

The GM Dialogue: Government response

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9 March 2004

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Published by the Department for Environment, Food and Rural Affairs.

Executive Summary

1. **The Government and the Devolved Administrations have carefully considered the findings of the GM public debate, science review and costs and benefits study. We take public concern very seriously, and we have weighed public opinion alongside the scientific evidence. We will:**

- **protect human health and the environment through robust regulation of GM crops on a case-by-case basis, consistent with the precautionary principle**
- **ensure consumers can choose between GM and non-GM products through tough new labelling rules**
- **safeguard farmers' interests by putting in place effective and proportionate measures to facilitate the coexistence of GM and non-GM crops**
- **provide guidance to farmers wishing to establish voluntary GM-free zones**
- **consider the best ways of providing the information which the public wants and in an open and transparent way.**

2. Very few GM crops are currently commercially available worldwide, and even fewer have been approved for commercial cultivation in the EU - to date only three types of GM maize. And no GM crop currently has all the approvals needed for commercial cultivation in the UK. A number of other GM crops, including soya and maize, have been approved for import, processing and use in food or animal feed. GM tomato puree was approved and sold well until increased public concern about GM food led to it being withdrawn from supermarket shelves.

3. Decisions on genetically modified organisms are taken collectively by EU member states, and the Government's approach must reflect that. The EU's regulatory framework is firmly based on the precautionary principle. Each GMO is subject to a comprehensive assessment of the potential risks to human health and the environment, on the basis of the scientific evidence.

4. GM crops are only one application of GM technology. GM can also be used to produce veterinary medicines and, potentially, human medicines. All of these applications are strictly regulated in the EU on the same case-by-case basis.

5. The GM public debate arose from a recommendation in the Agriculture and Environment Biotechnology Commission's report 'Crops on Trial', published in September 2001. In May 2002 the Secretary of State announced that the UK Government and the devolved administrations would sponsor a national GM dialogue on GM issues. The aim was to create a dialogue between all strands of opinion on GM, to deepen public understanding of the issues surrounding GM technology, and to improve the evidence base to enable Government to make informed decisions. It comprised three main components:

- a public debate, managed by an independent steering board;
- a review of the scientific issues relating to GM crops and food, conducted by a panel of independent scientists chaired by the Government's Chief Scientific Advisor working with Defra's Chief Scientist; and
- a study into the overall costs and benefits of GM crops, by the Government's Strategy Unit.

6. All three strands have now submitted their final reports and these have been carefully considered by the UK Government and the Devolved Administrations. This is our **joint response**.

7. We accept that the findings of the **public debate** broadly reflect the current state of public opinion on GM crops. We acknowledge that people are generally uneasy about GM crops and food, and that there is little support for early commercialisation of GM crops in this country. However the results suggest that the general public may have a lower degree of outright opposition to GM than the participants in the debate, while still being very cautious. The debate has also confirmed that people's attitudes towards GM crops are shaped by a complex range of issues and concerns, and that to some extent GM crops have become a focus for much wider concerns.

8. The **Science Review** addressed the key science-related concerns which are frequently raised about GM crops and food. Its overall conclusion was that GM is not a homogeneous technology, and that each application must therefore be considered on a case-by-case basis. It found that worldwide there have been no verifiable ill effects reported from the consumption of products from GM crops over seven years, and there is no evidence to suggest that current GM foods pose a greater risk to human health than their conventional counterparts. It found that the main environmental risk with current GM crops is their potential impact on farmland biodiversity. The impact of these herbicide tolerant crops has been thoroughly investigated by our Farm-Scale Evaluations. The science review also acknowledged that there are some gaps in current scientific knowledge and identified areas for further research.

9. The **Strategy Unit's study** on the costs and benefits of GM crops concluded that any economic benefit from the crops presently available is likely to be limited in the short-term but that future developments in GM crops could potentially offer more significant benefits. The balance of costs and benefits will depend on a range of factors, and there will inevitably be trade-offs. Much will depend on consumer attitudes towards GM food and crops, and on the ability of the regulatory system to continue to manage any risks effectively.

10. In deciding our policy on GM crops we have given due consideration to the findings of all three strands of the GM Dialogue. We have also considered all the other evidence available to us, the results of our Farm-Scale Evaluations of GM crops and the AEBC's report on coexistence and liability. Taken all together, this represents a uniquely diverse body of evidence on which to base our decisions.

11. We have concluded that case-by-case regulation of GM crops remains the right approach. We are committed to evidence-based policy-making, and the scientific evidence supports neither an outright ban nor a blanket acceptance of all GM crops (nor does the European regulatory regime allow for an outright ban). The results of the Farm-Scale Evaluations demonstrate very clearly that each crop is different, and each must be considered on its own merits.

12. GM crops will of course continue to be strictly regulated. Our top priority is to protect human health and the environment. No GM crop can be grown in the EU unless it has been carefully tested and specifically approved. Each crop is first subject to a comprehensive assessment of the possible risks to human health and the environment, on the basis of the scientific evidence, and decisions to approve or reject individual crops are taken collectively by EU member states.

13. This precautionary and evidence-based approach strikes the right balance between managing the risks and harnessing the potential benefits of GM crops. While the current generation of GM crops may offer limited benefits, some farmers may still want to grow them, particularly for animal feed. More importantly, we should not turn our backs on the potentially more significant benefits which future generations of GM crops could offer.

14. We take public concern very seriously, and we recognise the need to address the people's legitimate anxieties about GM crops. We have therefore carefully considered each of the concerns raised in the public debate. The main concerns, and our response, can be summarised as follows:

Caution and precaution

15. The UK Government and the Devolved Administrations take a precautionary approach to GM crops, and the EU's regulatory regime is also firmly based on the precautionary principle. No GMO can be released into the environment unless it has been tested and specifically approved. We will only give our approval if we are satisfied that a particular GMO is safe for human health and the environment. We will also require GM crops to be closely monitored, particularly during the introductory period.

Protecting human health

16. The science review concluded that there is no evidence to suggest that current GM foods pose a greater risk to human health than their conventional counterparts. All GM food and animal feed is strictly regulated in the EU and is subject to a comprehensive safety assessment. The EU approval process has recently been further strengthened and we believe that it is sufficiently rigorous to ensure that approved GM foods are as safe as their non-GM counterparts.

Protecting the environment

17. The risk of adverse effects on the environment is specifically addressed as part of the approvals process for GM crops. EU legislation also allows conditions to be imposed on marketing consents for GM crops requiring the

consent holders to undertake effective post-market monitoring. This is designed to ensure that any unforeseen adverse effects are picked up quickly.

Providing choice for consumers and farmers

18. We are committed to providing choice for both consumers and farmers. Mandatory labelling enables consumers to choose between GM and non-GM products. From April new EU rules will require any food and animal feed with 'adventitious' or technically unavoidable GM content above 0.9% - and with any deliberate GM content - to be labelled, and will extend labelling rules to cover products derived from GMOs.

19. Now that advice has been received from the AEBC on the issue of coexistence of GM and non-GM crops, we will take steps to put in place suitable measures to facilitate such coexistence. We fully accept that the introduction of GM crops needs to be carefully managed, even though in any event the take-up of GM crops by UK farmers is likely to be limited in the short-term. We believe that as the AEBC advised, GM farmers should bear the main responsibility for implementing coexistence measures, and that these should be designed to deliver the EU's 0.9% labelling threshold. We envisage that these measures should have statutory backing. We will consult stakeholders on the feasibility of applying a lower threshold to organic production. We will consult on options for a compensation scheme for non-GM farmers who suffer an economic loss through no fault of their own. We will also provide guidance to farmers wishing to establish GM-free zones.

Providing information

20. The public debate revealed a strong demand for more and better information on GM crops and food. We will consider the best way of doing this, and seek to ensure that any information provided by Government is useful and accessible, in particular by making information available on our websites.

Openness and transparency

21. We will be as open and transparent as possible about the way we make decisions on GM crops, and about the degree of scientific uncertainty and risk involved. The EU regulatory framework has been improved to provide for mandatory public consultation on each GM crop application, and we will do everything practicable to facilitate this. We will continue to seek independent advice on all applications from our independent advisory committees composed of scientific experts, and we will improve public access to the work of these committees.

Gaps in scientific knowledge

22. We fully acknowledge that there are gaps in scientific knowledge about GM crops, but this is true of any developing technology. From the perspective of regulation the key issue is to assess the importance of gaps in knowledge and uncertainty in the framework of the risk assessment process, and to ensure that further research is undertaken as appropriate.

Developing countries

23. We believe that GM crop technology has the potential to provide benefits to developing countries, but that it is for developing countries themselves to make their own informed decisions on whether or not to import or adopt GM crops, taking account of the views of their citizens. The UK supports and has ratified the Cartagena Protocol on Biosafety, which provides a common framework for risk assessment, decision-making and information exchange on GM crops and other products.

