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Genetically Modified Crops and Food

This paper gives a brief overview of current issues in genetically modified crops and food. For crops, it discusses the position on field trials and moves towards commercial development. For food, it provides some background to the regulations on the labelling of genetically modified food

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Summary of main points

- Both GM crops and GM foods are subject to systems of control.
- The main arguments for and against GM crops are briefly stated, although not evaluated.
- The House of Lords Select Committee on the European Communities recently produced a favourable report on the EU system of regulation of GM crops.
- English Nature criticised that conclusion, arguing that the use of herbicide-tolerant crops would encourage farmers to use more herbicides and damage wildlife.
- The Government has denied newspaper reports that it has agreed a three-year moratorium on the planting of GM crops.
- The Government's position on GM food is stated.
- The Food Labelling (Amendment) Regulations 1999 (SI 747) are explained in the context of the EU labelling requirements.
- The experience of other EU countries and of the USA is briefly explained.

CONTENTS

I Introduction

The whole topic of genetically modified crops and food has become extremely controversial over the past two years, and particularly over the past two months. This paper describes the regulatory background, the position of the Government and some of the issues raised. It also describes the role of the new regulations on the labelling of genetically modified (GM) food. This paper does not attempt to summarise the scientific debate, let alone judge the conclusions.

There are several reasons for not doing so. First, there are many reports aimed at providing a summary, including a recent select committee report and a report by the Parliamentary Office of Science and Technology in 1998.[1] Second, the evidence is based upon a number of individual studies, particularly for the environmental consequences of GM crops. Merely reporting the results of the studies in summary form may give a distorted view of the scientific debate. Third, there are some parts of the debate in which there is so much controversy about the interpretation of the results that it would be unrealistic for a paper of this type either a take a position or even to summarise the opposing interpretations in a generally acceptable way.

Crops and food are treated separately, because different issues are raised. The use of GM crops raises environmental questions. It is regulated by the Department of the Environment, Transport and the Regions (DETR) and the Health and Safety Executive (HSE), as well as the Ministry of Agriculture, Fisheries and Food (MAFF). The use of GM food, raises food safety questions and is regulated by MAFF and the Department of Health. Two advisory committees are very important. The Advisory Committee on Releases into the Environment (ACRE) advises the Secretary of State for the Environment on the release of GMOs. The Advisory Committee on Novel Foods and Processes (ACNFP) advises on the safety on novel foods, including GM food. In each case the secretariat consists of civil servants, but the membership consists of independent experts. These are mostly scientists in appropriate disciplines, but a few consumer representatives are included. Other advisory committees may also be involved.

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1 Select Committee on the European Communities, *EC Regulation of Genetic Modification in Agriculture,* 15 December 1998, HL 11 1998-99; Parliamentary office of Science and Technology, *Genetically Modified Food,* May 1998

II What scientists can do

Genetically modified (GM) crops are products of the modern biotechnology industry, which has developed after the discovery of the structure of DNA in 1953 by Crick and Watson. Although, it took some decades for the possibilities to develop into commercial techniques, since the 1970s many new applications have appeared.[2]

Food has been the product of science for millennia. Processes such as winemaking, brewing or the preserving of foods have involved chemical changes and could be considered food technology. Selective breeding of animals has been undertaken for centuries and systematic selective breeding of farm animals to develop better stock has been operating in the UK for about two hundred years. Modern food, of course, is partly the result of the application of modern science. Crops are grown with the help of fertilisers and pesticides. Additives are used to help preserve the food and to control its taste. Otherwise, it would simply not be possible to obtain such a wide range of foods, of uniformly good quality, on the supermarket shelves.

The techniques of biotechnology go well beyond that. It is becoming increasingly possible to identify, within an organism, exactly which gene confers each particular quality and to either alter that gene, or even transfer that gene to an organism of a different type. Of course, the complexity of life is such that a particular quality is very rarely determined by a single gene, but there are cases where the transfer or alteration of a single gene can change particular qualities, either in a plant or occasionally in an animal.

The term "genetic modification", when applied to food, refers to any artificial alteration in the genetic makeup of a food, animal or plant, or to the use of genetic engineering techniques in the production and manufacturing of food. It therefore covers a whole range of techniques.

Once a gene has been altered, or a copy made of all or part of a gene, "copy genes" do not have to be put back into the same type of animal or plant from which they were extracted. They might originate from one organism and be inserted into another species altogether. This transfer can even take place from an animal to a plant, so that an animal gene is copied into a plant, or *vice versa*. Any animal or plant that carries genes from another species is known as a "transgenic" organism.[3] However, it is very important to note that only copies of the information contained within genes are inserted in all cases, the original genes themselves are not transferred.

Important applications have already been developed. Plants can be genetically modified to confer resistance against pests or to remain edible longer before becoming mouldy. Such genetic modification might reduce the need for pesticides or it might merely benefit the retailer. GM techniques can also be used to manufacture pharmaceuticals.

