecessary'. Almost one-fifth of respondents suggested that it would be unacceptable to grow GM crops because cross-pollination would remove the choice of adjoining farmers about whether or not to grow such crops.
- Some respondents questioned the assumption that mankind has the right to manipulate creation for its own benefit. Concerns about 'playing God' were most often raised in individual rather than in institutional responses. Some religious organisations suggested that there may be a moral obligation to modify crops genetically, if this will alleviate suffering, while others perceived genetic modification to be impermissible.
- 6 Utilitarian arguments advanced by some respondents in favour of GM crops suggested that they would increase consumer choice, lower the costs of food, protect the environment by lowering the amounts of insecticide or herbicide used, lessen the amount of land required for agricultural purposes

and supply the increasing amount of food needed to support an increasing world population. Such respondents often concluded that it would be unethical *not* to use GM crops to promote human well-being.

#### Ethical obligations to distinguish between GM and non-GM foods

Approximately five percent of respondents thought that there was no ethical obligation to ensure that non-GM foods would continue to be available and distinguishable from GM foods, asking upon whom such an obligation could be placed. It was suggested that market forces need be the only determinant of whether non-GM food remains available, as consumers would 'vote with their pockets'. Almost half the respondents, some of whom considered that only a minority of society would want non-GM foods, suggested that there should be an ethical obligation to cater for such preferences, in a similar manner to the way in which the dietary requirements of minority religious groups are catered for. Some of these respondents suggested that there should be an obligation on companies and governments to ensure such food remains available so as to preserve choice, maintain biodiversity and provide employment for those wishing to cultivate conventional crops.

# Principles which should govern the regulation of GM crops

- Approximately one-sixth of respondents explicitly suggested that a risk/benefit approach should control the development and application of GM crops. A few respondents suggested specific additional considerations including: the availability of alternatives, economic consequences, necessity, safety, utility, sustainability and issues of justice and freedom. The Working Party noted that many of the above considerations were outside the remit of current regulatory authorities.
- Fears were expressed consistently about the safety of GM crops and a number of respondents suggested that the 'precautionary principle' (paragraphs 1.12–13) should be applied by regulatory authorities. In particular, concerns were expressed about: the time-scale needed to assess the safety or otherwise of GM crops; dangers to human health though GM contamination of the food chain, and allergenic risks or unexpected side-effects of introduced genes. Some proposed that minimal risks from GM crops should be tolerated because the benefits were currently minimal.
- Approximately one quarter of respondents proposed that there should be a moratorium on planting and importation of GM crops, at least until further research is carried out into their long-term effects on the environment and human health. Opinions differed about whether the moratorium should be restricted to commercial crops or should extend to research plots. Others considered that, until more was known about the results of growing GM crops, such crops should be carefully monitored and a moratorium only imposed if the risks were unacceptable. Over one-fifth of respondents suggested that GM crops should only be permitted where it could be shown that there was a need for them.
- A number of respondents suggested that additional measures for regulatory purposes should include a study of the way farmers will routinely use GM crops rather than the effects produced under controlled conditions. They also pointed to the need for a wide range of experts to be consulted about the identification and investigation of potential risks of GM crops. Several felt that a wide range of possible consequences of GM crops should be considered including impact on the environment, agricultural practices, the food supply chain and the need to label food. It was suggested that these issues could not be covered by approval of GM crops on a case-by-case basis. A few respondents proposed that the remit of ACRE be widened to include these broader considerations.

# Managing uncertainty about the impact of GM crops

Most respondents considered that uncertainty about the long-term environmental impact of GM crops should be handled by extensive monitoring. It was suggested that monitoring should be mandatory, independent, long-term and assess environmental and well as socio-economic effects. A few emphasised that the cumulative effects of GM crops must be monitored. Some respondents also noted the need for research to be carried out to reduce the risks associated with GM crops.

