Crops on trial : a report / by the AEBC.

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AGRICULTURE AND ENVIRONMENT
BIOTECHNOLOGY COMMISSION

Crops on Trial

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CROPS ON TRIAL

A REPORT BY THE AEBC

September 2001

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PART 1

INTRODUCTION AND CONTEXT

PART 1.1 INTRODUCTION

1. The issues thrown up by genetic modification (GM) technology are hugely challenging, but two facts at least seem clear. The first is that the remarkable advances in our understanding of molecular biology are here to stay. They have created the possibility of GM products of many kinds. Many of these – like the use of genetically modified bacteria to produce insulin for diabetics, or chymosin (used in the making of cheese) have attracted little criticism, or indeed have been positively welcomed. GM products may deliver demonstrable environmental benefits, as with the significant reductions in the use by farmers of chemical pesticides that has followed the introduction of insect resistant cotton in the USA. But this and other possible uses have nonetheless given rise to intense discussion in many countries as well as our own as to the terms and conditions on which they might now be developed in useful and socially acceptable ways. This highlights a second clear fact – that the political arrangements needed to deal legitimately with these issues in countries like the UK are immature, and in immediate need of further development. This report makes some proposals for how these may start to be improved.

2. The Agriculture and Environment Biotechnology Commission (AEBC) is a new and distinctive kind of independent body. We were set up in June 2000 with a brief to look at current and future developments in biotechnology which have implications for agriculture and the environment, and to advise the Government on their ethical and social implications and their public acceptability. Our remit requires us, amongst other things:

- to advise the Government on the ethical and social implications arising from developments in biotechnology and on their public acceptability;
- to consider the wider implications of the lessons to be learnt from individual cases requiring regulatory decision;
- to make recommendations as to changes in the current structure of regulatory and advisory bodies.

3. Our terms of reference specify that in the context of the work of the Commission, the term "Government" comprises the UK Government and the devolved administrations. We use the term in that sense in this report.

4. The AEBC's twenty members come from different backgrounds. Some work in agriculture, in ecological research, in academia or in biotechnology, while others are involved in non-Governmental organisations (NGOs), social research and consumer matters. And they cover all shades of opinion on GMs. Some came into these discussions as sceptics, others were cautiously optimistic about the potential benefits GM crops may bring, while still others were undecided. In this sense, the membership of the AEBC reflects the spread of public attitudes towards GM in the country at large.

5. At our first meeting, in July 2000, we noted that the Government's Farm-Scale Evaluations (FSEs) of genetically modified herbicide-tolerant (GMHT) crops had caused considerable controversy since they were first announced in late 1998. Looking closely at these trials seemed likely to be a good way of getting to grips with some of the issues. The intensity of public interest and concern which they aroused seemed to have

surprised and puzzled the Government, the industry and the scientists most directly involved. The trials had become the focus both of local resentments and of wider national concerns about possible GM crops and foods. So we decided to evaluate the role of the trials in the regulatory process, looking at the reasons for setting them up, their objectives (and the extent of consultation in agreeing those objectives), the data they were expected to produce and the gaps which might still remain – and, in particular, to try to understand and explain the evident public concern. As a result of this study, we hoped to be able to provide advice which, in accordance with our remit, would assist in future decision-making in the sphere of biotechnology and its implications for agriculture and the environment.

6. This is a report of the whole Commission. It is based on work by a sub-group of seven AEBC members, with a spread of interests and backgrounds reflecting that of the Commission as a whole. Over six months, the group held discussions with local people in areas affected by the trials and took evidence from both national and local organisations and institutions. The whole Commission deliberated at two separate meetings on the group's proposals, held public meetings and took evidence formally in public.

7. Coming from such different backgrounds, members of the Commission have debated intensely among themselves. In the process, we have learnt a lot about how best to air and examine varying beliefs, assumptions and attitudes. There are many matters on which we have agreed – more than some of us might have expected. The fact that there are other issues on which we disagree has not prevented us from reaching a number of shared conclusions on how these matters might be handled better by Government in the future. We trust that this report, benefiting from the diversity of opinions and values which the Commission's membership embraces, can help illuminate public discussion of what is now at stake for society. And we trust that Government too will benefit from our recommendations.

8. Our report is structured so as to provide first a brief summary of the context of the FSEs (Part 1.2), then our conclusions and recommendations (Part 2). Our thoughts which led to those conclusions and recommendations are in Part 3, and Part 4 presents more detailed background information.

PART 1.2 THE CONTEXT: THE FARM-SCALE EVALUATIONS AND THE LEGAL FRAMEWORK

9. To set the context for our conclusions and recommendations in the next Part, we give here a brief outline first of the Farm-Scale Evaluations, and then of the legal framework governing the commercial cultivation of GM crops.

The Farm-Scale Evaluations[1]

10. The Farm-Scale Evaluations (FSEs: "the trials") are a programme of scientific investigations at field level which are being undertaken in the UK on the basis of an agreement between the Government and the body representing the farming and biotechnology industry, SCIMAC (the Supply Chain Initiative on Modified Agricultural Crops). After a pilot project in 1999, the main project started in spring 2000, and will end at harvest 2002 for spring sown crops and harvest 2003 for winter sown crops. Four genetically modified herbicide-tolerant (GMHT) crops are involved in the trials: winter and spring varieties of oilseed rape, beet (fodder and sugar) and forage maize. In all, between 60 and 75 fields, varying in size from 4 to 30 hectares, are to be planted for each of the four crops. Each field is split into two, one half being sown with a GMHT crop and the other with an equivalent non-GM variety.

11. The objective of the FSEs is not to evaluate the effects of the GMHT crops themselves, whose safety has already been evaluated in the laboratory and in small-scale field trials and approved by the regulatory authorities. It is to find out whether the herbicide management associated with these GM crops, as compared with that used on the non-GM equivalents, has any effects on some aspects of farmland biodiversity – that is to say, on the number and diversity of plants and animals. Some key indicators of biodiversity will be measured to check if there are differences between the two halves of each field.

The legal framework[2]

12. The regulatory arrangements for GM crops are more rigorous than has been the case in the past for the introduction of technological and agronomic changes in farming. They are based primarily upon case-by-case assessments of new seed varieties. This involves securing approval for each new GM crop/food under several separate processes that are governed by EU rules (with supporting UK legislation):

- the EU Directive on the deliberate release of GMOs (implemented in the UK via the Environmental Protection Act 1990 and subordinate legislation);
- the EU Novel Foods Regulations (for decisions on whether GM crops are safe as food);

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[1] For more detail and a critical analysis, see Parts 3.2 and 4.3.
[2] For more detail, see Part 4.2.

- regulations which require the approval of new pesticide uses (if a GM plant is linked to a specific pesticide/herbicide); and
- rules that require new agricultural crop varieties to pass trials for inclusion on the National Seeds List (or EU Common Catalogue) before they can be marketed.

13. Clearance for GM animal feed is presently handled under the Deliberate Release Directive, but proposals have recently been issued by the European Commission for new EU rules covering the approval of both GM foods and animal feeds. To illustrate how these procedures work in practice, Annex A to this report contains an illustrative case study of the regulatory process which has been undergone by one of the crops (oilseed rape) involved in the FSEs.

14. The principal measures currently in force are the Deliberate Release Directive and the Novel Food Regulation, and national legislation made under them. The regulatory scope of the Deliberate Release Directive is narrow. It requires Member States, in accordance with the precautionary principle, to ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment from the deliberate release or marketing of GMOs. It prescribes a licensing procedure. There is no burden of proof on the applicant to demonstrate an absence of adverse effects, but the applicant is required to assess the impacts and risks and draw a conclusion. This is then reviewed by the regulatory authorities before making a decision. Hence, there is a case by case environmental risk assessment which is scientifically constructed, though the decision to be made by Ministers and Governments on whether to allow deliberate release is not, and cannot be, a wholly scientific judgement. It must include a decision, on behalf of the public, as to the acceptability of any risk. Nonetheless, the regulatory process is implicitly based on the principle that, in the absence of unacceptable adverse effects on human health or the environment, there is no regulatory barrier to the deliberate release of a GMO or, ultimately, to the marketing of a GM crop.

15. There are two stages of approval within the Directive. Part B covers releases for research and development, and Part C covers commercial releases (referred to in this report as commercialisation). Applications under both Parts are made to the competent authority of the Member State where the release is to take place, or where the product is to be placed on the market. For Part C applications, that competent authority first evaluates the dossier, and may reject the application. If it views the application favourably, the dossier is submitted to the European Commission for circulation to the other Member States for evaluation by them, "taking into account the particular health and environmental safety issues unique to their territories". If a Member State objects, an attempt is made to resolve the objection but it may ultimately be overridden by a majority (under the usual arrangements for qualified majority voting) in a committee, or if the application is not then approved, by putting the matter to the Council of Ministers (again using qualified majority voting).

16. Once consent is given under these procedures for a GMO to be placed on the market in the EU, it extends to all Member States. The legislation does not allow the European Commission or any Member State to turn down an application on grounds other than those specified in the Directive. Consent could not, for example, be refused on the grounds of public concern about the technology in principle. Public concerns which go beyond the criteria prescribed for the regulatory arrangements have no

expression in this process. It is a case by case process, not an opportunity to review generic issues about biotechnology. This has caused some tension between and within Member States, and has contributed to the seizing up of the EU regulatory system: no decisions have been taken on Part C applications under these procedures for the past three years.

17. A parallel regime, though outside our immediate remit, is provided by the EU Novel Foods Regulation 258/97. This provides for a statutory, pre-market safety assessment of all novel foods, included those obtained from genetically modified sources. An application for approval for a GM food is first considered by one Member State, which produces an initial opinion, which is then considered by all the other Member States. If the initial assessment is favourable and there are no objections, the GM food can be marketed. If any objections are raised, the application is referred to the Standing Committee for Food for final agreement, seeking the advice of the EC Scientific Committee for Food, if necessary.

18. GM foods are assessed for safety on a comparative basis to ensure that they are at least as safe as the conventional foods that they are intended to replace. This safety assessment takes into account any possible adverse effects of the genetic modification of the source organism on the nutritional and toxicological characteristics of the foods derived from them, and includes an assessment of potential allergenicity. A detailed characterisation of the genetic modification event is also required.

PART 2

CONCLUSIONS AND RECOMMENDATIONS

PART 2 CONCLUSIONS AND RECOMMENDATIONS

Our starting point

19. At the outset it is important to acknowledge the wide differences of perspective on GM crops. Views and concerns at both ends of the spectrum – and in between – are genuinely and staunchly held, among members of the AEBC as well as in the country as a whole. Some see the ability to isolate and transfer DNA as a useful progressive evolution of selective plant breeding. For others, it marks a disturbing watershed in human intervention in nature, for which political and regulatory frameworks are ill-prepared.

20. We chose the Farm-Scale Evaluations of genetically modified herbicide-tolerant (GMHT) crops as a case study of regulatory decision-making in relation to GM because recent antagonism to GM crops has been focussed on them. There are particular reasons for this. GM crops are not new, either to the UK (where they have been planted in field tests since 1987) or internationally (where in 2000 they were being grown commercially on over 44 million hectares (ha) in 14 countries). But the FSEs have made the prospect of GM crops real to many people in the UK for the first time, and the specific local issues to which the FSEs have given rise (like concerns over groundwater and gene flow) have served to bring out more fundamental worries. The majority of the public may or may not be opposed to GM technology *per se* – but it is reasonable to assume that they do wish to be sure of the integrity and comprehensive nature of the decision-making processes governing how these crops may be used. We suspect that, far from offering reassurance, experience of the FSEs has tended to fuel further concerns. Local citizens' reaction to the rationales for, and processes surrounding, particular FSEs at local level may now itself be contributing actively to growing disrespect for the Government's policy. This dynamic is an important one, but under-appreciated by both politicians and officials.

21. We believe that robust public policies and regulatory frameworks for GM crops need to expose, respect and embrace the differences of view which exist, rather than bury them. The appropriate development of GM technology has suffered as a result of the lack of opportunity for serious debate about the full range of potential implications of GM agriculture, on the basis of clear understandings of what is involved, away from concern that has been promoted by campaigning elements of the media. There have been public protests around the FSEs. At some sites hostility – either local or more widely orchestrated – has led to farmers and their families being threatened and crops and farm equipment being damaged.

22. We believe that the Government must now encourage comprehensive public discussion of the ecological and ethical – including socio-economic – issues which have arisen. Time is needed for people to overcome differences of language and explore the extent of their shared understandings, and above all there is a need to include those who have felt themselves to be excluded and hence to have no control over events. We have initiated such a discussion, and we look forward to continuing it.

23. Our conclusions and recommendations fall under three main headings:

- completion of the trials (Recommendations 1 and 2);
- the criteria and processes relevant to decisions as to whether the crops in the trials should be cleared for commercial cultivation (Recommendations 3, 4, 5, 6, 7, 8 and 9); and
- the implications of GM crops for the development of agricultural policy (Recommendation 10).

A. Completion of the trials

24. An important effect of the agreement between the Government and the industry to carry out the FSEs has been to buy some time. The next major decisions on the cultivation of GM crops in the UK cannot be made until the FSEs are complete (harvest 2002 for spring sown crops; harvest 2003 for winter sown crops), and the data from them have been statistically analysed. This gives a window of opportunity which if used wisely could reduce further conflict. We believe that within this period the Government and the other stakeholders should act on the basis of the recommendations which follow.

25. Whilst the FSEs are expected to produce useful data which can contribute to the decision about whether or not the crops involved should be commercialised, we are clear that they are not a sufficient condition for reaching those decisions. They cannot be, as widely interpreted, the final piece of the jigsaw before commercialisation can proceed. Additional information, and consideration of a wide range of viewpoints, must be factors in the eventual decisions. Our recommendations propose steps that the Government should take to ensure that such decisions are based on comprehensive information, and are taken in a way that is transparent and inclusive.

26. If the Government and industry accept these other elements as fundamental to the decision on whether to commercialise, we believe the trials should be completed because of the relevance of the additional data they will provide. They are the first large-scale manipulative experiments in this area (other large-scale studies having been observational), and they may well therefore provide important insights into how particular changes in land management are linked with changes in certain aspects of biodiversity. They also reflect a more precautionary approach towards licensing the commercial use of new technologies, and as such they are of strategic importance.

27. However, the relationship with organic farming has been a critical point in the trials to date. Throughout the FSE programme to date there has been an impasse between SCIMAC and the leaders of the organic sector, as to how far that sector's position in relation to GM crops should be protected. Despite efforts, communication between the two has failed. This situation ill-serves the nation's strategic interests. It obscures rather than illuminates debate about the potential for coexistence of GM and other types of agriculture (both conventional and organic) in the UK.

28. We understand that to date there has been no removal of organic status from any crop as a result of the FSEs, and our first recommendation below is intended to ensure that this position is maintained. On the basis that the FSEs are experimental uses of GM crops, we believe that separation distances should be established which will

maintain a high level of precaution for the remainder of the trials, to ensure that the FSEs will have no material adverse impact on the conduct of organic farming.

29. Our recommendation has another important purpose. It is to provide a real opportunity for confidence and trust to develop between SCIMAC and the leaders of the organic and other non-GM sectors. The arrangements that we propose for the remainder of the trials should be without prejudice to the criteria by which separation distances might be established in the event of the future commercial growing of GM crops in the UK. That would be another step. It would require fresh agreement. It would not be simply a technical issue, but one which would build upon a basis of mutual respect between the different values and priorities of the parties. This is crucial in the development of a coherent UK agricultural policy for the future. Without the development of trust and openness in working and communication now, there is little prospect for any satisfactory strategic outcome for the longer term.

30. Furthermore, the concerns around the FSEs have arisen partly from the handling of the choice and announcement of trial sites. The sites offered by SCIMAC have been selected by the Research Consortium, using scientific criteria set by the Scientific Steering Committee, and this underpins the scientific basis of the evaluations. But the absence of consultation, the very short notification, and the particularly unfortunate location of some of the chosen sites, have made it seem that the trials have been conceived and designed in a secretive way, with key players not fully engaged. Some local people have felt excluded from decisions which they perceive as affecting their environment and compromising their local socio-economic objectives. We urge the Government (in conjunction with the industry) to approach the next stages of the programme more constructively.

31. In particular, there should be no reduction in the current benchmark of a minimum of 4 full weeks' notice of the proposed location of a trial site, and as a demonstration of its goodwill we urge SCIMAC to seek out sites that are well clear of existing organic operations, to strive for 6 weeks' notice and to take full account, in their consultations, of the interests of local stakeholders.

Recommendation 1: The programme of FSEs should be completed subject to:

- ***the Government confirming its commitment to no commercial cultivation of GM crops in the UK at least until the trials are complete and the results have been evaluated alongside other factors and other evidence identified below;***
- ***the Government working with SCIMAC and representatives of the organic farming industry to set adequate separation distances for the remaining trials to ensure that the interests of all parties are accommodated. By "adequate" we mean separation distances that allow current organic standards to continue to be maintained, but recognising that some flexibility will be required to ensure that the trials can be completed;***
- ***the objectives and limitations of the trials being clearly stated and communicated to the public;***
- ***effective local consultation taking place on the selection of plots, which, whilst maintaining the scientific basis of site selection, takes into account***

within the SCIMAC agreement other factors beyond the current regulatory regime, and in particular the interests of local stakeholders.

Communication

32. Because there are so many different concerns about GM crops, it was particularly important for the Government to succeed in communicating exactly what the FSEs were designed to address. Unfortunately this has not always been achieved. Firstly, people have not always understood that the FSEs are not an attempt to test whether the GMHT crops being grown are "safe" in themselves. Secondly, there has been confusion over the extent of the information which the FSEs could provide. The FSEs are a useful and unprecedented attempt to look at the effects on biodiversity of some of the management practices associated with the GMHT crops being grown. But it has not always been understood that the trials are not designed to address *all* the possible effects on biodiversity, or that even for the indicators which have been chosen, the analysis of the results will involve judgements about their ecological significance that are not purely scientific. The Government is fully aware that the information which will be provided from the FSEs will be limited, yet statements by Ministers have not always made this clear.

33. We think it is vital that, however GM technology develops, the communication of scientific issues is clear and accurate. This is a problem, because science does not often lend itself to convenient sound-bites. The Government has a particular responsibility to ensure accuracy and clarity in its statements. So do scientists, NGOs and the media.

Recommendation 2 Take particular care to ensure that Government press releases and publications are expressed in clear and precise language, so that messages are not distorted and cannot easily be misinterpreted.

B. Decisions on the potential commercialisation of GM crops following the completion of the trials

34. Concern over the FSEs has been exacerbated because many people believe that the decisions on commercial growing depend solely on their results. This belief is understandable, in view of the terms of the agreement between the Government and the industry, and Ministerial statements which have pointed in the same direction. However, it is clear, given the extent of public concern about the use of GM technology in agriculture, that the Government must also take into account other matters, such as scientific information from other sources, ethical concerns, the strategic and economic issues which will be raised by the forthcoming review of UK agriculture, and the concerns which have been expressed by the public. The FSEs have become a lightning rod for people's concerns about GM technology more generally, and it will be important to ensure that future decision-making is based on the fullest information, is transparent and is inclusive. This must involve a wide-ranging discussion with key stakeholders.

35. This is, broadly speaking, a process of political decision-making. Yet it is not a context in which the Government has unlimited powers. The Government, along with other European Member States, operates within a framework of European and world

trade laws. Decisions on commercialisation of at least two of the crops involved in the FSEs will be governed by the revised EU Directive on Deliberate Release. The Directive does not provide an opportunity for European governments simply to halt all developments in agricultural GM on the ground of perceived lack of public support for the further use of GM technology. In the absence of evidence of risk of adverse effects on human health of the environment, the applicant is entitled to be granted the consent.

36. But nor is this a wholly scientific or technical exercise. The new Directive (2001/18) itself acknowledges the particular importance of respect for ethical principles in Member States, and accepts that ethical considerations may be taken into consideration when GMOs are placed on the market. It authorises the European Commission to take advice on general ethical issues from a special Ethical Committee. Hence there is a locus for deliberation over such wider concerns as the use of terminator gene technology, or the use of human or animal genes in the modification of plants. The Commission is obliged to make an annual report to the European Parliament on ethical issues it has considered, accompanied if appropriate by a proposal to amend the Directive.

37. The Directive stresses the significance of the precautionary principle in decision-making. It authorises the imposition of conditions regarding the use, labelling, handling and packaging of the GMOs, and conditions for the protection of particular ecosystems or environments, and/or geographical areas. It also explicitly requires consultation with the public on proposed releases for Part B consents; and on notifications for Part C commercialisation consents if they are proposed for approval by the UK or another EU country. Ministers must, through proper consultation, engage with the public.

38. Given this framework, Ministers will no doubt wish to take account of ethical and other wider-ranging concerns that may be expressed to them in the course of such a formal consultation process. They are required to take a decision on behalf of society as to what is an acceptable level of risk to health and environment from the commercial growing of GM crops, and they will wish to have as comprehensive an understanding as possible both of the science and of public opinion as to the acceptability of that risk. This is not, of course, a simple one-way question. There are also risks to agriculture and the environment from continuing with the status quo.

39. Of course, the Government must ultimately balance these options within the legal framework outlined above, both under the Deliberate Release Directive and the other relevant regulatory controls: to do otherwise would be to invite legal challenge. Our recommendations below relating to the role and significance of the FSE data, the need for independent scientific review of all the relevant data relating to risk management, and the need to identify and fill gaps in knowledge, are all relevant to this process.

40. But the Government's consultative processes must invite an even wider-ranging debate, to assist it not only in the taking of the immediate decisions over commercialisation, but also in its future discussions and negotiations within the European Union over the appropriate regulation of GM technology, where decision-making has presently ground to a standstill. It will also be important in relation to the Government's future relations with the principal actors in the UK. Without a higher level of public consent, or consensus, than exists at present, a decision to allow commercial growing of GM crops might offer the industry no more than a precarious basis for

proceeding, and, as with the SCIMAC agreement, there may well be further opportunities for voluntary arrangements going beyond the legal framework.

41. Our recommendations below therefore set out a path towards developing greater consensus about the future of agricultural biotechnology, and we urge the Government to take the broadest possible view of its remit. We also urge that these considerations are borne in mind in discussions over other EU initiatives, including the recently published proposal for a Regulation on genetically modified feed, and the proposed Regulation on the traceability and labelling of GMOs and the traceability of food and feed produced from GMOs, under which products containing GM material will be required to be labelled as such. The labelling of products derived from GM ingredients but containing no GM material will have to refer to the fact that the product was produced from a GMO but that no GMOs are present in the final product. Food produced with the help of enzymes from GM sources and food from animals fed GM feed will not require labelling. The proposal also acknowledges that adventitious contamination cannot be totally avoided. The proposal allows for GMOs that have been favourably assessed by the relevant EU Scientific Committee, but not yet fully approved, to be present in food or feed up to a maximum of 1 per cent.

42. With specific regard to the FSE results, there will be important issues with regard to their analysis and interpretation. If there is a statistically significant change in a biodiversity indicator species, it will then be necessary to decide whether the change is not only statistically significant but also ecologically significant. Moreover, the impacts may vary in different directions for the different indicators that are being measured. The question then would arise as to whether it is possible, for example, to put a relative value on caterpillars, ladybirds, *rhizobium* and a host of other organisms within the agricultural environment. It will not be possible to base socially robust judgements about the significance of impact on the scientific data alone; decisions will ultimately have to rest on a combination of scientific and social values.

43. It is also clear to us from the evidence that we have taken, and the public scepticism surrounding the Government's previous statements, that if it wishes to gain support for its decisions, the Government will need to be unequivocal and transparent in relation to all the evidence that has been considered and assessed by the various committees on which it depends for advice. It is important therefore that there should be an independent scientific review of all the information that will complement the results from the FSEs. This includes all information that is relevant to the risk assessment of these crops, and the management regimes associated with them. This review would serve to inform the public consultation process, would enhance the transparency of any decisions made at the close of the FSEs and would provide a basis on which to advise the Government on the level of publicly funded research.

44. The data required for this review should be collated and available for the completion of the FSEs, ie following the harvest of 2003 at the latest.

45. It is also important to identify any other gaps in knowledge which may remain, and to take action to fill them before decisions are taken. There is a general lack of information about the effects on biodiversity of current and new non-GM crops or agricultural technologies. The FSE results may show changes in certain biodiversity indicators as between the GM and non-GM trial plots. But they will give no indication of how

ecologically significant those changes are. In order to contextualise the FSE results, we need to be able to compare any differences emerging from the trials with the effects on biodiversity of changes in conventional agricultural crops and techniques. The baseline data available on this are limited, but in the absence of such a comparison it may be that a disproportionate weight of regulatory emphasis is concentrated on GM crops.

46. We draw attention, therefore, to the need to ensure that the level of publicly funded research in the future is such as to secure an objective independent comparative assessment of the potential impacts of new technology on the environment. The aim must be to promote a genuine search for knowledge that will contribute to scientific understanding of the impact of new technology on agriculture and the wider environment (including issues such as those drawn to our attention about the impact of herbicides on groundwater, impacts on soil microbiology and geneflow).

47. To assist in the process of decision-making around possible future commercialisation, AEBC proposes to develop with the Advisory Committee on Releases to the Environment (ACRE), a series of discussions with the principal stakeholders during the period before the results of the FSEs are available. By hosting this process jointly, ACRE and the AEBC will be able to pool their expertise in developing appropriate advice to Ministers on the role of the FSE results in the eventual decisions on whether or not to commercialise GM crops. The discussions should cover the most crucial aspects of the decision-making process, in particular:

- how the significance of the data will be judged, in terms of deciding what may constitute adverse environmental effects, and of determining a balance between harmful and beneficial impacts;
- how the data will be used alongside other relevant ecological and sociological data, taking advantage of the experiences of other countries in which GM crops are currently grown;
- how the data might inform the development of post-commercialisation monitoring regimes, should commercialisation proceed.

Recommendation 3 Start developing policy now on how to use the results of the FSEs in future decision-making.

Recommendation 4 Commission an independent review of all information that will complement the results from the FSEs including:

- ***information collated by the Advisory Committee on Pesticides (ACP) on the herbicides in question;***
- ***information collated by ACRE on any direct and indirect effects of these crops compared to conventional varieties;***
- ***information from other studies such as BRIGHT and the Brooms Barn trials which have investigated a range of management regimes under which these crops could operate;***

- ***any relevant information from other countries in which these crops are grown commercially.***

Recommendation 5 ***Ensure that the level of publicly funded research is such as to secure an objective independent assessment of the potential impacts of both current practices and new technologies on agriculture and the wider environment.***

Recommendation 6 ***Commit to an open and inclusive process of decision-making around whether the GM crops being grown in the FSEs should be commercialised, within a framework which extends to broader questions.***

Post-commercialisation

48. Despite rapid advances in scientific understanding in any area of knowledge, unknowns will always remain. So if GM crops are to be approved for commercialisation, proper post-commercialisation monitoring will be crucial. Among other things, it will need to cover those environmental issues which could not be covered in the FSEs because they would emerge only from monitoring over a larger scale (such as the effects on birds and larger wildlife) or over a longer period (such as the effect of changed management practices on soil structure and fertility, and the possible effects of gene-stacking, which is the simultaneous presence of more than one transgene in an organism, usually a GM organism).