No need for GM crops?

24. We fully accept the Strategy Unit's conclusion that the current generation of herbicide-tolerant and insect-resistant GM crops may be of limited economic value to the UK, but it also concluded that future developments in GM crops have the potential to offer more wide-ranging benefits to farmers and to consumers. We believe that the regulatory framework strikes the right balance between managing the risks and keeping the door open to the potential benefits.

Ethical issues

25. We recognise that people have legitimate ethical concerns about GM crops. Nevertheless we believe that the responsible development of GM crop technology could offer significant potential benefits both in the UK and globally, including to developing countries. The Nuffield Council on Bioethics recently concluded that 'there is an ethical obligation to explore these potential benefits responsibly, in order to contribute to the reduction of poverty, and to improve food security and profitable agriculture in developing countries.'

1. Introduction

1.1 The GM public debate arose from a recommendation in the Agriculture and Environment Biotechnology Commission's report 'Crops on Trial', published in September 2001. The AEBC recommended that government should encourage public discussion and examination of the issues before decisions were taken on the commercialisation of GM crops. We asked the AEBC for advice on how the debate could best be carried out and the AEBC provided further advice in April 2002.

1.2 The Secretary of State announced on 31 May 2002 that government intended to accept the AEBC's recommendations for a full and informed debate, and that the public debate would be one strand of a wider public dialogue on GM issues. This dialogue would consist of:

- the public debate, managed by an independent steering board;
- a review of the scientific issues relating to GM crops and food, conducted by a panel of independent scientists chaired by the Government's Chief Scientific Advisor working with Defra's Chief Scientist; and
- a study into the overall costs and benefits of GM crops, by the Prime Minister's Strategy Unit.

1.3 The intention was to create a dialogue between all strands of opinion on GM issues, in the light of the fullest available information. Outputs from both the science and economic components would feed into the public debate and issues emerging from the public debate would help frame the direction of the other two strands. The three strands would report to, and be brought together by Ministers. Together with the FSEs and the AEBC's advice on the coexistence of GM and non-GM crops, they would provide the UK with a uniquely diverse and detailed evidence base on which to make decisions.

1.4 The Secretary of State gave a commitment that government would make a written response to the public debate report and that we would indicate what had been learned from the debate when making future policy announcements. We have taken the opportunity to reflect carefully on the findings, not only of the public debate report, but also the reports of the science review and the Strategy Unit's study into the costs and benefits of GM crops in the UK.

1.5 The public debate was co-sponsored by the UK Government and the Devolved Administrations in Scotland, Wales and Northern Ireland. This is our **joint response** to all three strands of the GM dialogue.

2. Summary of findings

2.1 All three strands of the GM Dialogue have now published their final reports. Their findings are summarised below.

Public debate

2.2 The report of the public debate identified seven key messages that emerged from the debate process. These are:

- People are generally uneasy about GM crops and food.
- The more people engage in the issues, the harder their attitudes and more intense their concerns.
- There is little support for the early commercialisation of GM crops.
- There is widespread mistrust of government and multi-national companies.
- There is a broad desire to know more and for further research to be done.
- Developing countries have special interests.
- The debate was welcomed and valued.

The full report can be found at www.gmnation.org

Science Review

2.3 The science review's conclusions can be summarised as follows:

Overall:

- GM is not a homogeneous technology, and each application to release a GM crop must therefore be considered on a case-by-case basis
- The science underlying risk assessments and the regulation of GM crops and food must keep pace with new developments in the technology and its applications

On the safety of GM food and animal feed:

- There is no evidence to suggest that current GM foods pose a greater risk to human health than their conventional counterparts, despite the fact that GM foods have been eaten by millions of people for several years
- There is no evidence that genes introduced in GM animal feed transfer into milk, meat or eggs produced from animals fed on GM crops
- For the future, it is important to further develop safety assessment technologies and even more effective surveillance, monitoring and labelling systems.

On the environmental impact of GM crops:

- Current GM crops are very unlikely to invade the countryside or be toxic to wildlife
- For the current generation of GM crops, the most important issue is their potential effect on farmland and wildlife. The impact of herbicide-tolerant crops on the environment has been thoroughly investigated by the Farm Scale Evaluations.

The full reports can be found at <http://www.gmsciencedebate.org.uk>

Cost and benefits study

2.4 The Strategy Unit's costs and benefits study concluded that:

- existing GM crops could offer some cost and convenience advantages to UK farmers;
- but any economic benefit is likely to be limited in the short-term, because only a narrow range of crops are currently suited to UK conditions, and negative consumer attitudes are likely to limit take-up;
- future developments in GM crops could potentially offer more significant benefits;
- the overall balance of future costs and benefits will depend on public attitudes, the ability of the regulatory system to manage uncertainties, and on technological developments;
- the decisions we make about GM crops will have an indirect impact on the wider UK science base and are likely to influence developing countries.

The full report can be found at

<http://www.strategy.gov.uk/output/Page3673.asp>

3. Weighing up the evidence

3.1 The **public debate** has helped to improve our understanding of what people really think about GM crops. The debate has also confirmed that people's attitudes towards GM crops and food are shaped by a complex range of issues and concerns, and that to some extent GM crops have become a focus for much wider concerns about issues such as globalisation and the role of multi-national companies.

3.2 We accept that its findings broadly reflect the current state of public opinion on GM. We recognise that people are generally uneasy about GM crops and food, and that there is little support for early commercialisation of GM crops in this country. However we note that there were some differences between the views of those who took part in the 'open' debate, and those members of the public who took part in the 'closed' discussion groups (the so-called "Narrow-But-Deep" element).

3.3 The report suggests that the Narrow-But-Deep sample were less emphatic and less definite in their first response. Whilst they still had strong anxieties and suspicions about GM crop technology, they were more willing to accept that GM crops may offer some benefits, especially medical benefits and advantages for developing countries. The predominant feeling among the Narrow-But-Deep sample was one of uncertainty and this was largely because they felt uninformed. The Steering Board concluded that "the "Narrow-But-Deep" element suggests that the general public is likely to have a lower degree of outright opposition to GM than the self-selecting component who involved themselves in the debate... However, it also suggests that the general public is likely to share all of the main concerns about GM."

3.4 We note the Steering Board's conclusion that "the more people engage in GM issues, the harder their attitudes and more intense their concerns." The Steering Board reached this conclusion on the basis of the results from the Narrow-But-Deep component. The participants' initial views on GM were compared with their revised views two weeks later after they had been asked to find out more about GM by conducting personal research. The report suggests that they became more concerned about all the risks frequently associated with GM, though they were also more willing to accept some potential benefits.

3.5 The results of the Narrow-but-Deep sample were described by the Steering Board to "give broad coverage across the general population" [para 142 of the Steering Board's report] and as such are likely to be more representative of public opinion than those from the 'open' debate "who took a conscious decision to get involved" [para 141]. Nevertheless we accept that whether or not people are engaged in the issues, everyone has a legitimate contribution to make to the debate, and their views must be taken seriously.

3.6 Overall, it is clear that many people have genuine anxieties about GM crops and food, and we recognise that these need to be addressed.

3.7 The **Science Review** sought to address all the key science-related concerns especially those which are most frequently raised about GM food and crops. It concluded that there is no evidence to suggest that current GM foods pose a greater risk to human health than their conventional counterparts. It endorsed the case-by-case approach to regulation that the EU has taken for over a decade. It also acknowledged the limitations of current scientific knowledge and pointed to areas where further research would be beneficial. There may be unknown risks associated with GM crop technology that are, by their very nature, not considered as part of the current regulatory regime. But this is true of any new technology. It follows that there is a need to proceed with caution, taking steps to ensure that GMOs are traced and labelled, and that immediate action is taken to address any unforeseen adverse effects.

3.8 The **Strategy Unit's** study showed that it is not possible to make a straightforward assessment of the potential costs and benefits of GM crops. The balance of costs and benefits will depend on a range of factors, and there will inevitably be trade-offs. Much will depend on consumer attitudes towards GM food and crops, and on the ability of the regulatory system to manage any risks effectively. The challenge for government is to strike the right balance between the costs and benefits of GM crops, taking into account a range of different policy objectives. In particular the regulatory system needs to be capable of managing the risks effectively without discouraging biotechnology companies from developing and marketing potentially valuable new crops.

4. Our key conclusions

4.1 In deciding our policy on GM crops we have given due weight to the findings of all three strands of the GM dialogue. We have also considered all the other evidence available to us, including the results of our Farm-Scale Evaluations of GM crops and the AEBC's report on coexistence and liability.