# Safeguarding consumer choice

- Respondents noted that to safeguard consumer choice it would be necessary to ensure that there was always an alternative to GM products in the food chain. In particular, respondents expressed concern about the example of the non-segregation of US GM soya. Almost one-quarter of respondents suggested that accurate and comprehensible labelling of GM food would be sufficient to safeguard consumer choice. Those most strongly in favour of consumer choice suggested that labelling should be mandatory and that resources should be made available to enforce the system. Concerns were expressed that current EU provisions for labelling were insufficient, confusing and allowed too many GM products to be excluded. A small number of respondents mentioned the expense and difficulty of ensuring the separation of GM and non-GM food throughout the production process.
- More than one-fifth of respondents expressed concerns that labelling would not be sufficient to safeguard consumer choice. It was proposed that if widespread planting of GM food were permitted then cross-fertilisation and natural hybridisation would result in all foods containing genetic modifications within a short space of time. The need for buffer zones and the perceived inadequacy on current such zones were discussed extensively. It was noted that the large-scale planting of GM crops near borders could remove the choice to remain free of GM-crops from individual landholders, counties, regions or even countries. Some suggested that if GM crops were to become substantially cheaper for the consumer, then a subsidy should be provided for those who continue to grow conventional crops, so that consumer choice is safeguarded. Additional measures proposed to ensure consumer choice suggested that consumer education would be as important as labelling.

# **Current regulatory structures**

- Respondents' views about the current regulation of GM crops varied widely between the opinion that it was already too restrictive and the view that regulatory structures were insufficiently rigorous, impartial or opaque. Some considered that the current regulatory structures were suitable but suggested areas for improvement. It was also noted that recent transgressions of regulations demonstrated the need for monitoring of compliance and adequate penalties to be imposed.
- Approximately three-fifths of respondents expressed concerns about the current regulatory system which covered a wide range of issues. There was a view that it was difficult to get information from regulatory bodies which had insufficient lay representation. Some thought that the BSE crisis had demonstrated that the food regulatory authorities could be unreliable. Criticism was made of the application of the precautionary principle by current regulatory systems, with many respondents concerned that such application was insufficiently rigorous. Two-fifths expressed fears that the commercial interests of large companies was driving the development of GM crops and that this may result in a less rigorous analysis than most people would consider desirable. It was proposed that in addition to the disclosure of documents, current regulatory systems should also disclose the assumptions that underlie their decisions.

# Public involvement in the decision-making process

- On the question of whether people wish to be more involved in decision making about GM technology, the views of respondents were again widely divergent. Eight percent of respondents asserted that the public did not have the capacity to be involved in such decision making or that the public (including themselves) wished someone that they trusted to make the decision for them. Nearly two-fifths of respondents thought that the public wished to and should be involved in the decision-making process.
- It was suggested that if the public wished to become more involved in the regulation of GM technology, then a large-scale and comprehensive publicity campaign would have to take place to inform them of the issues. A few respondents noted that the educational exercise itself may allay a lot of public concern, reducing the desire of people to become involved in the decision-making process. A variety of means of taking public opinion into account were proposed including: opinion polls, small-scale fora, a referendum and people's parliaments. It was suggested that regulatory bodies for GM crops should have lay members, representation from lay interest groups or extensive public consultation before decisions were made. It was also proposed that non-governmental organisations with high public credibility ratings be included in the decision-making process. A small number of respondents preferred that open-minded members of the public be involved rather than particular lobby groups. A few respondents also took the view that the public be involved in regional plans to plant GM crops, as well as national and policy decisions. A minority felt that if a crop had passed all other regulatory tests it should not be submitted to an additional test via public consultation, as such a hurdle was not imposed elsewhere.
- It was observed that there was no clear route for feeding the results of public consultation exercises into policy making. It was suggested that it would be useful to assess the effectiveness of different forms of consultation and the structure of advisory committees in meeting the public demand for greater involvement in decision making. Proposed means of encouraging public participation included publishing consultation reports in a similar manner to the way in which they are for planning and environmental pollution systems.