49. The new Deliberate Release Directive requires that a plant breeding organisation that is seeking to commercialise a GM crop must submit its proposed monitoring procedures for approval. We consider it crucial that this long-term monitoring programme should become a formal statutory requirement, that it should be undertaken in a way that is independent of the plant breeding industry and of interest groups, and that it should be kept under periodic review. There must also be agreement on how the results of the monitoring would be used – in particular, on how the powers for withdrawing approval if the monitoring revealed adverse effects would be used, and on issues relating to reversibility and product recall.

Recommendation 7 ***Give early attention to the framework for post-commercialisation monitoring.***

Without prejudging the issue of whether GM crops will be approved for commercialisation in the UK, the Government should be prepared to publish and consult widely on its proposals for the post-commercialisation monitoring which would be needed, and for the action to be taken if adverse effects were discovered.

Public attitudes

50. It was of course never to be expected that the FSEs could provide answers on the broader public concerns which have come into focus as a consequence of the trials, and which will need to be addressed in public debate and decision-making: they were not designed to do so. Yet we need to understand as much as we can about the reasons for those concerns, not only through direct contact with the public, but also through bringing together the work which has been done by social scientists in this area. There is a significant body of work emerging which in its sophistication has the capacity to go well beyond what is possible with opinion polls. However, it is varied and diverse, and needs to be drawn upon and developed. The AEBC sees further development of this methodology as likely to make a valuable contribution to a more sophisticated understanding of public views around agricultural biotechnology, and has already started to establish a network of social researchers working in this field. The aim is to gain a more systematic understanding of the basis of public responses to GM technology, thus providing the Government with useful information relevant to the decisions which will have to be taken.

Recommendation 8 Improve understanding of the basis of public views by drawing on the work of social scientists in this field.

The basis of decisions and the treatment of uncertainty

51. The FSEs address narrow issues of risk, not broader issues about the public acceptability of potentially irreversible changes. Many people are concerned that the decision-making framework, based on a risk assessment approach, does the same. Its scope is narrowly prescribed. No account is taken of the social or economic impacts which might flow from approvals for the commercialisation of GM crops, such as the possible effects on organic and non-GM farming and hence on the rights of choice for consumers and farmers.

52. The risk assessment approach does not address many people's wider philosophical or ethical concerns about what they perceive as a major human manipulation of nature. Nor does it tackle genuine concerns about some of the unknown impacts of GM technology, leaving some people feeling that the surprises which could lie ahead are being ignored and buried. We believe that the nature of different sorts of uncertainty and risk is a key pre-occupation which must be explicitly acknowledged and explored.

53. Nor does the decision-making framework take sufficient account of the fact that all forms of agriculture have a potentially adverse effect on the environment. There are also uncertainties in considering the future trajectory of the status quo, both for conventional and organic agriculture. There is only limited information available to enable us to compare the levels of uncertainty associated with any future path.

54. We welcome the increasing attention which is being given to the way in which risk is analysed and reported, and the development by ACRE of operating practices that reflect the principles set out in the Phillips report on BSE that "openness requires recognition of uncertainty where it exists" and "scientific investigation of risk should be open and

transparent". We wish now to reinforce this, and to ensure that emerging best practice is applied across the whole regulatory community that has responsibility for agricultural biotechnology, in a way that gives transparent effect to the precautionary principle. We endorse the recommendation in the guidelines promoted by Lord May when he was the UK Government's Chief Scientific Adviser, that "there should be a presumption at every stage towards openness in explaining the interpretation of scientific advice which may mean going further than the minimum obligations. Departments should aim to publish widely the scientific advice and all the relevant papers so those outside can satisfy themselves about the process by which the advice was formulated and that the conclusions are correctly drawn". The guidelines stress that key principles "will need to be followed particularly carefully when there is significant uncertainty" [3].

55. We identify a particular need to explore the different kinds of uncertainty involved in the applications of biotechnology and how they might be explicitly handled in the policy process. This would be a learning process for all concerned, helping to clarify different perceptions of uncertainty and different ways of talking about it. This exploration should initially focus on the FSEs, but would obviously have broader implications. In particular, the exercise would compare the way in which the various relevant advisory committees explain to the public how they have handled the areas of uncertainty and value judgement which they have identified in the risk assessment process, and make recommendations on best practice. In addition, the Office of Science and Technology should develop proposals to extend, to the biotechnology regulatory community, the work that it has already undertaken in relation to the regulatory bodies that have responsibility for food safety. The processes of defining and understanding uncertainty are central to the science itself, but they need to be properly communicated and understood in a regulatory process that is politically accountable. AEBC is willing to contribute to the development of good practice in this area.

Recommendation 9 Improve methods of dealing with risk and uncertainty in relation to the use of biotechnology in agriculture:

- ***by ensuring that all the relevant regulatory processes incorporate the principles developed by Phillips and by May, and that the regulators are publicly explicit about where areas of uncertainty occur in their deliberations and how they have tried to take them into account; and***
- ***by developing and disseminating examples of best practice.***

C. Potential implications of GM crops for agricultural policy

56. We see the issues relating to GM crops, and indeed to agricultural biotechnology more generally, as an important part of the overall debate about what kind of agriculture people want in the UK and how it can be achieved. There are, we believe, three component parts to this debate. One is the strategic overview that will be undertaken by the Policy Commission on Food and Farming. A second should be the start of detailed

[3] See Part 3.

negotiations, without prejudice to the Government's decision on the commercialisation of the 'FSE crops', about the separation distances that might be used for the possible future release of GM crops, and a third should be a broader public debate of the Commission's proposals and the role of GM technology in the future of UK agriculture.

The Policy Commission on Farming and Food

57. Hence, we welcome the setting up in August 2001 of the Policy Commission on Farming and Food and we look forward to being involved in the debate which it will instigate. The broad terms of reference for the Policy Commission require it to advise the Government on "how we can create a sustainable, competitive and diverse farming and food sector which contributes to a thriving and sustainable rural economy, advances environmental, economic, health and animal welfare goals, and is consistent with the Government's aims for CAP reform, enlargement of the EU and increased trade liberalisation". This review is confined to England, but similar exercises are being undertaken in the devolved administrations.

58. Within this remit, we are particularly concerned about the relationship between an agriculture sector that wishes to use GM crops, and other sectors of agriculture (whether conventional or organic) which wish to respond to demand for products which are GM-free or have a GM content below a certain defined level. This is a major strategic issue, and we urge the Policy Commission and the devolved administrations to consider within their reviews the question of whether and how to promote the co-existence of different forms of farming. The Policy Commission is intended to have only a brief life. Its objective is to propose the future agenda for agriculture, leaving it to others to devise strategies towards its realisation. Nonetheless, we hope that it will propose sufficiently clear strategic principles to guide the choices that will need to be made in the future. Fundamental to these is how to maintain the genetic purity of seed.

Seed Purity and Separation Distances

59. The genetic purity of seed production has traditionally and successfully been maintained in the UK by defining separation distances to be maintained between crops to minimise cross-pollination. In this context, the then Minister for the Cabinet Office, Dr Mo Mowlam, invited us last year to address the issue of public acceptance of levels of impurity in seed. We replied that, while we shared the concerns about this issue, they needed in our view to be considered as part of other wider questions such as consumer choice and gene transfer; we said that we would consider the issue (in liaison with the Food Standards Agency (FSA)) as we made progress with our workplan and developed our strategy.

60. More recently, the Minister for the Environment, Michael Meacher, invited us to assess the public mood on the separation distances which should be applied between GM and non-GM crops. In responding, there are two issues to be considered. The first is the separation distances which should be applied for the remaining stages of the FSEs. As we have proposed in Recommendation 1, we believe it necessary on an interim basis to adopt separation distances that will maintain the status quo in relation to organic farms.

61. The second issue is the question of separation distances in the event of approval for commercial cultivation of GM crops. This is a different set of circumstances, and the interim arrangements proposed in the preceding paragraph should not be regarded as a precedent for the longer term. There are several issues at stake, not least the problem of imported non-GM seed through the adoption of different separation distances elsewhere or through seed mixing. The greater the level of adoption of GM in crops, not only nationally but internationally, the more difficult it will be to maintain low thresholds for traces of GM in non-GM produce. If consumer choice is to be maintained, it will be necessary to develop better mechanisms for preventing any general upward drift in GM presence where it is not wanted.

62. There is a strong commercial interest for the organic sector in maintaining the image of organic produce, and a prevailing belief within organic farming that GM technology is alien to the organic ethos and presently offers no countervailing advantages to organic production. There is also a strong fear of gradual upward drift of GM content if any latitude is allowed to GM production. The organic movement generally therefore currently aspires to a GM content of zero, while recognising nonetheless that there are practical limits to what is detectable.

63. There is a legal foundation for this approach. The use of GMOs in organic production is prohibited by EU law[4]. This prohibition is enforced in the UK by the UK Register of Organic Food Standards (UKROFS) as the UK's "competent authority", and by certifying associations such as Soil Cert and the Farmers and Growers Assurance Scheme. They require operators to take all reasonable measures to prevent the use of GMOs, and they maintain the right to remove the organic status of a crop where traces of GM are found in it, or where a significant risk of contamination is established and the farmer is unable to take steps to avoid it.

64. Although EU law bans the use of GMOs by organic farmers, it does not directly prohibit the marketing of organic produce which has been inadvertently contaminated. A procedure was adopted in 1997 for the introduction of a prohibition "on the use of GMOs and GMO derivatives with regard, in particular, to a *de minimis* threshold for unavoidable contamination which shall not be exceeded". No such measure has yet been agreed, but there is a legal basis for the adoption of a contamination threshold which could allow the calculation of separation distances between organic and GM crops.

65. Separation distances will not in themselves guarantee that GM-free agriculture can co-exist in the UK with GM agriculture, but adequate separation distances can ensure that any impact of GM crops on organic crops through cross-pollination is kept below a predetermined threshold. The question is whether and how that threshold should be set; and how separation distances should then be agreed to maintain it. There are, inevitably, significant differences between crops. As a basis for coexistence, we understand that a threshold limit as low as 0.1% would not be impossible to achieve for most if not all crops (other, perhaps, than maize).

66. Although organic farming is a minority sector of farming in the UK, (it currently occupies around 2.5% of arable land), it is a rapidly growing sector. It has strong European and national Government support: in Wales, for example, the National

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[4] See Part 3.

Assembly for Wales has set an ambitious target for organic production to rise to 10 per cent of agricultural produce by 2005. Organic produce has found a ready market, and its principles are endorsed by the Government and the EU through policy, regulation and funding. But there is now an increasing tension between on the one hand the standards required for the products of organic agriculture and bee-keeping, and on the other hand the flexibility needed to maintain a competitive conventional agricultural sector at a time when GM crops are increasingly being grown overseas and a reduction in CAP support is anticipated.

67. The establishment of the FSEs has brought these strategic and practical issues into sharp focus. Their resolution is a matter of major significance for future food policy and agricultural policy decisions, and for the maintenance of consumer choice. These are issues for the whole of society and require wide debate.

A Broader Public Debate

68. The third component of our proposed way forward, therefore, and as a means of responding to the request of the Minister, should be the facilitation of a broader public debate. It will be crucial for the public to be involved in the important decisions which need to be taken. We have to find a way to foster informed public discussion of the development and application of new technologies: whatever decisions are ultimately reached, they will be more palatable if they have not been taken behind closed doors. At present, there seem to be no avenues for a genuine, open, influential debate with inclusive procedures, which does not marginalise the reasonable scepticism and wide body of intelligent opinion outside specialist circles. We need to harness new deliberative mechanisms, to develop participatory methods of public engagement, together with new capacities within Government and industry for digesting and responding to the implications.

69. It will be important to undertake this exercise by systematic and large-scale application of the techniques examined in the recent POST report (*Open channels: public dialogue in science and technology*). The discussions should take the form of a series of workshops, public debates and consensus conferences around the country, on the lines of those which AEBC has already begun to hold. They should include, but not be dominated by, the Government and current interest groups – the biotechnology and farming industries, NGOs, and scientists. But to have public credibility and added value over the current level of debate, they must reach beyond these interests to a wider public. To this end it might be useful to involve one or more bodies with access to a broad range of opinion and expertise, such as the Royal Society (possibly through its Science in Society programme), the RSA (the Royal Society for the Encouragement of the Arts, Manufactures and Commerce, possibly through its science and society project), and the Nuffield Foundation. But this will be only a starting point. There will be a strong need to go through organisations at a community level and find people wherever they are already involved in thinking and discussion around these issues. Other processes might also be explored to increase public involvement, for example through museums and through the emerging network of science cafes. It is also important to seek to maintain Parliamentary interest.

70. AEBC is interested in advising on the development of this process.

Recommendation 10 Include specific consideration of the future of GM crops in the discussions about the future of agriculture in the UK.

The various strategic reviews of farming and food being undertaken by the UK administrations should explicitly address how to promote the co-existence of different forms of farming in the UK. There should then be a wider public debate involving a series of regional discussion meetings to consider what role GM crops might have in UK agriculture in the future. The AEBC is willing to contribute to this process.

The Role of the AEBC

71. Some of our recommendations, including the one immediately above, could give rise to an enlarged role for the AEBC. It would be helpful if the Government could indicate the extent to which it wishes us to extend our present functions in order to help implement these recommendations, and to develop accordingly a costed programme of work in time for 2002-03.

PART 3

OUR THOUGHTS

PART 3.1 THE BROAD ISSUES

72. The Farm-Scale Evaluations of GM crops have aroused intense public interest in the way they have been handled and in the use which will be made of the results[5]. We chose them as a case study partly because of this, but also because they have provided a focus for a wider debate. They have brought to the fore in the UK the tensions and differences of perspective about GM technology and GM crops, and the implications for agriculture and for consumer choice of the decisions to be reached on the use of GM crops. They have stimulated questions about how decisions on the adoption of such technologies should be made. This Part considers these wider issues.

Is it appropriate that the FSEs have become the focus for broader concerns?

73. To some members of the Commission it has seemed inappropriate that the FSEs should have provoked wide public debate about issues beyond the actual modest scope of the trials. They see many of the claims and concerns expressed by national and local critics as excessive and alarmist, reflecting – and prompting – media exaggeration and even hysteria, and they find the loose terms used ill-informed and misleading. So they have a degree of scepticism about both the quality and the focus of much of the expression of public concern. Other members cannot see how pinning broader debate to the FSEs can be described as "inappropriate", given that there was no other focus for it. They point to the lack of effective national fora where the merits of commitment to the widespread commercialisation of GM crops could be explored and debated. They accept that some of the public criticism is couched in less than precise scientific terms, but they believe that the concerns expressed are real, often arising from previous experience of science-based controversies where public debate has also been lacking.

74. Yet it does not surprise us that the initiation of local trials should have crystallised broader concerns. Social scientists have noted in other contexts[6] that the full implications for society of the deployment of a new technology can be realistically seen and tested only when there is a specific land use proposal, at a specific location. That is when real people in real places begin to experience, articulate and debate the real-life implications of what has previously been a largely theoretical proposal. It is evident that concerns about the perceived possible site-specific effects of the FSEs have fuelled many people's broader concerns over GM crops. These people have seen the trials as a watershed, both in relation to GM crops and as heralding another stage in the intensification of agriculture.

75. In any case, whether or not *we* see it as justifiable for these concerns to have been raised in the context of the FSEs, the point is that they *have* been raised. Their weight is itself an important social fact – and we think that they need to be addressed.

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[5] These issues are explored in the next part of this report (Part 2.2).

[6] R Grove-White, "The Emerging Shape of Environmental Conflict in the 1990s", *RSA Journal* 139 (1991); B Wynne, "Uncertainty and Environmental Learning: Reconciling Science and Policy in the Preventative Paradigm" *Global Environmental Change* 2 (1991). Recent examples are civil nuclear power and urban waste incineration.

What are the broader concerns being expressed?

76. Before considering the substance of the concerns being expressed, it may be useful to look at the language used to express them. The recent report of the House of Lords Select Committee on Science and Technology on *Science and Society* suggests that "people use common sense to interpret and evaluate what they hear about technological advances, and attempt to put it into its cultural, social and ethical context and to translate it into terms which are useful or at least relevant to themselves"[7]. It seems to us that even criticisms appearing to be narrowly addressed to the FSEs themselves, or apparently couched in imprecise scientific terms, often reflect deeper concerns. References in the evidence we received to the impact of the trials on bee-keeping, earthworms or gene flow, or to the possible effects of GM technology on people's children and grandchildren, were sincere in themselves, but we suggest that they may also sometimes have been ways of expressing wider, analytically more elusive ethical concerns. Such concerns are fundamental in determining how people react and respond to a new technology, which is not fully understood and which they may not be inclined to accept. They make it crucial – as well as hard - to build trust in how the technology is being promoted and supervised.

77. People have fundamentally different perceptions of and attitudes to GM technology. It can be very difficult for those starting from different viewpoints even to communicate with each other, let alone to agree. In our own discussions, we have gradually come to understand the range and complexity of the views of our colleagues, and to respect them even if we do not agree with them. We think that it may be helpful to the process of broader public debate for us to expose some of the fundamental perceptions and attitudes, so that people can become involved in the debate in a constructive way by understanding their own position in relation to that of others.

78. At one end of the spectrum is the view that GM technology and gene modification in plants represent a progressive evolution of selective plant breeding, and a substantive outcome of the science surrounding it. Seen from this perspective, there is no more reason for concern about GM crops than about conventional crop improvement methods (such as mutation breeding) which have played an important role throughout the world for some fifty years, and have served society well. Those who hold this view tend to express enthusiasm for and confidence in the developing biotechnologies. They point out that GM technology has played a crucial part in other welcome advances in biology (such as the production of insulin for diabetics, human growth hormone and food processing enzymes including chymosin for the production of vegetarian cheeses instead of using rennet from calves' stomachs). They believe that in the longer term the introduction of transgenic crop production has the potential to bring about less environmentally damaging forms of agriculture as well as new crop types and nutritionally enhanced food products.

79. They argue that even when scientists do not know all about an organism's physiology or biochemistry, they make progress by a careful step-by-step approach

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[7] House of Lords Paper 38, 3rd Report Session 1999-2000, paragraph 2.56, referring to Irwin and Wynne, eds, *Misunderstanding science?* Cambridge University Press, 1996.

through trials[8], followed by monitoring as use is scaled up. It is true that any unwanted effects of changes in agricultural practice could take a long time to reverse, but this is a more general problem, not only related to GM crops[9]. Although there have been a few surprises, they would argue that thousands of successful biotechnological products (having passed the relevant regulatory processes) have been of enormous benefit to society. The risk of unknown outcomes should be balanced against the risk of not growing GM crops, which would include forfeiting any potential environmental and health benefits from such crops.

80. At the other end of the spectrum is the view that GM technology is not simply an advance in molecular biology, but a major and irreversible watershed in human intervention in nature. Seen from this perspective, the specific concerns expressed about the uncertainties and limitations of present GM knowledge often demonstrate a wider ontological unease[10] at the hubris of such fundamental human manipulation of nature. There are worries about possible undesirable outcomes – the inherently unpredictable future mishaps or surprises (the "unknown unknowns") which could follow a commitment to rapid agricultural deployment of GM technology – in relation to which the FSEs can obviously not provide reassurance.

81. Those who express these worries fear that it will not in fact be possible to contain and manage the risks, and that any adverse effects resulting from the release of GMOs might not be reversible. They claim that there may turn out to be significant gaps in scientific knowledge, citing in justification the historical experience of the effects of other new technologies[11].

82. The mutual lack of understanding sometimes leads to suspicion of the motives of those at the other end of the spectrum, and assumptions about the way they behave.

83. In relation to motives, for example, some claim that the impartiality of the scientists working in the area of GM crops may be compromised because many of them are involved in research with industry funding. Others claim that the organisations campaigning against GM crops are themselves driven by commercial pressures, so that their need to raise revenue to support and expand their operations affects their choice of causes to support.

84. As to behaviour, those who see GM technology as a watershed feel that those who will ultimately take the decisions on the commercialisation of GM crops, and those providing scientific advice to the decision-makers, trivialise and dismiss their concerns. They perceive the decision-makers as being comfortable with the current approach to risk assessment, regarding "risk" and "safety" as determined on the basis of current scientific evidence as the only relevant issues. They argue that, because their concerns are not acknowledged in the regulatory frameworks, the present approach to decisions

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[8] For plants, from the laboratory through greenhouse trials to field trials to three years of official multi-location trials; for drugs from the laboratory through animal experiments to several phases of clinical trials.

[9] For example, the organic movement has recently decided to phase out the use of copper sulphate as a fungicide because it is causing damage to soil, and high copper levels in soil could take many decades to return to their normal level.

[10] An unease relating to the intrinsic nature and essence of things, which political science research suggests is often expressed metaphorically.

[11] For example, in society's commitment to widespread fossil-fuel consumption, despite the increasingly recognised dangers to the global climate.

is not likely to create public confidence in science, or in the technology that flows from it. They claim that the Government has acted uncritically in favour of GM technology, and they draw analogies with BSE and other recent food scares. They argue that frustration at the lack of mechanisms for debate of their views has contributed to their disenchantment, and to active obstruction of the FSEs; they claim that those views would be completely ignored by the powerful corporate and scientific interest without the voice of the NGOs.

85. Those involved in developing the science and in advising on decisions do not accept that they belittle the public's concerns: on the contrary, they spend a lot of time communicating with the public. They fully recognise that scientific evidence is not the only relevant issue in decision making. They consider that time spent on Government advisory committees is aimed at improving the quality of decision-making and the responsible application of new technologies. They agree that a broader debate is needed, but they wish to see it conducted on a rational basis, and they are frustrated at the difficulty of conveying reliable information to the public when the media seems only to be interested in controversy. They argue that, rather than reflecting public opinion, the NGOs are in fact moulding it by anti-GM propaganda, using alarmist terms. They suggest that the destruction of research plots which are intended to generate knowledge to help with biosafety assessment falls into the same category as book-burning.

86. There are fundamental differences in approach here which cannot be resolved simply by talking, even if they can be better understood. But there are other areas where there may be less difference of view than at first appears. For example, many share an unease that GM technology may often be driven by what is seen as a commercially-oriented science dominated by multinationals rather than by publicly funded research organisations, for which funding is now increasing limited or no longer available. And many are concerned about the increasing ownership of relevant scientific knowledge by a small number of biotechnology corporations, reinforced by the patenting of genes and plants, and the consolidation of the seed market. This they see as further undermining farmers' autonomy, so that ultimately the global food system could come under corporate control. Some go further, being suspicious of claims that GM crops must be developed "to feed the world", believing on the contrary that GM technology as it is being developed today could damage food security, particularly in developing countries. Some, accepting this, maintain that it is important to allow developing countries to make this choice themselves on the basis of an evaluation of GM crops and their potential, and not have the choice either way pre-empted by the developed world.

87. Robust public policies and regulatory frameworks will need to expose, respect and embrace the differences of view which exist, rather than bury them. We think that much of the controversy persists because it is easier to construct stereotyped views of others than to pick one's way thoughtfully through the genuine arguments – which is what we have tried to do in this report.

Can UK agricultural policy preserve consumer choice?

88. The FSEs have highlighted one of the major tensions for agricultural policy in the UK. Organic and other farmers who do not use GM crops,[12] and bee-keepers, are concerned that their livelihoods should not be affected adversely by the introduction of GM crops. In one of our evidence sessions[13], we discussed with a range of farmers the following principles as they might relate to GM crops:

- farmers should be free to engage in the method of farming and grow the crops that they choose;
- to preserve the right of choice for both farmers and consumers the conventional and organic sectors must be able to retain their integrity;
- farming practices adopted by individual farmers must not be to the detriment of another farmer or the public.

While these tenets appear rational and equitable, it is not clear whether they can be put into practice. Not surprisingly, it emerged in our discussion that what constitutes "integrity" and "detriment" are hotly contested from different perspectives.

89. This debate is usually articulated in terms of "contamination"[14] by GM products. Traces of GM material will be detected in non-GM crops and food unless:

- the crops concerned are not able to cross-pollinate
- the separation distances between GM and non-GM crops are great enough to ensure that cross-pollination is below the detectable level;
- GM and non-GM seed are strictly segregated; and
- product integrity is maintained throughout the food chain, through storage and processing.

90. The question which must be addressed is whether agricultural production in the UK can continue to meet the demands of the various segments of the market. To put it bluntly, can cross-pollinating GM and non-GM crops co-exist on our small islands – and if so how? Different sectors of the agricultural industry will hold different views on this fundamental question.

Farmers and their markets

91. Farmers who favour the introduction of GM technology argue that they must be free to use it in order for their products to be competitive on domestic and world markets. They contend that growing GMHT crops will result in the reduced use of synthetic chemicals, in significant cost savings (for example through lower herbicide usage and a

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[12] We note a confusion in terminology here. In its strict sense the term "conventional" farmers means all farmers who do not use crops defined as being GM, but it is often used to mean non-organic farmers.

[13] AEBC sub-group meeting with representatives from the National Farmers' Union, the UK Register of Organic Food Standards and the Soil Association, 26 March 2001.

[14] Although this term itself has sometimes been contested as being emotive, it has been used for decades in the seed production industry. It has been defined in the following terms: "Contamination – the term is not used in a pejorative sense. It is defined as "the unintended presence of a plant or plant part". A single non-gm seed in a gm seed sample would be a contaminant, as would a single gm seed in a non-gm seed sample" C.L. Moyes and P.J. Dale. *Organic Farming and Gene Transfer from Genetically Modified Crops*. John Innes Centre. May 1999.

reduction in tillage operations), with better weed control also leading to increased yields. They argue that such savings will be all the more vital for UK agriculture if CAP financial supports continue to diminish. These farmers are fully aware that any potential benefits for them from GM technology and its products will be realised only if there is consumer demand for the products. They believe that in the longer term this demand will come, because these products lead to reduced crop losses through disease or pest damage, and increased marketability because of improved product appearance[15]. They have also seen benefits in those countries where GM crops are grown extensively. The UK farmer and the UK consumer could also ultimately expect to benefit from these developments.