4.2 We have taken into account a range of different policy objectives: environmental protection, food safety, consumer choice, sustainable food and farming, thriving rural communities, science and innovation, industrial competitiveness, international development, and trade.

4.3 We take public concern very seriously, and we recognise the need to address the people's legitimate anxieties about GM crops. But having weighed up all the evidence, we have concluded that we should continue to assess each GM crop on an individual case-by-case basis. This is also consistent with the way other applications of GM technology, such as veterinary and human medicines, are regulated in the EU.

4.4 This Government is committed to evidence-based policy-making, and the scientific evidence supports neither an outright ban on nor a blanket acceptance of all GM crops (nor does the European regulatory regime allow for an outright ban). The results of the Farm-Scale Evaluations demonstrate

very clearly that each crop is different, and each must be considered on its own merits.

4.5 GM crops will of course continue to be strictly regulated. Our top priority is to protect human health and the environment. No GM crop can be grown in the EU unless it has been specifically approved. Each crop is subject to a comprehensive assessment of the possible risks to human health and the environment, on the basis of the scientific evidence, and decisions to approve or reject individual crops are taken collectively by EU member states. We will not agree to the commercial cultivation of any crop if there is evidence to suggest that it poses an unacceptable risk to human health or the environment.

4.6 Even when a GM crop has secured approval for commercial cultivation, this does not mean that it can be grown without any further restrictions. The biotech companies will be required to monitor approved crops closely and to report any unforeseen adverse effects immediately. This combination of pre-market approval and post-market monitoring will ensure that any risks can be managed effectively.

4.7 The case-by-case approach is supported by both the science review and the conclusions of the costs and benefits study. Where we have enough scientific evidence we should proceed to make decisions. Where we do not, we will continue to ask for or conduct further research. If we do not have enough evidence to enable us to make sound decisions then we will not give our approval.

4.8 We believe that this precautionary and evidence-based approach strikes the right balance between managing the risks and harnessing the potential benefits of GM crops. While the current generation of GM crops may offer limited benefits, some farmers may still want to grow them, particularly for animal feed. More importantly, we should not turn our backs on the potentially more significant benefits which future generations of GM crops could offer.

4.9 In reaching this conclusion we have taken due account of the findings of the public debate. The report of the public debate suggested that people's opinions about GM food and crops are shaped by a wide range of issues and concerns. We have looked at these concerns carefully, and we have concluded that for the most part the regulatory regime which is now in place is capable of addressing them, but that on some issues further action is required. In particular we are committed to providing choice for consumers and farmers. Tough new EU regulations which apply fully from April this year will extend mandatory labelling for consumers. We also accept that coexistence measures need to be put in place on a crop-by-crop basis to safeguard the interests of farmers.

4.10 The next section discusses the public's concerns in more detail, and explains how we have taken them into account.

5. Addressing the public's concerns

5.1 The Steering Board reported that across the whole range of debate activities people raised the same types of issues and concerns about GM crops. This section discusses each of these concerns and sets out our response. It explains how the regulatory system seeks to address them, and where appropriate it identifies the additional action which we plan to take in response to the public debate.

Caution and precaution

5.2 The public debate found that one of the major arguments against GM crops is the concept of **precaution**.

“This expression recurs often in the debate, although people use it in a slightly stronger and wider sense than its conventional usage in the discipline of environmental risk management. As most commonly used in the debate the concept is shorthand for saying that no major technological change should be introduced into the environment and into society until its impacts, including long-term ones, are known and measurable.” (paragraph 48)

5.3 The UK Government and the Devolved Administrations fully understand the desire for precaution expressed by participants in the debate. We will continue to take a precautionary approach to GM food and crops. The broad basis on which we apply the precautionary principle in the UK is summarised in the box below, and is set out more fully in the Government's sustainable development strategy.

Applying the precautionary principle

The *Rio Declaration* defines the precautionary principle as 'where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation'. Precautionary action requires assessment of the costs and benefits of action, and transparency in decision-making.

The precautionary principle means that it is not acceptable just to say "we can't be sure that serious damage will happen, so we'll do nothing to prevent it". Precaution is not just relevant to environmental damage - for example, chemicals which may affect wildlife may also affect human health.

At the same time, precautionary action must be based on objective assessments of the costs and benefits of action. The principle does not mean that we only permit activities if we are sure that serious harm will not arise, or there is proof that the benefits outweigh all possible risks. That would severely hinder progress towards improvements in the quality of life.

There are no hard and fast rules on when to take action: each case has to be considered carefully. We may decide that a particular risk is so serious that it is not worth living with. In other cases society will be prepared to live with a risk because of other benefits it brings. Transparency is essential: difficult decisions on precautionary action are most likely where there is reason to think there may be a significant threat, but evidence for its existence is as yet lacking or inconclusive. Decisions should be reviewed to reflect better understanding of risk as more evidence becomes available.

5.4 In 1998, when English Nature and others raised concerns that the introduction of GM herbicide-tolerant crops could further exacerbate the decline in farmland wildlife, we reached a voluntary agreement with the industry to call a halt to commercial growing. We put precaution into practice by commissioning a four-year programme of GM crop trials – the Farm-Scale Evaluations – the largest anywhere in the world. Our voluntary agreement made clear that there would be no commercial cultivation of GM crops in the UK until we had assessed the results of the trials. In the meantime we have also sponsored the public debate, the science review and the costs and benefits study. No other country has put in place such a thorough and comprehensive process to inform its decision-making on GM crops.

5.5 The EU's regulatory regime for GMOs is also based very firmly on the precautionary principle. GMOs have been strictly regulated in the EU since 1990, and the regulatory regime has been significantly strengthened over the last few years. Each GM crop is thoroughly tested in the laboratory, and then in research trials, before it even reaches the stage of possible commercialisation. No GMO can be released into the environment unless it has been specifically approved. Each one is subject to a comprehensive assessment of potential risks to human health and the environment, on the basis of scientific evidence. No GMO will be approved if there is evidence that it poses an unacceptable risk to human health or the environment.

5.6 Nevertheless it is important to recognise that it is impossible to completely eliminate risk and scientific uncertainty. This is true of any developing technology, not just GM crop technology. The appropriate response is not to ban the technology, but to put in place a regulatory system which is capable of managing the risks effectively. A risk-based approach to the regulation of GMOs is entirely consistent with the precautionary principle.

5.7 The report of the public debate suggests that people are concerned that we simply do not know enough about GM crops at the moment and that much more research is necessary. The science review identified some gaps in scientific knowledge and areas for further research, and also concluded that we should proceed to make decisions on a case-by-case basis. This will enable us to assess each application on its own merits, and to consider whether we have enough information to enable us to make a decision. If we felt that we did not have enough information to enable us adequately to assess the potential risks of a particular GMO then we would object to the issuing of a marketing consent at EU level – and indeed have already done so

on a number of occasions. The biotechnology company concerned would then be required to provide the necessary scientific evidence to enable a full scientific assessment to be made.

Protecting human health

“People cite the unknown risks of GM food to human health. They argue that no specific health tests have been conducted on it and are unwilling to accept the evidence of consumption in the United States that it was free of health problems....Some suggest that health problems might not show up for 20 years or more, others suggest that they have already shown up, and that there might be a link between consumption of GM products and the rise in allergies and in diseases of the gut in the United States. Other health anxieties associated with GM food include stomach and colon cancers, and resistance to antibiotics.” (paragraph 54)

5.8 People understandably want to know that the food they are eating is safe. We accept that they have concerns about health risks from GM food. The experience of BSE has clearly contributed to the public’s cautious attitude to GM food and crops. We are committed to ensuring that the regulatory regime delivers against our objective of safe food.

5.9 In the light of public concerns, the Science Review looked at all the available scientific evidence relating to the safety of GM food products. It concluded that to date world-wide there have been no verifiable ill-effects resulting from the consumption of products from GM crops by millions of people over seven years. Some argue that this, coupled with the fact that GM foods are extensively tested during development in order to satisfy regulatory requirements, provides important assurance of safety. Others argue that just because there is no evidence of harm this does not prove that GM foods are safe. The Science Review panel concluded that there is no evidence to suggest that current GM foods pose a greater risk to human health than their conventional counterparts. However they pointed out that future generations of GM food and crops could pose greater risk management challenges, and that it was therefore necessary to ensure that the regulatory system keeps pace with developments.

5.10 The Food Standards Agency (FSA) is the responsible UK authority for evaluating the safety of GM foods under the relevant European Union legislation. The FSA was set up specifically to protect consumers’ interests in relation to food, and operates at arm’s length from ministers. The FSA’s current view is that the existing safety assessment procedures are sufficiently rigorous to ensure that approved GM foods are as safe as their non-GM counterparts.