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2 The general issues, and the legislation relating to the release of GM organisms are discussed in more detail in an earlier Library Paper: *Genetically Modified Organisms, Transgenic Animals and Animal Patenting*, Library Research Paper 93/55

3 For further details, see Library Research Paper 93/55, *Genetically Modified Organisms, Transgenic Animals and Animal Patenting*

III Controls over GM crops

A. An overview of the system of controls

The Government issued a consultation paper in the summer of 1997 on genetically modified herbicide tolerant (GMHT) crops,[4] which listed the current controls on the use of GMHT crops:

> 5. The Environmental Protection Act 1990 and the Genetically Modified Organisms (Deliberate Release) Regulations 1990 and 1995 say that, before any genetically modified organism (GMO) can be released into the environment a consent has to be issued by the Secretary of State for the Environment. The UK Agriculture Ministers act jointly with the Secretary of State in matters in which they have an interest, including all agricultural crops. The Advisory Committee on Releases into the Environment (ACRE) advises Ministers on applications to release GMOs. Consents may be given to the release of GMOs for experimental purposes, or for the commercial marketing of a GMO. The UK legislation mentioned above implements an EU Directive covering the release and marketing of GMOs. Applications to market are considered by all Member States, and consents issued which apply across the EU.
> 6. The aim of these statutory controls is to protect human health and the environment, and there is no suggestion that GMHT crops pose any new hazard in these respects. But the controls do not specifically address the potential disadvantages of GMHT crops for agriculture.
> 7. Before seed varieties, including GM crops, can be marketed in the UK, they need to be listed either on the UK National List or on the EU Common Catalogue of Varieties. This involves official testing to confirm that the new variety is distinct from and, in the case of the main agricultural crops, shows real improvements over existing varieties.
> 8. Only herbicides approved under the Control of Pesticides Regulations 1986 or the Plant Protection Products Regulations 1995 may be sold, supplied, stored, advertised or used in the UK. Applicants must demonstrate the efficacy and safety of their product. Approvals are product specific and most are for use on named crops only. If tolerance develops towards particular herbicides, their approval may need to be reviewed.

EC proposals to amend Directive 90/220 are currently under discussion.[5] The aim of the proposal is to amend the procedures. Risk assessment will have to take into account direct and indirect, immediate and delayed, effects of the release of GMOs into the environment. The R&D procedures would be changed, removing the possibility of simplified procedures.

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[4] MAFF News Release 196/97, *Minister seeks public's views on new genetic crops*, 10 July 1997

The Government's response in the Explanatory Memorandum is unenthusiastic.

> 15. The Government's view is that implementation of the Directive has proceeded well as regards research releases, but that the procedures for authorisation of GMO products are not satisfactory, particularly in respect of the timetable for the approval of products. The Government is primarily concerned however that the Directive does not provide the framework necessary to address the increasing concerns of the public and industry.
>
> 16 Whilst accepting the need for reforming procedures, DETR believe that some amendments to the proposals are necessary in order to ensure that, while maintaining the high level of protection of the environment and human health and addressing public concerns, the Directive meets growing public concerns regarding ethical, environmental and social issues and achieves a more transparent regulatory regime.

The German Presidency hopes to reach a common position in the June 1999 Council on the proposal.[6]

B. The regulatory system announced in October 1998

A modification to the regulatory process was announced on 21 October 1998, in a statement by Environment Minister Michael Meacher to House of Lords Select Committee:

> I am grateful for the opportunity to make this brief opening statement to highlight three issues in this fast moving debate on the introduction of genetically modified organisms. Firstly the negotiations on the amendment of Directive 90/220, the UK welcomed the Commission's proposal, which helps to address some outstanding issues. But we think it can go a little further. Our aim is to strike the right balance between protecting the environment and human health on the one hand, and on the other, maintaining the proper degree of certainty needed by business for the development of new products. I think it right to be cautious at this relatively early stage of the large scale use of the technology in the environment and to make sure that for every product we have practical evidence on safety before we take a decision to move to commercialisation.
>
> For these reasons, the UK is seeking to make sure that the scope of the directive and of the environmental risk assessment are well-defined and broad enough to cover indirect as well as direct effects of GMOs. We want to strengthen the links between this directive and EC product legislation, such as the Novel Foods Regulation, and we are strongly promoting the introduction of mandatory monitoring of the effects of products in use following marketing approval. We shall also press for changes to ensure that member states views are effectively reflected in any decisions on marketing of products. This is crucial in making the best possible judgement on safety and will also help acceptance of the technology. To make the regulatory process predictable, we are asking for sensible, but defined time frames for each of

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5 Council Document 6378/98 of 26 February 1998

6 HC Deb 16 March 1999 c 583W

the steps in the decision-making process. We have pressed for maximum disclosure of information and supported consideration of ethical issues at the Community level.

There appears to be considerable support for these ideas and we are hopeful that when the amendment finally comes into force, we shall have an improved regulatory regime. But we must not pin everything on that because it will be a number of years before the amendment is agreed and comes into force. At the same time we are not despondent: there is much that we can do now, even within the framework of the present Directive, and we are trying to exploit every opportunity for improved controls and debate.

Secondly in addition to the important work on revising the Directive, I have been considering how best to respond to calls from groups such as English Nature for a moratorium on the commercial release of certain GM crops and to the great public anxiety that surrounds this whole technology. The concerns of English Nature and others centre on fears that the widespread planting of GM herbicide tolerant crops may lead to changes in agricultural practice that will reduce our already declining biodiversity. I feel strongly that the commercial use of GM crops in agriculture must not put unacceptable pressure on our countryside and wildlife and prejudice our goal of maintaining and where possible enhancing farmland biodiversity.

I am very pleased to be able to announce this morning that we have reached agreement in principle with the plant breeding industry for a programme of managed development of herbicide tolerant GM crops whereby the first farm-scale plantings are strictly limited and monitored for ecological effects along with comparable plantings of conventional crops. This process will be underpinned by the strict guidelines for best practice in using GM crops referred to by Jeff Rooker. The results of these farm-scale evaluations will be carefully assessed before moving further. I feel it is extremely important that we do not travel further down the road to commercialisation of GM crops before we have this information. If, during this process, we find evidence of harm then we can take appropriate action.

The industry has also made the important commitment that no insect resistant GM crops will be introduced into the UK for the next three years. The concept of managed development provides a precautionary way forward to investigate in a proper scientific framework the concerns that some GM crops might be harmful to the environment.