92. However, not all non-organic farmers share this view. Some believe that the potential risks associated with the introduction of this new technology outweigh any perceived advantage. They wish to keep their crops GM-free, in the sense of having a GM content below the level at which products must be labelled as containing GM and which consumers consider acceptable. The position of organic farming is particularly important, because of its rejection of the use of GM technology in organic production. This is not an outright rejection of biotechnology, and organic farmers grow crops that have resulted from mutation breeding using chemical mutagens or irradiation. Nor is it simply a self-imposed trade requirement, but a binding legal requirement, under European law, for the marketing of produce as organic. However, the law has not yet adequately dealt with the question of contamination from other sources.

93. At EU level, minimum standards for organic production were first prescribed in 1991[16]; they apply across Europe, with some flexibility to allow for local conditions.

94. The original 1991 EU Regulation made only limited provision in respect of GMOs, prohibiting the use of genetically modified micro-organisms for biological pest control[17]. However, an amending Regulation in 1999 went much further[18]. Its introductory paragraphs recorded that "Genetically modified organisms (GMOs) and products derived therefrom are not compatible with the organic production method; in order to maintain consumer confidence in organic production, genetically modified organisms[19], parts thereof and products derived therefrom should not be used[20] in products labelled

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[15] They point out, for example, the benefits to the consumer as well as the producer of the GM tomato (one of the first transgene products available on the UK market), in which the ripening process was modified so that the fruit developed full flavour and colour without losing firmness, avoiding the risk of rapid deterioration during transportation and storage and reducing price to the consumer as well as production costs. Insect tolerant and viral resistant GM potatoes are already successfully marketed in North America, and similar results are expected from the current development of blight resistant potatoes.

[16] Council Regulation No 2092/91 on organic production of agricultural products and indications thereto on agricultural products and foodstuffs, Article 5 (OJ L198, 22 July 1991) sets a threshold of 5 per cent non-organic content for a product defined as organic.

[17] Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs (OJ L 198, 22.7.1991, p. 1), Annex II, Part B.

[18] Council Regulation (EC) No 1804/1999 of 19 July 1999 supplementing Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs to include livestock production (OJ L 222, 24.8.1999, p. 1)

[19] Defined in terms of the Deliberate Release Directive.

[20] "Use of GMOs and GMO derivatives" is defined as meaning ". . . use thereof as foodstuffs, food ingredients (including additives and flavourings), processing aids (including extraction solvents), feedingstuffs, compound feedingstuffs, feed materials, feed additives, processing aids for feedingstuffs, certain products used in animal nutrition (under Directive 82/471/EEC) . . ., plant protection products, veterinary medicinal products, fertilisers, soil conditioners, seeds, vegetative reproductive material and livestock".

as from organic production". The Regulation then went on to ban the use of GMOs and their derivatives altogether in organic farming, with the exception of veterinary medicinal products[21]. It also insisted that the organic production method implied that for seeds and vegetative reproductive material, the mother plant in the case of seeds and the parent plant(s) in the case of vegetative propagating material have been produced without the use of GMOs and/or any products derived from such organisms, for at least one generation or, in the case of perennial crops, two growing seasons.

95. A new Article 13 was inserted into the original 1991 Regulation by the 1999 Regulation, allowing for the adoption of implementation measures under a special procedure prescribed by Article 14, "according to scientific evidence or technical progress to apply the prohibition on the use of GMOs and GMOs derivatives with regard, in particular, to a *de minimis* threshold for unavoidable contamination which shall not be exceeded."

96. Hence whilst European law bans the use of GMOs in organic production, it provides a basis for coexistence with others who use GM crops by allowing the adoption of a contamination threshold, though none has yet been agreed. If such a threshold were established, it could be used as a basis for calculating separation distances between organic and GM crops.

97. Beyond Europe, there is no international legal regime, but basic international standards for organic production are agreed and monitored by the International Federation of Organic Agriculture Movements. As with the amended European Regulation, the Federation's General Principles provide that "Genetic engineering[22] has no place in organic production and processing, and the document goes on to insist that "Certification bodies/ standardising organisations shall set standards and make every effort including relevant documentation to ensure that no genetically engineered organisms or products thereof are used in organic production and processing."[23]

98. Under European legislation, each Member State has a "competent authority" to administer the standards, which can also establish its own standards where the Regulation is silent. In the UK, the competent authority is the United Kingdom Register of Organic Food Standards (UKROFS), whose focus has now changed from policing its own standards to ensuring that other certifying bodies (of which there were eight in 2000) correctly interpret and implement the Community legislation.

99. UKROFS has therefore transposed into its own requirements the EU approach to banning the use of GMOs in organic agriculture[24]. But its standards do not address the issue of external contamination, and hence do not establish either a contamination threshold or separation distances: indeed the UKROFS Board agreed as recently as

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[21] Article 13, inserting new Article 6(1)(d).

[22] Defined as ". . . a set of techniques from molecular biology (such as recombinant DNA) by which the genetic material of plants, animals, micro-organisms, cells and other biological units may be altered in ways or with results that could not be obtained by methods of natural reproduction or natural recombination."

[23] *OAM Basic Standards for Organic Production and Processing* (adopted Basel, 2000: the current draft revision of those standards is in identical terms).

[24] UKROFS *Standards for Organic Food Production* (OB4) February 2001, Part 15, which bans the use of GMOs in organic production and allows for the withdrawal of organic certification from specific land, crops or products where GMOs have been used.

May 2001, following a lengthy study, that it would not propose minimum thresholds[25]. The largest of the UK certifying bodies is SA Cert, which handles inspection and certification on behalf of the Soil Association, requiring food described as organic to contain no genetically modified ingredients whatever. This standard reflects the Soil Association's interpretation of what the market expects from organic foods, including the integrity of the system as a whole, the values it encompasses in terms of promoting human and environmental safety and therefore confidence in the organic sector, and its market future. Farmers see this as central to their consumers' expectations of the organic ethic, and are reluctant to countenance dilution of the fundamental principles. Bee-keepers are similarly responding to the demands of their market. Organic farming (defined in the Soil Association's sense) now uses about 2.5 per cent of the agricultural area in the UK[26], and is catering for an expanding market (accounting in 2000 for 2.5 per cent of the total UK retail food market[27]).

Separation distances

100. Separation distances are used to create buffer zones between GM crops and conventional crops in order to reduce the chance of cross-pollination. The greater the separation distance, the lower the chance of cross-pollination, but the curve is leptokurtic (ie, it falls away sharply) so that after a short distance the amount of fall-off is very low. The distance required to achieve a given probability will vary from crop to crop, depending on the susceptibility of the crops in question to cross-pollination, and the distance to which the pollen concerned will travel.

101. The separation distances which currently apply in the UK have been developed by SCIMAC[28] in association with MAFF. They are designed to "help ensure" that any cross-pollination between the FSEs and nearby sexually compatible crops is below 1 per cent[29]. They are based on the legal separation distances that apply for seed production, but they were developed further on the basis of a MAFF-commissioned review, carried out in 2000 by the National Institute for Agricultural Botany, of the available scientific data in this area. For the spring 2001 FSEs, the distances to be observed between the GM crops and nearby crops of the same type were as follows:

- *oilseed rape*: 200m from seed or organic crops; 50m from conventional varieties and restored hybrids; 100m from varietal association and partially restored hybrids (which are more susceptible to cross-pollination)

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[25] *Minutes of the UKROFS Board Meeting* 17 May 2001, para 265.

[26] Concentrated particularly in the South and West of England, and in Scotland. Second Report of the House of Commons Agriculture Committee, Session 2000-01, *Organic Farming*, HC 149-I, paragraph 11. That Report was not wholly uncritical: it stressed, for example, the need for the benefits of organic farming to be more closely defined, so that Government could set measurable and achievable objectives for its financial assistance to the sector (para 25); and for the organic sector to market its products so that they appealed not to sentimental but to proven benefits (para 2).

[27] The Soil Association expects this to grow to 20 per cent by 2005, though others question whether such rapid expansion is possible: *ibid*, paragraph 20.

[28] The Supply Chain Initiative on Modified Agricultural Crops, whose members are the British Society of Plant Breeders (BSPB); the Crop Protection Association (CPA); the National Farmers' Union (NFU); the UK Agricultural Supply Trade Association (UKASTA) and the British Sugar Beet Seed Producers Association (BSBSPA).

[29] DEFRA, *Genetically modified crop FSEs: some questions answered about GM crops and the Farm-Scale Evaluations* (first published August 2000; updated March 2001).

- *sugar and fodder beet:* 600m from seed or organic crops; 6m from other crops (which will not be affected because beet is not allowed to flower)
- *maize:* 200m from seed and organic crops; 200m from sweetcorn; 80m from forage maize[30].

102. The currently prescribed separation distances do not guarantee the complete freedom from GMOs required for the purposes of the Soil Association's organic certification scheme. The Association carries out an initial risk appraisal for any organic holdings with a GM crop within six miles. If the crop is shown to be within the risk distances set out in a report by the National Pollen Research Institute[31] (1 km for beet, 3 km for maize and 6 km for rape), a full inspection is then conducted. If a significant risk of cross-pollination is established and the farmer is unable to take steps to avoid it, the Soil Association considers that it would have no option but to decertify the crop or the field (though we understand that this has not yet happened in practice). Another organic body, Organic Farmers and Growers, similarly prohibits genetic engineering in organic farming and food production, and requires operators to take all reasonable measures to prevent its use in organic systems. Certification may be withdrawn from specific crops or land where they consider that GMOs or their derivatives have been used, and they specify a maximum presence of 0.1ppm quantifiable GM material. Supermarket policies have proved influential. Some UK bee-keepers who supply supermarkets have adopted a policy of maintaining their hives at least 6 kms from FSE sites in order to keep contamination with GM to a minimum, though the same stores may also stock honey from Canada, where 74 per cent of the canola crop, a rich source of nectar, is GMHT.

103. Farmers favouring the growing of GM crops see arguments for separation distances wide enough to prevent all cross-pollination as impractical, and as damaging to the potential competitiveness of their own mode of agriculture. They point to the fact that organic agriculture already accepts a degree of cross-pollination with conventional crops, of non-organic presence in animal feed, and of spray and fertiliser drift from conventional farming, as well as the use of certain permitted chemicals. They suggest that there is scope for the extension of this sort of compromise.

104. We note that the National Assembly for Wales (one of the UK's designated competent authorities) has now taken action under section 110 of Part VI of the Environmental Protection Act 1990 to give legal force to the SCIMAC separation distances between T25 GM maize crops and non-GM maize crops in Wales. The UK has notified the Commission[32], through the Article 16 procedure[33] that the National Assembly for Wales takes the view that the unrestricted release of T25 maize involves a risk of damage to the environment, in that the lack of controls on its planting would prevent the maintenance of an environment where organically pure crops can continue to be grown, and could damage the integrity of other non-GM maize crops because of

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[30] *Ibid.* These distances are also being applied for the autumn 2001 trials.
[31] R. Treu and J. Emberlin, University College Worcester, National Pollen Research Unit , *Pollen dispersal in the crops Maize, Oilseed rape, Potatoes, Sugar Beet and Wheat,* report for the Soil Association. January 1999.
[32] Letter from the UK Permanent Representation to the European Union to the Director General, Environment of the European Commission, 13 July 2001.
[33] Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of GMOs (OJ L117, 8 May 1990).

the potential for cross-pollination. The National Assembly has taken this action on the basis that this issue was not considered during the process leading to the grant of Part C consent in 1998. The European Commission has therefore been notified in order to trigger the Community review provided for under Article 21 of the Deliberate Release Directive. The Directive requires that the Commission, in association with the Member States, must take a decision on the matter within 3 months.

Seed contamination

105. "Contamination" may arise not only from cross-pollination, but also from seed-mixing (that is, the inadvertent use of seed with GM content). Seed is imported into the EU from countries such as the USA and Canada where GM crops are widespread. The law allows the import only of approved varieties of seed, and provides that those with any GM content should be labelled as such. However, in 2000, some batches of unlabelled oilseed rape seed on sale in the UK and the rest of Europe were found to contain just under 1 per cent of GM seed (the actual level varied between the batches that were sampled); by the time this was discovered, a number of farmers in the UK had already planted the seed[34]. While not admitting legal liability, the seed company concerned agreed to compensate the farmers affected; this raised more general questions about liability[35].

106. The source of the contamination of the seed is not known. Nevertheless, this event has intensified public concern about gene flow and seed mixing, with the Soil Association claiming that after only a few years of GM crop cultivation in the USA no canola, maize and possibly soya seed imported from there can be guaranteed GM-free. To the extent that it was a pollen problem[36], the incident also raised questions about separation distances, since the oilseed rape seed in question had reportedly been grown at over 4 kms from the nearest GM pollen source. In response, the Government reviewed the separation distances for the FSEs, and in 2001 announced increased distances for maize and varietal associations of oilseed rape[37].

The Government's requests to AEBC

107. In June 2000, following this incident (and just after the AEBC was launched), Dr Mo Mowlam (then Chair of the relevant Cabinet Committee, the Ministerial Group on Biotechnology and Genetic Modification) asked us to address the issue of public

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[34] The seed, of an oilseed rape variety known as Hyola imported by Advanta Seeds, contained GM glyphosate- and glufosinate-tolerant seed. The Government could not order the farmers who had planted it to plough in their crops, because there was no tangible risk to human health or the environment. However, the farmers concerned would not have been able to sell the harvest because the GM variety was not authorised for commercial marketing, and the Minister of Agriculture announced to the media that if he were an affected farmer he would seriously consider ploughing-in the crop. See Eighth Report of the House of Commons Agriculture Committee, Session 1999-2000, *Genetically modified organisms and seed segregation,* HC 812, and evidence for that Report.

[35] A topic which the AEBC will be considering separately, in the light of this report and other AEBC work (for example on gene flow and on the concept of "harm").

[36] The impurity may have also arisen from GM volunteers growing in the same field, from unclean cleaning equipment, or poor seed handling.

[37] "Government outlines arrangements for spring trials of GM crops", DETR press release (joint announcement with MAFF), 6 February 2001: these are the distances quoted above.

acceptance of levels of impurity in seed. She noted that the food labelling threshold of 1 per cent GM adventitious contamination, set at the European level, seemed to have been accepted "as the best practicable and deliverable level", but that in the wake of this incident there had been public calls for greater purity. She added: "We have always said that consumers have a right to choose, but feel that in a world where GM crops are grown and exported internationally, and with no health or safety grounds for banning such imports, a level of GM contamination, however small, might be inevitable". She considered that because of the recent events there was "momentum to deal with this issue at a European level". Our reply was that the concerns about seed impurity needed to be considered as part of other wider questions such as consumer choice and gene transfer, and that we would therefore look at the issue as part of our overall workplan[38].

108. The Minister for the Environment, Michael Meacher, has now made a related request of the AEBC, saying:

> "Separation distances constitute an important additional issue that I should like you to consider. The Soil Association has raised with me the question of what, if any, level of GM presence in organic food is acceptable. The question could be broadened to include conventional food. This leads onto the issue of separation distances. The purpose of separation distances is to help ensure that any cross-pollination with nearby compatible crops is minimised. Separation distances for the spring 2001 Farm-Scale Evaluations were announced in my Department's News Release of 6 February. The agreed separation distances were based on scientific work by the National Institute of Agricultural Botany. These distances should reduce cross-pollination to a maximum of 1 per cent for any crop. The News Release also said that the distances will be kept under review for future plantings. I am convinced that the issue of separation distances is not simply a matter of science, but equally a question of public acceptability. I take the view that a cross-pollination threshold of 0.1 per cent is much more likely to be acceptable. Such a threshold would require greater separation distances than currently apply. The practicality of introducing greater separation distances would need to be considered. It would be most helpful if the AEBC could assess the public mood on this issue, by way of a consultation process, and advise both on the question raised by the Soil Association and on the issue of separation distances. The Government would need your advice in good time before the difficult decisions that might need to be taken on possible commercialisation of GM crops" [39].

109. In considering these requests, we need to bear two points in mind. Firstly, it is difficult to measure the presence of GM elements at very low levels, because of the limitations of the analytical methods available. So if zero-GM status was desired, it would not actually be possible to know whether it had been achieved. It is partly for this reason that the EU definition of "non-GM" tolerates the presence of a small level of GM material. Secondly, no separation distance can guarantee zero-GM status, because – for example – a bird could eat seed and drop it at a distance far beyond any prescribed

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[38] Letter of 14 June 2000 from Dr Marjorie Mowlam, Minister for the Cabinet Office to Professor Malcolm Grant, Chair of AEBC, and his reply of 20 July 2000, printed at Annex B.

[39] Letter of 21 May 2001 from Michael Meacher, Minister for the Environment, to Professor Malcolm Grant, printed at Annex C.

separation distance. Because of this, the Soil Association fears that zero-GM status cannot be achieved for organic products if the production of GM crops on a commercial scale is allowed in the UK. And the risk of inadvertent "contamination" suggests that to achieve zero-GM status might also involve banning all seed imports in respect of crop species that are being grown in GM form elsewhere in the world. But even that would not be sufficient, particularly if GM crops came to be more widely grown in the rest of the world. Natural pollen and seed spread does not recognise national boundaries, and it would be unrealistic to expect that import restrictions could be 100 per cent effective in blocking contamination through imported materials.

110. In our view, therefore, the real issue is not simply a question of separation distances. The issue is whether it is appropriate – or indeed inevitable – for organic farmers (and other farmers who do not wish to use GM crops), and bee-keepers, to accept (in respect of cross-pollinating crops) a degree of cross-pollination and seed-mixing in order that farmers who wish to do so may take advantage of the crop biotechnology already being used abroad and in order that imported seed may be used. The future compatibility of different forms of agriculture appears to be at stake.

111. Plainly, these difficult issues of producer and consumer choice cannot be separated from the wider strategic judgements now facing UK agriculture, in the context not only of increasingly deregulated global trade but also of such recent root-and-branch upheavals as BSE and foot and mouth disease. We are therefore glad to note that a broadly based examination of UK agricultural policy is now taking place. The UK Government appointed a Policy Commission on Farming and Food on 9 August 2001. The Commission has broad terms of reference[40], and must report to the Prime Minister and the Secretary of State for Environment, Food and Rural Affairs by the end of 2001. The Commission is restricted in its inquiry by the European framework within which significant issues of policy and funding for food and farming are determined[41]. The inquiry extends only to England, though parallel reviews are also being conducted in the devolved administrations.

112. The timescale and the terms of reference suggest that this will be more a strategic review than a detailed study. It will be important, nonetheless, that the Policy Commission inquires as to the contribution that conventional farming, organic farming and biotechnology may make to a sustainable, competitive and diverse farming and food sector. We look forward to initiating public discussion of these issues during and beyond the life of the Policy Commission . A recent report from the Parliamentary Office of Science and Technology (POST)[42], has pointed to the range of deliberative mechanisms

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[40] "To advise the Government on how we can create a sustainable, competitive and diverse farming and food sector which contributes to a thriving and sustainable rural economy, advances environmental, economic, health and animal welfare goals, and is consistent with the Government's aims for CAP reform, enlargement of the EU and increased trade liberalisation.".

[41] The terms of reference require that, in carrying out its tasks, "the Commission should take account of the following institutional factors:
domestic agriculture and food policy is governed to a significant extent by EU law and the sectors operate within the framework of the EU single market.
while responsibility for UK negotiations on EU matters such as the Common Agricultural Policy rests with the Government, agricultural policy within Scotland, Wales and Northern Ireland is the responsibility of the devolved administrations. UK policy towards the CAP is decided by the Government in consultation with the devolved administrations in accordance with concordats drawn up as part of the devolution settlement"

[42] *Open channels: public dialogue in science and technology,* POST Report 153, March 2001.

which can be used for interaction between scientists and the public over the directions and forms of new technological development of this kind (citing for example consensus conferences, citizens' juries, focus groups, multi-attribute analyses and so on). We need to explore – with professional help – which of these would be most appropriate for the topics with which we are concerned.

Is there an outright rejection of GM technology?

113. Despite the strength of feeling expressed both about the trials and about GM crops more generally, our evidence has not generally shown outright rejection of GM technology. For example, Highlands and Islands GM Concern told us that they did not necessarily want GM technology to be banned, and that they were not anti-innovation: it was just that in relation to the trial in their area they wanted a way of ensuring that account was taken of their views, concerns and uncertainties about the implications for their local economy, organic production and environmental safety[43]. Similarly, we were told that the Women's Institute had passed a national resolution in 2000 supporting the FSEs, but not supporting full commercialisation of GM crops[44]. This suggests that many people might not be so concerned about potential applications of the technology if they had confidence that the regulatory regimes were attuned to social concerns[45].

114. The current procedures for reaching decisions on the use of GM technology start from the assumption that proposals should be judged on a case-by-case basis on their own merits, in the light of science-based risk assessments. For agriculture, the approach is to establish whether or not particular GM plants are safe, by evaluating each against known risk pathways and variables.

115. The new Deliberate Release Directive[46] specifies a wider range of potential adverse effects which must be considered in reaching decisions: public concerns have evidently served to broaden the assessment and the research agenda[47]. However, it still does not include socio-economic or agricultural impacts, and it has been criticised as suffering from the same problems as conventional risk assessment and cost benefit analysis in other areas – for example, lack of knowledge and uncertainty are poorly dealt with, complex social and political judgements are made by experts in ways that are not transparent, and there is little opportunity for public participation. It has been argued, therefore, that this approach to the evaluation of GM crops as a whole does not take on

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[43] Evidence to AEBC sub-group meeting, Inverness, 19 February 2001, from Highlands & Islands GM Concern.
[44] Informal meeting of AEBC sub-group with members of the Women's Institute, Women's Food and Farming Union and local authorities, Norwich, 7 February 2001.
[45] For example, children from a school near Inverness suggested to the sub-group that decisions should be made by "mixed committees" representing national and local interests: AEBC sub-group meeting with pupils from Fortrose Academy, 19 February 2001.
[46] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC (OJ L106, 17 April 2001): for more detail see Part 3.2.
[47] L. Levidow and S. Carr, UK: precautionary commercialisation? *Journal of Risk Research* 3 (3): pp 261-270, 2000.

board all the demands of precaution[48] (though it has also been argued that it does not take sufficient account of potential benefits).

116. The preamble to the new Deliberate Release Directive states that "the precautionary principle has been taken into account in drafting this Directive and must be taken into account when implementing it". The precautionary principle has been defined as follows: "Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation"[49]. The object is not to inhibit progress or to stifle innovation, but to ensure that risks are fully investigated and guarded against.

117. The European Commission's recent Communication on the precautionary principle[50] (looking at the issue generally, not specifically in terms of GM) recognises the limitation of risk assessment and calls for wider input and consideration of alternatives as part of a precautionary approach. Specifically, it suggests that risk assessment "may include non-quantifiable data of a factual or qualitative nature and is not uniquely confined to purely quantitative scientific data ... Examination of the pros and cons of an action cannot be reduced to an economic cost-benefit analysis. It is wider in scope and includes non-economic considerations. A society may be willing to pay a higher cost to protect an interest, such as the environment or health, to which it attaches priority". It recommends that where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*:

- *proportional* to the chosen level of protection;
- *non-discriminatory* in their application;
- *consistent* with similar measures already taken;
- *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis);
- *subject to review,* in the light of new scientific data; and
- *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment.

118. Looked at more broadly, the precautionary principle has been said to build on a series of straightforward and well-established ideas: that prevention is better than cure; that the polluter should pay; that we should look for "no regrets" options; that alternatives should be appraised at the level of production systems taken as a whole; and that we should recognise the intrinsic value of non-human – as well as human – life. More specifically, a precautionary approach acknowledges the complexity and variability of

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[48] A. Stirling "Risk at a Turning Point?", *Journal of Risk Research*, 1(2): pp 97-110, 1998; A. Stirling "On Precautionary and Science-Based Approaches to Risk Assessment and Environmental Appraisal", EUR 19056 EN Volume II, Seville: IPTS, 1999.
[49] Bergen Ministerial Declaration on Sustainable Development, 1990.
[50] Commission Communication, *The Precautionary Principle*, COM(2000) 1.

the real world and embodies a certain humility about scientific procedures and knowledge. It implies recognition of the vulnerability of the natural environment and prioritises the rights of those who stand to be affected by an activity, rather than those who stand to benefit from it. It requires scrutiny of all available alternatives and an examination of justifications and benefits as well as risks and costs. In short, a precautionary approach involves the adoption of long-term, holistic and inclusive perspectives in environmental protection[51].

119. It is noteworthy that the EU approach has so far been to legislate specifically for GMOs, thus tending to suggest that GMOs are unique in their potential impact on the environment[52]. From a scientific perspective, there is no reason why the full weight of regulatory oversight should fall on GM crops. Many argue that there are potentially more environmentally damaging practices taking place in conventional agriculture. GM crops are generally expected to reach the same standard of safety as conventionally bred varieties. But there is little information on the environmental impact of different methods of conventional farming, because there have been few detailed studies in this area. It is important, therefore, to carry out an assessment in the context of plant varieties bred by the full range of conventional plant breeding and their use in conventional agriculture. It would seem inappropriate to require low levels of environmental damage from a GM crop while ignoring higher levels of damage from a non-GM crop. Our aim should be to move towards agricultural systems, whether they are GM or conventional, which minimise such damage.

120. The narrowly-based risk assessment approach to decision-making seems to us to be at the root of much of the public concern. The public is not necessarily expressing a lack of trust in science or scientists, but simply pointing out that judgements are being made, both within and beyond the science, which demand wider public involvement. The House of Lords Science and Technology Committee report on *Science and Society* suggests that what appear to be negative public responses to "science" may actually be directed at "the way in which ... reduction to a scientific issue alone distorts or excludes other legitimate concerns"[53]. In the specific context of GM crops, the UK Government's former Chief Scientific Adviser, Sir Robert May[54] noted: "There are real social and environmental choices to be made ... They are not about safety as such, but about much larger questions of what kind of a world we want to live in"[55]. Both this House of Lords report and an earlier report of the Royal Commission on Environmental Pollution, *Setting Environmental Standards*[56], pointed to an urgent need for the issues on which

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[51] C. Raffensberger and J. Tickner, *Protecting Public Health and the Environment: implementing the Precautionary Principle*. Washington: Island Press, 1999; T. O'Riordan, and J. Cameron, *Interpreting the Precautionary Principle*, London: Earthscan, 1994; E. Fisher, and R. Harding, *Perspectives on the Precautionary Principle*, Sydney: Federation Press, 1999.

[52] The exception is environmental liability, which was decoupled from the revised directive on deliberate release of GMOs, to be dealt with separately under generic environmental liability legislation currently under preparation. The European Commission has said that it anticipates that future legislation will increasingly be through product legislation (so-called vertical legislation, as opposed to the horizontal approach of the Deliberate Release Directive), the approach which tends to be preferred in the USA and Japan.