5.11 GM food and animal feed are strictly regulated in the EU. All novel foods – whether GM or non-GM – have to be specifically approved before they can be marketed in the EU. Each is subject to a comprehensive safety

assessment and risk analysis against criteria including toxicity and allergenicity. The regime recognises that the consumption of food is not risk-free and requires any novel food to be at least as safe and nutritious as conventional food.

5.12 In April this year new EU rules on the approval of GM food and feed products will take full effect. The authorisation and control of GMOs for food and feed will effectively be centralised in the new European Food Safety Authority, which will be responsible for undertaking the initial assessment of all new GM food and feed products. Final decisions on whether or not to approve individual products will continue to be taken collectively by the member states. In the UK, the Food Standards Agency will continue to be responsible for assessing the food safety aspects, while Defra and the devolved administrations will retain responsibility for conducting environmental risk assessments for GM food and feed crops. Further details can be found at Annex 1.

5.13 It has been suggested that we cannot be sure whether GM foods are safe because no **long-term studies** have been carried out on health effects. The Science Review noted that the long-term assessment of the health effects for whole foods and feeds is considerably more difficult than the post-market monitoring and surveillance of a simple substance such as a single medicine. Unlike pharmaceutical products, foods are complex mixtures of compounds that vary widely in their composition and nutritional value. Detecting any potential adverse effects and relating these conclusively to an individual characteristic of the food would be extremely difficult.

5.14 The Food Standards Agency has also looked at the feasibility of long-term monitoring of GM food consumption using commercial databases and concluded that this would be very difficult to conduct given that GM crops may be used in a variety of processed foods. Identifying health effects attributable to a specific GM crop would be difficult to measure. Under the new EC Regulation on GM food and feed there is a requirement for a proposal on post-market monitoring regarding use of the food for human consumption, to be submitted as part of the application for authorisation, where appropriate.

5.15 The weight of evidence suggests that the risks to human health from eating GM food are as low as for non-GM food. But we recognise that some people would still prefer not to eat GM food, which is why we are committed to providing consumers with choice through mandatory labelling of products containing GM ingredients. Further details about labelling can be found below.

5.16 Another common concern is that people may develop unforeseen **allergic reactions** to GM foods. GM crops are developed in a step-by-step process and are studied extensively in the laboratory before commercialisation is even considered. Tests for potential allergenicity are conducted at an early stage in this process, and only if no adverse effects are identified will development progress to the next stage. The regulatory risk

assessment for GM crops and foods also takes into consideration the potential for increased allergenicity.

5.17 The Science Review pointed out that allergic responses to food generally are not well understood, and that we should continue to exercise caution when assessing all new foods, including foods and animal feed derived from GM crops. It noted that changes in allergenicity are probably easier to identify in novel foods developed using GM techniques as opposed to some conventional breeding methods. It concluded that the GM foods consumed at present do not appear to have produced allergic reactions.

5.18 Finally, some people are concerned that eating GM food could lead to increased **antibiotic resistance** in humans, because antibiotic resistance markers have been used in the development of some GMOs. The science review concluded that this was not very likely and in any event the risks were not significant because antibiotic resistance is already widespread as a result of the use of antibiotics in medicine and in animal feed. In any event technological advances mean that the use of antibiotic resistance genes can now be avoided, and the use of antibiotic resistance markers which may have adverse effects is to be phased out in the EU by 2008.

Protecting the environment

“People fear that GM crops could be a threat to the environment, wildlife and biodiversity. They argue that over time GM crops need more pesticides, not less, because of the development of resistant “superbugs” and “superweeds”. They refer to the potential contamination of native wildlife species, and the danger of extinction of weeds and insects, which might change the balance of nature.” (para 53)

5.19 We are committed to ensuring that GM crops do not damage the environment and accept that some GM crops could pose a risk to the environment. However, it is important to bear in mind that others could offer environmental benefits, such as reduced pesticide use or the replacement of persistent, toxic herbicides with more benign ones. This was demonstrated very clearly by the first set of results from our Farm-Scale Evaluations (see box below). This again underlines the need to consider each crop on a case-by-case basis.

5.20 The risk of adverse effects on the environment is specifically addressed as part of the approvals process for GM crops. The risk assessment looks at a whole range of possible adverse effects, whether direct or indirect, immediate or delayed. ‘Direct effects’ include whether the crop will invade the countryside or be toxic to wildlife, and ‘indirect effects’ issues such as the effect of the associated herbicide use on farmland biodiversity.

5.21 When the FSEs were commissioned there was no requirement for the risk assessment process to address ‘indirect effects’ such as the impact of the

herbicide use associated with GM crops. EU legislation has since been amended to require an assessment of indirect effects, so the onus is now on the biotech companies to provide the evidence needed to enable this assessment to be carried out.

5.22 EU legislation allows conditions to be imposed on marketing consents for GM crops requiring the consent holders to undertake post-market monitoring. This is designed to ensure that any unforeseen adverse effects are picked up quickly so that any necessary remedial action can be taken. Similarly it will enable us to assess whether any claimed environmental benefits are actually being delivered. Indeed, for a number of applications currently being considered by the EU we are insisting on tighter monitoring requirements.

5.23 The science review addressed the main environmental concerns which have been raised in relation to GM crops. It is often argued that cross-pollination between the GM crop and native wildlife species could lead to a loss in biodiversity. The science review concluded that the current generation of GM crops is very unlikely to invade the countryside or be toxic to wildlife. It concluded that for the current generation of GM crops, the most important issue was their potential effect on farmland and wildlife. This has been thoroughly investigated in the Farm Scale Evaluations (see box below).

5.24 The science review considered whether GM crops might lead to the development of pesticide-resistant insects or weeds. It noted that these problems are not unique to GM but can also arise with traditional plant breeding methods. Similarly the use of chemical pesticides can lead to the development of resistant weeds. In conventional agriculture pesticides and herbicides can often become less effective over time. In principle, it is possible to have measures that will delay or limit the possible build-up of resistance to GM pest-resistant crops. For example, farmers might be required to plant 'refuges' of conventional crops to ensure that the target pest population is not exposed exclusively to the resistant GM crops. We will consider whether such measures might be required on a case-by-case basis.

5.25 Another concern about GM herbicide-tolerant crops is the emergence of so-called 'superweeds'. It is argued that if GM crops with different GM traits are grown, these could cross-pollinate with wild relatives to produce weeds which are resistant to a number of different herbicides as a result of 'gene stacking'. The science review concluded that this was a distant future possibility for the UK. If different varieties of the same crop with different GM traits were proposed for commercial cultivation in the EU, the risks and any possible mitigation measures would be considered as part of the approvals process.

The Farm-Scale Evaluations (FSEs)

The Farm-Scale Evaluations (FSEs) were designed to compare the impact on farmland wildlife of growing four GM herbicide-tolerant (GMHT) crops (maize,

beet, and spring- and winter-sown oilseed rape) with growing conventional varieties of the same crops. The trials were conducted over a three-year period by an independent Scientific Steering Committee. The results for the three spring-sown crops were published on 16 October. In broad terms the results suggested that:

- Growing conventional beet and spring oilseed rape was better for many groups of wildlife than growing the GM herbicide-tolerant varieties.
- Growing GM herbicide-tolerant maize was better for many groups of wildlife than growing conventional maize.

It is important to note that the FSEs were effectively measuring the effect of herbicide use. The differences observed do not arise simply because the crops were genetically modified.

The results also showed that the differences between the environmental impact of different crops were bigger than those between conventional and GM varieties. The crop which was best for wildlife was a conventional crop (beet) and the crop which was worst for wildlife was also a conventional crop (maize). So the results raise wider questions about the level of environmental protection which we expect farmers to deliver. Defra will build on the FSE results to address this issue as we develop our policy on sustainable food and farming.

5.26 Although the regulatory system is designed to address known risks to the environment, it cannot entirely exclude the possibility that GM crops could have unforeseen adverse effects. People therefore want to know who will be liable if GM crops cause environmental damage. Ministers already have powers under the Environmental Protection Act 1990 to require companies to take remedial action if they have committed a criminal offence. Similar powers for Northern Ireland are contained in the Genetically Modified Organisms (NI) Order 1991.

5.27 The EU is expected shortly to adopt a Directive on Environmental Liability. The Directive will cover the release and contained use of GMOs, but only in relation to any damage which may be caused to European protected species and natural habitat types. In this context, the relevant biotechnology company may be held liable for damage caused by one of its products. We will consider how the Directive is to be implemented in the UK when the details have been finalised.

5.28 The Agriculture and Environment and Biotechnology Commission (AEBEC) has recommended that the Government should use the general approach of the proposed EC Environmental Liability Directive in developing the UK's liability regime for any damage caused by the release of GMOs into the environment. In addition it recommended that the Environmental Protection Act 1990 should be amended to allow environmental remediation to be ordered by the regulatory authority without the need to first secure a

conviction for an offence. We are currently considering consider the AEBC's recommendations on environmental liability and will respond in due course.