Thirdly I also welcome the announcement of the new cabinet committee. I am acutely aware of the public unease over genetic modification and the widely held belief that these concerns are not being heard or addressed by Government. In my own area of responsibility, I am also aware of the need to look at developments on a generic level in order to take a more strategic approach and ensure that the wider issues are addressed properly. Many from both sides of the debate have proposed an environmental stakeholders forum to discuss and advise on environmental issues raised by biotechnology. Such a forum might include representatives of everyone with an interest, such as farmers, plant breeders, conservation bodies and public interest groups. This group would work in parallel with ACRE, which would remain a scientifically based committee considering applications to release or market genetically modified plants and other organisms on a case by case basis.[7]

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[7] Select Committee on the European Communities, *EC Regulation of Genetic Modification in Agriculture*, 15 December 1998, HL 11 1998-99

Mr Rooker then added a statement about MAFF's approach to GM crops.

> If I may, Chairman, I should like to make a short statement about MAFF's approach to the control of GMOs.
>
> Public health and protection of the environment are this Government's first priorities on GMOs. I want to make it clear that we shall apply all the relevant legislation - that on GM foods and GM crops, where we share responsibility with DH and DETR respectively; plus that on seeds and pesticides, where MAFF takes the lead, fully and rigorously. Applications relating to GMOs will be dealt with fairly, but they will not be given any preferential treatment.
>
> We need to recognise however that GM crops are now being grown in considerable quantities in other countries and that the UK's policy towards their use, and that of their products, must be based on a clear analysis of the scientific facts so that it is capable of being fully defended in international fora.
>
> In addition to the statutory requirements, MAFF has been considering what further safeguards need to be introduced to respond to the concerns that organisations and members of the public have expressed about the possible impact of GM crops when grown commercially.
>
> I am aware of concerns that herbicide tolerance, which is one of the main traits being engineered into crops for use in the UK, may cause serious problems as a result of their spreading to neighbouring crops and related wild plants. The best way to avoid such problems is for extra care to be taken when the crops are grown on the farm. MAFF has therefore urged the proponents of GM crops to draw up guidelines on their correct use, on proper identification and on full record-keeping. The industry group dealing with this has made a good deal of progress which I welcome. But we are pressing them further to implement measures to secure compliance with the guidelines. Not until we are fully satisfied will we give our endorsement to this approach.
>
> There is also concern about the impact on biodiversity of the herbicides which would be applied to GM crops. The argument is that their use would interrupt the food supply chain for insects, small mammals and birds. There are differing views as to whether there would be environmental advantages or disadvantages in using a single, broad-spectrum herbicide compared with the current practice of using several different products. I have therefore asked the Pesticides Safety Directorate to prepare for me a scientific review comparing the likely impact on biodiversity of current and possible future practice.
>
> Some people have suggested that the level of herbicide usage on herbicide tolerant crops will rise, while others have suggested it will fall. In order that we are properly informed on this point, I have asked that the scientific review should include an analysis of the likely level of herbicide usage.
>
> A prior review of this kind should be able to make useful forecasts. But there is no substitute for monitoring the actual usage when the crops are eventually

> grown. I am asking my officials to discuss with the industry an enhancement of the Pesticide Usage Survey to give us specific information on this point.
>
> I am also ensuring that herbicides to be used on GM herbicide tolerant crops will have to be specifically re-assessed for this purpose. Their existing approval will not automatically be transferred to this new use. The assessment will cover their effect on non-target species.
>
> Last, there is the issue of the long term safety of the products of these crops when used as foods. All GM foods are rigorously assessed for safety by the Advisory Committee on Novel Foods & Processes, using internationally recognised procedures endorsed by the World Health Organisation, before being allowed onto the market. However, the Government is currently looking into the possibility of going even further by introducing monitoring arrangements capable of picking up any unexpected effects should they emerge in the future. I hope to be able to make a further announcement about this shortly.
>
> I hope, Chairman, this demonstrates that in MAFF we are not rushing ahead, but thinking ahead on the control of GMOs. Our approach to these matters is of course an integral part of the Government's overall policy towards the use of biotechnology and I very much welcome the announcement yesterday of the new cabinet committee, under the chairmanship of my Rt Hon friend Dr Cunningham, to oversee developments in this area. This will enable us to ensure that the Government's policies in this complex area continue to develop in a fully co-ordinated way.[8]

A magazine hostile to genetic modification reported the announcement without enthusiasm:

> Amidst Europe-wide pressure for a moratorium on commercialisation of genetically engineered (GE) crops, the British government has disappointed environmentalists by delaying full-scale commercialisation by only a single year. Earlier the government had hinted that it was considering a mandatory three-year moratorium. Instead, there will be "farm scale" trials of herbicide-tolerant crops on an unspecified number of farms next year…The biotechnology industry has also agreed a voluntary three-year delay in commercialisation of insect-resistant crops, although none were scheduled for commercialisation during this period.[9]

C. Is there to be a moratorium on the planting of GM crops?

There has recently been widespread newspaper speculation that the Government has agreed with the industry a three-year moratorium on the planting of GM crops. However, no official announcement to this effect has been made, and a reply to a PQ by Dr Cunningham on 17 March 1999 contained a strong denial.

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8 ibid, also DETR News Release 877, *Government announces fuller evaluations of growing genetically modified crops*, 21 October 1998

9 "UK opts for 'managed introduction' of GE crops", *GenEthics News*, October/November 1998

> My hon. Friend's question gives me the opportunity to lay another ghost to rest. It is not true that the Government have reached or are seeking any secret deal with the industries on genetically modified foods or crops.[10]

The policy, therefore, presumably remains that stated in the information pack given to Members of Parliament on 18 February 1999.