[53] House of Lords Paper 38, 3rd Report Session 1999-2000, paragraph 2.49.

[54] Now Lord May of Oxford.

[55] *Genetically modified foods: facts, worries and public confidence*, OST, February 1999; quoted in House of Lords, *op cit*, paragraph 2.51.

[56] 21st report, Cm 4053, 1998.

scientific evaluations of technological innovations are based to be more sensitively attuned to wider public values. So also the recent report of the New Zealand Royal Commission on Genetic Modification, which proposed a precautionary approach that would allow the co-existence of all forms of agriculture in New Zealand, and included in its recommendations a proposal that public research funding should extend to research on the socio-economic and ethical aspects of the releases of GMOs[57]. Although the revised Directive on Deliberate Releases suggests a broader approach, the risk assessment approach for GM crops used by the regulators in the EU and the UK is not yet designed to be attuned to, or to evaluate, such issues. So even though the assessment methods in themselves may command confidence, this can only be within the narrow context defined by the terms of reference of the regulatory bodies.

121. Moreover, uncertainty and lack of knowledge, themselves inevitable features of scientific inquiry, need to be more explicitly recognised in technologically sensitive areas. The House of Lords report refers to "current research [which] suggests that the public in fact understands uncertainty and risk well, on the basis of everyday experience"[58], and we suggest that this makes it not only possible but imperative to expose these issues in terms which are consistent with everyday common sense experience.

122. Scientists need to communicate more effectively about the areas in which uncertainty remains, as Lord May recommended in his guidelines for UK Government departments. These state that "in line with the Government's Code of Practice on Access to Government Information, there should be a presumption at every stage towards openness in explaining the interpretation of scientific advice which may mean going further than the minimum obligations. Departments should aim to publish widely the scientific advice and all the relevant papers so those outside can satisfy themselves about the process by which the advice was formulated and that the conclusions are correctly drawn". The key principles "will need to be followed particularly carefully when there is significant uncertainty" [59]. This position was echoed in the Phillips report on BSE, which includes among its lessons to be learned: "Openness requires recognition of uncertainty where it exists" and "Scientific investigation of risk should be open and transparent"[60].

123. It is striking that in our conversations with many of the main participants in the debates around the trials we have received few constructive suggestions for ways out of the current impasse. In order to discover what might satisfy the public, it would be useful to have a more systematic understanding of the basis of public responses to new technology. There is already a large body of existing research by social scientists and market researchers, but this is dispersed and fragmentary: an over-arching study distilling and integrating the various approaches would be invaluable. We see a need for a network of social researchers working in this field to create a continuing body of improved social intelligence, which the Government can use in decision-making.

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[57] Report of the Royal Commission on Genetic Modification (2001), Recommendation 6.14.
[58] *Op cit* , paragraph 2.56.
[59] OST, *Guidelines 2000 – scientific advice and policy making*, DTI, July 2000, paragraphs 25 and 1 (www.dti.gov.uk/ost/whatsnew).
[60] *Report of the BSE Inquiry*, Vol 1, Stationery Office, October 2000, paragraph 1301.

PART 3.2 IMPLICATIONS OF THE FARM-SCALE EVALUATIONS

124. As well as the more general concerns about GM crops which we have examined in the previous Part, many criticisms have been expressed of the Farm-Scale Evaluations themselves. At the heart of many of these lie misunderstandings about what the trials can be expected to establish – and fears about the use that will be made of the results. In this part of our report, we briefly describe the FSEs and their origins[61]. We then look at what they are (and are not) designed to test, and at how the results can contribute to the process of decision-making about the commercialisation of GM crops.

What are the FSEs?

125. The FSEs are a programme of scientific investigations at field level which are being undertaken in the UK on the basis of an agreement between the Government and the agricultural industry. After a pilot project in 1999, the main project started in spring 2000, and will end at harvest 2002 for spring sown crops and harvest 2003 for winter sown crops. Four genetically-modified herbicide tolerant (GMHT) crops are involved in the trials. Of these, three (winter and spring varieties of oilseed rape and beet (fodder and sugar)) have nearly completed all the necessary regulatory approvals to allow them to be grown on a commercial basis in the UK; the fourth (forage maize) already has such approval.

126. In all, between 60 and 75 fields are to be planted for each of the four crops. The sites, in England, Wales and Scotland[62], vary in size from 4 to 30 hectares, with the beet and maize mainly in the smaller fields, and the oilseed rape in the larger fields. Each field is split into two, one half being sown with a GMHT crop (the "test") and the other with an equivalent non-GM variety (the "control").

What are the FSEs designed to show?

127. The objective of the FSEs is not to evaluate the effects of the GMHT crops themselves. Their safety – in terms of the physical risks they might pose to health and the environment – has already been evaluated in the laboratory and in small-scale field trials, and the Government says that consent to grow them in the FSEs would not have been granted unless the regulatory authorities had already judged them to be safe (though it is clear from the evidence we received that not everyone accepts this judgement)[63].

128. In the trials, the "test" half of the field is managed according to the herbicide regime recommended by the company supplying the seed. The "control" half is managed by the farmer according to his normal herbicide practice. The scientific method involved is to test what is known as the null hypothesis, which is "that there are no

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[61] Part 4.3 gives some additional details on the FSEs.
[62] To date, no sites have been identified for FSEs in Northern Ireland.
[63] Part 4.2 gives details of the approval process, which is particularly helpfully explained in a paper from the UK Joint Regulatory Authority, *Genetically Modified Organisms: The Regulatory Process,* February 2001.

significant differences between the biodiversity associated with the management of GM winter oilseed rape/ spring oilseed rape/ maize/ beet crops that are tolerant to particular herbicides and [of] comparable non-GM crops at the farm scale". In other words, the stated objective of the trials is to find out whether the herbicide management associated with these GM crops, as compared with that used on the non-GM equivalents, has any effects on farmland biodiversity – that is to say, on the number and diversity of plants and animals. Some key indicators of biodiversity will be measured to check if there are differences between the two halves of each field. The indicators being used[64] have been selected on the basis that they are measurable and representative. According to Dr Firbank, the Project Director for the FSEs[65], they are intended "to tell us about the food chains in and around the field"; they focus on weed and invertebrate species that support the food chains of higher organisms such as birds.

Why are the FSEs being carried out?

129. As plant science developed during the 1980s and 1990s, so did opinions about its application in the UK[66]. In particular, conflicting opinions emerged about the potential impact of GMHT cropping systems on farmland wildlife.

130. On the one hand, English Nature, the RSPB and other conservation bodies expressed concern that the use of GMHT crops might exacerbate the decline in farmland wildlife already observed as a result of the intensification of farming over the last 25 years. This might not happen because of the characteristics of the GM crops themselves, but because farmers growing those crops would be able to remove weeds more efficiently using herbicides, thereby reducing certain wildflower species directly, and also reducing food resources available to wildlife further up the food chain[67]. These concerns were also being raised by NGOs, who were calling for a five year moratorium on the commercial growing and importation of GM crops and food[68]. And they had been recognised by ACRE[69].

131. On the other hand, it was argued that GMHT crops might actually be beneficial to farmland biodiversity. Recent studies at the Institute for Arable Crops Research at Broom's Barn, Suffolk, have investigated alternative management techniques for GMHT crops that allow stubble to be left until the spring[70] and herbicides to be applied later than in conventional weed management programmes, so that weed populations remain

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[64] Listed in Part 4.3.
[65] AEBC evidence taking session, Norwich, 6 February 2001.
[66] An account of the developments, and of the views of various stakeholders, is given in Part 4.1.
[67] B. Johnson, English Nature, *Farm Scale Evaluations of herbicide tolerant crops in the United Kingdom: the precautionary principle in action?* Paper prepared for the Harvard Conference on the Precautionary Principle, 2000.
[68] See Part 4.1.
[69] In 1994, in considering an application for the commercial use of GMHT oilseed rape, ACRE took the view that "while the risks of the GM crop itself appeared to be low, the potential environmental effects associated with the use of broad spectrum herbicides should also be assessed" (DETR Background Paper, *The History of the Farm-Scale Evaluations*, August 2000). ACRE considered the issue to fall under pesticide legislation rather than GMO legislation, but mentioned its concern in its Annual Report for 1996-97 (chapter 3, paragraph 3.5).
[70] Meeting with farmers, Norwich, 6 February 2001.

in the fields for longer[71], and species such as pollinators and the natural predators of pests are favoured.

132. It was thus apparent that information on the potential indirect environmental impacts of these crops was missing; this gave rise to the suggestion that a large scale ecological experiment should be carried out to provide some data pertinent to this issue. In June 1998, Michael Meacher (the Minister for the Environment) discussed the matter with the statutory nature conservation agencies, some NGOs, ACRE and other Government departments, reaching general agreement that studies were needed on the impacts of GM crop management on farmland wildlife[72].

133. In October 1998 the Government reached a voluntary agreement with SCIMAC to delay large-scale commercial planting of GM crops for one year, whilst a programme of monitored plantings was carried out[73]. Following that initial year, the Government negotiated a new agreement with SCIMAC, announced in November 1999[74], which provided that the FSEs would be continued for the next three years, and there would be no "general unrestricted cultivation" of GM crops in the UK until they were complete. This agreement was described as forming part of a "programme for the managed development of GMHT crops to limit their introduction whilst ecological monitoring was carried out"[75]. The Government is meeting the costs of the research components of the FSEs[76], while the industry is meeting the other costs (such as purchase of seed, compensation payable because the crop cannot be sold, and cost of disposal). This agreement provided a breathing space for both parties.

134. This gave the Government some time to reflect on its position, in light of public opposition and developments within the EU. At EU level, by 1998 consent had already been given to the commercialisation of GMHT forage maize (T25) and insect resistant Bt maize. In early 1998, Member States had voted to give consent to a type of oilseed rape (PGS rape), and though the French (to whom the initial application had been submitted) had refused to issue the consent, it could have been issued at any time. The Government was anxious to secure a standstill. It was advised that the imposition of a moratorium on the commercialisation of GM crops would be illegal under the Deliberate Release Directive[77]. The only possible route to secure a delay might have been to use Article 16 of the Directive, which provides that a Member State may provisionally restrict the use and/or sale of a product on its territory where it has justifiable reasons to consider that the product constitutes a risk to human health and the environment. This has subsequently been used by the National Assembly for Wales[78]. The obvious area where there might be such reasons was the impact of growing GMHT crops on

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[71] M.J. May, IACR. *Note on weed manipulation studies at Broom's Barn.*
[72] DETR Background Paper, *The History of the Farm-Scale Evaluations*, August 2000.
[73] Announced by Michael Meacher, Minister for the Environment, in his evidence to Sub-Committee D of the House of Lords Select Committee on the European Communities on 21 October 1998 (see HL Paper 11-II, 2nd Report Session 1998-99, Q 603).
[74] DETR News Release 507, "Voluntary Agreement on GM Crops Extended", 5 November 1999.
[75] DETR Background Paper, *The Farm-Scale Evaluations of Genetically Modified Herbicide Tolerant Crops – Rationale and Chronology*, January 2001.
[76] Total cost £4.4 million over the period March 1999 to December 2003: reply to Parliamentary Question, *Hansard*, 29 March 2000, col 131.
[77] Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ L117, 18 May 1990). See Part 4.2 for more details.
[78] See para 104 above.

biodiversity, where the relevant advisory bodies (including ACRE and English Nature) agreed that more information was needed. This approach enabled the Government to justify the FSEs within the framework of this Directive. But it may also have encouraged the presentation of the FSEs as the final part of the jigsaw puzzle, and thus exaggerated their real scope and significance.

135. Another factor in the debate was the recognition that the EU deliberate release Directive did not formally require consideration of any changes in management practice that might be associated with a GM crop (as opposed to the safety of the GM plant itself). This was discussed at EU-level and in 1998 all Member States agreed informally that they would work on the basis that possible effects arising from changes in management practice would be taken into account in the GMO risk assessment process. This became a legal requirement with the amendment of the Directive earlier this year.

136. The industry was also influenced by the strength of public feeling. An assessment within the industry of the acceptability of GM technology in the UK was reported in 1998 to have concluded that the climate was inhospitable: the British public was sceptical about scientific progress, the collapse of public support for biotechnology and GM foods was paralleled by the hostility of the press, and there was disenchantment among retailers, who supported a moratorium on GM food to give them time to clarify their positions[79]. Following a vigorous anti-GM media campaign, demand for GM products had fallen; indeed by mid-1999 the majority of British supermarkets and food producers had removed GM ingredients from their products[80]. And the industry had little to lose from agreeing to a voluntary moratorium, since there was little chance of gaining early approval for further GM crops through the EU system (which was paralysed by the impending revision of the Deliberate Release Directive and the stance taken by certain Member States to delay progress in the execution of the existing Directive).

Why have there been antagonistic local reactions to the FSEs?

137. There has been considerable public antagonism to the FSEs at local level in some of the areas involved. We believe that much of this stems from the wider concerns which we have considered in Part 4.1 of this report. But in addition the lack of genuine consultation before specific trial sites were announced has generated tension and a sense of grievance. The position of potential participating farmers has been difficult. Some had a genuine willingness to be open, at both local and national levels, about the nature and implications of the experiments. This was compromised in a number of cases by subsequent experience of personal abuse, threats and damage to property.

138. The EU Deliberate Release Directive permits (but does not require) prior consultation before the planting of GM crops is approved. The Government and SCIMAC recognised the need to give information to local people about the sites which had been chosen. The aim was to do this as soon as possible, but because the final

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[79] Report by Greenberg Research (USA) to Monsanto, *Re: The British test. The Fall 1998 Research*, 5 October 1998, as reported in GeneWatch Briefing No 5, Genetic Engineering: *A Review of Developments in 1998*, 1999.
[80] GeneWatch Briefing No 5, *op cit*, and GeneWatch Briefing No 9, *GM Crops and Food: A Review of Developments in 1999*, 2000; and references therein.

decisions depended on the vagaries of climate and crop prospects, negotiations for many sites were not concluded until just before the list was finalised. The procedure for informing the public has varied. The farmers involved were given guidance by SCIMAC that they should discuss their cropping plans with their immediate neighbours and with all relevant local organic growers.

139. The Government took the following steps for England and Wales:

- July 1999: a seminar was held in London, to which representatives from NGOs and some interested members of the public were invited;
- Spring 2000: 12 advertised public meetings were held in areas where FSEs were to be sited, including Lincoln, Norwich, Cambridge, Colchester, York, Worcester, Banbury, and Luton;
- Spring 2000: letters with information packs were sent to all parish, district and county councils where FSEs were planned. Parish Councils were given copies of the relevant FSE consents and risk assessments and asked for their views. DETR also published an explanatory leaflet, *GM Crops – Take a Closer Look*, and placed explanatory material on the FSEs on its website;
- Autumn 2000: Chairmen of parish councils were invited to a meeting with Michael Meacher in London[81], and DETR officials visited parish councils on request;
- Spring 2001: letters and information were sent to councils in England and Wales on the day that the sites were announced, and DETR offered to send an official to local meetings organised by parish councils[82].

140. DEFRA has hosted meetings with beekeepers to discuss their concerns in relation to GM trials, leading to SCIMAC taking steps to ensure that beekeeping organisations know about FSE sites and offering to explore advertising in their trade magazines so that word gets through to individual beekeepers as soon as possible. DEFRA has also promoted a dialogue between the organic sector and SCIMAC. Before this year's spring round of FSE plantings plans for exchanging information were agreed to improve organic growers' awareness of proposed trials in their vicinity. The idea was for the organic sector bodies to provide lists of their members who might be growing maize or oilseed rape within the envisaged trial areas, and for SCIMAC to use this information to get the FSE growers to contact their organic neighbours.

141. This was to be in addition to the FSE growers contacting all their immediate neighbours (conventional or organic) as a matter of course. In the event, practical constraints meant that the organic sector bodies were unable to indicate specifically which of their growers might be growing maize or rape, only those producing arable crops in general. We understand that DEFRA intend to revisit these plans and try and build on them in relation to next year's spring FSE round (no similar action was taken for the 2001 autumn FSE round on the understanding that there is no organic winter oilseed rape).

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[81] We understand that four accepted this invitation.
[82] We understand that 12 out of the 80 Parish Councils contacted accepted this offer.

142. Many of those involved in the public meetings found them less than satisfactory. Some complained that they were not attempts to consult but top-down announcements of a *fait accompli*[83]. Others complained that, although the meetings had been well attended, many of those present were not local[84].

143. In Scotland, the Scottish Executive has taken a number of steps in addition to statutory requirements to assist public awareness and understanding of the issues, seeking to ensure that as much notification as possible about proposed trials is given to enable everyone with an interest to obtain factual information about what is involved. The Executive has published and distributed a leaflet giving information about the GM trials taking place in Scotland, and has placed more extensive information on a dedicated GM web-site. It has written to local authorities and all community councils in the vicinity of the proposed trials, and has notified key stakeholders including the National Farmers' Union (Scotland), the Scottish Beekeepers Association, and organic interests. The Scottish Executive has arranged public meetings in all the trial areas, with expert speakers from the Executive, the biotechnology company and the scientists involved in the research programme. In addition, officials have met with the two local authorities in whose areas trials were proposed. The Minister for Environment & Rural Development has met Highland MSPs, representatives of Highland Council and Highlands and Islands GM Concern to provide information about what is involved and to hear at first hand about areas of uncertainty. In order to reach as wide an audience as possible, the Minister has also participated in a radio phone-in answering questions from a cross section of the Highland population. Moreover, the Scottish press release announcing the autumn 2001 FSEs says that it allows time for "everyone with an interest in the proposals ... to comment if they wish", and that Scottish Ministers will then "determine whether or not to grant approval for the proposed sites ... Approval will be granted only when Scottish Ministers are satisfied on the scientific evidence available to them that the GM crop can be grown on the selected sites without posing a threat to the environment or public health ... If any evidence comes forward to indicate that the GM trials pose a threat then the programme will be halted"[85]. Although it has been on a limited basis, we commend these approaches to consultation.

144. We also note with interest the report earlier this year from the Scottish Parliament's Transport and the Environment Committee, which whilst concluding that there was a role for the FSEs "in a rightly cautious, but not unnecessarily restrictive, approach to GM development" [86], went on to urge the need for further research into the potential environmental risks associated with GM releases, to address not just biotechnology issues but also wider agricultural management and socio-economic issues. The Committee also recommended that the AEBC should take account of these aspects in drawing up its forward work programme[87].

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[83] Including the NGOs Friends of the Earth and GeneWatch UK: see Annex to submission from Friends of the Earth to the AEBC, February 2001.
[84] See note of informal meeting between AEBC sub-group members and farmers, Norwich, 6 February 2001, where the distinction was drawn between "the public" and "activists", with the suggestion that meetings should focus on the real issues and not be diverted by extreme views.
[85] Press Release SE1740/2001, 23 July 2001.
[86] *Report On Petition PE51 From Friends Of The Earth Scotland On Genetically Modified Organisms*, para 35.
[87] Paras 45 and 46.

145. In a debate in May 2001 on the spring 2001 oilseed rape trial at Low Burnham, the UK Minister for the Environment said that a fresh approach was needed ("I should like to see improved notification and consultation processes for future rounds of the evaluations"), and he said that he would seek to agree with SCIMAC that this should be done six weeks before sowing[88]. The statutory requirement for notification is only 15 days before sowing, with advertisements appearing within 10 days of notification, and longer notification times are not part of the Government's agreement with SCIMAC on the running of the FSEs. However, since the FSEs started, the Government has sought agreement from SCIMAC to announce the proposed sites earlier than the statutory minimum times – in some cases successfully: for example in spring 2000 the sites were announced on 17 March for sowing that took place through to the end of April, and for spring 2001 oilseed rape and beet sites were announced on 28 February, which gave up to 6 weeks notice for some sites. The announcement for the autumn 2001 sites was 4 weeks before the first possible sowing, so that again for some sites the period of notice was in practice greater than 4 weeks. SCIMAC maintains that it is generally harder to give advance notice for autumn crops because of the shorter period (relative to the spring) between the previous harvest and the next sowing, and because of late decision-making by farmers.

146. It has been suggested to us[89] that the lack of any agreed procedures for legitimising the choices of particular trial sites (comparable, for example, to those offered under the statutory Town and Country Planning framework), on matters seen as being of serious local environmental and economic significance, has given rise to bad feeling and mistrust within some communities. Although we doubt whether the planning system itself would provide an appropriate mechanism, we understand the desire for a comparable mechanism to legitimise decisions, involving recognised criteria and consultation at local level.

147. There is a real dilemma as to what "consultation" can mean in the context of the European Directive. It certainly does not mean public consent. As part of the formal procedure for the consideration of any proposal to release GMs, there is an opportunity for members of the public to comment to the Joint Regulatory Authority[90] . But only comments on matters within the scope of the defined risk assessment procedure are considered relevant. Some matters are regarded as already determined: for example, in the context of the applications for the FSEs comments on the safety of gene flow would not have been taken as relevant to the decision, because the issue was held to have been considered thoroughly by ACRE already. Other matters, such as economic impacts on organic farmers, non-GM farmers and bee-keepers are not regarded as relevant to a "safety" (in terms of health and environment) evaluation.

148. The new Deliberate Release Directive[91], which must be implemented in UK law by October 2002, presents a confused picture. It introduces a formal requirement to

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[88] Michael Meacher, *Hansard*, 1 May 2001, col 206WH.
[89] Evidence to AEBC: note of AEBC public consultative meeting, Norwich, 5 February 2001; note of sub-group meeting in the Highland Council Chamber, Inverness, 19 February 2001.
[90] Consisting of DEFRA (previously DETR and MAFF), HSE and the devolved administrations.
[91] Council Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms (OJ L106, 17 April 2001). See Part 4.2.

consult the public about experimental (Part B) releases[92]. This raises the prospect of direct public participation to inform decision-making. However, the range of choices available to regulators is still restricted. It is a case-by-case process, and consent may be refused only where there is a risk of adverse effects on human health or the environment from the particular release. Broader socio-economic impacts are seemingly irrelevant in this process[93]. So, for example, the desire expressed to us by the Highland Council and groups in Scotland[94] to promote a type of agriculture in that region which was seen as pure and natural, as an important dimension of the region's economic success, will still not be a relevant criterion under the formal process. Yet the Directive accepts the overall relevance of ethical and socio-economic considerations. It makes provision for consulting ethical committees on matters of a general nature, and for periodic reporting on the socio-economic implications of deliberate releases and on the placing of GMOs on the market. But it provides no obvious machinery for giving effect to any adverse conclusions, beyond asserting a higher level of precaution in relation to the risks with which the Directive is concerned.

149. In considering whether there should be some formal way for local concerns to be aired, we note that formal regulatory approval of this kind is not needed for any other agricultural food crop. However, it is interesting that subsidy-backed trade agreements do operate to restrict areas in which some crops can be grown[95]. For example, High Erucic Acid Rape (HEAR) contains high levels of erucic acid, a glucosinolate which has toxic effects on animals and humans. In order to allow HEAR to be produced for industrial uses without entering the food chain, separation distances of 50m between it and other varieties of oilseed rape have been agreed. A grower who fails to observe the separation distance stands to lose arable area payments. As a result of these arrangements, no contamination of food crops has occurred in the UK or in other EU Member States, despite the relative ease with which rape can out-cross.

150. Another such example is the scheme operated by the North Essex Seed Zoning Committee, with the support of seed merchants and seed companies in the area. Since its inception in 1938, this scheme has protected seed crops of certain plant species which are sensitive to cross-pollination. Its aim is to maintain North Essex as a uniquely secure area for the production of seed from these species, which it has done successfully for over 60 years – demonstrating that separation distances can be effective[96]. The industry has experience of voluntary agreements which can be built

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[92] There are also requirements for providing an opportunity for the public to make comments to the European Commission on certain Part B, and on summaries of applications for Part C marketing consents and proposals for the variation of such consents (Articles 16 and 24).

[93] This dilemma is recognised in the DEFRA consultation paper on implementing the new Directive, *A Consultation Paper on the implementation of the Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms* (DEFRA July 2001), para. 3.14 and 3.15.

[94] The Highland Council, *A Forward Strategy for Scottish Agriculture – Highland Council Response to SEERAD's Discussion Document*, September 2000.

[95] In addition, there are Government restrictions on some crops known to present a specific risk, such as hemp which could be introduced into the drugs trade by mixing it with the leaves of cannabis (from which it cannot be distinguished in the field). Following inspection by the local police and the Drugs Inspectorate, a farmer is licensed by the Home Office to grow a specific crop of hemp. The fibre from these plants is used for the parcel shelf in some cars and for horse bedding; further uses may be developed in future.

[96] Roger Turner in *GM Crops: Understanding the Issues*, a booklet produced with the support of the UK Agricultural Biotechnology Industry. See also MAFF, *Guide to the Arrangements in N Essex for the prevention of injurious cross-pollination of seed crops of Brassica, Beet (Beta) and Onion (Allium)*, 1995.

upon in relation to biotechnology without the need for formal regulation. The SCIMAC initiative is itself a voluntary agreement.

How much can the FSEs tell us about biodiversity?

151. There is an intimate relationship between agriculture and the countryside: many species of plants and animals have become more or less common because of past agricultural practice, so it is likely that any future change in land management will influence the range of species. The FSEs are expected to provide valuable new information on agricultural ecosystems. They are the first large-scale experiment of their kind in Europe to examine the ecological effects of the use of particular management regimes or crop varieties (whether GM or non-GM). Manipulative experiments of this scale (some 240 fields in total over the three years) offer the best prospect of being able to link changes in agricultural practices to changes in biodiversity, because any observed changes can be attributed to the factor which has been manipulated (in this case the paired crops and their management regimes). Other large-scale studies have been observational, or have relied on "pairing" similar farms and making comparisons; such studies throw up useful patterns, but do not allow the mechanism which is causing differences to be identified, because many things vary simultaneously.

152. However, like all scientific experiments, the FSEs have been set up to investigate a specified range of issues. The scientists most closely involved have always openly acknowledged the focused nature of the trials and consequently of the information which they are likely to provide, and they have attended public meetings, made public statements and issued written material to this effect[97]. In particular, the trials:

- focus on *selected species* which are taken to stand as indicators for overall biodiversity;
- focus on the effects of the changed farming practice associated with GMHT crops on numbers and balances of wild plants and animals *only on the land in question*, so the value of the results will be limited in relation to birds and mammals (which tend to forage over wider areas) and will not necessarily remain valid for widescale commercial production in varying ecological contexts;
- are *short-term* (three harvest years), whereas biodiversity impacts or interactions may take some years to reveal themselves.