Providing choice

5.29 The risk of “contamination” of non-GM plants and organisms was the concern most frequently raised by participants in the public debate. People are worried that GM crops would destroy freedom of choice for farmers and consumers and would deprive people forever of the chance to choose organic. It is important to bear in mind that GM contamination in this context is not a safety issue. GM crops will not be approved for commercial cultivation unless they are considered safe.

5.30 We do, however, take these concerns seriously, which is why we are committed to providing choice for both consumers and farmers. Mandatory labelling will provide a basis for consumers to make informed decisions, and we will put in place coexistence measures to ensure farmers can choose whichever production method they prefer. Further details are set out below.

5.31 But it is also important to bear in mind that freedom of choice works both ways. Not allowing GM crops to be grown in the UK would deny farmers access to the benefits of a technology which is available to farmers in other countries. While there may be little consumer demand for GM food products at present, consumer attitudes could change if GM foods became available which offered significant benefits (e.g. lower price, extended shelf-life, enhanced nutritional value).

Labelling

“Some people called for a very strict labelling regime, identifying GM products at every stage of the food chain, others claimed that no labelling regime could ever guarantee customers food “uncontaminated” by GM, particularly because of imports from outside the EU, and therefore called for an outright ban on all GM products.”
(paragraph 59)

5.32 We have always supported labelling rules that are practical, proportionate and effective. Current EU legislation already requires any food or food ingredient with an ‘adventitious’ or technically unavoidable GM content of 1% or more – and any deliberate GM content – to be labelled accordingly, and requires GMOs to be traced throughout the supply chain. The rules will be further tightened in April when new EU regulations on Traceability and Labelling and on GM Food and Feed will become fully operational in the UK. Under the new rules:

- the labelling threshold for ‘adventitious’ or technically unavoidable GM content will be reduced to 0.9% for GMOs approved in the EU;

- a lower threshold of 0.5% will apply to GMOs which have been assessed as safe but which are still awaiting final approval in the EU;
- labelling will be extended to include any food ingredient that is derived from a GM product, even if it does not have any detectable GM content (e.g. highly refined oils);
- labelling will be extended to animal feed.

5.33 The labelling thresholds recognise that because we live in a world where GM crops are already widely grown, it would be difficult to try and avoid very low levels of GM presence. More generally, it is normal within agriculture to operate a pragmatic tolerance for perceived impurities. This already happens, for example, in seed production and in organic production.

5.34 We will shortly be consulting stakeholders on the implementation of the new EC regulations in the UK. The European Commission is required to review the operation of the regulations by 2006.

Coexistence of GM and non-GM crops

5.35 Consumers want to continue to be able to choose conventional and organic products if GM crops are grown commercially in the UK, and farmers must be able to maintain different production methods, so that they can respond to consumer demand. We therefore intend to take steps to facilitate the coexistence of GM, conventional and organic crops. In this context we have given careful consideration to the AEBC's report 'GM Crops? Coexistence and Liability', which was published in November 2003, and to the European Commission's guidance to member states.

5.36 It is important to keep the immediate challenge in perspective. The Strategy Unit's cost and benefits study concluded that the current generation of GM crops may offer limited benefits to UK farmers, and that negative consumer attitudes will limit take-up. The only crop which might secure approval in time for commercial sowing in spring 2005 is a GM herbicide-tolerant fodder maize (which is used only for animal feed). There is currently very little organic cultivation of these crops in the UK.

5.37 We fully accept that arrangements do need to be put in place to facilitate the coexistence of GM and non-GM crops. These arrangements should:

- facilitate consumer choice, while recognising that all farmers are free to choose their method of production (conventional, organic or GM);
- be determined on a crop-by-crop basis;
- be practical, proportionate, effective and equitable;
- build on existing experience or arrangements as far as possible.

5.38 If and when GM crops are grown commercially, we agree with the AEBC's recommendation that there should be a **carefully managed**

introductory period. This will enable us to monitor the effectiveness of coexistence measures and amend them as necessary to achieve the required threshold(s). It will also allow us to assess what levels of GM adventitious presence are achievable in practice on a crop-by-crop basis in a commercial farming context.

5.39 We believe it is reasonable to expect GM farmers to bear the main responsibility for implementing measures to minimise GM presence in non-GM crops. We envisage that **these measures should have statutory backing**, and are likely to include a requirement to notify neighbouring farmers, separation distances between crops, the control of crop weeds and the cleaning of farm machinery. It should be designed to ensure that non-GM farmers do not have to label their produce as 'GM' under EU labelling rules, which require food and feed with an unavoidable GM content above 0.9% to be labelled. We expect all farmers to co-operate with their neighbours to identify the most pragmatic and effective solutions. The key to this will be discussion and agreement on respective cropping plans, so that any necessary separation between crops can be achieved without imposing a significant burden on either party.

5.40 The AEBC was unable to agree on whether coexistence arrangements should also be designed to deliver a 0.1% threshold for organic produce. **We will explore further with stakeholders whether a threshold lower than 0.9% could be reliably delivered at reasonable cost on a crop-by-crop basis.** The introductory period should also provide helpful data in this regard. The European organic farming regulation allows for the setting of a specific threshold for the unavoidable presence of GMOs in organic produce, but no threshold has been set. The European Commission has issued guidance to member states which states that in the absence of such a specific threshold, the general thresholds apply.

5.41 We will consult stakeholders on options for providing **compensation** to non-GM farmers who suffer financial loss through no fault of their own as a result of their produce having a GM presence exceeding statutory thresholds. Any compensation scheme would need to be funded by the GM crops industry, rather than by Government or producers of non-GM crops. This would provide a further incentive for the biotech companies to ensure that coexistence arrangements are effective and that farmers comply with them.

5.42 We are aware that some farmers are interested in establishing **GM-free zones**, in which there is no commercial cultivation of GM crops. The European Commission has confirmed that mandatory GM-free zones would not be compatible with EU legislation, but that voluntary arrangements are allowed. We will therefore provide guidance to those farmers who are interested in establishing voluntary GM-free zones in their areas.

5.43 We remain committed to helping to secure the success of organic farming. Our approach to GM crops is compatible with our support for the Organic Farming Action Plan, which aims to increase the share of the UK organic food market that is supplied by UK producers from 30% to 70% by

2010. A similar target is contained in the Scottish Executive's Organic Action Plan, which aims to see Scottish organic produce meet at least 70% by value of consumer demand. Defra has already made available considerable sums of money in support for farmers converting to organic farming and has made a further £140 million available under the Organic Farming Scheme (part of the England Rural Development Programme), which we expect will triple the area under organic management by 2006. Similar support has also been provided for organic farmers in Scotland, Wales and Northern Ireland. Defra is also providing other support, for example through the Department's Research & Development programme, which includes a large component dealing with research on organic farming, and through the provision of free advice to prospective organic farmers. This activity is mirrored in the support provided in the Devolved Administrations.

Providing information

"In all parts of the debate, both from active participants and the Narrow-But-Deep sample, people expressed a very strong wish – almost a longing – to be better informed about GM from sources they could trust. They wish to be able to resolve for themselves the contradictions and disputes, claims and counter-claims, in the existing body of information, science and research on GM issues. They want a corpus of agreed "facts", accepted by all organisations and interests. They also want confidence in the independence and integrity of information about GM – the assurance that it does not reflect the influence of any group with a special interest for or against GM (including government and business). There was a general feeling that no one knows enough at the moment and that much more research is necessary."

5.44 We accept that one of the key challenges facing Government – and other stakeholders - is to improve the provision of information on GM crops and food to the public. While the debate has helped to raise awareness of the issues, it has been generally acknowledged, including by the Public Debate Steering Board, that the information material which was provided to participants in the debate was disappointing. It is probably unrealistic to expect that it would be possible to agree a corpus of "facts" which would be accepted by all organisations and interests.

5.45 We will consider how we can best meet the public's demand for information about GM. We will seek to ensure that the information provided by Government is useful and accessible. The Food Standards Agency has introduced a series of new features to its website [www.food.gov.uk] to provide an explanation of genetic modification and its history. It also explains how GM food is regulated to ensure that it is safe. Defra's own website [www.defra.gov.uk] has also been recently improved to make it easier to find information on GM crops policy and EU assessment procedures, as has the Scottish Executive's [www.scotland.gov.uk]. They also provide access to the procedures for the EU-wide public consultation on every application to import

or cultivate GM crops. Information is also available through DTI's i-Bio portal [www.i-bio.gov.uk].

5.46 We will publish in full on Defra's website final reports of all research projects commissioned by Defra to underpin the GM regulatory regime, together with summaries for the non-specialist. We will also publish a clear and comprehensible guide to the new regulatory regime and the EU assessment process.