# Responsibilities of companies developing GM crops

- Approximately one-tenth of respondents noted that the primary responsibility of companies was to make profits for their shareholders and to comply with relevant regulation and legislation. A few respondents contrasted this with the question, 'What ought society to require of companies?' It was suggested that independent monitoring of GM crop research, development and wide-scale planting should be undertaken, as the companies who developed these crops had a vested interest in making a profit and were not necessarily the best parties to monitor the consequences of their crops impartially. Nearly one-third of respondents stated that companies had an ethical obligation to ensure that their crops are safe for the environment and food chain. It was proposed that companies had a responsibility to clearly communicate to the public and regulatory bodies any risks associated with their GM crops, so that it could be determined if such risks were acceptable. A few respondents suggested that companies already had these responsibilities in relation to other foodstuffs that they produced. Some respondents suggested that companies had a duty to segregate GM and non-GM foodstuffs to facilitate consumer choice.
- 21 Nearly one-quarter of respondents suggested that companies had a duty to repair any damage caused by their crops, including compensating organic farmers who lost income as a result of cross-pollination of their organic crops with nearby GM crops. It was suggested that compulsory insurance or payment into a liability fund would be an appropriate means of providing the funds to

repair any damage. A few respondents suggested that companies who produced GM seeds should maintain banks of non-GM seeds or take other steps to preserve biodiversity.

#### **Patents and GM crops**

- A wide variety of views were expressed regarding the ethical acceptability of patents associated with novel GM crops. Approximately one-fifth of respondents suggested that the patenting of any DNA sequences is unacceptable while a similar number accepted that patents should be granted over genuinely novel crops. Some respondents who were not in favour of patents believed that patenting amounted to an unacceptable ownership of a life form. A few believed that the patenting of GM crops permitted the patenting of a discovery, rather than an invention, and that the creators of GM crops had not therefore been involved in an inventive step which deserved intellectual property protection. In addition, such patents deprived all of those who had done earlier research in a relevant area from the right to share any resulting profits, or would restrict access to a 'common inheritance'. Some respondents were concerned that if GM crops reduced biodiversity, the holders of patents on GM crops could have an unfair monopoly over food production. As a result, a few respondents suggested that owners should make patented developments available to developing countries on non-exploitative terms. In addition, to preserve choice, it was proposed that patent holders should have a duty to continue to provide non-GM seed.
- Arguments in favour of patents were largely utilitarian, noting that the patenting system was not necessarily ideal, or even the most effective way of allocating intellectual property rights, but that it should be upheld until a more acceptable means was found. Some took the view that without such a system there would be no reason for companies to develop beneficial new technologies. Of those respondents, many also drew attention to the difference between the idea of patents conferring ownership of all the plants grown of a particular GM crop (which is how some respondents perceived such patents) and the exclusive right to the commercial application of the GM invention (which is what a patent actually confers).

# Consequences of GM crops for developing countries

- Respondents had very differing views about the benefits GM technology could offer the developing world. Almost three-tenths of respondents cited factors in favour of GM crops, which included allowing crops to be grown in inhospitable areas, which would assist in alleviating food shortages. In addition, it was proposed that GM crops would require less use of developed world technology in the form of pesticides and herbicides, thus lessening costs for the developing world farmer. A few suggested that GM crops would be vital to feed the world's rapidly growing population and to provide edible plant-based vaccines.
- In contrast, approximately one-third of respondents suggested that GM crops would increase costs for developing world farmers as they would be forced to buy new seeds each season because GM crops would be designed to produce sterile seeds or no seeds at all. In addition, if crops were designed to be used with particular herbicides or insecticides, farmers would be forced to buy these. Doubt was expressed by some about whether developing specialised GM crops for use in poorer parts of the world was financially attractive to companies. Some suggested that food shortages were largely a political, rather than an environmental issue, so that increasing the capacity to grow crops would not solve problems of under-nutrition. A few respondents expressed concerns that if GM crops grown in the developed world proved to be substantially cheaper than developing world crops then the lack of an export market would increase poverty in the developing world, especially as more land became devoted to growing cash crops.

Many respondents, whether or not they agreed that GM crops would be beneficial to the developing world, were concerned that any profits made from intellectual property rights over gene sequences from the developing world be shared with the traditional users of the plants from which the DNA was taken. Concerns were also raised that regulations regarding the introduction and cultivation of GM crops would be more lax in the developing world which could result in avoidable environmental and public health disasters, or in the developing world being used as a 'testing ground' for GM crops. In particular, a few thought that the benefits of GM crops could accrue to the developed world while the developing world bore most of the attendant risks. Some noted that vital natural habitats and centres of biodiversity might be destroyed as GM crops were grown in areas that were previously unsuitable for them. A few respondents suggested that instead of asking what benefits GM crops could have for developing countries, attention would be better focused on what developing countries thought that they needed.

