Chapter 8

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 BioIndustry 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 developing 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.