GM SCIENCE REVIEW

FIRST REPORT

An open review of the science relevant to GM crops and food based on the interests and concerns of the public

PREPARED BY THE GM SCIENCE REVIEW PANEL (JULY 2003)

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Foreword by Professor Sir David King, Government Chief Scientific Adviser

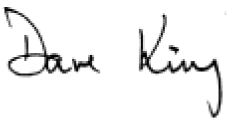
The GM Science Review was commissioned as part of the wider GM public dialogue by Mrs Margaret Beckett, the Secretary of State for the Environment, Food and Rural Affairs; with the agreement of the responsible Ministers in the devolved administrations. This report has therefore now been formally submitted to Mrs Margaret Beckett MP, Mr Allan Wilson MSP at the Scottish Executive, and Mr Carwyn Jones AM at the National Assembly for Wales to help inform Government decision making on GM crops and food.

The Review has endeavoured to take an open look at the science relevant to GM crops and food, and to do so in a way that recognises the interests and concerns of the public as well as the science community. So I am sure this report will be of widespread interest. **The Review Panel invites and welcomes your comments on the report. Over the Summer, our Review website[1] will be open to receive them. We also continue to welcome scientific contributions to the website. All contributions must be submitted by 15 October 2003**.

The Panel will then reconvene in late Autumn to consider these comments together with the report of the GM public debate “GM Nation?[2]”. In the light of these, we will wish to consider whether there are any further issues we should address. We will also look to see if there have been significant developments in GM science over the summer that we should report on, and will consider the results of the farm scale evaluations of GM crops if these are available.

Those who attended our open Panel meetings will know that the Panel members cover a wide range of expertise and of views on GM. I would like to pay tribute to all those members who have given real commitment to the Review, expending a great deal of time and working extremely hard and cooperatively to ensure that the issues we have considered have been fully explored. Whilst respecting differences in views and recognising that Panel members do not individually cover all the areas of expertise, I am pleased to say that a really good degree of consensus was reached on the basis of the available science and that the Panel has collectively taken ownership of the review.

Finally, on behalf of the Panel, I would also like to thank all those who spoke at our open meetings around the country, those who hosted them and, of course, those who came along and took part. Our thanks go to the British Association for the Advancement of Science for organising this series of open meetings, as well as the Royal Society and the Royal Society of Edinburgh. We would particularly thank all those who contributed to the website; we have sought to take account of your submissions. We have also valued our contacts with the those running the public debate and with the Prime Minister’s Strategy Unit who have produced the report on the costs and benefits of GM crops and food[3]. We are grateful to the Food Standards Agency and their advisory committees for their comments. And I am sure that the Panel would wish to acknowledge the dedication of the Secretariat, whose members have laboured mightily to bring this First Report to print.



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[1] http://www.gmsciencedebate.org.uk For guidance on how to submit comments.
[2] http://www.gmnation.org.uk
[3] Fieldwork: Weighing up the Costs and Benefits of GM Crops. http://www.strategy.gov.uk

Members of the Panel

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EXECUTIVE SUMMARY

BACKGROUND

Ever since the beginnings of agriculture, some ten thousand years ago, people have been selecting plants to develop into new crops. We now know that the process of plant breeding builds on changes brought about in a plant's genetic structure, with the information being encoded by genes (typically some 30,000 genes in each plant cell). Since the 1970s, it has become possible to modify the genetic information of living organisms in a new way, by transferring one or more gene-sized pieces of DNA directly between them. Such transfers have become an everyday tool in biological research and are already the basis of a considerable number of commercial applications in drug and food development that involve the genetic modification of micro-organisms such as yeast and bacteria. When applied to the production of crop plants, genetic modification can involve gene transfer from another plant species, or from a completely different organism such as a bacterium or virus. The process shares some common features with earlier plant breeding tools, as well as exhibiting unique differences.

World-wide, genetically modified (GM) crops occupy a relatively small proportion of the world's agricultural acreage. However, in 2002, GM crops were cultivated on some 59 million hectares globally. Almost all (99%) of this was grown in only four countries: USA (66%), Argentina (23%), Canada (6%) and China (4%). Three crops comprise 95% of the land under GM cultivation: soybean (62%), maize (21%) and cotton (12%). Traits achieved by genetic modification primarily involve herbicide tolerance (75%) and insect pest resistance (15%), or a combination of both in the same crop.

No GM crops are currently grown commercially in the UK although they are grown to a limited extent in some EU countries. There are, though, GM foods and animal feeds approved for consumption in the EU and these include processed products from GM herbicide tolerant soybean and maize, and oil from GM oilseed rape. Tomato paste made from slow-ripening GM tomatoes is approved but is not currently available, although it was widely sold in the UK in the late 1990s. Products made from GM micro-organisms are widely used in some sectors of the food industry (e.g. as a processing aid in cheese manufacture) and in medicine. However, the issues surrounding GM micro-organisms are not included in this science review which focuses specifically on GM crops and their products.

THE SCIENCE REVIEW

Many claims have been made about potential benefits available from GM crops. At the same time considerable reservations and concerns have been expressed. This review specifically addresses the science surrounding GM crops, with a focus on topics shaped by public questions and concerns. It differs from standard scientific reviews in its attempts to engage with the public and explore different viewpoints. For instance, the remit for the review mandated that the work be 'driven' by public interests and concerns and that deliberate attention be given to 'divergences of view among scientists' and 'uncertainties, unknowns and gaps in knowledge'. Through a series of public workshops and meetings and through a website, we have solicited and considered concerns and interests of the public, whether or not professionally involved in science, agriculture or the food industry.

The review does not aim to be exhaustive in surveying all that is known scientifically about the various GM crops that have been developed to date. However, the review does aim to cover those areas where there is evident public concern. As a result of the public consultation exercise and input from the panel itself, seventeen topics were chosen for detailed analysis. In each case, the topic was considered within a framework that aimed to: (1) summarise the range, quality and degree of agreement of scientific studies that have investigated the issues; (2) ask whether the topic is unique to the processes and products of genetic modification or whether there are commonalities with crops bred conventionally; and (3) ask whether there are important scientific uncertainties. Two other components of the framework involved 'looking to the future', exploring relevant developments in scientific research, agricultural practice and also regulation.