Consultation responses

# **Organisations**

ADAS

A G Brockman & Company

AgrEvo

Biotechnology and Biological Sciences Research Council (BBSRC)

British Buddhist Association

The British Dietetic Association

British Ecological Society

British Medical Association (BMA)

The British Society of Plant Breeders Ltd & British Sugar Beet Seed Producers Association

BTG International Limited

The Church of England, General Synod, Board for Society Responsibility

Confederation of British Industry (CBI)

Consument & Biotechnologie

Consumers in Europe Group

Dalriada School, Co Antrim, Northern Ireland: (55 VI form students)

Devon County Council, Trading Standards & Consumer Protection

DTI, Office of Science & Technology, Foresight Health & Life Sciences Panel

English Nature (joint response with Scottish Natural Heritage & Countryside Council for Wales)

EuropaBio

European Commission DG XII (Science, Research & Development)

The Farm and Food Society

Farming and Livestock Concern

Food & Drink Federation

The Food Ethics Council (endorsed by Dr Ben Mepham, Dr Peter Lund, Professor John Webster, Dr Paul Evans, Professor Ruth Chadwick, Mr John Verrall and Dr Vernon Jennings)

GeneWatch

Horticulture Research International

Institute of Biology (joint response from specialist affiliated societies: The Association of Applied Biology, The British Crop Protection Council, The British Ecological Society, The British Electrophoresis Society, The British Grassland Society and The Institute of Horticulture)

Institute of Food Science & Technology (UK), Technical & Legislative Committee

Institute of Grassland & Environmental Research

International Bee Research Association

Joint Ethico-Medical Committee of the Catholic Union of Great Britain and the Guild of Catholic Doctors Marks & Spencer

Mobbs Environmental Investigations on behalf of the Free Range Environmental Activism Network

The National Council of Women of Great Britain

National Farmers' Union

National Institute of Health, Maryland USA

The National Trust

Natural Environment Research Council (after consultation with the Institute of Virology and Environmental Microbiology and the Institute of Terrestrial Ecology)

Office of the Chief Rabbi

Presbyterian Church in Ireland

Quaker Ethics and Genetics Network

Quaker Social Responsibility & Education, Northampton & Wellingborough meeting group

The Royal Society of Health

SAFE Alliance

Scottish Crop Research Institute

Society, Religion and Technology Project, Church of Scotland

Tameside & Glossop Local Research Ethics Committee

Unilever

Wageningen Research Group on Technology and Agrarian Change, Wageningen Agricultural University

#### **Individuals**

Appelmelk, Anna

Barrett, Mr Vic

Barton, A E M

Barton, Eva

Bayes, Julia

Bell, Mrs J D

Black, Dave

Booth, Philip

Boulter, Professor D: University of Durham, Department of Biology

Cantley, Mr Mark: OECD

Carr, Dr Susan: Open University, Faculty of Technology

Carter, Yvonne

Carruthers, S P: University of Reading, Centre for Agricultural Strategy

Collins, Mr Ken: MEP for Strathclyde East

Deane-Drummond, Dr Celia: University College, Chester

Dimmer, Clare

Durant, Professor John: Science Museum

Elworthy, Joy

Emmott, Steve

Frewer, Dr Lynn: Institute of Food Research

Greene, Lesley

Petition signed by 17 people from The Grange, Newnham on Severn

Haggis, Geoffrey

Harris, R M

Heaf, Dr David

Hermes, Karin

Jackson, David

Johns, Ken

Kennet, Lord & Lady

Kirst, Rudolf

Krakiewicz, A

Leather, Ms Suzi & Bryant, Professor John: University of Exeter, School of Biological Sciences

Lee, Mrs Maria

Levidow, Dr Les: Open University, Centre for Technology Strategy

Levitt, Dr Mairi: University of Central Lancashire, Centre for Professional Ethics