Openness and transparency

5.47 We will seek to address this by being as open and transparent as possible about the way we make decisions on GM crops and food, and about the degree of scientific uncertainty and risk involved.

5.48 The EU regulatory framework has been improved to provide for mandatory public consultation on each application. The European Commission is responsible for making the relevant information available to the public and for forwarding any comments to the member states. But in order to facilitate the consultation process all new applications are published on Defra's website, and members of the public can ask to be alerted whenever a new application is notified. We will also consider all reasonable requests to make available full copies of application dossiers, with the exception of any commercially confidential material.

5.49 Each application is referred to our independent advisory bodies as appropriate, each of which is composed of leading scientific experts:

- the Advisory Committee on Releases to the Environment (ACRE) is a statutory body whose main function is to give advice to Ministers in the UK Government and the Devolved Administrations on the risks to human health and the environment from the release and marketing of GMOs.
- the Advisory Committee on Novel Foods and Processes (ACNFP) is a non-statutory body whose main function is give advice to the Food Standards Agency on any matters relating to novel foods (including genetically modified foods) and novel processes (including food irradiation). The Committee carries out safety assessments of any novel food or process submitted for approval under the EC Novel Food Regulation.

5.50 The criteria which ACRE and ACNFP use to assess applications are set out in the relevant EU legislation. Both ACRE and ACNFP publish the reports of their evaluations and the minutes of their meetings, as well as annual reports on their work, though their meetings are not usually open to the public. ACRE held two open meetings to take evidence from experts and stakeholders on the results of the Farm-Scale Evaluations. ACRE will in future hold regular open meetings to consider general issues related to the

release of GMOs into the environment. The ACNFP holds an annual open meeting to consider general issues in relation to GM food safety.

5.51 In addition to the scientific advisory bodies, the Agriculture and Environment Biotechnology Commission provides independent, strategic-level advice, taking ethical and social issues into account as well as the science. The Commission, which meets in public and makes all its paperwork publicly available, is made up of members with a wide range of skills and expertise, representing all sides of the stakeholder community.

Gaps in scientific knowledge and further research

5.52 The Science Review identified a number of gaps in knowledge in a range of areas. This is not a surprise and is an inevitable consequence of the nature of science. Science proceeds by constantly refining and updating the consensus view, and the generation of questions is at least as important and central to the process as the generation of answers. As a result it is very likely that as more detailed scientific scrutiny of a particular subject takes place new areas of uncertainty will be exposed. As the Science Review acknowledges, we cannot know everything and if we are paralysed by gaps in knowledge we would never get anywhere new.

5.53 From the perspective of regulation the key issue is to assess the importance of gaps in knowledge and uncertainty in the framework of the risk assessment process. As the Review states, risk is a product of hazard, i.e. actual or potential harm, and the likelihood of exposure to that hazard. While we recognise that the boundaries between hazard and risk are not always clear – the Science Review itself blurs these concepts in places – the risk assessment approach allows for uncertainty to be dealt with and managed.

5.54 An example serves to illustrate this point. The Science review concludes that there is uncertainty in the extent to which DNA from crop plants may transfer to micro-organisms in the soil. The uncertainty is particularly acute with respect to micro-organisms other than bacteria. But the uncertainty here can be dealt with by taking a precautionary approach and assuming that such transfer of DNA does occur. The decision as to whether this represents a risk depends on the nature of genes that might be transferred (i.e. the hazard) – if there is clear evidence that particular genes do not pose a hazard following transfer to soil micro-organisms then it is possible to conclude that risk is low, even in the face of uncertainty concerning the rate at which such transfer occurs. If, on the contrary, there is evidence that gene transfer may be harmful or at least some uncertainty concerning this point, then it cannot be concluded that the risk is low.

5.55 The main gaps in scientific knowledge identified by the Science Review which may be relevant to safety and risk assessment, and our response to them, are listed in Annex 2.

Keeping pace with the technology

5.56 As well as endorsing the case by case approach to the regulation of GMOs, the Science Review also stresses that it is important for the regulatory regime to keep pace with the development of the technology. We fully accept this conclusion.

5.57 The legislative framework for GMOs has been continuously evolving over the last decade, and it will continue to do so as the technology develops. But as well as modifications to the legislation, it is central that scientific knowledge and expertise is continually extended, so that new developments can be anticipated and prepared for. We need a regulatory system that is proactive not reactive. Government is committed to continuing its funding of research to underpin risk assessment of GMOs. It is also important to bear in mind the global perspective in the development of GMOs. Whatever the rate of deployment of GM technology in the UK, the nature of international trade and the rate of deployment overseas will mean that we need an effective regulatory system here.

5.58 A key part of delivering an effective regulatory regime for the future is horizon scanning – the systematic examination of potential threats, opportunities and likely future developments which are at the margins of current thinking and planning. Horizon scanning may explore novel and unexpected issues, as well as persistent problems or trends. This is a central part of Defra's Science and Innovation Strategy, and will continue to play an important role in the area of GM technology.

Developing countries

“In all parts of the debate, there was at least an initial assumption that GM technology might help developing countries produce more food and offer them medical, social and economic benefits. There was then a clear divergence between the views of active participants in the debate and those expressed in the Narrow-But-Deep sample. The former rejected, by a majority, the idea that GM technology would benefit developing countries: the latter supported it, and their support slightly increased after people got more engaged in GM issues.”

5.59 We believe that GM crop technology has the potential to provide benefits to developing countries, but that it is for developing countries to make their own informed decisions on whether or not to import or adopt GM crops, taking account of the views of their own citizens. We fully accept that GM crop technology in itself will not solve the problem of world hunger. But it could be used safely and effectively to promote development and reduce poverty, if managed responsibly and applied to those crops on which the poor rely.

5.60 There is evidence of rapid take-up of some GM crops in developing countries, where they are commercially available. In 2003 almost one third of

global production of GM crops was in developing countries, and the area under cultivation is growing faster in developing countries than in industrialised countries. Of the six countries responsible for growing 99% of GM crops by area, four were developing countries: Argentina (21%), Brazil (4%), China (4%) and South Africa (1%). Almost all of Argentina's soybean production is now GM, while GM cotton now accounts for 58% of China's total cotton area.¹

5.61 The UK supports and has ratified the Cartagena Protocol on Biosafety, a multilateral environmental agreement which provides a common global basis for risk assessment, decision-making and information exchange on GM crops and other products. This will enable all countries of the world to make informed choices about GM crop technology and about the import and export of GMOs. It provides a safety net for the protection of biodiversity in developing countries that do not have the necessary systems and capacity in place to manage trade in GMOs. With its strong precautionary approach, it will help to ensure that developing countries are not disadvantaged by the development of GM technologies. The Protocol's Biosafety Safety Clearing House will serve as a global source of risk assessment information about GMOs, enabling all countries of the world to take informed decisions on imports of GM products on the same basis.

No need for GM crops?

"The third common line of argument against the introduction of GM crops is that they offer no benefits for the United Kingdom" (paragraph 52).

5.62 We fully accept the Strategy Unit's conclusion that the current generation of herbicide-tolerant and insect-resistant GM crops may be of limited economic value to the UK, particularly given current negative consumer attitudes towards GM crops. However, the Strategy Unit also pointed out that future developments in GM crops have the potential to offer more wide-ranging benefits to farmers and to consumers. Possibilities include GM crops with agronomic benefits more suited to the UK, GM crops delivering direct health benefits (for example, delivering foods with reduced allergenicity or added nutrients), or non-food GM crops used as a source of pharmaceuticals and vaccines.

5.63 Case-by-case regulation will enable UK farmers and consumers to benefit from future developments in GM crop technology, if they so choose. At the moment we do not have a clear view of what this technology may achieve because it is still at a relatively early stage of development. While GM carries potential risks it also has the potential to deliver benefits if used wisely, and it may be possible to do things with GM crops that are not possible, or very difficult to achieve, by other means. We believe we should keep an open mind and allow the technology to develop within a strict

¹ Source: ISAAA, *Global Status of Commercialized Transgenic Crops: 2003*

regulatory system that is designed to protect human health and the environment while providing choice. Ultimately the market will decide whether GM crops are a success or not. If farmers and consumers do not see the benefits of GM crops and GM foods, then they will not grow or buy them.

Ethical issues

“GM technology attracts resistance from people because it is owned and promoted by multi-national companies whose power, profits and motives they find objectionable... People suggest that these companies are using their ownership of GM technology to secure monopoly control within the food chain, to reduce farmers to dependency, especially in developing countries, and to gain control over consumers and even governments.”

(paragraph 55).