The review panel included both specialist and non-specialist scientists and social scientists from a wide range of backgrounds. The institutions from which panellists were drawn included universities, specialist research institutes, research groups associated with biotechnology companies, and organisations with particular environmental concerns. Whatever their background and current employment and interests, all panel members acted as individuals in their own right, with a shared vision of producing a balanced, accurate and well-informed review. We hope that this review will enable debates and decisions to be informed by sound scientific evidence.

The review is specifically concerned with the potential use of GM crops in the UK. Assessing the implications of the adoption of GM technologies in other countries is beyond its scope, although issues with regard to the use of GM crops elsewhere, particularly in developing countries, were raised in the consultation exercise and discussed by the review panel. We hope that the approach we have used, and the scientific material we have brought together, may be of use in other countries in clarifying issues and generally informing debate.

THE SCIENTIFIC PROCESS

The bedrock of this Report is peer-reviewed published scientific literature in the relevant areas, but other sources of appropriate scientific evidence have also been considered where appropriate. Good scientific results have a sound basis in terms of existing knowledge and stand up to careful experimental and observational investigation. A good scientific paper explains clearly its claimed advance in knowledge and the evidence for it. When submitted for publication, the paper is read carefully by other experts in the field to see whether its conclusions are justified, and this process of 'quality control' is called *peer review*. A paper that passes this test is published in the scientific literature and becomes part of the public body of knowledge on which future scientific work can be based. No single peer-reviewed paper should be believed uncritically, and if a paper makes a surprising claim or a substantial advance, it becomes an obvious candidate for further scientific investigation. The aim of this whole system, which has grown up over more than three hundred years, is that knowledge should continually be challenged, refined and improved, through a developmental process based on appropriate evidence, valid inference and the work of a large and open scientific community.

Some of the questions asked about GM crops are purely scientific, whilst others are not of a scientific nature at all, but may be economic, social, ethical or even personal. For science, as for other areas, the answers given may often depend on the way the question is asked and be open to divergent interpretations. Accordingly, scientific issues represent only a part, albeit an important one, of the wider debate over GM crops. Being ‘rational’ is not enough to make a question scientific; the question and/or its potential solution must be amenable to objective testing. Of course, there are many questions that are not wholly or even primarily scientific, but are such that scientific understanding can make an important contribution to their resolution.

STRUCTURE OF THE MAIN REPORT

The first two chapters describe the scope and methodology of the review. Chapter 3 discusses the role of science in regulation. Chapter 4 discusses the reliability of GM plant breeding compared with conventional methods. Seventeen topics reflecting issues of public concern are then grouped into three chapters, broadly covering food, feed and animal safety, environmental impact, and gene flow.

HOW RELIABLE IS GM PLANT BREEDING? (CHAPTER 4)

Concern has been expressed that GM plant breeding is too unreliable and imprecise for crops to be grown and consumed safely, or at least without more extensive testing. One argument presented is that it is necessary to produce about 100 GM plants to obtain one that has the desirable characters for its use as a basis of a new GM crop variety. There is also evidence that genes introduced by genetic modification vary in their effects depending on precisely where they insert into the host plant’s genetic material

To address such concerns it is important to place GM crop breeding in the context of non-GM crop breeding methods such as gene transfer by pollination, mutation breeding, cell selection and induced polyploidy. Most of these so-called conventional plant breeding methods have a substantially greater discard rate. Mutation breeding, for instance, involves the production of unpredictable and undirected genetic changes and many thousands, even millions, of undesirable plants are discarded in order to identify plants with suitable qualities for further breeding. The success of all methods of breeding relies on careful testing and evaluation and on rejection of plants with undesirable qualities. The rejection rate is substantially higher for most non-GM crop breeding methods than it is for GM crop breeding.

All plant breeding methods, however, have unique features and the main special feature of GM plant breeding is that it allows a wider choice of genes for modifying crops in novel ways. No other plant breeding technique permits the incorporation of genetic material from such diverse biological sources. Inevitably this raises the possibility that some new consequences of GM plant breeding may be unexpected. This presents challenges for their regulation and management in the future that will need to be managed carefully and intelligently.

THE SAFETY OF FOOD AND ANIMAL FEED DERIVED FROM GM CROPS (CHAPTER 5)

A number of issues of public concern are considered in detail. Might GM crops result in more food allergies? Could GM foods be less nutritious or more toxic than their conventional counterparts? More generally, could DNA from GM crops harm people, either through being consumed directly in GM-derived food, or by entering the food chain through animal feed?

Possible nutritional and toxicological differences in GM food (5.2)

All novel food in the UK, which includes food produced by GM organisms, is subject to an EU-based and internationally determined regulatory regime, with procedures for safety assessment and risk analysis. The regime recognises that the consumption of food is not risk-free and requires any novel (including GM) food to be at least as safe and nutritious as any traditional food it replaces or complements.

To date world-wide there have been no verifiable untoward toxic or nutritionally deleterious effects resulting from the cultivation and consumption of products from GM crops. However, absence of readily observable adverse effects does not mean that these can be completely ruled out and there has been no epidemiological monitoring of those consuming GM food. Some reason that the absence of evidence of harm should not be treated as evidence of the absence of harm. This argues for greater reliance on scientific research and epidemiological monitoring. Others reason that the combination of testing by developers to demonstrate safety equivalence to commercial crops in order to satisfy regulatory requirements for clearance and extensive use around the world over long time periods and large exposed populations and absence of evidence of harm, does provide important experience of safety. The long-term assessment of the health effects for whole foods and feeds is considerably more difficult than the post-marketing monitoring and surveillance of a simple substance such as a single medicine. Countries are working to develop post-marketing surveillance to detect potential human health effects of food in general, but at present there is nothing yet available for GM foods in any country.

Safety assessment technologies such as screening and profiling techniques will need to continue to evolve, incorporating data on all possible entry-points for new hazards and to cope with uncertainties and gaps in knowledge. The complexity of the safety assessment process is likely to increase with the development of ‘second generation’ GM crops. These crops and their products aim to: decrease levels of anti-nutritional factors (e.g. toxins); increase levels of health promoting factors (e.g. antioxidants); and modify levels of macro or micronutrients (e.g. vitamins).