153. We have found that these limitations have not always been clear to those interested in the FSEs. We think that this is partly because of the way the hypothesis being tested in the trials was formulated, referring simply to the effects of "biodiversity" without qualifying that term in any way. We do recognise that information on precisely what was being examined was publicly available to those who cared to investigate, but that is no substitute for clear public statements. In fact, we think that the broad claims made by Ministers and their advisers have tended to exacerbate the confusion rather than dispelling it. For example, Michael Meacher, Minister for the Environment, said: "We cannot take action in respect of GM crops unless we can show evidence that they

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[97] See for example information on the web at http://www.environment.defra.gov.uk/fse/raq/index.htm.

constitute a risk of harm either to human health or the environment. *These trials will show whether there is such evidence*"[98]. DETR has accepted that "in trying to speak simply and not using too many words, there has sometimes perhaps been given the impression that the Farm-Scale Evaluations were looking at more than they actually are", and has apologised for any confusion[99]. But in the light of the statements which were made, it is not unreasonable for the public to assume that the trials will give information on the effects on *all* aspects of biodiversity – or even on all aspects of the environmental impact.

154. When the data collected during the FSEs are analysed, they will require interpretation. They are likely to show impacts in both directions on the various indicators of biodiversity which are being measured. For example, the effects may vary at different stages of the season: high biodiversity early in the growing season would be of benefit to many species of birds which nest at that time, whereas later in the growing season it would have an impact on the quantity and diversity of weed seeds produced and therefore entering the seed bank over winter. The results for each individual indicator will be tested to determine if it is enhanced or reduced to a statistically significant extent. If all these individual tests are combined, they may show a strong signal in one direction or another, or they may illustrate that the signal is variable[100]. If there is a statistically significant change in a biodiversity indicator species, it will then be necessary to decide whether the change is ecologically significant. This will be difficult because there are no comparable data from similar experiments in conventional agriculture. The effects of the management regimes of the GM crops on the trial fields are being compared only with the effects of the regimes of the conventional crops on the other half of the field. So, to take a hypothetical example, if the results show that the ladybird population in the GM half of a trial field has declined by 20 per cent compared with the non-GM half, this might appear to be ecologically significant. However we do not know whether there is a similar decrease in the ladybird population outside these trials as a result of particular conventional agricultural crops or practices. Without detailed knowledge of the impact of a range of agricultural crops and practices on farmland biodiversity, any ecological conclusions drawn from the results will rest on a relatively narrow knowledge base. The ecological significance of an impact on biodiversity can only be judged effectively by comparison with the diversity of crops and practices in conventional agriculture.

155. The results of the FSEs will inform future research, enabling investigations into how we can move from results concerning individual species to determining a more holistic picture of what constitutes environmental impact (which is a wider concept than "harm")[101]. Ways are being investigated of integrating information from the FSEs on the relative sensitivity of biodiversity indicators in order to produce scientifically robust signals of biodiversity change, and to assess the strength of these signals. This could

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[98] DETR News Release 535, 3 August 2000; emphasis added.
[99] Dr Linda Smith – AEBC evidence-taking session, Norwich, 6 February 2001.
[100] Dr Les Firbank – AEBC evidence taking session, Norwich, 6 February 2001.
[101] We note that ACRE has established a new sub-group to consider "the criteria and baselines used to gauge 'harm' when considering the risks of releasing GMOs to the environment". The subgroup will be focussing on an analysis of the scientific attributes of harm (such as spatial and temporal effect, severity, irreversibility, uniqueness) rather than the social responses to harm (such as dread, distrust and equity issues) or the legal aspects. We look forward to co-operating with the work of this sub-group.

result in the identification of a series of indicator species and experimental methods which could be used to test the potential environmental impact of any farming system (not only systems associated with GM crops). The work may include building models based on the empirical information gathered in the trials, so that any future field trials would be starting from a much higher base of knowledge[102].

156. So as a result of the FSEs the UK will continue to be at the forefront in developing methods to measure and assess the impact of agriculture on the environment. On the other hand, the FSEs alone will not provide an unequivocal analysis of the ecological impact of the management of the crops under trial.

Should more issues have been covered in the FSEs?

157. Some of the environmental issues which have been drawn to our attention were not included in the design of the FSEs. Of these, three particular themes have been mentioned repeatedly – the implications of GM plants and the herbicides used in their management for *soil biodiversity*; the potential impacts of those herbicides on *groundwater quality*; and the issue of *gene flow*. We asked ACRE for its views on the adequacy of present knowledge on these issues[103].

158. As regards *soil biodiversity*, ACRE has pointed recently to the need for further research programmes to improve understanding of the impacts of GM crops on biota in the soil[104]. In the light of this, we asked whether ACRE considered that the information that is at present required in applications for approval to commercialisation was sufficient to allow it to reach a judgement on possible impacts. In reply, the ACRE Chairman says that the risk assessment provided by the applicant is only the starting point for its own assessment: its members add "their own experience, expertise and knowledge of the scientific literature". He notes that the GM crops in the FSEs have been grown widely in field trials over the last eight years, and have been grown commercially in some parts of the world, with no reports of adverse effects "as judged by observed changes to soil health, fertility or disease problems". He acknowledges the possibility that there may be undetected changes (for better or worse) in soil communities when a GMHT crop is grown, but says that ACRE "remains satisfied that growing the GM crops in the FSEs presents no greater risk to soil biodiversity than does growing equivalent conventionally bred crops". ACRE has identified the need for more research not because it is concerned about the possible impact of the current generation of GM crop traits, but because "there may be future applications that might give rise to concerns" which more information would be helpful in identifying and resolving, given that so little is known about the ecology and population dynamics of communities within agricultural soils. So an ACRE subgroup "will review the current state of knowledge and identify priorities for future research on soil biota/crop interactions so as to equip risk assessment for the likely challenges ahead".

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[102] Dr Les Firbank – AEBC evidence taking session, Norwich, 6 February 2001.

[103] Letter of 29 June 2001 from Justine Thornton, convenor of AEBC sub-group A, to Professor Alan Gray, Chairman of ACRE, and his reply of 6 July 2001.

[104] *Annual Report*, 2000. This issue is not of course confined to the effects of GM crops and their management: for example, two herbicides used in the FSE trials are already in widespread commercial use on conventional crops, on set-aside land and hard surfaces, and the impact on soil biodiversity of different organic farming practices is unknown.

159. On implications for *groundwater quality*, there is a general question about the potential impact of the herbicides being used on the GMHT crops (glyphosate and glufosinate ammonium), and concerns have been expressed in at least two trial areas about the lack of site-specific risk assessments of their impacts[105]. We recognise that the herbicides concerned are already widely used in agriculture and are actually less persistent than many used with conventional crops. Nevertheless, partly because of our concern that this issue might fall between institutional stools, we asked ACRE about its role in ensuring groundwater protection, and how it interacted with the Advisory Committee on Pesticides (ACP) and the Environment Agency in determining the potential effects of a GMHT crop on groundwater. In his reply, the ACRE Chairman confirms that the impact of the herbicides used in the FSEs is not within ACRE's remit, saying that any concerns should be addressed to the ACP (on which the Environment Agency is an assessor). However, he emphasises that ACRE and the ACP work closely together on pesticide matters in relation to GM crops: "we have forged strong links through our respective subgroups and secretariats", with cross-membership and joint meetings.

160. On *gene flow*, additional studies have been added to the FSEs because they provided an ideal opportunity to gather more data in an larger scale experiment to validate or modify earlier estimates of gene flow. There is also other relevant recent and current work[106]. We noted the concerns expressed to us by bee-keepers, organic farmers and others that even minor cross-pollination threatened the perceived integrity of their products. We also noted that ACRE had recently identified a need for more research into the effects of the flow of genes which might confer an ecological advantage to plants outside the agricultural environment[107] (though we understand that this is very unlikely to be an effect of HT genes because they confer an advantage only when a plant is sprayed with a specific herbicide). We therefore asked ACRE how far it was looking at gene flow risks, and sought confirmation that its earlier risk assessments still stood in the light of any new information available to it. In his reply, the ACRE Chairman confirms that the likelihood and consequences of gene flow from GM crops is a major component of the risk assessment process. ACRE is content that gene flow from the GM crops in the FSEs poses little or no risk to the environment, and is not aware of any scientific data which would change its view. He mentions the two research contracts which DETR has let for "add on" experiments to augment the current understanding of gene flow from these crops[108].

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[105] Genetically Modified Oilseed Rape Crop Trial – Castle Bytham, Lincolnshire: submission to the AEBC from Castle Bytham Parish Council, 15 January 2001. Genetically Modified Oilseed Rape Crop Trial – Munlochy, Highland County: evidence to AEBC sub-group meeting, Inverness, 19 February 2001. The winter use of glufosinate is currently banned by the PSD because of concerns over contamination via run-off, so there is a particular concern about its use with GMHT winter oilseed rape in the trials, for which special licences were issued for the FSEs.

[106] For example, BBSRC and NERC are funding a joint research initiative on a range of issues linked to gene flow, some of which apply just as much to conventional crops (for example, mathematical models investigating the rates of establishment of selectively neutral genes). Details of the projects funded by this initiative are at http://www.bbsrc.ac.uk/science/initiatives/gene_flow.html.There is a wealth of research into gene flow in bacterial communities, and how this contributes to bacterial diversity and adaptability, for example a European programme focusing on mobile genetic elements (sections of genetic material that move readily between compatible bacteria), details of which may be found at http://mecbad.bba.de).

[107] ACRE *Annual Report*, 2000.

[108] See Part 4.3.

Are the FSEs intended to be the final piece in the jigsaw for decisions about the commercialisation of GM crops?

161. Many people believe that decisions on the commercialisation of GM crops hang solely on the results of the FSEs. They see the trials as a watershed in the commercialisation process not only of these particular GM crops but also of GM crops more widely, and as having been politically motivated to facilitate that process (a view which has fuelled the antagonism to them). The agreement between the Government and SCIMAC setting up the FSEs said that once the results from the FSEs were available, freedom to pursue commercialised planting of GM crops would "be dependent upon the recommendations and advice the Government receives from the Scientific Steering Committee based on the results of the FSEs, together with all relevant approvals required under current UK and EU legislation"[109] (which, as DETR explained to us[110], would also involve advice from ACRE).

162. It seems to us that Ministers and officials have fostered the impression that the FSE results are the last piece of the jigsaw, for example by saying:

- "These farm scale trials will ensure that the managed development of GM crops in the UK takes place safely"[111];
- "The farm-scale evaluation of GM crops is extremely important research which will ensure that the managed development of GM crops will take place safely"[112].
- "We cannot take action in respect of GM crops unless we can show evidence that they constitute a risk of harm either to human health or the environment. These trials will show whether there is such evidence"[113]

163. Given the precise and highly circumscribed scope of the trials, such statements seem likely to have created serious misunderstandings. They could be perceived as reflecting official confidence in the adequacy of existing GM-related science in all other respects. It seems to us that their definitive character in circumstances of such political sensitivity has encouraged scepticism about Ministerial statements.

164. The announcement in Scotland of the autumn 2001 FSEs suggests a broader approach, saying that "the Scottish Executive has stressed that the Farm-Scale Evaluation Programme is important research designed to assess the potential implications of growing GM crops *on certain aspects of* biodiversity and the wider environment", and that the evaluation of the FSE results will "*be one factor in* future decisions on commercialisation" [114]. However, the announcement of the autumn 2001 trials in England seems once again to imply that the results of the FSEs will be decisive: "There will be no commercial growing of GM crops until the FSEs are completed and only then if the crops and associated farming practices are assessed as causing no

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[109] Agreement of 1 November 1999 between the Government and SCIMAC. On the relevant approval process, see Part 3.2.
[110] DETR Background Paper, *The History of the Farm-Scale Evaluations*, August 2000.
[111] DETR Farm Scale Evaluation Fact Sheet, 1999.
[112] Michael Meacher, Minister for the Environment, DETR Press Release, 14 June 1999.
[113] *A Better Quality of Life: A Strategy for Sustainable Development in the UK* Cm 4354 (May 1999), para 6.64.
[114] Press Release SE1740/2001, 23 July 2001; emphasis added.

unacceptable effects on the environment"[115]. Some passages in Michael Meacher's recent letter to us[116] might give the same impression. For example, in pointing out that oilseed rape and both varieties of beet do not yet have approval for commercial use, he says that if this issue comes up for decision before the FSE results are available, the UK will take a decision as to how to vote "based on the advice of ACRE". If the FSE results are available, the decision will be based on "the results together with advice from ACRE".

165. However, the letter goes on to confirm that the UK Government is now contemplating a more inclusive process which may respond better to some of the concerns which have been expressed. The Minister recognises the fact that "the [FSE] research work has been confined exclusively to questions around the management of the crops" is "a major limiting factor". He says that after the data have been analysed, as well as seeking advice from ACRE and ACP, "the Government will also conduct a public consultation exercise as part of the evaluation of the results, and public attitudes to commercialisation will form a crucial part of the decision. In the light of such evidence, Ministers, together with the devolved administrations, will take a joint decision as to whether to allow the commercial growing of each of the GMHT crops involved in the FSEs". It is right that the first step in considering the significance of the FSE findings should be for ACRE and ACP, but in so important a matter involving a political judgement about the acceptability of risk, it is also right that the outcome of the public consultation exercise that the Minister proposes should be taken into account in coming to the final decision. We therefore welcome his assurance to this effect.

166. In his letter, the Minister also recognises that further research may be needed to complement the FSEs: "In the light of the various consultations that will take place at the end of the trials, [one option is] to require further research work to be carried out, not least to ensure that public consent can be secured for commercial planting – that protection of the economic interests of other farmers (whether conventional or organic) can be secured. [Another] is to consider... what further work should be carried out to examine the effects of moving from field-scale planting of GM crops to district-wide GM cultivation, or further step change that will need to be tested".

167. He also explains that there are other regulatory procedures which crops and their associated management practices must go through before full commercialisation would be permitted. The herbicides must pass pesticide regulations; they currently have provisional licences, but the results of the FSEs might aid the Government in any decision about their effects on the environment. The crops would have to perform successfully in National Seed List trials for distinctiveness, uniformity and stability, and have a value in use[117]. And the Government must have regard to the Novel Food Regulations overseen by the FSA (which are used in decisions on whether GMHT crops

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[115] DEFRA News Release 60/01, 23 July 2001.

[116] Letter of 21 May 2001 from Michael Meacher, Minister for the Environment, to Professor Malcolm Grant: see Annex C.

[117] The scheme is run by DEFRA's Plant Variety Rights Office: see *Guide to National Listing of Varieties of Agricultural and Vegetable Crops in the UK* (available at www.defra.gov.uk/plant/pvs/nlguide). We note that, separately from the FSEs, there are a small number of sites where GM crops are being grown under the National Lists trials system (DETR news release 061, 7 February 2001).

are safe as food). We welcome all these tests, insofar as they contribute to ensuring the safety of the crops and their management systems.

168. Asked how he proposed to take into account any uncertainty in the results, the Minister recognises that uncertainty might take various forms. On the statistical results of the programme, "it is possible that the interpretation of the results might provide differences of opinion between scientists who have expertise in this field. A public consultation following the advice from the Government's own expert committees would allow for different opinions to be aired and considered. On the likely effects of the crops, to resolve continued uncertainties we must continue to monitor all releases of GM crops and take the advice of our expert committees". He adds that "third, there will certainly continue to be claims that the FSE trials do not constitute a real test of the full effects of a GM agronomic system, either in the relationship between herbicide use [and] biodiversity conservation or in the long-term management of volunteers".

169. We hope that, given the likely complexity of the results from the FSEs, the Minister will accept the importance of considering them together with the information generated for example by BRIGHT[118], CSL[119] and the Broom's Barn[120] experiments, and by other relevant ecological, agronomic and socio-economic data from Europe and the US[121]. The FSEs are only designed to investigate the potential impacts of one particular use of the technology. They do not, for example, include a variety of management regimes as one of their treatments, but allow the farmers to manage the crops according to the label and having regard to indicative guidance from SCIMAC, whereas the experiments at Broom's Barn investigate different management regimes (eg different timing and method of spray application) and soil types.

Is there a need for continued monitoring after any approval to release?

170. Some biodiversity issues, by their very nature, cannot be examined even in trials like the FSEs, which are inevitably restricted both in space and in time. The limitation on space is important because, for example, birds and small mammals move over areas larger than the fields used in the trials, and a rare hybridisation event which is insignificant in a one-hectare field experiment may be important when a crop is grown on 100,000 hectares. The limitation on time is important because some impacts may take several years to become apparent. One particular example is the potential impact of changes in land management on soil structure and fertility. GM crops provide the potential for reduced tillage or no tillage operations, reduced frequency of spray operations and delay of spray operations: these changes in management practices could have significant positive environmental effects. On the other hand, the changed patterns agricultural practice and herbicide use over time could have adverse effects[122].

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[118] P.J. Lutman and J.B. Sweet. "Field experimental programmes in Great Britain to evaluate the environmental and economic consequences of growing herbicide-tolerant crops". *Proceedings XI Colloque international sur la biologie des mauvaises herbes*, Dijon, 2000, pp 643-650.

[119] MAFF contract RGO 114, *Consequences for agriculture of the introduction of genetically modified crops*

[120] M.J. May, IACR, *Note on weed manipulation studies at Broom's Barn*.

[121] For example, research recorded in various abstracts from the Weed Science Society of America.

[122] For example, *Progressive Farmer*, 3 January 2001 (www.biotech-info.net/soil_fungus.html) refers to research undertaken in Missouri, USA where the use of recommended rates of glyphosate in herbicide resistant crops may have increased the incidence of Fusarium – a disease causing fungal pathogen.

Concerns have also been raised about the possible effects of genestacking – the combination of different herbicide tolerance genes, either intentionally by breeding or unintentionally by gene flow. It is possible that more than one herbicide tolerance gene (from either GM or conventional plant breeding) could be transferred to a weed species by pollination; if so, the effects would appear only in the longer term[123].

171. It follows that even though scientists are generating models which can be used to indicate the large scale and long term implications of growing GM crops[124], it will also be necessary to watch what happens in practice. Post-release monitoring will be crucial to ensure that any scale-dependent or longer term issues not detected prior to release can be identified and appropriate action taken. Such monitoring is a statutory requirement in the new EU Deliberate Release Directive[125], and it will be necessary for a company wishing to commercialise a transgenic crop to gain approval for its monitoring procedures. If commercialisation is allowed, it will be important to ensure that this monitoring is properly carried out. Expert bodies must consider very carefully which indicator species or biological features are most relevant, what the monitoring scheme should be, and which organisations should be responsible for this. Such long term environmental monitoring should be independent of industry and interest groups, must be legislated for, and should be kept under periodic review.

172. However, it must always be remembered that monitoring after the event does not remove risks: it merely allows their consequences in terms of adverse effects and benefits to be recognised after the event. If harm has occurred, subsequent action may be insufficient to restore the situation. So decisions are needed on what degree of risk is acceptable.

[123] We understand that gene-stacking cannot occur with the FSE crops.

[124] See for example A. Watkinson *et al*, "Predictions of biodiversity responses to genetically modified herbicide-tolerant crops", *Science* 289, pp 1554-1557, 2000; and discussed by L.G. Firbank and F. Forcella, "Genetically modified crops and farmland biodiversity", *Science*, 289, pp 1481-1482, 2000.

[125] Council Directive 2001/18/EC of 12 March 2001, Articles 13, 19 and 20, and Annex VII. The applicants for oilseed rape and beets have already put forward their plans for post-commercialisation monitoring. Forage maize was given approval under the former Deliberate Release Directive, but a plan will now be required.

PART 4

THE BACKGROUND

PART 4.1 THE SCIENCE, ITS APPLICATION AND PUBLIC OPINION

173. This Part provides a summary of recent developments in plant science and its application, and in the biotechnology industry. It also sketches the development of public views in the UK.

Plant science and its applications

174. A scientific approach to plant breeding has been practised since the early years of the last century. Whereas plant breeding once relied principally on moving genes into crops by pollination, various techniques were developed more recently to speed up the selection of preferred traits. Embryo culture methods, making it possible to rescue hybrid embryos that would otherwise not survive, were developed to move genes across sexual barriers. The next significant development was inducing mutation in seeds using chemicals or radiation to bring about wide ranging and random genetic changes, after which plants with desirable traits are selected and retained. Induced mutations have also been produced by cell cultures, where selection for particular plant characteristics can be carried out *in vitro*. For example, it has been sometimes possible to select extremely rare cell mutations that are tolerant to a particular herbicide; plants regenerated from these cells can also be tolerant to the herbicide and can then be used in the production of herbicide tolerant crops for commercial use. Many food crops, particularly cereals, have had induced mutation somewhere in their plant breeding pedigree.

175. The most significant scientific plant breeding development during the last 20 years has been the ability to isolate DNA and genes from any class of organism and introduce these genes into crop plants, a technique often referred to as gene modification. Because the position of gene insertion on the chromosome is random (or close to random), the way in which the introduced genes work varies. It is usual, therefore, to make one hundred or more transgenic plants, discard the majority, and select only those plants that have the introduced genes working in the desired way. As compared with previous breeding methods, GM plant breeding offers a more precise analysis, which is knowledge-based, of the resulting transgenic organisms. It also makes it possible to use several genes to introduce new biosynthetic pathways that are likely to be required for the production of certain oils, plastics, vitamins or pharmaceuticals.

176. Two significant features distinguish GM technology from conventional plant breeding. One is precision: the genes inserted are few in number, and known, whereas conventional plant breeding involves introducing thousands of unwanted genes with unknown side effects – though under both scenarios, plants with the desired agronomic traits, and without any unwanted plant toxins, must be carefully selected during the breeding programme. The other is that the range of possible genes that may be inserted by GM techniques is much greater: to investigate the potential ecological consequences of this, it is vital that the GM plants undergo a rigorous step by step risk assessment

during the course of their development, considering both human health, and direct and indirect impacts on the environment.

177. The first GM field trials in the UK were carried out by the Plant Breeding Institute, Cambridge in 1987 to test the stability and expression of introduced genes (potato with marker genes)[126]. Since then a whole range of GM plants have been developed world wide with novel traits, initially for herbicide tolerance and pest resistance, and more recently for resistance to viral, fungal or bacterial diseases, increased nematode resistance, enhanced frost tolerance or increased photosynthetic efficiency[127]. Future developments are likely to include plants with increased productivity, further enhanced disease resistance, increased resistance to environmental stresses and improved product quality. The BBSRC suggests that genetic modification offers new ways of improving crop yield: for example, oilseed rape might be modified to reduce seed loss from pod shatter, and product quality in wheat might be modified to enhance its bread-making properties[128].

178. The first experiments to measure gene flow by pollen started in the UK in 1989 with potato, followed in 1990 by experiments with glusofinate-tolerant oil seed rape[129]. Since then considerable research experience has been gained internationally in certain crops, including the measurement of distance of travel of viable pollen and the testing of sexual compatibility between crops and related species[130]. Research continues in these areas. Experiments have also been undertaken in the UK to assess the invasiveness of certain GM crops into the wider environment[131].

The biotechnology industry

179. Much of the early work in this area was carried out in the public sector. But with the developments in plant breeding and the advent of genetic modification techniques came a change in the plant breeding industry. Large private companies (in particular in the agrochemical industry) have acquired both plant breeding companies and small biotechnology companies, with the result that they now dominate seed production.

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[126] R.A. Jefferson, "New approaches for agricultural molecular biology from single cells to field analysis". In Gustafson, J.P. ed., *Gene Manipulation in Plant Improvement II. 19th Stadler Genetics Symposium.* Pp. 365-400. New York: Plenum Press, 1990.
P.J. Dale and H.C. McPartlan "Field performance of transgenic potato plants compared with controls regenerated from tuber discs and shoot cuttings". *Theor. Appl. Genet.* 84, 585-91, 1992.

[127] The Royal Society of Canada, *Elements of Precaution: recommendations for the regulation of food biotechnology in Canada*, Ottawa, January 2001.

[128] BBSRC, *GM agriculture in the UK?* July 1999.

[129] H. McPartlan and P.J. Dale "An assessment of gene transfer by pollen from field grown transgenic potatoes to non transgenic potatoes and related species" *Trans. Res.* Vol 3, 216-225, 1994.
J.A. Scheffler, R. Parkinson and P.J. Dale, "Frequency and distance of pollen dispersal from transgenic oilseed rape (*Brassica napus*)", *Trans Res* Vol 2, *356-264*, 1993.

[130] J.A. Scheffler and P.J. Dale, Opportunities for gene transfer from transgenic oilseed rape to related species. *Trans. Res.* 3, 263-278..

[131] M.J. Crawley *et al*, "Ecology of transgenic oilseed rape in natural habitats", (1993) *Nature,* 363, 620-623, 1993.; M. Rees *et al*, "An ecological perspective to risk assessment", p 9-24 in the First International Symposium on the Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms (ed. Mackenzie DR & Henry SC), ARI, Maryland, USA. R.S. Hails et al,, "Burial and seed survival in *Brassica napus* subsp. *Oleifera* and *Sinapis arvenis* including a comparison of transgenic and non-transgenic lines of the crop", Proc. Roy. Soc. Lond. B., Vol 264, 1-7, 1997. M.J. Crawley et al, *Nature*, Vol 409, 682-683, 2001.

180. Commenting on the future for biotechnology, Tait and Chataway[132] say: "Biotechnology has been identified in numerous Foresight exercises as the source of the next technological revolution following the information and communication technologies. Most of the multinational companies involved in developing products for agriculture were, and are, agrochemical companies and they have had to transform their organisational cultures to cope with new modes of working. They have invested very large sums of money over unusually long periods of time to develop products well in advance of any market demand or even a public awareness of the technology and its potential benefits and risks. They have also had to cope since the earliest stages of research and development with uncertainty about the eventual nature of the risk regulatory regime under which they would be operating and more recently with rising levels of public concern about some of the environmental and health implications of the new technology".

181. The industry points out how fast the use of GM crops is spreading internationally. In 2000, the global area of transgenic crops was 44.2 million hectares (an 11 per cent increase from 39.9 million ha in 1999), with seven crops grown commercially in 14 countries[133]. Adoption rates for transgenic crops are unprecedented, being the highest for any new agricultural technology. These high adoption rates are believed to reflect grower satisfaction with products which offer them significant benefits: more convenient and flexible crop management, higher productivity and/or higher net returns. The industry argues that these products also offer a safer environment through decreased use of conventional pesticides, and that together, these benefits contribute to a more sustainable agriculture. For example, Bt insect resistant cotton helped farmers use 2.7 million pounds less chemical sprays in 1999 than in 1995. In Louisiana, use of insecticides on cotton has fallen by 25 per cent. And a recent US Department of Agriculture study found almost no insecticides in water run-off from fields planted with Bt cotton in Mississippi[134].