> **Shouldn't the Government introduce a moratorium on genetically-modified crops?**
> No. Those that argue for a moratorium do so because they feel that there is insufficient information on the environmental impact of genetically-modified crops. We agree that more needs to be learnt in this area, but we do not believe that a fixed period moratorium is the answer. The voluntary arrangements which the industry has agreed with us will allow us to monitor carefully larger scale cultivation of these crops. We will only move to full scale cultivation when we are satisfied that we have enough information about the environmental impacts to be able to make a sound decision.

[10] HC Deb 17 March 1999 c 1108

IV Some Issues relating to GM crops

It is unfortunate that European public interest in GM crops and food began with the import from the USA of soya and maize in a way that mixed in the GM and normal crops. Consumers were extremely hostile and the public image of GM food has suffered. Many people associate GM crops exclusively with US corporations like Monsanto. However, the suitability of GM crops is a completely separate issue, from that, of the merits of large corporations. Many researchers, not necessarily in large corporations, have been developing GM crops with characteristics aimed at benefiting the consumer, such as strawberries that will not need to be sprayed so much with herbicides and fruit with improved taste.

One particular technique is highly controversial, that of the so-called "terminator" seeds. The technique works by attaching a gene called Late Embryogenesis Abundant to a gene that stops germination and inserting this into a seed. When the seed has grown into a plant, the promoter triggers the "terminator" gene, which sterilises the plant's maturing seeds.[11]

A. Some Concerns about GM crops and some replies

The following concerns have been raised:

- Cross fertilisation with other plants, perhaps creating herbicide resistant weeds.
- Damage to biodiversity through allowing increased herbicide use in farming.
- The use of "terminator" seeds would erode the custom of using farm-saved seed and place farmers, particularly in the Third World, in a weak bargaining position relative to a few seed companies.
- Predators eating the GM crop might be damaged, something that could have serious consequences in the case of benign predators such as ladybirds that eat pests.
- Farmers might choose to use more herbicides because their use would now be compatible with the GM herbicide resistant crops. The effect might be harmful to other plants and wildlife.

Supporters of GM crops have the following replies:

- Cross fertilisation takes place mainly with closely related plants and could be prevented. If it is a major concern, then crops with "terminator" seeds could be planted, although it would be necessary to check that the hybrid seeds retained the "terminator" property.
- The question of appropriate farming practices could best be approached by a code of practice for farmers rather than a ban on the crops. Herbicide resistant crops can be

[11] R.Edwards, "Devilish seed: US officials fear a backlash over 'terminator technology'", *New Scientist*, 10 October 1998

developed through conventional technology and no controls apply to them in that case.

- Under British law, farmers have the right to use farm-saved seed, but have to pay for so doing, to the company that developed it. Seed companies say that if the farmers buy GM crops, so as to be sure of a certain property, such as herbicide resistance, then it makes sense to use fresh seed in which that property can be guaranteed, rather than farm-saved seed in which it cannot.
- It would be possible to genetically modify a crop, so that predators were harmed, but that is something for which tests can be undertaken and it should be possible to genetically modify crops so that predators are not harmed.

B. Field Trials

A reply to a PQ in June 1998 explained the extent of field trials at that stage:

> **Angela Eagle:** Currently there are 64 experimental trials of genetically modified crops in progress covering a total of approximately 841 acres. Of these one site is 494 acres, with the remainder consisting of small size plots with an average area of less than 2 acres. In addition to the sites for experimental releases, there is one oilseed rape trial for commercial seed production covering 17.5 acres.
>
> The majority of the experimental trials are for oilseed rape (27), sugar beet (16), and potatoes (14), although GM wheat (3), maize (2), chicory (1) and barley (1) are also grown.[12]

Another reply at this time mentioned the possibility of cross-pollination:

> With respect to cross fertilisation, the risk assessment for applications for consent to release GMOs always considers firstly, the likelihood of gene transfer occurring and secondly, the consequences of gene transfer for human health or the environment. In coming to a view on gene transfer we also take into account internationally agreed standards for seed purity which have been developed over years of plant breeding experience. These set out required isolation distances to achieve the required level of seed purity for seed certification.[13]

The information pack sent to Members of Parliament on 18 February 1999, said that the area under cultivation for trials of GM crops in the UK in 1999 is expected to be approximately 300 hectares.

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[12] HC Deb 8 June 1998 c 418W

[13] HC Deb 8 June 1998 c 418W

C. Are GM Trials Illegal?

R v (1) Secretary of State for the Environment (2) Ministry for Agriculture, Fisheries and Food, ex parte Watson (1998) CA 21/7/98

In a hearing, in the Court of Appeal in 1998, an organic farmer challenged the right of Sharpes International Seeds Ltd to undertake a trial of GM seeds in the neighbouring fields. The organic farmer lost his case, but the judges accepted one argument, that the conduct of the field trials was not in accordance with the *Seeds (National List of Varieties) Regulations 1982* as amended. The regulations said that applicants for the proposed listing of a new seed variety had to submit "the results of two replicated trials", but the Department of the Environment had not been requiring replicated trial results since 1995. In this sense, the trials were not covered by the regulations and therefore illegal. DETR was therefore left with the option of either requiring the results of replicated trials or of amending the 1982 regulations. The Minister has since explained the reasons why the requirement for replicated trials was dropped.[14]

Before seed varieties, including GM crops, can be marketed in the UK, they need to be listed either on the UK National List or on the EU Common Catalogue of Varieties. This involves official testing to confirm that the new variety is distinct from and, in the case of the main agricultural crops, shows real improvements over existing varieties. The National List system for varieties was established to implement an EC Directive, to establish whether seeds are distinct, uniform and stable, and have value for cultivation and use (VCU). The reason why in practice replicated trials had not been required for some years was explained in a MAFF news release:

> The Seeds (National Lists of Varieties) Regulations 1982, as amended, sets out the legal requirements for addition of a variety to the National List. Regulation 11(3) provides that applicants must submit the results of replicated trials with their applications. This provision was first introduced in 1979 when the system was overloaded with varieties which had little chance of meeting requirements for addition to the National List. It was intended to encourage breeders to do their own pre-entry trials to screen out those varieties unlikely to be successful in full National List trials.
>
> Following a review in 1992/93 a streamlined system of VCU trials was introduced, which reduced the burden of the trials system…Once the pressure on the official trials system was relieved, the requirement to submit replicated trials had no value whatsoever and was not enforced.[15]

The legal position was rectified by the *Seeds (National Lists of Varieties)(Amendment) Regulations 1998* (SI 2726). Details of trial sites are available on the internet at http://www.shef.ac.uk/ uni/projects/doe/reg98.html

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[14] HC Deb 29 July 1998 c 353W

[15] MAFF News Release 394/98, *Amendments to the National Seed Lists Regulations*, 8 October 1998

V The Report by the House of Lords Select Committee on the European Communities

A. The Conclusions of the Report

A report by the House of Lords Select Committee on the European Communities has produced a favourable report on genetic modification in agriculture.[16] The following are the main conclusions on genetically modified crops.

Potential benefits and risks

172. Biotechnology in general and genetic modification in particular offer great potential benefits to agriculture, industry, consumers and even to the environment. We consider that GM technology may offer much to organic systems, for example through reduced inputs (paragraphs 65-72, 78).

173. There are potential risks relating to the environment, including the impact on ecosystems of out-crossing, pest resistance and stress and multiple tolerances (paragraphs 73-86).

174. We consider that environmental risks and benefits should be assessed at the same time (paragraphs 87-88).

Risk assessment

175. The risks involved in genetic modification can, we believe, be controlled, if a strict risk management process is in place. A clear, coherent set of principles for environmental impact analysis is needed which allows for consistent interpretation by Member States (paragraphs 89, 92-93).

176. We recommend that risk assessment should include direct, indirect, immediate and delayed effects. The regulatory system should attempt to predict interactions. A system which attempted to identify an integrated approach would be preferable to what amounts to a first come, first served approach (paragraphs 94-95).

177. In assessing risk, we recommend that modified plants and their management schedules should be compared with the use of a similar non-modified crop and best agricultural practice (paragraph 90).

178. We recommend that there should be triggers other than genetic modification which bring the assessment and management system into action, as is the case for novel foods. We recommend that, from now on, any crop with

[16] Select Committee on the European Communities, *EC Regulation of Genetic Modification in Agriculture*, 15 December 1998, HL 11 1998-99

novel traits which may have the potential to impact significantly on the environment should be subject to an oversight system (paragraph 91).

179. The knowledge of how a crop grown on farm and commercial scales will interact with the environment can only be acquired by growing it on such scales. Large scale trials are needed. We consider that an outright moratorium would be inappropriate (paragraphs 96-99).

Risk management

180. We welcome the ability to set specific conditions for each commercial release. We are however concerned that the draft Directive does not envisage an end-point at which the GM crop is considered safe enough to be released into the environment without such constraints (though perhaps with certain management conditions) (paragraphs 100-101, 170).

181. Conditions and regulations should only be imposed where necessary, but must be adhered to when imposed. The general conditions may best be established through a (preferably pan-European) government-sponsored code of practice. It may be the case in this instance that a voluntary code of practice will not be sufficient; if so, the code of practice should be backed up by regulation (paragraphs 105-107).

182. Monitoring is not a substitute for risk assessment but can complement it. We consider that those involved should report on any predicted effects which do not occur and any unexpected events which do occur. We recommend that monitoring (to Community-wide standards) should be performed by an independent organisation, funded through levies on applicants. There must also be a Community-wide audit of enforcement as monitoring standards (in many fields) have in the past been subject to too great a variation (paragraphs 102-104).

B. The Government's Response

The Government's response to the House of Lords Report was announced on 24 March 1999:

Food Safety Minister Jeff Rooker today announced the Government response to the House of **Lords** Select Committee on the European Communities **Report** on EC Regulation of Genetic Modification in Agriculture.

In a Parliamentary answer Mr Rooker said:

"The Government has welcomed the Report as making an important contribution to the intense debate on the regulation of GMOs in agriculture through the presentation of a balanced and considered perspective on the key issues surrounding the application of biotechnology in agriculture and food production.

"The Government's response in particular welcomes a number of the Committee's recommendations.

> "It makes the point that rigorous and wide-ranging assessment of risks to the environment and human health must continue to form the foundations of the regulatory process and that the Government is committed to ensuring that risk assessment provisions are strengthened and extended to include indirect and delayed environmental effects.
>
> "The response also supports the Committee's recommendations on monitoring on the grounds that this will allow a clear picture to be built up of the environmental effects of GMOs, and enable the assumptions in the risk assessment to be verified.
>
> "The response further welcomes the Committee's recommendations on labelling and makes clear that the Government is pressing the European Commission to develop further proposals on thresholds for adventitious contamination and a list of materials from GM crops that will not require labelling.
>
> "Finally, the response states that the effective and timely revision of Directive 90/220 on the deliberate release into the environment of GMOs is a major priority for the Government. It offers the opportunity to reinforce the existing legislation to secure full protection for human health and the environment, while providing a stable and predictable regime which will maintain UK and EU competitiveness in the commercial exploitation of biotechnology and genome research.
>
> "The European Parliament adopted its first reading Opinion in February 1999. The Government welcomes the Opinion, and supports the Parliament's call for moves to reach a common position shortly."[17]

C. English Nature's Criticism of the House of Lords Report

Responding to the recent report from the Lords Select Committee dealing with Genetically Modified Crops, English Nature, the Government's statutory adviser on wildlife and the Countryside, issued the following statement:

> It is unfortunate that the presentation of the House of Lords report gave the impression of unqualified support for the benefits of genetically modified crops. The environmental risks of GMOs to wildlife and the environment have become increasingly accepted both by the regulators and the informed public. Indeed almost half of the Committee's recommendations are concerned with broadening and making more rigorous the risk assessment and regulatory process necessary to deal with these risks.
>
> English Nature cannot understand how, while stressing the need for considerable tightening of the process of research and appraisal before any release of organisms was agreed, the overall message from the report can be that GMOs should go ahead.