Food allergies from GM crops (5.3)

Changes in allergenicity during the breeding of conventional crops are not assessed in a regulatory framework and are not formally evaluated.

GM technology enables a particular gene construct for a new protein to be introduced, and the potential allergenic effect of that protein is a focal point for safety assessment. In addition, the regulatory process, with its case-by-case approach, must take account of possibly increasing exposure to a GM protein, especially if it is expressed in a diversity of different GM plants, and thus introduced into a diverse range of foodstuffs. In the hypothetical case, where an GM allergen was not recognised in regulatory screening, and its effects only emerged in the longer term, avoidance of the allergenic protein by the consumer could be difficult, because they would not be able to recognise its presence in the foodstuffs. The likelihood of this scenario is very low for a number of reasons. However, avoidance in a GM or non-GM case would depend on the relative effectiveness of labelling, traceability and recall systems and it would be for the regulatory system to ensure that any GM allergen once known, with a potentially significant effect on any consumer, should be labelled in a fail-safe way or withdrawn from the marketplace.

It is probably easier to evaluate the risk of introducing allergenic proteins and altering the allergenic composition of the target crops after use of GM than with some conventional breeding techniques.

There is an accepted approach, based on a standard set of safety tests, to the assessment of the allergic potential. But there is some contention over the value of specific tests and if, and how they can be improved. These tests are under continuous evaluation and improvements are considered in the scientific and regulatory literature.

The GM foods consumed at present (by large numbers of people for up to seven years) do not appear to have elicited allergic reactions. The same arguments for and against the significance of this are the same as for nutritional and toxicological effects (see 5.2 above). Our relative lack of knowledge about factors that are important in sensitisation and the elicitation of an allergic response suggest that we should continue to exercise caution when assessing all new foods, including foods and animal feeds derived from GM crops.

The fate of transgenic DNA (5.4)

The food we consume from conventionally bred crops contains large quantities of DNA, since DNA is a universal component of all living organisms and is not typically removed by the extraction and processing technologies used by the food and drinks industry. Some processes, such as sugar purification and the production of refined oils, remove most, sometimes all, of the DNA from a product before it is consumed. Other processes, such as heat treatment, whilst not removing DNA entirely, cause extensive inactivation and breakdown. The consumption of raw vegetables and fruits does, of course, mean that intact DNA is ingested.

DNA, like other large molecules in food, is very largely degraded (broken down to smaller molecules) in the gut, but this process of structural degradation whilst inactivating the DNA's genetic information, is not 100% efficient. Fragments of ingested DNA have been found throughout the digestive system and elsewhere in the body, including the blood stream. Our guts contain very large numbers of bacteria which help us to digest the food we consume. Whilst it is possible that these bacteria take up DNA from their environment (i.e. our digestive systems and the foods they contain) there are a series of well-established barriers in place to prevent the genomic integration and expression of foreign genes. This process is unlikely to be of biological significance unless: (1) the bacterial cells can use at least some of the genetic information that the DNA encodes; and (2) that information confers a selective advantage, leading to an increase in the proportion of the bacteria that contain this new DNA.

In GM food, the introduced DNA will have the same fate as DNA present in conventional food and will be inactivated and increasingly degraded as the food progresses through the digestive system. If the food originates from a GM crop in which bacterial DNA is part of the transgene, then, whilst still likely to be a rare occurrence, there is increased opportunity for that DNA to transfer into gut bacteria. This possibility makes it essential, in the achievement of maximum risk reduction, for the regulatory process to consider each GM crop as an individual entity with its own potential risks.

Antibiotic resistance is not only widespread as a consequence of antibiotic and feed additive usage, but because it is highly selected for in microbes in the wild. Bacterial genes conferring antibiotic resistance have been a commonly used tool for selection in GM technology, but alternatives have now been developed and it is possible to eliminate antibiotic resistance gene markers following GM plant construction. So, the presence of antibiotic resistance genes can now be avoided in GM plants intended for food use. The use of antibiotic resistance genes in plants remains controversial, with differing views on its potential impact. There is a scientifically well-supported argument that any rare resistance gene transfer event from a GM plant or food would have no impact as antibiotic resistance is already widespread as a consequence of antibiotic usage in medicine and animal feed.

The effect of GM derived feed on the food chain (5.5)

Animal feed is a major product of conventional agriculture, and of crops developed using GM technology. The processing of crops into animal feed often completely degrades such constituents as DNA and proteins, but this cannot be assumed always to be the case. Most DNA is degraded in the gut, but some survives and there is evidence that some DNA fragments from feed ingested by poultry and livestock can appear in the blood and other tissues.

However, food and feed safety studies have been unable to find introduced feed DNA or its gene products in milk, meat or eggs produced from animals fed GM crops. Many millions of people, particularly in the United States, Canada and Argentina, have for up to seven years been eating food products derived from animals fed on GM diets and no substantiated ill effects have been reported. There is a similarly lack of evidence for any adverse effects of GM feed on the health, welfare and productivity of livestock.

However, as mentioned in relation to nutritional and toxicological differences, the absence of readily observable adverse effects in humans or animals does not mean that these can be completely ruled out for any crop GM or non GM, existing or novel. For example, rare, mild or long-term adverse effects are not easy to detect and could in future be the subject of post-marketing monitoring and surveillance. The safety assessment of crops with significantly altered nutritional qualities will need careful consideration where there may not be historical knowledge of assumed safe use.

THE ENVIRONMENTAL IMPACT OF GM CROPS (CHAPTER 6)

There has long been concern about the ways that GM crops might affect the environment, and this was reflected in the public consultation exercise. In addition to direct environmental impacts, there could be indirect effects, for example in the ways that cultivation of GM crops might change agricultural practices and rural landscapes. The latter seems most likely and could bring benefits as well as risks. The great majority of all GM crops currently in cultivation are grown in the USA, Canada and Argentina. In each of these countries the crops tend to be grown on large-scale farms that are geographically quite isolated from wilderness areas. More recently, many smallholder farmers in China have also adopted GM crops. The circumstances are distinct from the many smaller-scale farms embedded in the countryside that are characteristic of the UK and the rest of Europe. These differences in scale and farming practices must be considered in harm/benefit analyses of the potential environmental impacts of GM crops in different parts of the world. It is also essential to compare the environmental impact of the GM crop with other current and evolving practices in conventional agriculture.