“There is also a cluster of arguments which challenge GM on a different moral plane...Some of these arguments are religious: GM (especially trans-species GM) interferes with the Creation. More frequently, people suggest that the human species has no right to use GM technology to alter the course of nature and that the present generation has no right to make irreversible changes in the world environment for future generations.” (paragraph 56).

5.64 As a society we have to make judgments about the ethical issues raised by new technologies like GM. Our current view is that the responsible development of GM crop technology could offer significant potential benefits in the UK and globally, including to developing countries. EU legislation acknowledges that member states may take ethical issues into consideration. Directive 2001/18 on the deliberate release allows either the European Commission or member states to consult its advisory committees on ethical issues. It also requires the Commission to submit regular reports to the Council on ethical issues and, if appropriate, propose amendments to the Directive. As no decisions have yet been taken to approve any GMOs under Directive 2001/18, it would be premature to consider further amendments to the Directive at the current time.

5.65 Although some people may be uneasy about the role of multi-national companies in developing and promoting GM crop technology, we believe the appropriate response is to ensure that the technology is effectively regulated to protect the public interest. The Cartagena Protocol provides a common framework for decision-making on GMOs, and will help developing countries to make their own informed decisions. The Nuffield Council on Bioethics, in its recent report on the use of GM crops in developing countries, concluded that ‘there is an ethical obligation to explore these potential benefits responsibly, in order to contribute to the reduction of poverty, and to improve food security and profitable agriculture in developing countries.’

5.66 Some people have expressed fears that sterile seed (or ‘terminator’) technology could be used to lock poor farmers into a cycle of dependence on agribusiness. The UK has taken a cautious line with respect to applications of these technologies that might disadvantage poor farmers. This reflects decisions taken by the Parties to the Convention on Biological Diversity in Nairobi in May 2000. We support a strict, case-by-case, precautionary approach to control the field testing and commercial development of terminator technologies.

5.67 Other concerns over the role of biotechnology companies relate to the use of intellectual property rights such as patents. As noted above, our current view is that responsible development of GM technology could offer significant potential benefits in the UK and globally. Intellectual property rights have a significant role to play in acting as a stimulus to research and innovation in this area. Exceptions to IPRs are provided in EU law to provide safeguards for farmers, for example by allowing the saving of patented seed for replanting in some circumstances.

Annex 1- The EU regulatory regime for GMOs

1. In April 2004 an enhanced regulatory framework is due to come into full effect in the EU. This will complete the implementation of the principles that:
 - the commercial importation, cultivation or use as food of a GMO is prohibited without EU consent;
 - decisions are made on the basis of a case-by-case risk assessment based on sound scientific evidence to avoid adverse effects on human health and the environment; and
 - consumers should be able to make an informed choice through product labelling.
2. The new regulatory regime consists of three main pieces of legislation. These are the EC Directive on the Deliberate Release of GMOs into the Environment, which is already in force, and new Regulations on Traceability and Labelling of GM products and on GM Food and Feed, both of which will be fully in force on 18 April 2004.
3. The **Deliberate Release Directive [2001/18/EC]** introduced a number of improvements. One of these was the explicit requirement for each application to include an environmental risk assessment to cover indirect and long-term effects of GMOs (e.g. on biodiversity) as well as direct effects. Another important change was the introduction of a requirement for a post-market monitoring plan. This allows the EU to assess applicants' proposals for surveillance and reporting any unanticipated adverse effects.
4. Under the new **GM Food and Feed Regulation [1829/2003/EC]** the safety assessments of GM food and animal feed will be led by the European Food Safety Authority (EFSA), although Member States will still be involved in assessment and reaching decisions. At the beginning of the process, applications will be sent to the national competent authority of a member state, which will forward the information to EFSA. EFSA will then inform the other Member States and the Commission of the application and make the information from the applicant available to them. A summary of the dossier will be made publicly available.
5. Under the next stage, EFSA and its scientific committees may carry out the entire assessment procedure or may ask for assistance from the appropriate food or feed assessment body of a member state or the designated competent authority under the Deliberate Release Directive.

6. Where authorisation is requested for environmental release in addition to food and feed, EFSA must consult the national competent authorities designated under the Deliberate Release Directive [Defra in the UK]. The competent authorities will have 3 months to inform EFSA of their opinions.
7. EFSA will endeavour to reach an opinion on an application within 6 months unless supplementary information needs to be requested from the applicant. EFSA will forward its initial opinion to the Commission, Member States and the applicant. This will include a report describing its assessment, the reasons for its opinion and the information on which the opinion is based, and the opinions of the competent authorities under Directive 2001/18/EC. The opinion minus any commercial in confidence information will be made public. The public then have a further 30 days to send in comments to the Commission, who have a further two months to submit a draft decision to the Standing Committee on the Food Chain and Animal Health, upon which all Member States are represented. If the Committee does not reach agreement, the decision will be sent for discussion at Council of Ministers. If the Council fails to act, the final decision rests with the Commission, acting on the basis of the advice from EFSA.
8. The Food Standards Agency will be the competent authority for the GM food and feed regulation in the UK. In considering the food and feed aspects of the dossier submitted in support of an application for authorisation and EFSA's opinion, the FSA will take advice from its scientific advisory committees, the Advisory Committee on Novel Foods and Processes (ACNFP) and the Advisory Committee on Animal Feedingstuffs (ACAF). Where applicable, the FSA will forward sections of the dossier specifically relevant to the environmental release of the GMO and the opinions of the relevant competent authorities to Defra for advice. Defra will seek advice from its scientific advisory committee, the Advisory Committee on Releases into the Environment, and consult the Devolved Administrations.
9. Defra and the Devolved Administrations will retain responsibility for licensing research trials of GM crops and the commercial importation or cultivation of non-food GM crops. These will continue to be processed under the Deliberate Release Directive.
10. The third strand of the new regulatory regime is the new **Traceability and Labelling Regulation** [1830/2003/EC]. This extends the requirements for traceability and labelling to GM products to include those which are derived from GMOs, such as oil, even if the product does not contain any genetically modified protein. It also reduces the labelling threshold, so that products in which 0.9% of any one ingredient is from an approved GMOs must be labelled, however small a part that ingredient is overall.

11. New regulations have also been introduced for the export of GM products out of the EU. This completes EU implementation of the Biosafety Protocol, by requiring, for the first time, exporters of GM products from the EU to notify third countries and follow consistent procedures. This will help enable developing countries to take decisions about imports of GMOs on same basis as developed countries.

Seeds and Pesticides Legislation

12. In addition to satisfying the requirements of the GM regulatory system, GM crops for commercial cultivation will also continue to require approval under seeds legislation and, where appropriate, pesticides legislation.
13. EC Directives [2002/53 and 2002/55] require that before seeds of the main agricultural and vegetable species can be marketed, they must be on a Member State's National List. This means that they must be shown in official growing trials to be:
 - distinct, uniform and stable (DUS), i.e. a new variety that is produced consistently; and, for agricultural species, but not vegetables
 - have a value for cultivation and use (VCU) in the Member State, i.e. offers agronomic improvements as a crop or in the uses to which it can be put.
14. Candidate varieties are tested to establish whether they meet the necessary standards. If they do, a proposed decision to add the variety to the UK National List is published. In the case of GM varieties, the appropriate GM approvals must be in place before this happens. Once added to the National List, varieties can be marketed freely – though there are provisions in National List and GM legislation which would prohibit marketing if, in a GM context, there is new evidence of harm to human health or the environment. Varieties added to a Member State's National List are usually added automatically to the EC Common Catalogue. Once on the catalogue, Member States must not restrict marketing in their territory, unless they impose a marketing prohibition notice which must be justified (after the event) in Brussels. The European Commission is also developing proposals for amending the Seeds Directives to introduce labelling thresholds for the adventitious presence of approved GMOs in non-GM seed.
15. The principal aim of pesticide regulation is to protect the health of human beings, creatures and plants and to safeguard the environment. Plant protection products (broadly agricultural pesticides) are covered by Directive 91/414/EEC. This Directive covers all products first placed on the market after 25 July 1993 and also provides for a review programme for products on the market before this date. Evaluations are based on an scientific and technical assessment of the application. In seeking any extension of approval of a pesticide to include GM crops, the necessary safety and efficacy data would have to be supplied by the applicant. Defra would then evaluate the application against the considerations of human

and environmental safety, which have been established for all pesticide uses. This would take account, for example, of the effects on the environment and residues from spraying the crop at a different time of year and the different residues that might arise due to novel metabolism produced by the GM crop. Statutory conditions, such as maximum dose rates and the maximum number of applications, are attached to pesticide approvals to ensure safety in use of that pesticide. The Advisory Committee on Pesticides provides independent statutory advice to ministers on pesticides approvals.

Annex 2 – Gaps in knowledge and areas of uncertainty identified by the Science Review

How Reliable is GM Plant Breeding?