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[17] MAFF News Release 105/99, *Government welcomes the House of Lords report on GM crops*, 24 March 1999

> We are very disappointed that this Committee appears to have failed to understand the implications for farmland wildlife of growing genetically modified herbicide tolerant (HT) and insect resistant (IR) crops. They say that these crops may benefit wildlife but there is no scientific evidence from Europe, the US and Canada supporting this.
>
> The Committee has completely failed to grasp the point that applying broad spectrum herbicides to HT crops during the growing season will give many more farmers the power to remove all weeds from fields, putting yet more pressure on our already beleaguered wildlife. We are also concerned that IR crops containing insecticides may have serious effects on non-target insect populations, reducing still further the food available to farmland birds.
>
> In the past 20 years populations of 10 farmland bird species such as skylark, corn bunting and grey partridge have crashed to an all-time low and we now have strong evidence that a major factor in this decline is the increase in the use and effectiveness of pesticides, including herbicides.[18]

A further statement from English Nature clarified its position:

> Contrary to what has been reported, we are not asking for a moratorium on commercial release of all genetically modified crops. We consider that there may be potential in some of this technology for producing more environmentally-friendly crops and better food in the future, but that this needs further research, proper regulation and adequate safeguards in use. We are however very concerned about the effects that introducing herbicide tolerant crops would have on biodiversity. These new varieties give the farmer the ability to eliminate wildlife in crops where they cannot easily do so. This type of genetic modification will make farming even more intensive and is undesirable in the British countryside where farming and wildlife must co-exist…
>
> Our position on the likely effect of herbicide tolerant crops is based on several pieces of good scientific research which demonstrate that declines in wild plants, insects and birds on agricultural land is partly due to the use of more efficient herbicides. More research on this topic has been commissioned by DETR and MAFF, but will not report until 2003 at the earliest. In the light of this scientific evidence, we were taken aback by the decision of the Advisory Committee on Releases to the Environment last week to approve the release of herbicide tolerant rape.
>
> Our advice to the government has been that herbicide tolerant crops and insect resistant crops, not all GM crops, should not be released commercially until this research has been completed and assessed by the regulatory system.[19]

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[18] English Nature Press Release, *English Nature criticizes presentation of House of Lords report*, 22 January 1999

[19] *Letter from the Chair of English Nature to the Prime Minister*, 4 February 1999, Library Deposited Paper 99/157

VI Genetically Modified Food

A. Introduction

Genetically Modified food has become a very controversial topic since late 1996, with concerns about labelling requirements and possible environmental effects. On the whole the USA sees this as a scientific advance and is going ahead, while the European authorities are more cautious and a large part of European public opinion seems positively hostile.

Only a very few foods or ingredients are available in the UK, as the following reply to a PQ in March 1999 shows:

> **Lord Donoughue:** The GM foods and food ingredients currently on sale in the UK were approved on the following dates:
>
> GM tomato puree February 1995
>
> GM soya ingredients February 1995
>
> GM maize ingredients May 1996
>
> The tomato paste has been clearly labelled by the manufacturer since its market launch in February 1996.
>
> An EC regulation requiring all foods containing GM soya or maize ingredients to be clearly labelled took effect on 1 September 1998. Prior to this the labelling of these foods was voluntary but the Government made clear their intention, soon after coming into office, of pressing for EC legislation to make such labelling compulsory.[20]

However, the soya appears in a wide range of processed foodstuffs, so that the consumer may be consuming products deriving from genetic modification already. Such products would not necessarily contain genetically modified organisms (GMOs), because the processing may mean that it is no longer a living organism. An organism is defined as "any biological entity, cellular or non-cellular, with capacity for self-perpetuation and response to evolutionary forces; includes plants, animals, fungi, bacteria and viruses".[21] Therefore, a genetically modified tomato would be a GMO. Even though no longer a living plant, it would retain the capacity for reproduction through its seeds or by propagation of plant tissue in, for example, a petri dish. On the other hand, processed GM tomato paste would probably not contain a GMO. Indeed, processing may

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[20] HL Deb 4 March 1999 c 192WA

[21] MAFF, *Report of the Committee on the Ethics of Genetic Modification and Food Use*, 1993, p 42

completely destroy the genetically modified material, as the Polkinghorne Report explains;

> 2.17 The presence, or absence of functional genetic material is likely to determine attitudes to the acceptability of particular GM foods. Tests have demonstrated that mild food processing techniques such as making puree or paste from fruit, will have a negligible effect on the state of the DNA. However, subjection to high temperatures, for example in making jam from GM strawberries or canning food, would degrade the DNA into non-functional components.[22]

B. An overview of the system of controls

In Britain, anyone wanting to produce genetically modified food must:

Notify the Health and Safety Executive (HSE) for approval;

The HSE consults the Advisory Committee on Genetic Modification (ACGM);

The Secretary of State for the Environment must then give approval before the plants can be grown in field trials;