Could GM plants become more widely invasive or persistent? (6.2)

Notwithstanding the case-by-case approach taken by the regulatory authorities in evaluating invasiveness, there are two principal models that have been influential in considering the potential for GM crops to become more invasive of natural habitats than their conventional counterparts. One is the *alien species model*. The hypothesis is that roughly 0.1% of introduced GM plants would become pests, because that was the rate of invasive alien plants species (some 15 problem plants out of an estimated 15,000 alien species introduced into the UK). The other is the *crop model*, which argues that GM crops will behave in much the same way as conventional crop plants except for the GM trait that may influence fitness. Conventional annual crop plants generally do not prosper outside arable fields. Although escaped plants of crop species are found, they do not tend to increase in abundance but are replenished each year by fresh 'escapes'. Detailed field experiments on several GM crops in a range of environments have demonstrated that the transgenic traits investigated do not significantly increase the fitness of these plants in semi-natural habitats, and therefore they behave in a similar way to non-GM crops.

We do not have an exact understanding of what changes in a plant's life history will affect its invasiveness. More knowledge on the potential effects of releasing GM plants with traits such as pest and disease resistance and stress tolerance is required since these may significantly alter a crop plant's ability to survive outside the agricultural environment. In particular, we need to know whether GM for fitness-affecting traits like growth rate, longevity, plant size, or survivorship in plant species with potentially more invasive life histories (e.g. woody plants, perennial grasses, thicket-forming herbs) is consequential.

Could GM crops be toxic to wildlife, and what might be the impacts? (6.3)

Crop breeding, whether through genetic modification or 'conventional' methods, has the potential to alter levels of plant toxins or create novel compounds that are toxic to some wildlife. Such effects are unusual but they are a key element of the risk assessment process for experimental and commercial release of GM crops. The principal risks arise for crops that have been deliberately bred to contain toxins to control key pests or diseases. GM pest- and disease-resistant crops are unlikely to be grown commercially in the UK in the near future. Nevertheless, evidence from the USA and China indicates that for some, but not all, GM pest-resistant crops there have been significant reductions in pesticide use. In every case when attempting to determine the effects of pest-resistance, it is necessary to judge the crop-pesticide combination as a 'system' rather than simply considering the ecological impacts of the crop in isolation

There is little scientific dispute about the fact that GM plants engineered to produce toxins can sometimes be toxic to non-target wildlife, since even in nature toxins are rarely species-specific. However, no significant adverse effects on non-target wildlife resulting from toxicity of GM 'Bt ' plants, for example, have so far been observed in the field. This suggests that Bt crops are generally beneficial to in-crop biodiversity in comparison to conventional crops that receive regular, broad-spectrum insecticide applications. Despite this, benefits would probably be restricted (or even negated) if Bt crops required insecticide applications to control target or secondary pests that were not sufficiently controlled by the Bt toxin. Studies on the impacts of GM crops on soil processes have shown some differences in soil microbial community structure, but so far there does not seem to be any convincing evidence to show that GM crops could adversely affect soil health in the long term. The differences in soil microbial communities observed beneath GM crops have been within the range of variation in microbial community structure and of the order of magnitude of the differences observed under different crops of even different cultivars of the same crop. However, almost all this data is drawn from small-scale, short-term studies and there is a need for larger, more agronomically realistic studies to be undertaken to demonstrate absence of harm to non-target organisms.

There tends to be scientific disagreement about the amount of information needed to demonstrate that growing GM pest and disease-resistant crops is environmentally sustainable in the long term. Some scientists argue that current evidence of reductions in pesticide use and increases in biodiversity compared to conventional crops are sufficient to demonstrate absence of adverse impacts, while others advocate the need for a greater fundamental understanding of the underlying processes.

Most of the possible negative impacts of GM crops on biodiversity are likely to be reversible, so small-scale field trials to test for impacts on relevant ecosystems are unlikely to pose any long-term environmental risks. After a crop has been approved for commercial use, the monitoring systems required for GM crops grown in the EU provide a valuable mechanism to collect ecologically relevant data. This will be useful to enhance our understanding of the impacts of GM pest-resistant crops on non-target species.

Could GM crops lead to particular problems in the development of resistant insects, weeds and diseases? (6.4)

A key long-standing target of 'traditional' plant breeding, including some uses of genetic modification, has been the development of crop varieties that are resistant to pests and diseases. Widespread, uniform cultivation of these varieties, together with any agrochemicals applied to reduce the incidence of disease or to kill weeds, provide a strong selection pressure for the emergence/evolution of resistant *target organisms* (pests, pathogen and weeds) that can attack the new variety or survive the pesticide application. The time it takes for a resistant target organism to emerge depends on the nature of the toxins and how they are expressed, the ecology, genetics and mating behaviour of the target organism(s), the mode of action of the toxin, and on the effectiveness of the crop management techniques deployed by farmers.

Current widespread scientific opinion is that 'single dominant resistance gene' mechanisms are less durable than resistance controlled by several genes. However, some sources of GM resistance, including *Bt* genes that confer resistance to a narrow range of target insects, appear to be particularly robust. However, there is no *a priori* reason to suppose that resistance genes introduced by GM will be any less susceptible to 'breakdown ' than those introduced by slower conventional breeding methods.

Over 120 species of weeds have been recorded worldwide that have become resistant to various herbicides in association with herbicide-tolerant crops, irrespective of whether tolerance was obtained by GM or conventional breeding technologies. Weeds that are closely related and hybridise freely with the cultivated herbicide-tolerant crop variety have the added possibility of obtaining tolerance gene(s) directly from the crop. However, unless the weed is exposed to the herbicide in question, this does not pose any ecological or selective advantage.

Therefore, although resistance-breaking strains of pathogens, pests or weeds can be expected to emerge, there is no reason to expect different responses depending on whether a crop's resistance was introduced by GM or by conventional breeding methods.

However, since GM has frequently employed genes which confer resistance to common herbicides and pesticides (e.g. glyphosate and Bt) in its weed and pest control strategies, impacts on agriculture and possibly biodiversity could be significant if some target organisms developed resistance to these compounds. The extent and possible severity of impacts on the environment are difficult to quantify and subject to much debate.