182. In the UK, the Supply Chain Initiative on Modified Agricultural Crops (SCIMAC) was established in June 1998 to support the open and responsible development of GM crops. Its five member organisations[135] believe that GM crops offer benefits to consumers, the food chain and the environment; they share a commitment to ensuring that UK adoption of the technology is carefully managed, identifies closely with public opinion, and delivers a meaningful choice to consumers.

183. Until 1998, the biotechnology industry took the view that the regulatory system for GM crops[136] was extremely robust, covering the direct implications of safety for health

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[132] J. Tait and J. Chataway, *Technical Foresight and Environmental Precaution – Genetically Modified Crops*, Scottish Universities Policy Research and Advice Network, Paper No 8, May 2000.

[133] The countries where most transgenic crops were grown in 2000 were the USA (30.3 million ha: 68% of the global total area); Argentina (10.0 million ha: 23%); Canada (3.0 million ha: 7%); and China (0.3 million ha: 1%). Most of the rest was grown in South Africa (0.2 million ha) and Australia (0.15 million ha), with small areas in Mexico, Spain, France, Germany, Portugal, Rumania, Bulgaria and Uruguay. GeneWatch Briefing No 13, *Genetic Engineering: a review of developments in 2000*, January 2001.

[134] Council for Biotechnology Information: www.ns.usda.gov/is/pr/2001/010307.htm . USDAARS News Service, 7 March 2001.

[135] British Society of Plant Breeders (BSPB); Crop Protection Association (CPA); National Farmers' Union (NFU); UK Agricultural Supply Trade Association (UKASTA) and British Sugar Beet Seed Producers Association (BSBSPA).

[136] See Part 4.2.

and the environment. However, the industry has accepted that the system is not designed to determine indirect effects, such as changes over a period of time in the balance or abundance of species which might result from changes in agricultural management entailed by a new GM crop variety. In its view there is no evidence (and no reasonable logic supported by fact or findings) to suggest that the GM crops ready for commercialisation are any more likely to have a negative impact on farmland wildlife than many forms of traditional agricultural management[137]. But it accepts that there is no substantial research evidence on the question of such impacts on farmland wildlife – either for conventional agricultural management, or for the management that would accompany the growing of the GM crops in question. As a result the industry associations represented by SCIMAC agreed with the Government a package of measures including the establishment of the FSE programme[138].

184. SCIMAC continues to believe that consumers and growers should be offered a choice, and is committed to delivering that choice for the UK. It believes that the rapid uptake of GM crops in other parts of the world has shown that there are real benefits from this technology in terms of reduced inputs, improved yields and flexibility of management. In the longer term, it considers that GM technology has the potential to offer direct consumer benefits in the form of crops with improved nutrition, enhanced stress tolerance, improved processing and storage characteristics. It also points to the potential for non-food crops to deliver renewable field-based production of many essential fuel and chemical feedstocks, at a time when the agricultural industry is facing a reduced role for primary food production. SCIMAC members firmly believe that these are developments which the UK cannot afford to ignore[139].

The public response

185. The public response to GM technology has been significantly influenced by the work of NGOs. During the 1980s and the early 1990s there was minimal public debate of GM issues, despite concerns expressed by Greenpeace, the European Environmental Bureau, Green Alliance and others. However, by the mid 1990s studies began to show widespread latent concerns about GM technology, GM foods, and the decision-making process, as well as a perception that the Government had an uncritical commitment to the technology[140].

186. Other studies[141] have pointed to widespread consumer unease about GM products, to differing degrees depending largely on the reasons for developing the product (for example, medical GM technology seems to be more acceptable at present). Core concerns are expressed as being about "meddling with nature"[142]. In 1997-98, the

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[137] M.J. May, "Efficiency and selectivity of RR and LL weed control techniques compared to classical weed control systems", *Proc. Of the 63rd IIRB Congress*, Interlaken, Switzerland, February 2000.
[138] Agreement of 1 November 1999 between the Government and SCIMAC.
[139] SCIMAC, *Key Issues Briefing – Farm-Scale Evaluations*, March 2001.
[140] See, for example, R. Grove-White *et al*, *Uncertain World – Genetically Modified Organisms, food and public attitudes in Britain*, Lancaster University, 1997
[141] *Uncertain World* (*op cit*), *Eurobarometer* (1997, 2000); *The public consultation on developments in the biosciences: a MORI report investigating public attitudes to the biological sciences and their oversight*, commissioned by the Office of Science and Technology, 1999.
[142] *Uncertain World*, *op cit*, page 6.

main concerns were focussed on food, but since then the prospect of widespread commercial crop releases has given focus to worries about gene flow, ecological impacts and other uncertainties, and concern about the importance of preserving choices. However, Government policy during the late 1980s and first half of the 1990s tended to be dominated by its commitment to biotechnology and its perceived importance for competitiveness.

187. The importation of GM soya and maize mixed with non-GM varieties, which began in 1997, was a significant event, giving rise to a public outcry questioning the adequacy of controls of GM foods[143]. Although GMOs such as soya beans or maize seeds themselves had to be labelled, there was no provision for labelling foods with a GM content, and because soya and maize are commodity crops, their derivatives were found in a majority of processed foods. Against this background, Greenpeace and Friends of the Earth raised their profile, becoming visibly active from 1997 onwards. By 1998, GMHT maize (T25) had GM commercialisation approval for growing in the EU (including the UK), and GMHT oilseed rape, fodder beet and sugar beet were close to completing the GM approvals process[144]. This led to an increase in public awareness and concern both in the UK and elsewhere in the EU[145].

188. Public opinion was clearly influenced by media coverage of GM food issues. Several newspapers (tabloid and broadsheet) adopted an anti-GM campaigning stance from early 1999 onwards. The nature and progression of the reporting during first six months of 1999 has been charted in detail by the Parliamentary Office of Science and Technology[146].

189. The concern also led to changes in buying habits of foods labelled as containing genetically modified ingredients, and to huge numbers of calls to supermarkets' customer care lines, in response to which all the UK's major supermarkets and food producers changed their product formulations or sources so that they no longer use GM ingredients in their products[147].

190. Until recently, this public response to GM foods was reflected in UK opinion polls, which from 1997 consistently indicated that many people wished to avoid GM foods[148]. However, according to a recent NOP survey, the proportion of people in Britain who say that they are happy to eat genetically modified foods is increasing. It was reported in April 2001 that "a poll by NOP found that 48 per cent will eat GM food and 44 per cent still refuse. Only 20 per cent believe that it is significantly less safe. Last year 50 per cent rejected GM food while 46 per cent ate it"[149].

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[143] *EU safety regulation of genetically-modified crops*, summary of a ten-country study funded by the European Commission (DGXII) under its Biotechnology Programme, Open University, 2000.

[144] DETR Background Paper, *The History of the Farm-Scale Evaluations*, August 2000.

[145] From 1996, various Member States refused approval for commercialisation applications and introduced bans or moratoriums on certain products (Open University, *op cit*).

[146] POST, *The Great GM debate – a survey of media coverage in the first half of 1999*, Report 138.

[147] GeneWatch Briefing No 5, *Genetic Engineering: A Review of Developments in 1998*, 1999; GeneWatch Briefing No 9, *GM crops and Food: A Review of Developments in 1999*, 2000.

[148] We note, however, that what people say about their choices in relation to GM foods may be different from how they actually behave, as shown by UK sales of GM tomato paste and vegetarian cheese.

[149] *Times*, 3 April 2001.

191. In any case, people do want to know what they are eating, so there is public support for labelling food with a GM content[150]. An EU Regulation[151] came into force on 1 September 1998 specifying when and how products containing GM soybean and maize ingredients should be labelled. Other GM foods are covered in the UK by the Novel Foods Regulation, which takes the same approach. The regulations do not consider *the means of production* (genetic engineering), but only *the content of the end product*. Products therefore only have to be labelled if they contain foreign protein or genetic material (DNA) which excludes many derivatives of GM crops such as the oil from GM soybean.

192. A comparison of the results of European surveys in 1991, 1993, 1996 and 1999 shows that while knowledge about GM technology has increased in Europe, optimism about its ability to improve the quality of life has decreased[152]. In 1996, 74 per cent of the European public supported labelling of GM foods; 60 per cent believed there should be public consultation about new developments; and 53 per cent felt that current regulations were insufficient to protect people from the risks of the technology. The results from the 1999 survey in the UK also indicated that the public see governments as aligned with the industry. In relation to the testing of GM crops specifically, in August 1999 a Greenpeace/MORI poll[153] showed that 62 per cent tended to be or were strongly opposed to having a GM trial in their local area, and 59 per cent believed that GM crop testing (though acceptable in laboratories) should be stopped on farmland.

193. At the local level, all of these issues have been added to local concerns about the fact that most agricultural developments, however significant or intrusive in their wider implications, lie outside the conventional (and publicly accessible) framework of planning controls[154].

194. NGOs have expressed a broad spectrum of concerns about GM crops and foods. These concerns span environmental issues (expressed for example by Greenpeace, Friends of the Earth and the RSPB); consumer choice and food safety (eg the Consumers Association and the Food Commission); agricultural implications (eg the Soil Association); impacts on developing countries especially in connection with patenting (eg ActionAid, Christian Aid and the Food Ethics Council) and the decision making process (eg GeneWatch UK). A focal point for them is the Five Year Freeze Campaign, which calls for a moratorium on the commercial growing and importation of GM crops and food, and on patenting of genetic resources. The Five Year Freeze is an alliance of over 120 organisations with a combined membership of over 4 million people including many of the groups already mentioned together with other representative groups such

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[150] See for example Guardian/ICM poll (*Guardian*, 4 June 1998: "Gene genie"); Friends of the Earth/NOP poll (FOE *Biotech Mailout*, Volume 4, Issue 7, 31 October 1998).

[151] Council regulation (EC) 1139/98 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC (OJ L159, 3 June 1998).

[152] Biotechnology and the European Public Concerted Action Group, "Europe ambivalent on biotechnology", *Nature* Vol 387 pp 845-847, 1997. G. Gaskell et al, "Biotechnology and the European public", *Nature Biotechnology*, Vol 18, pp 935-938, 2000.

[153] British Public Opinion, MORI Poll, Volume XXII, no 6, August 1999.

[154] Evidence to AEBC: note of AEBC public consultative meeting, Norwich, 5 February 2001; note of sub-group meeting in the Highland Council Chamber, Inverness, 19 February 2001.

as the Women's Institute, UNISON, the Local Government Association and the Townswomen's Guild[155].

195. The NGOs concerned believe that their scepticism has been vindicated repeatedly over the last five years, highlighting the failure of the regulatory authorities to detect "contaminated" Advanta oilseed rape seed imported from Canada as demonstrating that they will not be able to deliver on their promise to protect seed stocks from GM contamination[156].

[155] Submission from Five Year Freeze to AEBC consultation on Work Plan, 24 November 2000.
[156] See Part3.1.

PART 4.2 THE LEGAL AND REGULATORY FRAMEWORK

196. This Part gives brief details of the legal and regulatory framework governing the release and commercialisation of genetically modified organisms (GMOs) in the UK.

197. The European Community has "competence" in this area, which is to say that it makes the primary legislation. This is then implemented in the UK by domestic legislation: some of the relevant powers now lie with the devolved administrations. There are also relevant international agreements (for example in the World Trade Organisation).

198. In general, the regulatory framework is based on the principle that no release or commercialisation of GMOs can take place without prior approval, but that approvals will be granted where the authorities can be satisfied that all appropriate measures have been taken to avoid adverse effects on health or the environment.

EU legislation

199. Since 1990, the European Community has had a legislative framework governing the release of genetically modified organisms (GMOs), in order to protect human health and the environment. This consists of a number of specific sectoral measures covering areas such as novel foods and a series of horizontal Directives, notably:

- Directive 90/219/EEC on the contained use of genetically modified micro-organisms in research and industrial facilities ("the Contained Use Directive"); and
- Directive 90/220/EEC on the deliberate release into the environment of GMOs ("the Deliberate Release Directive")[157].

The Deliberate Release Directive is the one most relevant to this report. It is still in operation, but a replacement Directive ("the new Deliberate Release Directive") was agreed in March 2001[158], providing for the previous Directive to be repealed on 17 October 2002.

200. According to a paper supplied to us by DETR[159], the principles underlying the regulatory system are that:

- a case by case environmental risk assessment should always be carried out prior to a release of a GMO;
- the deliberate release of GMOs at the research stage is in most cases a necessary step in the development of new products derived from, or containing, GMOs;

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[157] OJ L117 (8 May 1990). Subsequently amended by Commission Directives 94/15/EC of 15 April 1994 (OJ L103, 22 April 1994) and 97/35/EC of 18 June 1997 (OJ L169, 27 June 1997), both "adapting [the Deliberate Release Directive] to technical progress".

[158] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC (OJ L106, 17 April 2001).

[159] All quotations in this Part not otherwise referenced are from: *The legal framework for decision-making on the release and marketing of GMOs in the UK,* a background paper by the UK Joint Regulatory Authority and the Secretariat to ACRE, August 2000.

- the introduction of GMOs into the environment should be carried out according to the 'step by step' principle, whereby initial releases are small and the scale of the releases increased gradually step by step, but only if the evaluation of each step indicates that the next step can be taken; and
- no product containing or consisting of GMOs and intended for deliberate release shall be considered for placing on the market without it first having been subjected to satisfactory field testing at the research and development stage in ecosystems which could be affected by its use.

201. Both the Deliberate Release Directive and the new Deliberate Release Directive provide for two regulatory regimes. Part B covers releases for research and development, and Part C covers placing GMOs on the market in the EU. In both cases, notification must be made to the competent authority in the Member State where the release is to take place or where the GMO is to be placed on the market for the first time.

202. To obtain consent for release under Part B, the Deliberate Release Directive provides that applicants must submit a detailed dossier of information to the relevant competent authority. This must include information on the nature of the GMO, how it has been modified, the precise nature of the research programme proposed, where the GMO will be released, and how the release will be monitored. The decision on whether to allow the release is made by the Member State to which the release has been notified, solely "on the basis of safety to human health and the environment. No other criteria are considered in the decision-making process". If approval is given, it applies only to specified location(s), and conditions may be imposed.

203. However, simplified procedures now apply for subsequent Part B applications once sufficient experience has been gained[160]. One site has to be notified in the main application, but others do not have to be notified until 15 days before each proposed release takes place. However, the regulatory authorities can stop the proposed releases within this timescale, if they consider that the risk assessment in the notification is not applicable for a particular site. For this procedure to apply, the GMO has to be well characterised, there must be information to demonstrate safety to human health and the environment, and the releases must be within a well defined programme of work. The procedure would not therefore apply to first time releases of GMOs which had not previously been considered by regulatory authorities.

204. An application for Part C approval is also made initially to the competent authority in a single Member State. That Member State takes the lead in evaluating the dossier, which in addition to the information needed for Part B consent must include a detailed risk assessment, as well as:

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[160] Commission Decision 93/584/EEC of 22 October 1993 establishing the criteria for simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC, and Commission Decision 94/730/EEC of 4 November 1994 establishing the simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC. This is the procedure which applies to the FSEs, though the UK has additional requirements that applications must be recorded in a Public Register and that applicants must place advertisements in newspapers circulating in the area(s) where the proposed releases are to take place.

- extended information taking into account the diversity of sites of use of the product, including information gained from research and development releases carried out under Part B consents;
- information concerning the ecosystems that could be affected by the use of the product and an assessment of the risks posed to human health and the environment; and
- conditions for placing the GMO on the market, including conditions for use and handling and a proposal for labelling and packaging.

205. After reviewing the dossier, the lead competent authority may reject it. However, if the lead competent authority is satisfied that the GMO poses a very low risk, it will submit the dossier to the European Commission with a favourable opinion. The Commission then circulates the dossier to the other Member States, which all evaluate it "taking into account the particular health and environmental safety issues unique to their territories". If one or more Member States objects, the Commission will attempt to resolve the objection, usually seeking an opinion from its Scientific Committee on Plants. If the Commission then judges that approval should be given, it will call on the Member States to vote on the proposal in a committee (on the basis of qualified majority voting). If the committee does not approve the proposal, the matter will be referred to the Council of Ministers, which decides the matter (again by qualified majority voting). Once the application is approved, at whatever stage, it is for the lead Member State to issue the Part C marketing consent, which applies across the entire EU.

206. Once Part C consent has been given, there is provision for a Member State to resist the release of a particular GMO in its territory if new scientific evidence comes to light. If the Member State is of the opinion that this changes the risk assessment, giving rise to concerns over the safety of the product, it may invoke Article 16 of the Deliberate Release Directive to restrict use and/or sale on a provisional basis. This provision has now been invoked by the UK on behalf of the National Assembly of Wales[161].

207. The main aims of the changes incorporated in the new Deliberate Release Directive are "to set for the first time a set of common principles for risk assessment; to apply a simplified set of procedures where this is justified; and to introduce greater transparency into the decision making process"[162]. Of most interest in the context of this report is that risk assessment remains the basis of the new Deliberate Release Directive. However a new technical annex on risk assessment has been agreed, which the Government says reflects existing best practice among EU Member States[163]. This annex provides, *inter alia*:

- that the potential adverse effects considered may be direct, indirect, immediate or delayed;
- that the risk assessment should be carried out on a case by case basis;

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[161] See Part 3.1.
[162] Report of House of Commons Select Committee on European Legislation, HC 155-xxvi (1997-98), paragraph 5 (29 April 1998).
[163] *Guidance on Principles of Risk Assessment and Monitoring for the Release of Genetically Modified Organisms.* DETR/ACRE Guidance Note 12. See also *Risk assessment for releases and marketing of GMOs in the EU*, a background paper by the UK Joint Regulatory Authority and the Secretariat to ACRE, August 2000.

- that if new information on the GMO and its effects on human health and the environment becomes available, the risk assessment should be re-examined; and
- that the information required in notifications must include possible impacts of the specific techniques used for the management of the GMO where these are different from those used for non-GMOs.

208. Also relevant to this report is the provision in the new Deliberate Release Directive for mandatory public consultation on Part B releases, not only by the Commission (Article 7) but also by Member States (Article 9). In addition, the new Directive requires more information to be made public than the previous one did, though UK legislation was already in line with the new requirements.

UK legislation

209. In the UK, the Deliberate Release Directive is implemented by Part VI of the Environmental Protection Act 1990 and the Genetically Modified Organisms (Deliberate Release) Regulations 1992, as amended in 1995 and 1997[164]. The new Deliberate Release Directive will have to be similarly implemented[165].

210. In reaching decisions in relation to the Deliberate Release Directive, the Government is advised on scientific issues and risks by the statutory Advisory Committee on Releases to the Environment (ACRE). The general approach of risk assessment used by ACRE is described in several DETR documents[166].

211. The Environmental Protection Act 1990[167] provides that a person who proposes to import or acquire GMOs shall take all reasonable steps to identify what risks there are of damage to the environment being caused as a result of this action, shall not import or acquire the organisms if it appears that there is a risk of damage despite precautions, shall keep himself informed of any damage to the environment which may have been caused, and shall inform the Secretary of State if at any time it appears that any such risks are more serious than was apparent when consent was granted.

212. In addition to the special requirements applying to GMOs, before being placed on the market in the UK GMHT crop seed (such as that being used in the FSEs) has also to satisfy the same requirements as conventional varieties of seed. All new varieties must pass a series of objective tests in field trials, which must show evidence that the new variety is distinctive, uniform and stable. It must also have a value for cultivation and use[168].

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[164] Separate but similar legislation applies in Northern Ireland. Consents for releases in Wales or Scotland are signed on behalf of the appropriate Ministers of the devolved administrations, with the agreement of the HSE.

[165] The Government has now gone out to consultation on this; see *A consultation paper on the implementation of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms*, DEFRA, July 2001, referred to above at para 148 Available at www.defra.gov.uk/environment .

[166] For example, *Guidance for Environmental Risk and Management*, DETR 2000 and *The Regulation and Control of the Deliberate Release of Genetically Modified Organisms*, DoE/ACRE Guidance Note 1, Chapter 4.

[167] Section 109.

[168] The results of the trials are adjudicated by the Plant Variety Rights Office in DEFRA on behalf of the UK Government and the devolved administrations; if the variety passes the tests it can be placed on the UK National List.

213. The herbicide with which the crop is to be treated must also satisfy the requirements of legislation controlling the use of pesticides. The principal aim of these controls is to protect the health of human beings, animals and plants and to safeguard the environment. The Government is advised on their application by the statutory Advisory Committee on Pesticides (ACP).

The UK Government and the devolved administrations

214. The Secretary of State for the Environment, Food and Rural Affairs is designated for the purposes of Section 2(2) of the European Communities Act 1972 in relation to the control and regulation of genetically modified organisms, having assumed responsibilities in this area which previously fell to the DETR Secretary of State and the MAFF Minister. Identical functions passed to Scottish Ministers by virtue of Section 53 of the Scotland Act 1998. The National Assembly for Wales exercises powers in this area under Part VI of the Environmental Protection Act 1990.

215. UK legislation gives effect to the Deliberate Release Directive. In 1993 the parties within Government then responsible for implementing that legislation –the Department of the Environment, HSE, MAFF, the Scottish Office and the Welsh Office – agreed a memorandum of understanding whereby the Department of the Environment handled the administration and assessment on behalf of all parties. DEFRA (combining the former competent authority responsibilities of DETR and MAFF) and HSE are now joint competent authorities for the purposes of 90/219/EEC and 90/220/EEC, as amended, in England. In consultation with HSE and FSA where appropriate, DEFRA has lead responsibility in England for policy, setting standards and guidance in relation to all environmental issues, whether in relation to contained use or deliberate release. In Scotland, the Scottish Executive has lead environmental responsibility, in consultation with HSE and FSA as appropriate. HSE in both England and Scotland retains responsibility for all health and safety issues affecting both contained use and deliberate release. The Food Standards Agency is responsible in both England and Scotland for all aspects of the safety of novel and genetically modified food, and acts as the UK competent authority responsible for the approval of these foods under the Novel Foods regulation 258/97/EC.

216. Under the Scotland Act 1998 environmental aspects of GMOs are devolved matters. As a result, Scottish Ministers have the same powers in these matters in Scotland as the Secretary of State for DEFRA does in England. The Scottish Executive has powers to act as a competent body for the deliberate release of GMOs in Scotland and Scottish Ministers may grant or refuse consents for releases. They may also determine a marketing consent, with the agreement of the other UK competent authorities. Similar arrangements apply in Wales and Northern Ireland.

Similar arrangements apply in other Member States, and a seed placed on the national list in any Member State can also go on to the EU Common Catalogue and can be sold in any Member State.

International agreements

217. The World Trade Organisation (WTO) has no locus in approving or preventing the cultivation of GM crops, but it does have a locus in deciding whether they and products from them may be traded internationally. One of the basic principles of the WTO is that in their trading practices member countries may not distinguish between "like products": that is to say, they may not distinguish between "substantially equivalent" goods on the basis of how they are produced. However, the Sanitary and Phyto-Sanitary Agreement[169] does allow countries to take measures to protect health, provided that they are based on scientific evidence. This could be interpreted as allowing member countries to take measures against imports of products concerning GMOs on the basis of the precautionary principle, provided that they continue to look for scientific evidence as to whether those measures are justified, but the position is not clear.

218. The Convention on Biological Diversity (CBD), adopted in 1992, requires contracting parties to regulate, manage or control the risks associated with the use and release of Living Modified Organisms (LMOs) resulting from biotechnology which may have adverse environmental impacts. The Cartagena Protocol to the CBD (also known as the Biosafety Protocol) was finally agreed in January 2000 in Montreal, although it is not yet in force. It is intended to cover the environmental safety of the trans-boundary movements of GMOs: Governments will signal whether or not they are willing to accept imports of agricultural commodities which include LMOs. Like the EU regulations, the Biosafety Protocol is based on the precautionary principle, but it also includes proposals for liability laws to be introduced. And (unlike the new Deliberate Release Directive) it allows importing countries to take socio-economic impacts into account when making their risk assessment. However, its relationship with WTO agreements remains unclear.

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[169] Reached as part of the WTO Uruguay Round, concluding in the Marrakesh Agreement in 1994; see House of Lords Select Committee on the European Union, *The World Trade Organisation: the EU mandate after Seattle,* HL Paper 124; 10th Report Session 1999-2000, paragraphs 216 ff.

PART 4.3 THE FARM-SCALE EVALUATIONS: MORE INFORMATION

219. The origin and nature of the Farm-Scale Evaluations is explained in Part 1.2. This Part gives some extra detail on certain aspects.

The indicators chosen to measure biodiversity

220. The null hypothesis for the FSEs is formulated in terms of the effects of the management regime on biodiversity. However, in practice variation in biodiversity could not be measured for all species. The indicators selected focus on weed and invertebrate species which act as sources of food for organisms higher up the food chain (eg farmland birds). They are:

- soil seed bank;
- arable plant diversity, biomass and estimated seed return;
- field margin and boundary vegetation (noting species in flower and signs of spray drift);
- gastropods (slugs and snails): abundance, activity and diversity measures;
- arthropods on vegetation, concentrating on plant bugs (*heteroptera*), spring tails (*collembola*), and the caterpillars of butterflies and moths (*lepidoptera*) and sawflies: diversity and biomass measures;
- carabid beetles and other ground-dwelling arthropods: abundance and diversity measures;
- bees and butterflies: observational studies.

After the first year, all these studies will continue in the follow-on conventional crops cultivated on the fields.

The management of the trials

221. DETR told us[170] that the specifications for the contracts were developed "in consultation with English Nature and well known ecologists". Fifteen major research organisations were invited to tender, and the contract was awarded to a Research Consortium[171]. The Consortium is overseen by an independent Scientific Steering Committee (SSC)[172]. SCIMAC finds farmers willing to offer fields for the evaluations.

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[170] DETR Background Paper, *The History of the Farm-Scale Evaluations*, August 2000.

[171] Consisting of the Centre for Ecology and Hydrology (CEH), the Institute of Arable Crops Research (IACR) and the Scottish Crop Research Institute (SCRI).

[172] The SSC's terms of reference are to advise the Secretary of State for Environment, Food and Rural Affairs, the Scottish Executive and the Welsh Assembly on the ecological studies in the farm-scale evaluations of genetically modified herbicide tolerant crops, particularly the progress of the ecological studies; all aspects of the design and methodology used in the studies; statistical analysis of data; the conclusions which may be drawn from the results; publication of results; and the need for further research. The SSC is chaired by Professor Christopher Pollock

From these, the Research Consortium makes an initial selection to be representative of regional geographical differences and the range of current farming methods, biodiversity and production intensities throughout the United Kingdom. The SSC approves the suitability of the selected sites.