The Department of Environment (DETR) carries out an environmental risk assessment following advice from the Advisory Committee on Releases to the Environment (ACRE);

If field trials are successful, the issue is considered by the Advisory Committee on Novel Foods and Processes (ACNFP);

The ACNFP can also ask for advice from the Food Advisory Committee (FAC), Committee on Toxicity of Chemicals in Food Consumer Products and the Environment (COT), Committees on Carcionogenicity and Mutagenicity, and the Committee on Medical Aspects of Food Policy (COMA);

and

Finally, a marketing consent allowing the product to be sold is only given by the Government following another full risk assessment.[23]

C. British Government position on GM Food

Successive British Governments have taken note of the issue of GM food. As early as 1992, the Government appointed a Committee, under the chairmanship of Dr

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[22] MAFF, Report of the Committee on the Ethics of Genetic Modification and Food Use, 1993, p 7

[23] MAFF News Release 408/98, *Food Minister welcomes shopper survey on Genetically Modified Foods*, 20 October 1998

Polkinghorne, a clergyman and scientist, to investigate the ethics of genetic modification and the resulting report appeared in 1993.[24] The conclusions were accepted and passed on to the Food Advisory Committee, which produced, among other things, guidelines on the labelling of GM food. The British labelling requirements, and parts of the system of control, were voluntary, but the Government knew that EU legislation was going to be necessary, so it did not want to introduce its own laws that would have had to be quickly repealed. In view of the very small number of crops ready for research, let alone commercial application, that strategy does not appear to have caused any problems. The EU legislation (particularly Regulation 258/97) was largely consistent with the British system.[25]

The coming of the US GM soya and maize, along with widespread public concern, has forced the current British Government to consider labelling issues in more detail. One sign of the Government's concern about the mixing of GM produce with other produce came with the announcement by the Food Safety Minister in March 1998 of a list of soya bean growers and distributors that can offer smaller retailers and manufacturers supplies of non-GM soya.[26] In a press notice in November 1998, the Food Safety Minister noted public concern.

> The farming industry and Government must take account of consumer concerns on genetically modified foods, Food Safety Minister Jeff Rooker said today.
>
> Tough new measures and additional checks are being introduced on genetically modified crops. Already, food with genetically modified ingredients must be labelled to give consumers a choice. And the Government will encourage greater openness in the way decisions are taken on genetically modified crops and foods. Addressing members of the Women's Farmers Union at their annual general meeting today, Mr Rooker said:
>
> "There are concerns about these new crops and foods. We must recognise that, and act on it. Consumers are also customers. It is not in the food industry's interests to ignore the concerns of their customers. Farmers are part of that industry.
>
> "We must be entirely open with the public and explain where Britain sits in the global marketplace for crops, vegetables and fruit; explain the drawbacks and the benefits of the new technology; and explain the tight regulatory controls we are putting in place to protect consumers."[27]

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24 MAFF, *Report of the Committee on the Ethics of Genetic Modification and Food Use*, 1993

25 UK Government Explanatory Memorandum to EC Draft 8050/92 which, after various revisions, became Regulation 258/97

26 MAFF News Release 123/98, *Non-Genetically Modified Soya Supplies Available*, 30 March 1998

27 MAFF News Release 434/98, *Concerns recognised on GM Foods says Rooker*, 5 November 1998

He announced new measures taken by the Government, but they relate to crops rather than to food.

D. The Joint Statement of 18 February 1999

The joint statement signed by five ministers was sent to all Members of Parliament on 18 February 1999. It contained the following passages on GM Food.

> 5. Only a very few GM food products are currently on sale in this country. They are a tomato paste, a type of soya and a type of maize. Although the genetically-modified soya and maize are used in a wide range of processed foods, it is the same two products that are used in each of these foods. Some cheeses and other products are made using enzymes produced from genetically-modified material but the foods themselves do not contain any such material. All of these products have been through a rigorous assessment procedure by the United Kingdom's independent Advisory committee on Novel Foods and Processes (ACNFP). Although the regulatory procedures governing this area are now determined at EU level, this is a relatively recent development…
>
> 6. The government's primary duty is to protect people and the environment. That is why we have a comprehensive framework in place to regulate and advise on biotechnology at EU and national level, and to assess new products rigorously before they are approved for use. We are confident that the GM products currently on sale are safe. No new product would be allowed onto the market unless and until it went through this safety assessment, which is set out in EU legislation. If our scientific assessment raises doubts about a product, we will oppose its approval at EU level.
>
> 7. All member states, including the UK, must respect final decisions taken at EU level on whether or not to approve a product. Once a food has been granted a licence, it can be marketed in each member state. However, if new information comes to light which calls into question the original approval, a member state can halt the sale of a product while the new information is evaluated.

VII Labelling

A. The background to the March 1999 Regulations

Until late 1996, there appeared to be reasonable consensus that labelling of all GM food was not necessary since the results were mostly indistinguishable from food produced using conventional techniques. However, the coming of soya and maize from the USA, not only unlabelled but mixed in with conventional crops, has created a hostile consumer and media reaction. There is now a great distance between supporters and critics of GM techniques. Supporters, including the regulatory authorities in the USA such as the FDA, see GM techniques as a scientific way of achieving either produce that could have been bred more slowly by conventional methods or improved varieties. US public opinion does not apparently see a problem in mixing GM and conventional crops, without requiring any labelling. In Europe, on the other hand, the agreement on labelling requirements, very much in line with British policy and the independent report of the Polkinghorne Committee in 1993, has not satisfied public opinion.