Will herbicide-tolerant crops offer new weed control strategies and if so what are the likely positive and negative impacts? (6.5)

GM herbicide-tolerant (GMHT) crops enable new weed control strategies. The key possibility is the replacement of existing approved but persistent, toxic herbicides by those with a more benign environmental profile. They may also enable farmers to spray crops less frequently and to relax weed management practices for conventional crops at different stages in the rotation. Hence they are an attractive option for farmers wishing to simplify crop management. It may also be possible to delay the date of herbicide application, avoid pre-sowing weed treatments and so leave emerging weeds in the fields for longer. Such a result might have benefits for biodiversity, though this claim is largely speculative and is not strongly supported by the current small-scale experimental studies. Similarly, evidence from the USA indicates that tillage can be reduced in HT crops, which provides environmental benefits that may not necessarily be relevant to the UK.

Fifty years of agricultural intensification has undoubtedly led to a decline in farmland biodiversity, but the role of herbicides in this decline is unclear. Broad spectrum herbicides used in conjunction with GMHT crops are known to provide highly efficient and reliable weed control in comparison to many ‘conventional’ herbicide regimes, and if their use resulted in fewer weed seeds and further declines in weed populations then organisms depending on those weeds during part of their life cycle could be adversely affected. We do not yet have sufficient evidence to predict what the long-term impacts of GM HT crops might be on weed populations. An important uncertainty is how farmers will apply this technology in the field.

The publication of the UK farm-scale evaluations of GMHT crops will clarify some of these uncertainties. Inevitably others will remain. The question would become more complex if farmers were to grow two or more herbicide tolerant crops in rotation.

Apart from herbicide tolerance, what are the major new traits that might give rise to significant environmental impacts? (6.6)

Over the next ten years, there is the possibility of introducing GM crops resistant to attack by insects, nematodes, fungi, bacteria or viruses. In all cases, we would expect these to enable reductions in pesticide use. There are potential negative impacts on non-target organisms, but in the case of insect resistance, field studies on commercially grown Bt crops have failed to identify any adverse effects. In addition, subject to regulatory approval, there will be imports of GM food, feed and fibre, with improved shelf life or nutritional quality, but these are not expected to affect the UK environment.

Further ahead, it becomes more difficult to make confident predictions about the commercialisation of GM crops and their possible environmental impacts. The horizon scan has identified the paucity of baseline data and models at different scales, from field to landscape scale, which is needed as a basis for future assessment of large-scale environmental effects. Many of the issues foreseen are not unique to GM crops and will be driven by economic, social and political rather than purely scientific factors. Current research points to GM crops for certain non-food purposes: pharmaceuticals, speciality and bulk chemicals and biomass for energy. These could provide renewable resources for industry, provide new medicines and could diversify rural landscapes and economies. Conversely, there could be undesired effects on wildlife caused by the way these crops might be managed and/or changes in patterns of land use. Another longer-term possibility is the development of traits aimed at improving crop production in marginal environments (e.g. tolerance of drought, heat or salt) with obvious advantages to certain growers in these environments. However, such crops could become more successful as weeds, there could be economic pressure to cultivate areas with wildlife and conservation value, and there might be adverse socio-economic and political consequences, for example with regard to optimal farm size.

Might GM crops change agricultural practice is the UK? If so, what might be the likely consequences? (6.7)

It is widely acknowledged that modern (non-GM) agriculture has already had significant negative impacts on biodiversity and the wider environment in the UK. Large changes over the last century, including recent decades, in the way farmland is managed have resulted in a decline in farmland plant, invertebrate and bird abundance and diversity.

The consequences of commercial growing of GM crops in the UK would depend on the nature of each individual technology and the decisions made by farmers, the public and policy makers. For example, some GM technologies could increase agricultural intensification, to produce more from the same area of land, while other niche and specialist GM crops could increase the diversity of the landscape. Some GM crops would lead to reduced agrochemical use while others would have the opposite effect.

Each potential agricultural application of genetic modification must, therefore, be examined on a case-by-case basis, taking careful account of the physical, social and political environments within which it would be deployed. There is a major need for policy makers to understand how these factors are likely to interface with the new technologies, to enable prediction of environmental outcomes and thus delivery of environmental targets because they will predict outcomes from the environment if targets are to be delivered.

What are the limitations of the science available to predict the environmental impact of GM plants? (6.8)

There are several approaches for determining the ecological consequences of GM crops. Examples include extrapolations from experience with comparable traits or with other crop varieties that are in some or all ways ‘equivalent’, laboratory and field experiments, experience of GM crops, and ecological modelling. In practice it is usually necessary to use a number of these methods in combination.

Most of the environmental issues raised by growing currently available GM crops do not differ qualitatively from conventional crops. In both the GM and conventional context, we are limited in our ability to predict ecological changes within complex systems. This applies to a wide range of ecological issues and to many aspects of agriculture: modern intensive, organic or conventional. Important gaps in knowledge include the possible rate of uptake of GM crops in the UK; detailed knowledge of farmland ecology; soil ecology.

GENE FLOW, DETECTION AND IMPACT OF GM CROPS (CHAPTER 7)

Gene flow is the movement of genes from one organism to another, and is something that takes place in nature all the time. There are various mechanisms by which gene flow can occur and various natural barriers to minimise its effects. None of these mechanisms is specific to GM plants; therefore a great deal of evidence from conventional agriculture is relevant.

Gene flow between crop varieties (7.2)

Genes can move between different varieties of the same species by the spread of seed and by cross-pollination. The complete genetic isolation of crops grown on a commercial scale, either GM or non-GM, is not practical at present. However, gene flow can be minimised, as currently happens in the case of oilseed rape varieties grown for food, feed or industrial oils. The levels at which gene flow can be maintained for different crop varieties are significant in determining whether co-existence of different types of agriculture is feasible. However, political decisions may ultimately affect whether co-existence is practical, in particular what thresholds are set for maximum GM presence in non-GM crops (and their products), whether conventional or organic. For some crops, maintaining thresholds of gene flow may be relatively straightforward, by employing separation distances and, more importantly, by reducing gene flow through seed. However, in other cases it may be difficult, if not impossible, to grow certain crops or use some existing farming practices (e.g. using farm-saved oilseed rape seed on farms where both GM and non-GM varieties are grown).