222. Interim reports are produced by the Consortium every six months for review by the SSC, after which they are published on the FSE website. At the end of the three years of research, the results will be published in peer-reviewed scientific journals.

Extension of scope of FSEs

223. The opportunity is being taken to use the FSE fields for other work where this does not interfere with the evaluations themselves. Work is being undertaken on the following aspects.

Gene flow

224. When the tender for the FSEs was announced DETR included the requirement to monitor to "validate the assumptions in the risk assessment regarding cross pollination"[173]. To this end, DETR has let two further contracts. The Central Science Laboratory (CSL) and the Centre for Ecology and Hydrology (CEH) are monitoring gene flow between the two halves of the FSE fields of maize and oilseed rape by collecting pollen and seeds. Separately, CEH is investigating the potential for gene flow between oilseed rape and wild relatives to a distance of 10 metres beyond the field, testing the null hypothesis "that genes transferred from GM crops to hybrid and volunteer populations do not persist within these populations and do not influence fitness under normal selection regimes within the farmland environment"[174].

225. In addition, SEERAD has let a contract to the Scottish Crop Research Institute (SCRI) to monitor gene flow at more distant sites from the FSEs in order to clarify the role of potential pollen vectors and to test predictions made in a previous MAFF-funded project of low-level gene flow into field crops over wide areas[175]. In each season for two years, over a defined area which includes oilseed rape FSE field(s), traps and standard feeding stations for pollinators will be set out in an array covering many square kilometres. By combining estimates of the activity of each pollinator over a defined period with quantitative determination of the rape pollen and GM rape pollen on these pollinators, an understanding will be developed of the relative contributions of each pollinator over this array. Within this array, artificial feral oilseed rape colonies will be set up to verify estimates of activity obtained at pollinator traps, and to provide seed

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(Institute of Grassland and Environmental Research), and the other members are Dr Nicholas Aebischer (GCT), Dr Alastair Burn (EN), Professor Mick Crawley (Imperial College), Dr David Gibbons (RSPB), Mr Jim Orson (Morley Research Centre) and Dr Nick Sotherton (GCT).

[173] Letter from DETR to interested parties, "Information on the FSEs of GM Crops and invitation to comment", 25 February 1999.

[174] "Monitoring movement of herbicide resistance genes from farm scale evaluation field sites to populations of wild crop relatives", tender to DETR from Centre for Ecology and Hydrology (CEH). The tender shows that the approach has been somewhat constrained by the needs of the FSEs so that, for example, bait plants cannot be used to investigate a worst case scenario.

[175] G. Ramsay, *The Significance and Mechanisms of Landscape-Scale Gene flow*, Scottish Crop Research Institute, 2001.

samples to determine the actual rate of GM gene flow. Unmanaged feral populations and related wild species will be mapped, and data from the array used to predict gene flow into these populations and verified by collecting seed samples and screening for transgenes. The opportunity will also be taken to verify the gene flow rates into other fields in the vicinity.

Effects on birds

226. Birds were not included in the biodiversity indicators being measured in the FSEs because they range too widely to be studied in an experiment confined to individual fields. However, a contract was let to the British Trust for Ornithology to carry out observational studies to see whether useful data could be obtained. The study (carried out in conjunction with the Edward Grey Institute at Cambridge) ended on 30 April 2001: any results will be published with other data at the end of the FSEs.

PART 4.4 WHO WE ARE

History

The need for independent strategic advice on developments in biotechnology and their implications for agriculture and the environment emerged from the Government's review of the advisory and regulatory framework for biotechnology[176]. The main concerns expressed during wide consultation were that the current arrangements were complex and difficult for the public to understand, did not properly reflect the broader ethical and environmental questions and views of potential stakeholders, and were not sufficiently forward-looking for a technology which was developing so rapidly.

The Government concluded that the existing regulatory and advisory committees should continue to consider whether to grant approvals for individual products or processes, in the context of protecting the health of the public and protecting the environment. But there was also a need for a strategic framework for the overall development of the technology in the UK, to reflect the broader ethical and environmental concerns of society and to consider the future implications of biotechnological developments. The Agriculture and Environment Biotechnology Commission was set up to help provide this.

Terms of reference

The Commission's terms of reference state that it will:

- offer strategic advice to Government on biotechnology issues which impact on agriculture and the environment;
- liaise closely with but not duplicate the work of the other two bodies which together with the AEBC form a new strategic advisory framework ie:
- the Human Genetics Commission (HGC) which will advise on genetic technologies and their impact on humans; and
- the Food Standards Agency (FSA) which will include within its responsibilities all aspects of the safety and use of genetically modified food and animal feed;
- keep under review current and possible future developments in biotechnology with actual or potential implications for agriculture and the environment;
- advise Government on the ethical and social implications arising from these developments and their public acceptability; and
- consider and advise on any specific issues relating to relevant aspects of biotechnology as requested by the Government.

As part of this process the Commission is expected to:

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[176] Cabinet Office, Office of Science and Technology, *The Advisory and Regulatory Framework for Biotechnology: Report from the Government's Review*, May 1999.

- identify any gaps in the regulatory and advisory framework;
- consider the wider implications of the lessons to be learned from individual cases requiring regulatory decision;
- advise on any changes which should be made to Government guidelines which regulatory bodies are required to follow;
- make recommendations as to changes in the current structure of regulatory and advisory bodies;
- co-ordinate and exchange information with the relevant regulatory and advisory bodies;
- seek to involve and consult stakeholders and the public on a regular basis on the issues which it is considering; and
- operate in accordance with best practice for public bodies with regard to openness, transparency, accessibility, timeliness and exchange of information.

The Commission will:

- in carrying out its work take into account European and global developments;
- nationally, adopt a UK perspective taking appropriate account of legal and other differences between England, Scotland, Wales and Northern Ireland; and
- draw up a work programme.

The Government may also ask the Commission for advice on a particular issue and, if necessary, direct it not to become involved in an area if this could be better handled elsewhere.

NOTE: In the context of the work of the Commission, "Government" comprises the UK Government and the devolved administrations.

Commission members

This report is agreed by the Commission as a whole. The work on the study was undertaken by sub-group A, whose members are denoted below by *. A full list of members' declared interests can be found at www.aebc.gov.uk and will be included in the Commission's forthcoming annual report.

Professor Malcolm Grant (Chair):

Professor of Land Economy at the University of Cambridge

Ms Julie Hill MBE (Deputy Chair)

Programme Adviser and former Director of Green Alliance

Professor Michael Banner

Professor of moral and social theology at Kings College, London

Ms Anna Bradley

Director of the National Consumer Council

Ms Helen Browning OBE

Tenant Farmer, Eastbrook Farm; Founder and Director of Eastbrook Farm Organic Meats Ltd

*Dr David Carmichael

Arable farmer concentrating on seed production from combinable crops

*Professor Philip Dale

Leader of the Genetic Modification and Biosafety Research Group at the John Innes Centre, Norwich

Dr Ed Dart CBE

Chairman of Plant Bioscience Ltd

Dr Matthew Freeman

Senior Researcher at the Medical Research Council Laboratory of Molecular Biology

Mr John Gilliland

Arable farmer with a particular interest in sustainable production systems and the pioneering of non food crops.

*Professor Robin Grove-White

Professor of Environment & Society, and Director of the Centre for the Study of Environmental Change, Lancaster University

*Dr Rosemary Hails MBE

Ecologist, and Principal Scientific Officer, Centre for Ecology and Hydrology, Oxford and lecturer at St Anne's College Oxford

Ms Judith Hann

Freelance Broadcaster and Writer who presented Tomorrow's World for 20 years.

Ms Chi Chi Iweajunwa

Member of executive evaluation group for NHS Direct, and member of Partners Council for NICE (National Institute for Clinical Excellence)

Dr Derek Langslow

Scientist specialising in nature conservation/biodiversity

*Professor Jeff Maxwell OBE

Former Director, Macaulay Land Use Research Institute

*Dr Sue Mayer

Executive Director and Board Member of GeneWatch UK

Professor Ben Mepham

Director of the Centre for Applied Bioethics at the University of Nottingham and Executive Director of the Food Ethics Council

*Ms Justine Thornton (Convenor of sub-group A)

Barrister specialising in environmental law

Dr Roger Turner

Chief Executive Officer, British Society of Plant Breeders

PART 4.5 WHAT PEOPLE TOLD US

The following letters, papers and other documents were submitted to the AEBC as evidence in its consideration of the Farm-Scale Evaluations of genetically modified herbicide-tolerant crops. Some of these papers have been published or placed on websites; others have not. They may all be viewed by prior arrangement with the AEBC Secretariat at the Office of Science and Technology, 94-98 Petty France, London SW1H 9ST. Please contact Chris Hepworth on 020 7271 2064 if you require further information.

In taking forward its work, the AEBC has also made use of a wide range of publications. These are noted as appropriate in the footnotes to the main text of this report.

Advisory Committee on Releases into the Environment (ACRE). *Background Paper on Gene Flow from Genetically Modified Crops.* (Published as Annex F to ACRE's Seventh Annual Report 2000*).

J. Bartlett. Email to AEBC with comments on the Farm-Scale Trials. 27 January 2001.

J. Bracey. Letter and email to AEBC with comments on the Farm-Scale Trials. 17 and 29 January 2001.

DETR. *The History of the Farm-Scale Evaluations - Background Paper.* August 2000*.

DETR. *The Science of the Farm-Scale Evaluations - Background Paper.* August 2000*.

DETR. *The Farm-Scale Evaluations of Genetically Modified Herbicide Tolerant Crops: Rationale and Chronology - Background Paper.* February 2001*.

DETR. *The Farm-Scale Evaluations of Genetically Modified Herbicide Tolerant Crops - Background Paper for AEBC meeting.* February 2001*.

DETR. *Brief on approvals for commercial growing of GM crops.* 12 February 2001.

DETR. *Farm-Scale Evaluations of GM Crops: Interim Report to the Scientific Steering Committee from the research consortium carrying out the fieldwork.* November 1999*.

DETR. *Farm-Scale Evaluations of GM Crops: Second Interim Report to the Scientific Steering Committee from the research consortium carrying out the fieldwork.* March 2000*.

DETR. *Farm-Scale Evaluations of GM Crops: Third Interim Report to the Scientific Steering Committee from the research consortium carrying out the fieldwork.* October 2000*.

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* Available at http://www.defra.gov.uk/environment/fse/index/htm

DETR. *Farm-Scale Evaluations of GM Crops: Fourth Interim Report to the Scientific Steering Committee from the research consortium carrying out the fieldwork.* March 2001*.

C. Diethe, Ardersier and Petty. Environmental Society. Letter to Charles Kennedy MP copied to AEBC as evidence. 19 March 2001.

P. Elliot. Letter to AEBC in advance of public meeting in Norwich. 28 January 2001.

L. Firbank on behalf of the FSE research project team. *A review of the Farm-Scale Evaluations of Genetically Modified Crops Research Methods for the AEBC.*

L. Firbank on behalf of the research project team. *The Farm-Scale Evaluations of GM crops – review of project methods.*

Friends of the Earth. Evidence to the AEBC. February 2001.

K. Graham. Emails to AEBC about the GM crop trial site at Lyng, Norfolk. 25 January and 21 July 2001. Associated correspondence from DETR and English Nature.

J & S Grant (Roskill). Notes for the visit of the AEBC sub-group to a farm near Inverness on 19 February 2001.

R. Grove-White. *Farm-Scale Trials – Some Claims.* Note of 5 December 2000.

Highland Council. *Response to SERAD's[177] Discussion Document – A Forward Strategy for Scottish Agriculture.* 4 September 2000.

Highland Council. Submission to the Agriculture & Environment Biotechnology Commission. November 2000.

Highlands & Islands GM Concern. Letter to the Scottish Executive objecting to the proposal to conduct further GM trials. 27 March 2001.

Highlands and Islands GM Concern. Submission to the AEBC sub-group meeting, Inverness. 19 February 2001.

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PART 4.6 WHAT THE WORDS MEAN

This glossary gives definitions applicable in the context of this report; some terms may of course have different meanings in other contexts.

Items in italics are defined elsewhere in the glossary.

ACAF	Advisory Committee on Animal Feedingstuffs: non-statutory body which advises the Government on all aspects of the safety and use of animal feeds and feeding practices
ACNFP	Advisory Committee on Novel Foods and Processes: non-statutory body which advises the Government on the safety of novel foods such as those derived from *GMOs*
ACP	Advisory Committee on Pesticides: statutory body established under the Food and Environment Protection Act 1985 which advises on all matters relating to the control of pesticides (including herbicides)
ACRE	Advisory Committee on Releases to the Environment: statutory body established under Part VI of the Environment Protection Act 1990, consisting of independent experts with a secretariat provided by *DEFRA*; advises the Government on the safety of proposed releases and marketing of *GMOs* and non-native species, and on related issues
AEBC	Agriculture and Environment Biotechnology Commission: established in June 2000 following a review in May 1999 by Government of the regulatory and advisory framework for biotechnology with a remit to give Ministers independent, strategic advice on developments in biotechnology and their implications for agriculture and the environment
Bait plants	Plants placed at different distances and directions from a *transgenic* pollen source to monitor the efficiency of *transgenic* pollen movement; usually male sterile, they do not produce their own pollen, and so trap passing pollen
Biodiversity	The number and diversity of plants and animals
Biodiversity Action Plan	The UK's strategy for the conservation and sustainable use of biological diversity, prepared in 1994 in response to the UN Convention on Biological Diversity; individual Action Plans have subsequently been published in the UK for species and habitat types of conservation concern
Biomass	The total mass of living matter within a given area

Biota	The combined flora and fauna of a region
BBSRC	Biotechnology and Biological Sciences Research Council: non-departmental public body principally funded through the Government's Science Budget; its remit is to fund research and training at universities and institutes in the non-medical life sciences
BRIGHT	Study of the Botanical and Rotational Implications of Genetically modified Herbicide Tolerant crops, part-funded by *DEFRA*, being carried out by the *BBSRC* Institute of Arable research
Broadacre agriculture	Large scale agricultural practice
Broad spectrum herbicide	Weed killer which controls a wide range of annual and biannual weeds
BSBSPA	British Sugar Beet Seed Producers Association
BSPB	British Society of Plant Breeders (a limited company)
BTO	British Trust for Ornithology
CAP	EU Common Agricultural Policy
Cartagena Protocol	Protocol to the *CBD* on biosafety (signed in Montreal, January 2000)
CBD	Convention on Biological Diversity: signed by over 150 governments at the 1992 Earth Summit in Rio de Janeiro, its principal objectives are the conservation, sustainable use and equitable sharing of the benefits of the use of biological diversity
CEH	Centre for Ecology and Hydrology (formerly known as *ITE)*, a component establishment of *NERC* which undertakes ecological research and research relevant to hydrology and the hydrological environment; CEH leads the *Research Consortium*
Commercialisation	Growing crops on a commercial scale, for the market
Commission, the	*AEBC*
Consortium	The *Research Consortium*
Conventional agriculture	Commonly used in two different senses, to mean either agriculture not involving GM crops or non-organic agriculture
CPA	Crop Protection Association
CPB	*Cartagena Protocol* on Biosafety
CSL	Central Science Laboratory, an Executive Agency of *DEFRA*, which provides a range of scientific services,

	applied research and technical support to public and private sector customers, specialising in the sciences underpinning agriculture
DEFRA	Department for Environment, Food and Rural Affairs (from June 2001)
Deliberate Release Directive	Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ L117, 8 May 1990) as amended by Commission Directives 94/15/EC of 15 April 1994 (OJ L103, 22 April 1994) and 97/35/EC of 18 June 1997 (OJ L169, 27 June 1997)
DETR	Department of the Environment, Transport and the Regions (until June 2001)
DNA	Deoxyribonucleic acid, a molecule which comprises the genetic material of most living organisms
ELISA	Enzyme-Linked Immunosorbent Assay: a diagnostic test which uses the high specificity of enzymes and antibodies to detect the presence of specific substances in a sample, usually by the production of a distinctive colour change
EN	English Nature: the statutory nature conservation body for England (whose counterparts are Scottish Natural Heritage and the Countryside Commission for Wales); these bodies are the statutory conservation advisers to Government, overseeing and enforcing much conservation legislation
EU	European Union
EPA 1990	Environmental Protection Act 1990
Eurobarometer	Survey of public opinion in the EU undertaken and published on behalf of the European Commission
Fitness	The genetic contribution of an individual to the next generation: the fundamental measure of evolutionary success
FOE	Friends of the Earth (environmental *NGO*)
Food chain	The transfer of energy from green plants (the primary producers) through a sequence of organisms in which each eats the one below it in the chain and is eaten by the one above
FSA	Food Standards Agency: established by Act of Parliament on 1 April 2000 with key functions including the provision of advice and information to the public and Government on food safety and protection of consumers through enforcement and monitoring

FSE(s)	Farm-Scale Evaluations of *GMHT* crops
GCT	Game Conservancy Trust
Gene flow	The movement of genes from one population to another
Gene stacking	Simultaneous presence of more than one *transgene* in an organism, usually a *GM* organism. Stacking may be induced deliberately, but can also occur as a result of natural geneflow.
Genome	The total set of genes carried by an individual or cell
Genomics	The study of *genomes*
Glyphosate	*Broad spectrum herbicide* to which certain crops (including the *GM* beet in the *FSE*) are tolerant
Glufosinate ammonium	*Broad spectrum herbicide*, to which certain crops (including the *GM* maize and *GM* oilseed rape in the FSE) are tolerant
GM	Genetically modified: see *GMO*
GMHT crop	*Genetically modified, herbicide-tolerant* crop
GMO	Genetically modified organism: defined as an organism in which the genetic material has been altered by the direct introduction of DNA (specifically defined in EU legislation)
Herbicide-tolerant	In the context of genetic modification, herbicide tolerance introduced by the insertion of a gene or genes capable of producing a gene product which inhibits or changes the effect of a herbicide on the plant. All crops are to some extent herbicide tolerant.
HGC	Human Genetics Commission: established following a review in May 1999 by Government of the regulatory and advisory framework for biotechnology with a remit to give Ministers strategic advice on the "big picture" of human genetics, with a particular focus on social and ethical issues
Horizontal transfer	Asexual movement of genes.
HSE	Health and Safety Executive: statutory body which ensures that risks to people's health and safety from work activities are properly controlled
HT	*Herbicide-tolerant*
IACR	Institute of Arable Crops Research: institute sponsored by *BBSRC*, which undertakes scientific research relevant to plant-based agriculture; part of the *Research Consortium*
ITE	Institute of Terrestrial Ecology (now known as *CEH*)
Insurance spraying systems	The use of persistent soil-acting herbicides to prevent weed seed germination in anticipation of a problem at a later stage

Joint Regulatory Authority	Joint Regulatory Authority: team of civil servants based in *DEFRA* administering the legislation on the deliberate release and marketing of *GMO*s on behalf of the UK Government and the devolved administrations; the team comprises administrators and professionally qualified scientists, who also provide the secretariat for *ACRE*
LEAF	Linking Environment and Farming: a charity which aims to help farmers improve their environment and business performance, committed to a viable agriculture which is environmentally and socially acceptable
LMOs	Living Modified Organisms
MAFF	Ministry of Agriculture, Fisheries and Food (until June 2001)
Marker assisted breeding	Use of *marker genes* to enhance the conventional breeding of crops and livestock
Marker gene	A gene or short sequence of *DNA* that acts as a tag for another, closely linked, gene
Mutation breeding	Selection of plants with natural or artificially induced (using irradiation or chemicals) mutations to produce novel varieties.
NERC	Natural Environment Research Council: non-departmental public body principally funded through the Government's Science Budget, whose remit is to fund research and training in the environmental sciences at universities and its own sites
NFU	National Farmers' Union
NGOs	Non-governmental organisations
NIAB	National Institute for Agricultural Botany
Null hypothesis	The hypothesis which an experiment is designed to test: in the case of the *FSEs*, the null hypothesis is "that there are no significant differences between the biodiversity associated with the management of *GM* winter oilseed rape/ spring oilseed rape/ maize/ beet crops that are tolerant to particular herbicides and [of] comparable non-GM crops at the farm scale"
OST	Office of Science and Technology: part of the Department of Trade and Industry
PCR	Polymerase Chain Reaction: technique used to replicate a fragment of *DNA* so as to produce many copies of a particular *DNA* sequence; commonly employed as an alternative to gene cloning as a means of amplifying genetic material for gene sequencing

POST	Parliamentary Office of Science and Technology
Power analysis	Statistical technique which helps to determine how large a sample is needed to allow accurate and reliable statistical judgements and the likelihood of detecting effects of a given size in a particular situation
PSD	Pesticides Safety Directorate: an Executive Agency of *DEFRA*, which administers the regulation of agricultural, horticultural, forestry, food storage and home garden pesticides
Public Register	Statutory register set up under the *EPA 1990*, containing specified information from applications to release or market *GMOs*, advice from *ACRE* about the risks to the environment posed by the proposed release, the decision on whether or not to grant the consent and a copy of the consent, any further correspondence from the applicant and a record of any enforcement action; open for inspection by the public at *DEFRA*; equivalent registers are available in Scotland, Wales and Northern Ireland
RCEP	Royal Commission on Environmental Pollution
Recombinant DNA technology	Deliberate insertion of genes into a *DNA* molecule using the techniques of modern molecular biology
Research Consortium	The group of contractors carrying out the *FSEs* (*CEH, IACR* and *SCRI*)
Risk assessment	A tool for extrapolating from statistical and scientific data a value which people will accept as an estimate of the risk attached to a particular activity or event
RSPB	Royal Society for the Protection of Birds
SA Cert	Limited company wholly owned by the *Soil Association*, for which it runs an organic inspection and certification programme for food
Set-aside	Agricultural land taken out of production
SSC	*Scientific Steering Committee*
Scientific Advisory Committee	Public body, with membership largely comprising external scientific experts and normally appointed by Ministers, which helps Government collect scientific information and make judgements about it
Scientific Committee on Plants	An EU committee of experts which advises the European Commission on issues relating to the release of *GMOs*
Scientific Steering Committee	The independent body of scientific experts set up by the Secretary of State for Environment, Transport and the

	Regions to oversee the *FSEs* and report on the outcome
SCIMAC	Supply Chain Initiative on Modified Agricultural Crops, representing UK industry organisations throughout the primary supply chain (member organisations are *BSPB*, *CPA*, *NFU*, *UKASTA* and *BSBSPA*)
SCRI	Scottish Crop Research Institute: non-departmental public body grant-aided by *SEERAD*, which undertakes fundamental and strategic research on agricultural, horticultural and industrial crops; part of the *Research Consortium*
Separation distance	The prescribed distance between GM crops grown in trials in this country and other crops; these distances are intended to reduce the chances of a GM crop cross-pollinating a conventional crop, and vary from crop to crop depending upon the susceptibility of the particular species to cross-pollination and the distance to which the viable pollen concerned will travel
SEERAD	Scottish Executive Environment & Rural Affairs Department
Soil Association	A registered charity with a Council elected by its members, which sets standards for the certification of organic food allowing no *genetically modified* ingredients in its production
Substantial equivalence (principle of)	A comparative approach, focusing on the determination of similarities and differences between genetically modified food and its conventional counterpart, which aids in the identification of potential safety and nutritional issues
Threshold levels	A quantity set by weight or number to define the maximum or minimum presence of one material in another (for example, the presence of *GM* seed in a batch of non-*GM* seed)
Transgene/ transgenic	Genes inserted by the direct incorporation of *DNA*, as opposed to endogenous genes
Trials	Farm-Scale Evaluations of GM crops (*FSEs*)
Trophic level	The position which an organism occupies in a *food chain*
UKASTA	UK Agricultural Supply Trade Association
UKROFS	UK Register of Organic Food Standards, whose Board and Certification Committee are appointed by Ministers to represent the broad cross-section of interests in organic food and processing in the UK
Variability	Variation between living organisms, usually arising from a combination of genetically and environmentally based variation

Varietal associations	A crop variety, containing more than one plant type (usually two, of which one acts as the pollinator, the other the pollinated)
Variety	A subdivision of a species. An agricultural variety is a group of similar plants that by structural features and performance can be identified from other varieties within the same species.
WTO	World Trade Organisation

DEFRA CASE STUDY OF THE REGULATORY PROCESS FOR GM CROPS

The development of Aventis' genetically modified oilseed rape (MS8/RF3)

Introduction

This brief summary has been prepared for the AEBC by DEFRA to illustrate how one of the GM crops in the Farm-Scale evaluations was developed and how it proceeded through the regulatory hurdles.

MS8/RF3 is a genetically modified oilseed rape developed by Plant Genetic Systems (PGS, now Aventis CropScience Ltd.) to be tolerant to the herbicide glufosinate ammonium. The rape is unaffected by the herbicide because its genetic make up has been modified by insertion of a new gene that makes the enzyme phosphinothricin acetyltransferase (PAT). PAT acts inside the plant, inactivating the glufosinate herbicide, making it non-toxic to the plant.

The PGS hybrid oilseed rape system

The increased yield, and uniformity, attainable by the development of F_1 hybrids is a goal of plant breeders working with several crops. The PGS hybrid system in oil seed rape was developed in the late 1980s and through the early 1990s to give higher yields and confer herbicide tolerance. The hybrid system utilises a dominant nuclear gene for male sterility (as opposed to cytoplasmic encoded male sterility, common in Brassicas) and a gene which restores male fertility, both linked to the same marker gene.

Male sterility is achieved by insertion of a gene coding for the ribonuclease enzyme barnase and restored by a ribonuclease inhibitor protein *barstar*. Both genes are derived from a bacterium (*Bacillus amyloliquefaciens*) and, in the PGS system, their expression in oilseed rape is under the control of a promoter (pTA29 from tobacco plant, *Nicotiana tabacum*), which ensures they are expressed exclusively in the layer of cells surrounding the pollen sac during anther development. The expression of barnase blocks pollen development and produces a plant without anthers (the MS line). When such male-sterile plants are crossed with plants expressing the barstar gene (the RF lines), the inactivation of the barnase enzyme in the F_1 progeny enables normal anther development and restores fertility.

Two marker genes are involved. One, the *neo* gene coding for the neomycin phosphotransferase II (NPTII) enzyme, is derived from the bacterium *Escherischia coli*, and confers resistance to the antibiotics neomycin and kanamycin. Neo is a widely-used selectable marker enabling the early *in vitro* selection of cells carrying the inserted DNA. The second marker is the *bar* gene, which codes for the enzyme phosphinothricin acetyl transferase (PAT), an enzyme which detoxifies phosphinothricin (the gene is from the bacterium *Streptomyces hygroscopicus*). Phosphinothricin (glufosinate-ammonium) inhibits glutamine synthetase, causing rapid accumulation of ammonia and death of plant cells. Plants expressing PAT are thus able to tolerate herbicides in which phosphinothricin is the active ingredient. Phosphinothricin is more commonly referred to as glufosinate and marketed under the trade names Liberty, Basta and Challenge.