Issues identified	Government response
Genetic interactions associated with the presence of multiple gene constructs in the same plant.	There is no evidence that such genetic interactions represent a particular hazard. Each combination of transformation events is separately analysed prior to any approval, and this assessment includes a consideration of potential interactions between GM events.
Mechanisms of genome evolution and induction of new variation within the genome.	There is no evidence that stably inherited GM events are any more likely to undergo changes than any other DNA. The Government accepts that it is important to continue with fundamental research concerned with evolution and operation of genomes, and that this fundamental research may have implications for risk assessment in the future.
Mechanisms of gene silencing – the inactivation of genes introduced by GM methods.	For the current generation of GMOs gene silencing of the transferred genes will simply lead to the loss of novel traits. However, in the future there may be GMOs where avoidance of gene silencing may be important for risk management (e.g. approaches to the reduction of allergens or toxins). These will be assessed on a case-by-case basis.
Detecting unexpected biochemical consequences of GM; use of molecular profiling techniques	Applications for marketing of GMOs already include considerable data on biochemical composition. It is important to assess this data against the background of natural variation in composition of foods and crops. The Government accepts the need to explore the use of new and emerging techniques such as molecular profiling to detect unexpected differences at the molecular and biochemical level. The Food Standards Agency (FSA) is funding a research programme, which is looking specifically at the use of profiling techniques and their potential use in refining the current safety assessment for the next generation of GM crops. This three-year programme will be completed in early 2005.

GM Derived Food and Animal Feed Safety

Issues identified	Government response
<p>Defining characteristics that can cause an allergic response from eating certain foods.</p>	<p>All foods derived from a GM source undergo a rigorous safety assessment before they are authorised for food use. The potential allergenicity of such foods is considered as part of this assessment. The assessment of allergenicity of GM foods follows internationally accepted guidelines and it is notable that there are no documented cases of allergies ascribable to GM foods. We accept that this is an important area that merits further fundamental research, not only from the perspective of GM foods, but also from the point of view of other novel foods. The FSA funds an extensive research programme which addresses the causes and mechanisms underlying food allergy and intolerance.</p>
<p>The fate of transgenic DNA in the human and animal diet, including the extent of trans-kingdom gene transfer from plant material to gastro-intestinal bacteria in humans and animals.</p>	<p>All GM crops undergo a rigorous safety assessment before authorisation is given for use in food or as animal feed. This includes an assessment of the characteristics of the introduced gene and its resulting protein and the safety implications regarding their consumption. The current regulatory system ensures that the introduced DNA is fully characterised and assessed for safety. DNA however is consumed as part of a normal diet. There is no evidence to date to suggest that introduced/ transgenic DNA behaves any differently to native DNA. There is limited direct investigation of gene transfer to gut bacteria so a lack of evidence is not surprising. The FSA and other organisations have funded projects which have addressed the survival of DNA in the gastrointestinal tract and the potential for horizontal gene transfer. DNA is degraded, although not completely, as it passes through the gastrointestinal tract and the risk of transfer of transgenic DNA to bacteria present in the gastrointestinal tract is extremely low.</p>

Issues identified	Government response
Use of molecular profiling techniques in food and feed safety assessment	Applications for marketing of GMOs already include considerable data on biochemical composition. It is important to assess this data against the background of natural variation in composition of foods and crops. The Government accepts the need to explore the use of new and emerging techniques such as molecular profiling to detect unexpected differences at the molecular and biochemical level. The FSA is funding a research programme, which is looking specifically at the use of profiling techniques and their potential use in refining the current safety assessment for the next generation of GM crops. This three-year programme will be completed in early 2005.

Environmental Impacts of GM Crops

Issues identified	Government response
Relationship between life history and stress tolerance traits and fitness and invasiveness in plants. Consequences of gene flow to non-crop relatives.	For the current generation of GM crops there is good evidence that the traits do not confer enhanced fitness or invasiveness outside the agricultural environment. However, as new traits are introduced it will be important to consider their potential implications on a case-by-case basis. This is an important area of future research and we will fund further work in this area.
Protocols for testing the impacts of GM crops on non-target species.	The impact of GM crops on non-target organisms forms an important part of current risk assessment procedures. The validity of data in support of this is assessed on a case by case basis. The current regulatory system takes into account the issue of non-target effects but internationally accepted standards may be helpful to regulators and applicants.

Issues identified	Government response
<p>Fate of <i>Bt</i> and other toxins in the environment, and especially their effect on non-target species and in the soil.</p> <p>Impact on biodiversity of the use of GM pest resistant crops in an agricultural ecosystem.</p>	<p>Current GM insect resistance technologies are not applicable to major insect pests in UK agriculture. However it is important that as novel insect resistance strategies are developed (e.g. to sap feeding insects) that the implications are fully assessed. Monitoring following any introduction of pest resistant crops has an important role to play.</p> <p>We have already commissioned a review of evidence concerning the fate of <i>Bt</i> toxins in the soil and this will be published shortly. The Advisory Committee on Releases to the Environment (ACRE) have identified soil ecology as an important area for further study. ACRE set up a sub group in 2003 which has published an interim report (available at http://www.defra.gov.uk/environment/acre/soilecology/index.htm). Following this, a Defra-funded research project is examining in detail current understanding of soil ecology. This project is expected to report during 2004, at which point ACRE will issue advice concerning further research needs.</p> <p>The extent to which large scale impact assessment is required for pest resistant crops will be determined on a case-by-case basis. The Farm Scale Evaluations of herbicide-tolerant crops will provide important information underpinning any future impact assessment.</p>
<p>The effectiveness of the refuge strategies for reduction in the rate of development of target resistance following the introduction of pest resistant crops.</p>	<p>Target resistance management is partly a matter for the developers of GM pest resistant crops. These issues apply equally to traditional chemical based pest control approaches, and there is a considerable body of theoretical evidence that allows the design of refuge strategies. Monitoring will allow the effectiveness of these strategies to be evaluated following any introduction of pest resistant crops. There are already monitoring programmes in place accompanying the introduction of <i>Bt</i> crops in Spain.</p>

Issues identified	Government response
<p>Impact of the use of broad spectrum herbicides that is associated with the cultivation of herbicide tolerant crops, including the implications throughout rotations and on higher trophic levels (e.g. farmland birds). General information on farmland ecology.</p>	<p>Consideration of indirect effects, such as the effects of weed management strategies associated with herbicide tolerant crops is a central part of the assessment of applications for commercial cultivation of crops. The Government funded the Farm Scale Evaluations of herbicide tolerant GM crops in order to address some of these gaps on knowledge. The first set of results of these studies, some of the largest ever on the agricultural ecosystem, were published in October 2003, and further data will be published during 2004. In addition to the FSEs Defra has funded research aimed at using the data generated in order to predict the implications of the widespread cultivation of GMHT crops on wider biodiversity. The Government welcomes the endorsement of the FSEs contained in the second report of the Science Review panel.</p>
<p>Impacts of GM crops, especially those modified for fungal or bacterial disease resistance, have on soil organisms and processes.</p>	<p>Current evidence suggests that soil processes and populations of soil organisms are affected by a range of agricultural practices, and that the impact of the current generation of GM crops is small in comparison. It will be important to evaluate new types of GM crop on a case-by-case basis. ACRE have identified soil ecology as an important area for further study. ACRE set up a sub group in 2003 which has published an interim report (available at http://www.defra.gov.uk/environment/acre/soilecology/index.htm). Following this, a Defra-funded research project is examining in detail current understanding of soil ecology. This project is expected to report during 2004, at which point ACRE will issue advice concerning further research needs.</p>

Gene Flow, Detection And Impact of GM Crops

Issues identified	Government response
Uncertainties about the rate of gene flow between organisms (specific areas of uncertainty are covered below).	Gene flow is not a risk <i>per se</i> as it only represents the 'exposure' component of the risk equation. If the hazards associated with particular genes are known, it is possible to carry out a robust risk assessment of the consequences of gene flow by assuming that there are high rates of gene transfer .
Long distance gene flow from crop to crop or from crop to sexually compatible wild relative.	Recent Defra-funded work has examined long distance gene flow between oilseed rape crops, and work in progress is further examining hybridisation frequencies between maize crops.
Knowledge and understanding of soil ecosystems, including the rate of DNA transfer between plants and soil micro-organisms.	ACRE have identified soil ecology as an important area for further study. ACRE set up a sub group in 2003 which has published an interim report (available at http://www.defra.gov.uk/environment/acre/soilecology/index.htm). Following this a Defra-funded research project is examining in detail current understanding of soil ecology. This project is expected to report during 2004, at which point ACRE will issue advice concerning further research needs. In the meantime we accept that gene flow between plants and fungi in the soil is an important area of uncertainty and will fund research in the near future to address this.