Gene flow from GM crops that have been approved for commercial release can be detected but unapproved GMOs present difficulties. Gene flow may be detected if commonly used transgenic DNA is present, but the actual source of the GM presence will be difficult, maybe impossible, to identify. Detection methods are very sensitive but they cannot guarantee a total absence of transgenic content. Equally, false positives may indicate that transgenic DNA is present when it is not.

‘Gene stacking’ is the accumulation of genes conferring a range of traits as a result of cross-pollination between different varieties. It is not unique to GM crops. However, if GM crops are to be grown commercially in the UK, assessments of the potential consequences of such gene stacking may well become a more prominent consideration for regulators. GM crops that produce non-food, non-feed products such as pharmaceuticals, bioplastics or biofuels pose different regulatory issues and would, as for all GN crops have to be judged on a case-by-case basis. In any case, such crops would (certainly, should) be designed and/or grown in ways that would preclude gene flow to food and feed crops.

More information is needed about the mechanisms and management of seed dispersal in agricultural systems, along with diagnostic and sampling methodologies for determining the extent of gene flow early in the production/supply chain. In the longer term, it is possible that gene containment systems will be developed that significantly reduce gene flow.

Gene flow from GM crops to agricultural weeds and wild relatives (7.3)

Gene flow can occur from GM crops to sexually compatible wild relatives and to agricultural weeds. Cross-pollination will occur to an extent that depends on the closeness of the relationship between the species and on other conditions. However, the key issue is whether any resulting hybrid plants survive, grow and reproduce successfully allowing the new gene to be introgressed (stably introduced into the new population). Hybridisation seems overwhelmingly likely to transfer genes that are advantageous in agricultural environments, but will not prosper in the wild. This general view is supported by specific studies on oilseed rape and on sugar beet, where there has been little or no detectable gene flow to semi-natural habitats even though there can be hybridisation within a field. Furthermore, no hybrid between any crop and any wild relative has ever become invasive in the wild in the UK.

Within current agricultural practice, more than 120 non-GM herbicide-resistant species have emerged worldwide in the last 40 years. In most, but not necessarily all cases, such plants are at a disadvantage away from agricultural conditions. This disadvantage has also been found in experiments carried out on GM plants. There have been some instances in Canada, where there is complete freedom to grow several herbicide-tolerant varieties, e.g. oilseed rape, of tolerance being transferred to weeds or stacked through hybrids in one variety. However, if herbicide-tolerant crops are carefully managed, this should delay, or even prevent, the emergence of any herbicide-tolerant weed problem.

Genes associated with resistance to pests and diseases have greater potential than herbicide-resistant genes to lead to the local expansion of a plant population. However, there are other natural constraints that could prevent an increase in population growth rates in such cases. Overall, genes for pest- and disease-resistance inserted into crops by conventional breeding have not produced invasions of wild relatives in semi-natural habitats.

However, there are gaps in our understanding of the potential consequences of gene flow, and the effect of particular traits on the fitness of the weed or wild relative, which may receive them, is an important target of ongoing research. In addition, several technological solutions to containing or reducing gene flow from GM crops have been proposed.

Can genetic material in GM plants transfer to soil microbes? (7.4)

Most plant DNA is degraded during the natural processes of decay, but there is a small possibility that genes in plant DNA could be acquired and expressed by environmental microbes. There is no evidence from complete bacterial gene sequences that genes from plants have successfully established during bacterial evolution, but bacterially derived transgenes in current use may have a higher probability of transfer to soil bacteria than average plant DNA. No such transfer under field conditions has yet been observed. However, there are limited tools, and there have been limited attempts to test the phenomenon under field conditions.

Most current transgenes are of bacterial origin. They are therefore unlikely to have any significant novel effect on bacteria that have already been exposed to them by gene transfer from other bacteria, though their similarity to bacterial DNA may increase the chance that bacteria acquire them. Inserting transgenes in plastids (i.e. chloroplasts) may increase the chance of horizontal gene transfer (HGT) to bacteria because of the increased copy number (several 100 copies per cell instead of 1 or 2 copies of nuclear DNA) and closer relationship to prokaryotic gene structure. Careful design of transgenes can greatly reduce the potential for HGT to bacteria. In future, inserted genes may encode proteins not found naturally. Although these will be less easily acquired by bacteria, their effects may need to be explicitly tested in representative bacteria.

HGT to other microbes, (e.g. fungi and protists), has not been as well researched as for bacteria. As with bacteria, there is some indication that the rate may not be zero. Since these are eukaryotes, some further consideration should be given to the likelihood of incorporation and expression of the transgenic DNA used in GM plants, as the work directed at bacteria will not be applicable.

Initially, a gene transfer event affects a single microbial cell. It will have no ecological impact unless the transgene confers an advantage on its recipient that causes it to become widespread in the microbial population. For most genes that may be used in GM crops, this is unlikely. A potential transgene should be assessed by first asking whether it could be expressed in microbes and could confer an advantage on them. In some cases, this may require direct testing, and high-throughput methods could be used to scan for unexpected patterns of gene activity and metabolism. If the answers are positive, then consideration must be given to the potential wider consequences if the recipients became established, so that transgenes that can be predicted to cause harm if expressed in microbes can be avoided. There is inevitably some uncertainty associated with this assessment. Our current understanding of microbial ecology does not allow us to make detailed predictions of the effect of genetic perturbations, whether these are caused by natural genetic evolution events, by normal agricultural practices, or by the spread of a novel microbe. Experience suggests that microbial community functions are fairly resilient, but a better understanding of microbial ecology is clearly desirable.

It is important to reduce the potential for expression and transfer of genetic material from GM plants to soil microbes by removal of unnecessary vector DNA that may provide homology with soil microbial DNA, origins of replication and sites for transposition, and also by introducing non bacterial features (e.g. introns) where possible.

Can genetic material in GM plants transfer to viruses? (7.5)

Since 1986, thousands of GM plant lines have been made that contain a range of DNA sequences of viral origin, mostly short fragments that regulate the way in which other (non-viral) transgenes are expressed. There have also been many hundreds of GM plant lines in which short viral DNA sequences have been introduced to confer resistance to viral diseases. This approach has proved to be a selective, measurable and environmentally sustainable method of crop protection. The conventional alternative is to use pesticides liberally to control the fungi and invertebrates that spread the viruses.