In the PGS system, the *bar* gene is physically linked to the *barnase* and *barstar* gene constructs, segregating with each as a single locus. It allows, by application of herbicide, the parental male sterility lines to be identified before they flower and the fertility restorer lines to be identified without having to test their restorer capacity by test-crosses to male-sterile lines. Therefore, phosphinothricin ("glufosinate")-tolerance is an integral part of the production of hybrid oilseed rape seed. PGS developed the GM plants in the laboratory and selected the best lines. These were multiplied by conventional breeding techniques in contained facilities. These were tested and evaluated in small scale field releases in Canada and in Europe in several countries including Belgium, France and UK.

The first two applications of the PGS hybridisation were based on three transgenic oilseed rape lines: a male sterile oilseed rape line, designated as MS1 (B91-4) or its progeny, and two fertility restorer lines, designated as RF1 (B93-101) or RF2 (B94-2) and their progeny.

PGS applied through the UK authorities in 1994 for Part C consent under Directive 90/220 to place MS1/RF1 on the market for seed production only. After due consideration, Member States agreed, and Part C marketing consent was granted by the UK in February 1996. In parallel, PGS applied through the French authorities in 1995 for Part C consent for MS1/RF1 and MS1/RF2 for general cultivation. Member States eventually agreed to authorise the Part C consent but to date France has declined to issue the consent.

As the technology developed, PGS brought forward the newer transgenic lines MS8 and RF3. These were based on the same system but with new transformation vectors in which the T-DNA was limited to the desired trait genes and excluded any antibiotic resistance genes.

These lines were tested in containment in Belgium in 1993 to 1995, and in small-scale field trials in Belgium, France, UK, Sweden and Canada in 1995.

Application for Part C consent to the Belgian authority

An application for Part C consent for MS8/RF3 was submitted to the Belgian Competent Authority (CA) in 1996. The scope of the application was to permit the growing of MS8/RF3 in Europe and the importation of oilseed rape seeds (grown mostly in North America) for processing into food and animal feed and for industrial uses. The applications were supported by extensive documentation and the required environmental risk assessment. Belgium evaluated the MS8/RF3 dossier and concluded that it complied with the Directive and that the oilseed rape was safe for the environment, human health and as animal feed and food. The Belgian CA therefore forwarded the MS8/RF3 dossier to the Commission with a favourable opinion. The Belgian authorities highlighted the following points in their assessment of the information in the PGS dossier:

(1) whether the introduction of the herbicide tolerance gene and the hybrid system into MS8/RF3 would enhance its capability to survive, establish and invade habitats. They agreed that based on numerous lines of evidence and their previous consideration of MS1/RF1 there is no indication that there had been any direct or indirect effect of the genetic modification on the ability of MS8/RF3 to survive or out-compete wild plants. The MS8/RF3 oilseed rape is no more likely to be invasive or weedy than non-GM oilseed rape varieties currently on the market.

(2) the transfer of genes between plants which occurs via cross-pollination between sexually compatible individuals. The presence of glufosinate tolerance would not confer a selective advantage, principally because herbicide tolerance is not a trait that would affect survivability or invasiveness in nature. Glufosinate herbicides are rarely used to control volunteer oilseed rape so any spread or transfer of the herbicide tolerance gene can be controlled using existing management strategies.

(3) an evaluation of the risks to people who come directly or indirectly into contact with MS8/RF3 oilseed rape or its pollen. Particular consideration was given to issues such as allergic reactions and possible toxicity.

(4) Field trials: data were submitted on monitoring the susceptibility of MS8/RF3 to a range of pests and diseases over three growing seasons in field trials. This included trials in Belgium, France, Sweden, Canada, USA and the UK. There were no differences in the susceptibility of MS8/RF3 oilseed rape varieties compared with non-GM oilseed rape varieties and no evidence therefore that MS8/RF3 was any more toxic or harmful to pests (and the beneficial creatures that eat the pests). Neither did MS8/RF3 show any differences in susceptibility to diseases compared to non-GM oilseed rape. Observations were carried out to consider the foraging behaviour of honey bees both in the greenhouse and the field. The bees showed no preference for or rejection of transgenic versus non-transgenic oilseed rape. There were no adverse effects observed in the colonies. Field observations and a bird feeding study were carried out to assess any change to the natural interaction between oilseed rape and birds. No change in

feeding habits or body weight were observed nor any clinical symptoms of toxicity. A similar programme was carried out for small mammals consisting of field observations and a rabbit dietary test. No differences between food consumption or bodyweight between those animals fed transgenic oilseed rape and those fed conventional oilseed rape. No toxicological effects on these animals were observed.

(5) Safety of food and feed

a. Substantial equivalence of seeds:

The seeds from the GM oilseed rape MS8xRF3 are substantially equivalent to seeds of non-transgenic plants. No differences in food (fatty acids e.g. erucic acid, chlorophyll, tocopherols, sterols, metals) and feed (amino acids, fibre, vitamin, minerals, glucosinolates) composition of the transgenic oilseed derived products compared to non-transgenic oilseed rape could be detected.

b. Meal:

The meal derived from oilseed rape seeds is used in animal feed. There are indications of the absence of novel enzymes in the meal derived from transgenic oilseed rape. Any proteins that would be present would be degraded by the temperatures applied during processing or in the gut of animals consuming the meal.

c. Honey

The honey produced by the bees foraging on the GM oilseed rape may contain low levels of pollen. However the pollen that is present in the honey is not toxic and is no longer viable. It was agreed that, in accordance with Directive 90/220/EEC, the consumption of this honey is safe and that can be referred to the tests that were done for the notification C/UK/94/M1/1 (RF1 x MS1).

d. Herbicide metabolites/residues

The safety assessment (toxicology, etc.) of glufosinate metabolites and residues and their implication in consumption of oilseed-derived products is required under Directive 91/414 on the Placing of Plants Protection Products on the Market.

In conclusion, all of the evidence available indicated that the genetic modification was very specific and involved non-toxic/non-allergenic gene products (PAT, barnase and barstar enzymes). The genetic modification of oilseed rape that resulted in MS8/RF3 had no direct or indirect impact on the nutrient content or wholesomeness of the oilseed rape.

Assessment in the UK

The UK and other Member States received the dossier from the Commission on 4 February 1997 to conduct their own independent safety assessments. Member states are required to respond within 60 days. ACRE reviewed the application and issued advice on 19 March 1997. ACRE concurred with the assessment from the Belgian Authorities and was satisfied that MS8/RF3 did not pose a risk to human health and the environment.

The Advisory Committee on Novel Foods and Processes (ACNFP) assessed the food safety of MS8/RF3 in detail. They concluded that the oil obtained from this line, and from lines derived from it and conventionally bred varieties and breeders lines, by conventional plant breeding methods, were safe for food use. They also concluded that the oil from this line did not differ in composition from oil from conventionally-bred oilseed rape.

Other Member States' Comments

A number of objections to the application were raised by other Member States. These included concerns about the potential for out-crossing to other oilseed rape crop plants, insufficient data on pollen and gene flow and long term effects of herbicide tolerant crops on the environment. PGS provided additional information to address the points raised. Only the UK and Germany were in full support of the application.

Reassessment of the environmental impact assessment

In 1998 DETR asked Professor Gray to review environmental risks of herbicide tolerant oilseed rape. His report reviews the application made by Plant Genetic Systems in 1994/95 and considered in detail the risk assessment made by ACRE. His review found no evidence from studies since 1994 to alter ACRE's original assessment that the PGS hybrid oilseed rape is no more weedy or invasive than untransformed varieties. Nor is there evidence to indicate that the transfer of herbicide-tolerance to neighbouring crops by cross-pollination involves a greater risk to the environment than ACRE anticipated from the data it had at that time. Recent research on hybridisation with wild relatives confirms that there is a low, but unquantifiable, risk of introgression of the transgenes into wild turnip populations, particularly where these occur in small numbers in oilseed rape fields. The review was endorsed by ACRE and published by DETR in March 1999[178]. This assessment is applicable to MS8/RF3 also.

Current position

In December 1998 European Environment Ministers agreed the principles for assessment of risk to be used for evaluating GM crops and that these procedures

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[178] *Environmental Risks of Herbicide Tolerant Oilseed Rape – A Review of the PGS Hybrid Oilseed Rape* DETR March 1999. The text is available on the DEFRA web-site.

should be taken into account ahead of the formal adoption of the revised Directive 90/220/EEC. The risk assessment procedures were based on the system already in use by the UK and included an explicit requirement to consider the impact of changes in management of the GM crops. ACRE were therefore requested to reconsider the PGS application in the light of the Environment Minister's decision. The Committee was content that the original risk assessment was still valid and the changes in agricultural management were being addressed satisfactorily by the farm-scale evaluations. ACRE also noted Aventis' undertaking that no widespread commercial planting will take place until the completion of the Evaluations programme.

Research published since the 1996 evaluation of MS8/RF3 indicates that some GM plants containing the Bt gene to make them insect resistant might have non-target effects on insects such as lacewings and monarch butterflies. ACRE has evaluated each of these cases and concluded that they have no impact on the safety of GM oilseed rape lines that, like MS8/RF3 herbicide tolerant oilseed rape, do not contain the Bt insecticidal gene. Likewise, a recent issue about the Cauliflower Mosaic virus (CaMV) promoter[179] was considered in detail by ACRE. The Committee advised that the CaMV promoter is safe and the risk assessments of approved products are unchanged.

There is an ongoing duty of care with all Part C consents that the consent holders and the regulatory authorities keep abreast of developments in science and evaluate these, where relevant, against the safety of approved GM products. If new scientific research gave justifiable reasons to believe that an approved GMO constitutes a risk to human health and the environment then Member States may take action to restrict or prohibit its use. There has been no new scientific evidence published since MS8/RF3 was approved that would indicate the original risk assessment was wrong.

Aventis has submitted additional information to support their original application in light of commitments in 1998 and 1999 and the adoption of Directive 2001/18. This includes proposals on post market commercial monitoring, traceability, labelling and product stewardship. These additions to the original dossier are currently being evaluated by the Belgian authorities before being forwarded to the Commission for the consideration of other Member States.

The next step in the regulatory process is for the Member States to vote by qualified majority on whether to approve MS8/RF3. This vote has been put off on three occasions as new information needs to be considered.

The PGS rape MS8/RF3 has completed the required National List trials but cannot be added to the UK national list unless it obtains Part C consent under Directive 90/220. It has been grown extensively in Canada and USA for a number of years now.

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[179] The CaMV promoter is a small stretch of DNA used in most GM plants to switch on the inserted gene or genes

ANNEX B

CABINET OFFICE
70 Whitehall, London SW1A 2AS
Telephone: 020 7270 0400

Minister for the Cabinet Office
Chancellor of the Duchy of Lancaster

RECEIVED
16 JUN 2000

Professor Malcolm Grant
Chairman
Agriculture Environment and Biotechnology Commission
Albany House
94-98 Petty France
London
SW1H 9ST

14 June 2000

Dear Malcolm,

PUBLIC ACCEPTANCE OF IMPURITY

I am grateful for your work in the launch of the Commission on 5 June at Greys Farm. I hope you agree that the resulting press coverage was positive, and set the tone for what I know is going to be an important and dynamic body.

I had not expected to write to you so soon, but given the recent GM-contamination of rape seeds, an issue has arisen which I would like to invite the Commission to consider. At the heart of the seeds story seems to be the question of public acceptance of levels of impurity. We have a 1% de minimis threshold for adventitious GM-contamination of foods at European level. This seems to have been accepted as the best practical and deliverable level, but differs from public calls for 100% purity in response to the seed contamination. You may be aware that the Ministry for Agriculture, Fisheries and Food has announced a package of measures to ensure international levels of seed purity, including pressing for European standards of seed contamination. We have always said that consumers have a right to choose, but feel that, in a world where GM crops are grown and exported internationally, and with no health or safety grounds for banning such imports, a level of GM contamination, however small, might be inevitable.

In discussing this with colleagues, we were of the view that, given your remit to "advise Government on the ethical and social implications arising from these developments and their public acceptability" and to "consider the wider implications of the lessons to be learned from individual cases", you might usefully consider public acceptance of impurity. I understand that your first task when you meet on 6 July will be to consider your workplan, but I would be grateful if you were able to consider looking at the above, in the light of the events of the past month, bearing in mind that there is now momentum to deal with this issue at a European level.

I am copying this letter to Michael Meacher and Baroness Helene Hayman.

MARJORIE MOWLAM

20 July 2000

Rt Hon Dr Marjorie Mowlam
Minister for the Cabinet Office
Cabinet Office
70 Whitehall
London SW1A 2AS

AGRICULTURE AND ENVIRONMENT BIOTECHNOLOGY COMMISSION

Thank you for your letter of 14 June, and for your good wishes for the AEBC's work.

Our first meeting on 6 July was a very positive and useful occasion, and I feel that it lays a good foundation for the future. I attach, for your information, a copy of our provisional minutes which are being posted on the AEBC's website.

You will see from these, that we discussed our initial thoughts about the Commission's work-plan. Our conclusion was that, while we shared the concerns about public acceptance of seed impurity raised in your letter, these needed to be considered as part of other, wider questions such as consumer choice and gene transfer. We agreed that, because of this, it was too early for us to address this specific issue on its own and that it would, therefore, be considered as we made progress with our workplan and developed our strategy.

We also agreed that any work on seed purity should be taken forward in liaison with the FSA. I have already had a meeting with Sir John Krebs and we will be keeping in close contact about this and other areas of mutual interest.

As with yours, copies of this letter go to Baroness Hayman and Michael Meacher. I am also writing to the Ministers of the three devolved administrations to inform them of our views.

I hope that at some convenient point you, and those Ministers with an interest in our work, will be able to meet with the Commission. If you agree, I will ask the AEBC Secretariat to contact your office to discuss suitable occasions.

Professor Malcolm Grant
CHAIR

A·E·B·C

AGRICULTURE AND ENVIRONMENT BIOTECHNOLOGY COMMISSION

The Rt Hon Michael Meacher MP
Minister of State
Department of the Environment, Transport and the Regions
Eland House
Bressenden Place
LONDON SW1E 5DU

22 February 2001

Dear Mr Meacher

Study of decision-making in biotechnology

I am pleased to report that the Commission has recently completed a major consultation exercise on its proposed Work Plan. A copy of the final plan, which was formally submitted to your Ministerial colleagues on 11 January, is enclosed for ease of reference.

I am now writing to seek your assistance. One of our priority work areas is an investigation of issues of strategic relevance to the decision making processes in biotechnology with respect to agriculture and the environment. This is taking the form of case studies of the current farm-scale evaluations (FSEs) and gene-flow. As with our other studies, the preliminary work has been undertaken by a Working Group of members of the Commission, although the final deliberation will be by the Commission as a whole. The detailed terms of reference for the Working Group appear in the Work Plan. They are studying the reasons for the initiation of the FSEs, the processes by which they were set up, and their role in the future regulatory framework and decisions governing the use of GM techniques in agriculture.

This is a difficult area of study, where there has been a polarised debate. The Working Group has painstakingly been assembling and analysing the evidence, including a wealth of background papers and other information. Much of this has been with the assistance of officials in your Department and your expert committees, and we are grateful for their continuing interest and support. We have also held two public meetings on this theme, involving the whole Commission, and in addition we held a public evidence-taking session at our recent public meeting in Norwich.

The Government's objectives in established the FSEs is one area of focus for the Working Group, and they are interested to seek from you, as the Minister responsible for the trials, your comments on the following issues:

Why, in your view, the trials were instigated.

2. How you intend to use the results of the farm scale trials.

3. The options open to you at the conclusion of the trials bearing in mind the position under Directive 90/220 and its successor.

Athena House 84-86 Petty France, London, SW1H 9ET

4. Whether you propose that the results of the trials will form the sole basis of your decision or whether you will take into account other considerations, and if so what?

5. How you propose to take into account any uncertainties in the results.

6. One of the areas of interest to the Group is public perception, especially in light of what we have heard at our public meetings and hearings. They are interested to explore the relationship between the scientific purpose of the FSEs and public perceptions, both of what their purpose is and what it ought to be. As part of this, the Group has been looking at statements the Government has made about the trials. Some of the statements that have been reported are summarised on the attached list (though this is not, of course, exhaustive), and there is a suggestion that the evaluations are in some way concerned with Implications GM crops might have for human health and safety. Was this intended?

We welcome your comments on the above questions and more generally.

I should be pleased to come and discuss this letter and the Commission's work more generally with you if that would be helpful.

Yours sincerely

Malcolm Grant.

Professor Malcolm Grant

Chair

Some Statements on the Farm-Scale Evaluations

'These farm-scale trials will ensure that the managed development of GM crops in the UK takes place safely'

DETR Farm Scale Evaluation Fact Sheet, 1999

'The farm-scale evaluation of GM crops is extremely important research which will ensure that the managed development of GM crops will take place safely'

Michael Meacher MP, Minister for Environment, DETR Press Release 14.6.99

'A contentious area at present is the development of genetically modified crops. At the farm level, the Government's approach is based on a full ecological evaluation of field-scale plantings before commercial crops are planted. The approach means that we shall be able to identify any problems in time to take the appropriate action, at the same time as being able to assess the potential benefits for the environment and for farmers alike.'

'A Better Quality of Life: A Strategy for Sustainable Development in the UK', White Paper Cm 4354, May 1999, para 6.64

'We cannot take action in respect of GM crops unless we can show evidence that they constitute a risk of harm either to human health or the environment. These trials will show whether there is such evidence'

Michael Meacher MP, Minister for Environment, in Glasgow Herald, 4.8.00

'The trials will show whether there is evidence of risk or harm to human health or the environment.'

Michael Meacher MP, Minister for Environment, in Lincolnshire Echo, 4.8.00

FROM THE RT HON MICHAEL MEACHER MP
MINISTER FOR THE ENVIRONMENT

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21 MAY 2001

Dear Prof. Grant

Thank you for your letter of 22 February seeking my comments on issues associated with the Farm Scale Evaluations (FSEs) of genetically modified (GM) crops. As you say in your letter this is a difficult area of study and I am happy to clarify the points you raise.

Reasons for instigating the Farm Scale Evaluations

The Government instigated the FSEs in 1998 on the grounds that if ever commercial scale use of genetically modified herbicide tolerant (GMHT) crops took place, the potential wider impact on farmland wildlife that might be caused by the use of herbicides with these crops needed to be fully evaluated. I set out my reasons for instigating the trials in my statement to the House of Lords European Communities Committee (Sub-Committee D) on Wednesday 21 October 1998 (a copy is enclosed).

English Nature and others expressed concerns that the widespread planting of GMHT crops could wipe out so much biodiversity and the ecosystem depends on as a result of treating the crops with very powerful chemicals.

The use of the results of the Farm Scale Evaluations

You ask how I intend to use the results at the end of the FSEs. The fieldwork on spring sown crops is due to be completed in the autumn of 2002, with the fieldwork on autumn sown crops due for completion in the summer of 2003. The results of the studies for each of the crops will be analysed individually by the research consortium against the null hypothesis *that there are no significant differences between the biodiversity associated with the management of the particular GMHT crop and the non-GM crop at the farm scale.* The research work has been confined exclusively to questions around the management of the crops, which is a major limiting factor. The data will

reveal if there are any statistically significant differences in the abundance and diversity of the indicator species between the GMHT cropping regime and its equivalent conventional cropping regime. The research consortium will present the results and statistical analysis to the independent Scientific Steering Committee overseeing the evaluations, who will scrutinise them. The work will be published in peer reviewed scientific journals and all the data will be made available for study.

The Government will also seek advice from the Advisory Committee on Releases to the Environment (ACRE) and the Advisory Committee on Pesticides (ACP). The Government will also conduct a public consultation exercise as part of the evaluation of the results, and public attitudes to commercialisation will form a crucial part of the decision. In the light of such evidence Ministers, together with the devolved administrations, will take a joint decision as to whether to allow the commercial growing of each of the GMHT crops involved in the FSEs.

Options at the conclusion of the Farm Scale Evaluations

Your third question asked what options may be open to the Government when the FSEs have been concluded. There are several different options available. One is to reject commercial growing of GM crops in the UK on the grounds that it is shown they cause damage to the environment. Another, in the light of the various consultations that will take place at the end of the trials, is to require further research work to be carried out, not least to ensure that public consent can be secured for commercial planning – that protection of the economic interests of other farmers (whether conventional or organic) can be secured. A third is to consider, even if the null hypothesis were confirmed, what further work should be carried out to examine the effects of moving from field-scale planting of GM crops to district-wide GM cultivation, or further step change that will need to be tested. A fourth is to explore a whole range of different systems of post-market monitoring. And clearly there are other options too.

Oilseed Rape and Beet

The oilseed rape and both varieties of beet in the FSEs are being grown under Part B (research) consents. At present applications for Part C (commercial) approval for these crops are delayed in the current impasse of notifications that are still under consideration in the European Union.

If these crops have not received Part C approval by the time that the FSE results are available, then the results together with advice from ACRE will be relevant in informing the United Kingdom's voting position on these crops.

The oilseed rape and varieties of beet might, however, proceed through the regulatory system before the results of the FSEs are known. If the UK is required to take a decision on whether Part C approval should be given to the oilseed rape, fodder beet or sugar beet before the end of the FSEs then it will do so based on the advice of ACRE. If these crops do receive Part C consent before the results of the FSEs are known then the regulatory procedures will be the same as those explained below for maize.

Maize

Maize already has Part C approval to be imported or cultivated within the EU. If the results of the FSEs demonstrate an adverse effect the UK could take action under Article 16 of Directive 90/220 or the comparable Article in the new Directive. Article 16 states that where a Member State has justifiable reasons to consider that a product that has been notified and has received written consent constitutes a risk to human health and the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. If the results were such that the

Government decided that Article 16 action should be invoked, the UK could do so, informing the European Commission of the decision and the new information that we might have from the FSEs. Once a restriction is placed on the use and/or sale of a Part C product a decision on the new information has to be taken by the EU within three months using the comitology procedure laid down in Article 21 of the Directive.

Other considerations at the conclusion of the Farm Scale Evaluations

There are other regulatory procedures that the GM crops in question and their associated management practices must go through before full commercialisation would be permitted. The herbicides that are being used in conjunction with the GMHT crops must pass successfully through the pesticide regulations overseen by the Ministry of Agriculture, Fisheries and Food before being allowed to be applied to the crops. Currently, the herbicides being used, glyphosate and glufosinate ammonium have provisional licences. The results of the FSEs might aid the Government in any decision about the effects of the pesticide on the environment. In addition, before being sold commercially the GMHT crops would have to perform successfully in National Seed List trials also operated by MAFF. These test the distinctiveness, uniformity and stability of all commercial crops.

The Government will have to agree a United Kingdom wide position for Directive 90/220 matters, such as applications for Part C approval. This will involve not only consulting with Ministerial colleagues in Westminster but also the devolved administrations, whose views will form a vital part of the consideration at the end of the FSEs. The views of the devolved administrations will also be sought by MAFF in deciding whether the GMHT crops should be included on the National Seed List or whether the pesticides receive full approval. In addition, we must have regard to the novel food regulations that are overseen by the Food Standards Agency. These regulations are used in decisions on whether the GMHT crops are safe to be used in animal feed or food chains.

Uncertainties in the results

You ask about uncertainty at the end of the FSEs: this may come in two forms. First, there might be a degree of uncertainty in the statistical results of the programme. The evaluations have been designed so that the number of sites proposed over the three years allows the null hypothesis to be tested with confidence and for statistically significant results to be produced for each indicator and for each crop. My officials are confident that the statistical analysis will be valid. It is possible that the interpretation of the results might provide differences of opinion between scientists who have expertise in this field. A public consultation exercise following the advice from the Government's own expert committees would allow for different opinions to be aired and considered.

Second, there may well be continued uncertainty concerning any possible direct and indirect effects on human health and the environment arising from the genetic modification of crops. To resolve these uncertainties we must continue to monitor all releases of GM crops and take the advice of our expert committees. The new deliberate release Directive also includes a specific provision that will ensure that the notifier continues to monitor and report after crops have been released under a Part C marketing consent. Under part VI of the Environmental Protection Act 1990, the person keeping GMOs is also under a duty to use the best available techniques not entailing excessive cost to prevent damage to the environment being caused as a result of continuing to release the organism. If damage to the environment include damage to crops grown by conventional or organic farmers, there will continue to be considerable dissension as to how this should be secured. Third, there will certainly continue to be claims that the FSE trials do not

constitute a real test of the full effects of a GM agronomic system, either in the relationship between herbicide use in biodiversity conservation or in the long-term management of volunteers.

Government statements on the purpose of the Farm Scale Evaluations

Your last question related to statements about the FSEs which have referred to the protection of human health and safety. All aspects of the possible impact on safety for human health and the environment have to be evaluated before a decision on approval of a GMO release is taken. This assessment is set out in the dossier of information provided by the company to support their application and is based on research and testing of GM plants over many years. If there is doubt about this information it can be investigated by the regulatory authority and advice sought from ACRE and other advisory bodies.

Separation distances

Separation distances constitute an important additional issue that I should like you to consider. The Soil Association has raised with me the question of what, if any, level of GM presence in organic food is acceptable. The question could be broadened to include conventional food. This leads onto the issue of separation distances. The purpose of separation distances is to help ensure that any cross-pollination with nearby compatible crops is minimised. Separation distances for the Spring 2001 Farm Scale Evaluations were announced in my Department's News Release of 6 February. The agreed separation distances were based on scientific work by the National Institute of Agricultural Botany. These distances should reduce cross-pollination to a maximum of 1% for any crop. The News Release also said that the distances will be kept under review for future plantings.

I am convinced that the issue of separation distances is not simply a matter of science, but equally a question of public acceptability. I take the view that a cross-pollination threshold of 0.1% is much more likely to be acceptable. Such a threshold would require greater separation distances than currently apply. The practicality of introducing greater separation distances would need to be considered. It would be most helpful if the AEBC could assess the public mood on this issue, by way of a consultation process, and advise both on the question raised by the Soil Association and on the issue of separation distances. The Government would need your advice in good time before the difficult decisions that might need to be taken on possible commercialisation of GM crops.

You suggest a discussion about the above questions and the work of your Commission more generally. I should welcome such a discussion. Perhaps you could contact my Private Office to arrange a date for us to meet.

Yours sincerely

Michael Meacher

MICHAEL MEACHER

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