Lowe, Dr Gwen

Lynch, Professor J M: University of Surrey, School of Biological Sciences

Macdonald, Sylvia: British Baker

Marsden, Dr John Megginson, Fiona

Miflin, Professor B J: Institute of Arable Crops Research

Moore, Mrs Rose

Morton, Professor David: University of Birmingham, Centre for Biomedical Ethics

Munday, Jacqui

Monro, Dr Jean: Breakspear Hospital

Nicholls, M A

Nicholls, Margaret

Nichols, Keith

O'Neil, Diana

Paris, Ms Robin

Pierce, Mandy and Loud, Ian

Polkinghorne, Rev Dr John

Pomfrey, Ms Vivien

Purdy, Ray: Imperial College, Environment Policy & Management Group

Reddy, K Srinvan SV: Agriculture College, India

Reiss, Revd Dr Michael: Homerton College, Cambridge

Roberts, Philippe

Rose, D J T and Mrs Dawn

Sellers, NW and LC

Shankland, Philip

Strathern, Professor Marilyn: University of Cambridge, Department of Anthropology

Timewell, Philippa

Timewell, Royston

Ross, Hugh McGregor, Clare and Carole

Varley, Jane

Warden, Michael

Wells, John

Woolven, Mrs Patricia

Workman, Sue

#### **Amino acids**

Molecules which link together to form proteins.

#### **Antibiotic**

A substance which kills micro-organisms such as bacteria. Many antibiotics are used in medicine to treat disease.

# Antibiotic marker gene

This is a gene which expresses a protein that enables the organism carrying the gene to tolerate the antibiotic concerned. A marker gene is one that has a characteristic which can be selected for in gene transfer experiments.

#### **Backcrossing**

Backcrossing is the process by which an FI hybrid, made by crossing two parent plants, is crossed back to one of the parents.

# Bt

The bacterium Bacillus thuringiensis which is toxic to some insects.

# Cell

The smallest component of a living organism which is able to grow and reproduce independently.

# Chromosome

The thread-like DNA in a cell is divided into several separate lengths. Each length forms a structure called a chromosome.

# **Construct**

A gene sequence made in a laboratory. It is usually designed to be incorporated into a specific organism (such as a soybean) where it is intended to express a desired characteristic (for example, make the soybean able to tolerate Roundup).

# Crosses

Breeding together different parental varieties

#### **Cultivar**

A plant variety

#### **DNA**

DNA (deoxyribonucleic acid) is the biochemical substance that genetic material is made of. DNA has a thread-like structure. The DNA in a cell is in several long lengths, each of which contains many genes.

#### **Dominant**

A gene which exerts its effect in the presence of another. The dominant gene often produces a biochemically active product.

#### **DUS** criteria

DUS are the criteria needed for a new inbred variety to be approved for Plant Varieties Rights regulations in the UK. These are: distinctness – is it different from anything already available on the market? Uniformity – are all the seeds exactly the same? And stability – is the variety stable over several generations?

# Expressed sequence tag (EST)

ESTs or expressed sequence tags are partial DNA sequences which represent genes that are turned on in a particular tissue type or organism

# F1 hybrid

F1 hybrid seed is produced by inter-crossing two predefined parental lines. F1 hybrids are favoured by producers because they display hybrid vigour or heterosis. F1 hybrids do not breed true and, therefore, farmers cannot save seed.

# Gene

A length of DNA which contains the information needed to make one protein.

# **Genetic modification**

Genetic modification involves the direct introduction of desirable characteristics by artificial transfer of foreign or synthetic DNA (deoxyribonucleic acid, the genetic material) into an organism. A GM organism or GMO has therefore been altered in a way that does not involve mating and/or conventional genetic recombination.

# Herbicide

This is a substance which kills plants and is used to control weeds. Different herbicides are toxic to different varieties of plants and some herbicides can kill a wider variety of plant than others.

#### Herbicide tolerance

This allows a plant to tolerate a herbicide which would otherwise kill it (see Roundup and Roundup Ready below).

#### **Hybrid**

A plant produced by breeding genetically dissimilar parents.

#### **Insect resistance**

The ability of a plant to kill an insect which is preying upon it. Bt insect-resistance genes come from the bacterium *Bacillus thuringiensis*. These genes code for a variety of toxins, which vary in the extent to which they are toxic to different insects.