Several GM virus-resistant crops have been grown commercially on a large scale in several countries for at least seven years.

Laboratory and greenhouse studies, since 1994, have shown that defective mutant viruses with a range of genetic defects can be restored to their wild type phenotype by acquiring the necessary sequence from a suitable GM host plant through recombination. Detailed studies have been carried out to look for the transfer of genetic material from GM plants to viruses under field conditions. None has been detected. These studies have involved a number of commercial GM crops, including papaya, squash and sweet potato. If such transfer did occur, the potential consequences would have to be assessed on a case-by-case basis of each virus-resistant GM variety.

Containment of any newly emerging plant virus would be through standard and widely accepted control measures. Since the 1970s, an accepted and approved practice has been to intentionally infect highly susceptible, high-value crops such as glasshouse tomatoes with a mild strain of a virus to protect them against severe strains of the same or a related virus. This practice poses greater (and documented) opportunities than GM for genetic recombination to create new virus strains.

It is theoretically possible, but extremely unlikely and without precedent, that transfer of viral genetic material from a tested and approved GM plant would make an invading virus fitter. This is because that rapid mutation, selection, genome reassortment and switching of genetic material between naturally occurring viruses are common natural events. It is therefore reasonable to assume that any new genetic trait beneficial to the virus would already have been tried and selected through millennia of evolution, or during natural or artificial mixed virus infections.

Nevertheless, several practical recommendations can be made in the design of transgenes containing DNA derived from viral sequences that would minimise the theoretical risk associated with their use.

CONCLUSIONS

New technologies always bring uncertainties and generate new gaps in knowledge. Uncertainty and divergence of interpretation are a key part of scientific development, providing the stimulus for new scientific hypotheses to be formulated and tested out, for uncertainties to be reduced and for new insights to be developed. Part of science is the ability to be honest about uncertainty and to be able to judge the quality or strength of evidence for a particular conclusion. Challenge is central to the scientific process and so too is speculation. The way to resolve controversies, when these are amenable to scientific resolution, is to do better science by going back to the real world and examining it with better tools and better ideas to improve understanding.

We cannot know everything and if we were paralysed by gaps in knowledge we would never get anywhere new. One of the paradoxes of science is that sometimes awareness of uncertainty grows as we learn more. At the same time, the lessons of history tell us that sometimes we have rushed forward incautiously to exploit new technologies, only subsequently to appreciate the medical, social, environmental or other costs. As individuals and as a society we have to be able to cope responsibly with incomplete knowledge and uncertainty.

We have conducted an issue-led, evidence-based review of the issues of concern to the science community and the general public. There are those who tend to state that, because GM is similar in many ways to conventional breeding, this is a useful baseline for comparison. There are others who reason that this approach understates the distinct differences between GM and non-GM and that, because the technology is relatively new, we know too little, the uncertainty is too great, and there are too many gaps in knowledge to pursue it safely at the current time. We have come face to face with both these arguments in our Panel discussions. However, we have progressed beyond this and we believe we have been helped in this by the framework we have developed and used. Absence of evidence of harm is not evidence of absence of harm. So what is the evidence for harm? And what is the evidence for the absence of harm? We have looked at this for each of the issues under review.

The reliability of GM technology is a feature of concern to many people. What is our response? It is clear that imprecision and unpredictability are features common both to conventional plant breeding and to GM plant breeding. In each case, testing needs to be adequate to ensure that plant varieties and the foods made from them are safe. For GM crops and GM food, it is important that testing also takes into account the potential unanticipated effects that might arise from the unique capability of placing genes into very different genetic backgrounds. It is appropriate and reassuring, therefore, that the regulatory system in place throughout the EU demands a high level of scrutiny in the testing of GM crops, and that powerful analytical tools are available to analyze GM plants with a degree of molecular precision impossible for all products of conventional (non-GM) plant breeding.

The current, and widely accepted view within the biological research and plant breeding communities is that the methods for evaluation of the current generation of GM crops for food and feed carried out within the European regulatory framework, are robust when consistently applied. There are those who are not so confident, and their challenge is an important factor in the improvement of the framework. Regulatory evaluation needs to keep pace with the challenges posed by developments in this technology and recognise progress in understanding and knowledge. It is important that research to ensure effective risk assessment is supported.

For human health, to date there is no evidence currently commercialised GM crop varieties or foods made from them, are toxic, allergenic or nutritionally deleterious. But what is the evidence for this? The principle arguments are that molecular tests done on products prior to commercialisation have been conducted, and that the combination of testing by developers to satisfy regulatory requirements for clearance, extensive use around the world over long time periods with large exposed populations, and the absence of evidence of harm, does provide important experience of safety. Others are less convinced, pointing out that the techniques have limitations; for example we still do not have an exact understanding of what causes us to be sensitised to allergens (GM or otherwise), and that systematic surveillance and post–market monitoring is not conducted. On balance, we conclude that the risks to human health are very low for GM crops currently on the market. But GM does present certain particular potential challenges in risk management and the situation may prove to be more challenging in future, depending on the crops developed. There is a need, therefore, to continue to develop safety assessment technologies, effective surveillance, monitoring and labelling systems, and to have in place effective avoidance strategies.

Transgenic DNA and non-transgenic DNA appear, from the studies conducted, to share the same fate once ingested by humans, being very largely, but not entirely, degraded in the gut. There is an interesting but not yet proven possibility that, because transgenes may share sequences in common with bacteria present in the gastro-intestinal tract, this might permit ‘horizontal gene transfer’ to gut bacteria. From the few studies that have been carried out to date there is no compelling evidence that gene transfer occurs under natural conditions, and, for this to happen, a series of natural barriers would need to be overcome.With respect to GM-derived animal feeds several research studies have been unable to find transgenic DNA (or its gene products) in milk, meat or eggs produced from animals fed on GM crops.

Turning to the environment, the UK is characterised by a landscape in which many small-scale farms are embedded in the countryside so that farmland biodiversity forms an important part of the plants and animals that inhabit this country. We know that conventional intensive agriculture has provided benefits in terms of affordable food and predictable food supply, but at a significant cost to the natural environment. It is against this background that the commercial introduction of GM crops is contemplated in the UK, and because GM is tightly regulated, we know that the first ones, if introduced, are likely be herbicide-tolerant fodder beet, oilseed rape, and maize.

Detailed field experiments on several GM crops, including these three, in a range of environments have demonstrated that they are very unlikely to invade our countryside or become problematic plants, although HT oilseed rape and beet could become weedier in agricultural settings. Nor are they likely to be toxic to wildlife or to perturb soil structure in such a way that the functioning of soil communities is substantially affected.

We also know the extent and pattern of gene flow for these particular crops. Maize has no wild relatives in the UK with which to cross-pollinate. Beet and oilseed rape do. However, field studies indicate that there is very little gene flow from these crops to wild relatives living in semi-natural habitats. The frequency of genes in populations is dependent on whether or not they confer any selective advantage and, equally importantly, the frequency of hybridization: which in these cases is very low. However, for the future, the effect of particular traits on the fitness of the weed or wild relative that may receive them is an important target of ongoing research.

The few studies that have been carried out so far have been unable to detect evidence for horizontal gene flow between GM plants and either bacteria in the soil or viruses. If such horizontal gene flow does occur, then preliminary indications suggest that it is a very rare event. The possibility of horizontal genes transfer to other microbes, (e.g. fungi and protists), has not been well studied and is an important area for future research.

Agricultural intensification has undoubtedly led to a major decline in farm biodiversity in recent decades in the UK, but the role of herbicides in this decline is less clear. We do not yet have sufficient evidence to predict what the long-term impacts of GM herbicide-tolerant (GMHT) crops would be on weed populations and the wildlife that depends on weeds for food. Above all other concerns, this poses perhaps the most serious potential harm arising from these particular crops. An important uncertainty is how farmers would apply this technology in the field. The publication of the UK farm-scale evaluations of GM herbicide tolerant crops will clarify some of these uncertainties. We aim to consider these results in the autumn.

Looking further ahead, it is clear that complexity and uncertainty will increase as the range of plants and traits introduced increases. Gaps in our knowledge exist in the areas listed below:

We do not have a precise understanding of which changes in a plant's life history affect its fitness. We do not know whether fitness-affecting traits like altered growth rate, longevity, plant size, or survivorship in plant species with potentially more invasive life histories (e.g. woody plants, perennial grasses, thicket-forming herbs) will result in invasive and problematic plants as is true of such as Japanese knotweed and rhododendrons.

Genes associated with resistance to pests and diseases have greater potential than herbicide-resistant genes to lead to the local expansion of a plant population if transferred from a GM crop. However, there are other natural constraints that could prevent an increase in population growth rates in such cases. It may be significant that genes for pest and disease-resistance inserted into crops by conventional breeding have not produced invasions of wild relatives in semi-natural habitats. This may be related to linkage drag. That is, the hybrid 'crop-wild relative' inherits the transgene plus a set of all genes from the agricultural plant that reduces the competitiveness of the plant outside the agricultural environment.

'Stacking' of transgenes in crop plants or wild relatives is a distant future possibility in the UK. However, if it occurred (as it has with herbicide-tolerance genes in oil seed rape in Canada) it would involve plants with unintended and unstudied gene combinations. Predicting the ecological behaviour of such plants in advance of their accidental and unintended production will provide scientific challenges to the regulatory system.

There is an extensive 'tool kit ' to consider the environmental impacts of GM crops, but it must also be acknowledged that, given the complexity of ecology, we do not have all the data to make precise predictions, nor are we necessarily asking all the right questions. A case-by-case approach to making assessments on environmental impacts continues to be the appropriate approach.

To date, in countries that have the experience of growing GM crops, there have been no reports of them causing any significant environmental damage. This is an important point to recognise, but equally, we must be cautious in drawing general conclusions as these observations are based on relatively few field experiments. In addition, the findings may not be entirely relevant to the UK situation. This point about the difficulty in generalising confidently from one country to another also applies to evidence from the USA, China and India indicating that use of some, but not all, GM pest-resistant crops has resulted in significant reductions in pesticides, and the replacement of certain herbicides by others with a more benign environmental profile.

So what is the appropriate agriculture for the UK? We cannot answer this question fully, but clearly it will need to be sympathetic to wildlife, and allow co-existence of farming systems. Political decisions, market forces and other pressures will ultimately decide whether co-existence of different farming systems is practical, and in particular what thresholds are set for GM presence in crops and food labelled non-GM. Uncertainty surrounds the way in which different factors determining co-existence will combine at commercial scales (i.e. the real-life consequences of the combination of unintended presence in seed, cross-pollination, and the contribution of volunteers). For some crops, this may be relatively straightforward to manage, for others it may be difficult without significant changes to current practices. Tracing genes in supply chains is possible, but there are limits to reliability, which are, to a large extent, determined by the degree of sensitivity required. The issues of traceability, segregation and gene flow become potential health issues where GM crops produce non-food, non-feed products such as pharmaceuticals, bioplastics or biofuels. Such crops pose challenging regulatory issues and will also have to be judged on a case-by-case basis. In any case, such crops would (and certainly, should) be designed and/or grown in ways that would preclude gene flow to food and feed crops. The impacts (positive or negative) of GM plants will be largely dependent on how GM technology is deployed by farmers and this in turn may depend in part upon incentives to optimise a combination of productivity and environmentally friendly usage.

Genetic modification is not a homogeneous technology and to answer many questions each specific application of genetic modification must be considered on a case-by-case basis. Each product brings different potential benefits for different stakeholder groups; each may pose different environmental or health risks. In making judgments about GM crops, it is also vital to scrutinise the uncertainties as well as the potential risks and benefits and to make comparisons with non-GM crops grown in conventional, organic or other lower intensity farming systems. It is also important to recognise that non-GM plant breeding is becoming progressively more sophisticated and able to provide novel modifications to crops that can raise similar issues as those considered in this review.

There is a clear need for the science community to do more research in a number of areas, for companies to make good choices in terms of transgene design and plant hosts, and to develop products that meet wider societal wishes. Finally, the regulatory system in the UK should continue to operate so that it is sensitive to the degree of risk and uncertainty, recognises the distinctive features of GM, divergent scientific perspectives and associated gaps in knowledge, as well as taking into account the conventional breeding context and baselines.