#### Methylation

Methylation is a natural mechanism by which many species, including humans, regulate when genes are turned on and off in particular cells, tissues or whole organisms. Some of the base pairs in DNA can have additional methyl groups added through the action of cellular enzymes. Such methylated stretches of DNA are then inactive.

#### **Pleiotropy**

This occurs when a single gene produces a biochemical effect which can give rise to several seemingly unrelated characteristics.

# **Precautionary Principle**

This is the rule that permits governments to impose restrictions on otherwise legitimate commercial activities, if there is a risk, even if not yet a scientifically demonstrated risk, of environmental damage.

# **Promotor**

A promotor is a DNA sequence that regulates the expression of a gene. Each gene has its own promotor which receives specialised proteins that bind and activate a gene.

# Recessive

A gene which only exerts its effect only if paired with an identical copy.

# Refuge

An area of crops which are susceptible to weeds or, more usually, insects, and thus provide a safe haven for them. These are planted near herbicide-tolerant or insect-resistant crops to reduce the selection pressure on the insects or weeds to evolve resistance.

#### **Roundup**

Roundup is a broad spectrum herbicide which can kill a wide variety of plants, including soybeans which have not been genetically modified to tolerate it.

#### Roundup Ready

'Roundup Ready' is the proprietary name given to crops which have been modified to contain resistance genes to the herbicide glyphosate (Roundup).

#### **SNP**

SNPs or single nucleotide polymorphisms are single DNA base pair mutations. In the human genome project they are being used as markers to locate disease genes. Most SNPs fall within the non-coding regions of human DNA and make no difference to the individual. A given set of SNPs is likely to be inherited with a particular gene and can be used to identify it.

#### Volunteer

An unwanted crop plant self-propagated from previous year's crop.

# **GLOSSARY OF ACRONYMS**

ACNFP Advisory Committee on Novel Foods and Processes
ACRE Advisory Committee on Releases to the Environment

BSE bovine spongiform encephalitis

Bt Bacillus thuringiensis

CAMBIA Centre for the Application of Molecular Biology in International Agriculture

CBD Convention on Biological Diversity (Biodiversity Convention)
CGIAR Consultative Group on International Agricultural Research

COPUS Committee on Public Understanding of Science

DES dietary energy supply

DETR Department of the Environment, Transport and the Regions

DFID Department For International Development

DH Department of Health
DNA deoxyribonucleic acid

DoE Department of the Environment
DUS distinctness, uniformity, stability criteria

EC European Commission

EPA Environmental Protection Agency

EPO European Patent Office
EST expressed sequence tags
EU European Union

FAO Food and Agricultural Organisation of the United Nations

FDF Food and Drink Federation

FSA Food Standards Agency

GIBiP Green Industry Biotechnology Platform

GM genetically modified

GMO genetically modified organism

GURT Gene use restriction technology (also known as 'Terminator' technology)

GUS Gene encoding  $\beta$ -glucuronidase HSE Health and Safety Executive

IARC International Agricultural Research Centres

ICARDA International Centre for Agricultural Research in the Dry Areas

IPGRI International Plant Genetic Resources Institute

ISAAA International Service for the Acquisition of Agri-biotech Applications

MAFF Ministry of Agriculture, Fisheries and Food MEP Member of the European Parliament NARS National Agricultural Research Systems

NFU National Farmers' Union NGO Non-government Organisation

NIAB National Institute of Agricultural Botany

OECD Organisation for Economic Co-operation and Development

OSR oilseed rape

OST Office of Science and Technology
PTO Patent and Trademark Office
R&D research and development

RAFI Rural Advancement Foundation International

SCIMAC Supply Chain Initiative on Modified Agricultural Crops

SD standard deviation

SNP single nucleotide polymorphism

TRIPS Trade Related Aspects of Intellectual Property Rights

UK United Kingdom

UPOV Union for the Protection of the New Varieties of Plants

US United States of America

USDA United States Department of Agriculture
USPTO United States Patent and Trademark Office

VCU value, cultivation and use

WIPO World Intellectual Property Organisation

WTO World Trade Organisation

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