The European Union (EU) agreed a Regulation on Novel Foods and Novel Food Ingredients, which came into force on 15 May 1997, requiring the labelling of all novel foods sold to the consumer where they are judged on the basis of a scientific assessment not to be equivalent to existing foods.[28] Novel foods are also required to be labelled if they give rise to health or ethical concerns. In addition, any product containing a genetically modified organism (GMO) has to be labelled. There are also further rules concerning the release of GMOs under a separate EC Directive.[29] Thus, for example, seed containing a GMO has to be labelled when sold to farmers.

The US imports of GM soya and maize, came before the EU had reached agreement on its labelling rules and they have, therefore, been covered by national legislation, with some EU countries offering stricter standards than others. There was considerable disagreement between Member States about the labelling criteria. A Commission Regulation appeared in September 1997[30] and agreement was not reached until May 1998.[31] The Food Safety Minister described the position:[32]

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28 Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, OJ L 43, 14 Februrary 1997

29 Commission Directive 97/35/EC of 18 June 1997 adapting to technical progress for the second time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, OJ L 169, 27 June 1997

30 Commission Regulation (EC) No 1813/97 of 19 September 1997 concerning the compulsory labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC, OJ L 257, 20 September 1997

31 Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided or in Directive 79/112/EEC OJ L 159, 3 June 1998

32 HC Deb 8 June 1998 c.453W

> **Mr Rooker:** The labelling rules in the Novel Foods and Novel Food Ingredients Regulation (258/97) apply to all foods and food ingredients covered by the regulation including those considered under the simplified criteria on the grounds of substantial equivalence. There are no plans to review this regulation at this time. However, last month detailed rules for labelling of genetically modified (GM) soya and maize ingredients were agreed which require all foods to be labelled where any material arising from the genetic modification process is present. These rules are expected to set a precedent for the way all future GM foods will be required to be labelled in Europe.

The rules to which reference is made are the *Food Labelling (Amendment) Regulations 1999* (SI 747), which were laid before parliament on 18 March 1999 and came into force on 19 March 1999. The labelling requirements will apply from 19 September 1999.

In reply to a PQ, Mr Rooker said that food with genetically modified additives should also be labelled, but that further EU legislation would be required.[33] A reply to another PQ in November 1998 shows the position on other labelling issues still not resolved:

> **Ms Shipley:** I thank my hon. Friend for his reply and for his extensive written replies to my constituents, many of whom, along with many organisations in Stourbridge, have written to me on the subject.
>
> Is there not a problem in that the EU thresholds for GM ingredients have not yet been agreed, and the labelling regulations which came into force on 1 September do not include ingredients which are part of the manufacturing and refining processes?
>
> **Mr. Rooker:** I agree with my hon. Friend. The rules that came into force on 1 September apply to the ingredients in the food purchased by the consumer; they do not affect the manufacturing process where GM materials may have been used but are no longer part of the ingredients.
>
> We are negotiating on the important issue of tolerance levels. The new rules do not apply to additives and flavourings. We think that they should and we are pursuing that in Brussels. It is important to have tolerance levels for GM produce. At a public meeting recently I learned that some manufacturers have commercial contracts for buying and selling foods to each other where tolerance levels of 0.1 to 1 per cent. are allowed for GM produce in allegedly non-GM foods.[34]

One complication is, that it has not been possible to test reliably for small quantities of GM material. If testing is not possible, then the food retailer or caterer can only rely upon his supplier, as being one whose policy on GM crops is known. However, testing techniques are improving and offer the prospect of accurate testing for very small quantities of GM material. A report of a new technique developed RHM technology, whose managing director is Bob Marsh, shows the position at the moment.

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[33] HC Deb 17 December 1998 c 1080

[34] HC Deb 12 November 1998 cc 470-471

> RHM technology of High Wycombe, Buckinghamshire, says it now has a test that detects traces of GM ingredients even in heavily processed products, such as those containing soya oil or lecithins…The test is also the first to measure accurately what percentage off an ingredient is genetically engineered, claims Marsh. That could be important for food inspection agencies. The EU is expected to introduce rules which allow food to be labelled GM-free is less than, say, 2% of the soya or maize within the product is genetically engineered. This will prevent companies being penalised for accidental contamination.[35]

B. Comment on the Regulations

It is too early for the catering industry to see how the regulations will work, but the Chartered Institute of Environmental Health (CIEH) has already raised concerns.

> The Institute of Trading Standards Administration (ITSA), in a view shared by the CIEH, warned that pizzas containing GM tomato puree, and foods with only trace elements of GM soya or maize, would not have to be declared. ITSA spokesperson Steve Butterworth said: "The regulations need to be extended to all ingredients and the Government needs to establish a definition of 'GM-free'. Unless this is sorted out, the situation is likely to unravel, confusing the consumers and undermining the value of food labelling laws."[36]

To some extent the appropriate labelling requirements depend on the reason for labelling. Normal labelling of contents can ignore very small quantities, if the concern is for example, avoiding excess fat intake. Labelling to avoid allergic attacks from consuming minute traces of peanuts cannot use the same cut-off criteria. The appropriate labelling requirement for GM food cannot be separated from a general view of the reason why labelling is necessary.

C. The House of Lords Report comments on food labelling

The report by the House of Lords Select Committee on the European Communities, to which reference has already been made, included the following conclusions on GM food, basically favourable but calling for tighter labelling requirements.

> **GM food**
>
> 183. We consider the regulatory process for assessing the safety of novel foods to be thorough and proper and we see no reason to doubt the safety of foods which have been approved by the regulatory process. The emphasis should not be on "genetically modified" but on the new characteristics of any individual product (paragraphs 109-116).

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35 A.Coghlan, "Freeze! Gene Police!" *New Scientist*, 27 March 1999 p 4

36 W.Hatchett, "New doubts on GM labelling", *Environmental Health News*, 26 March 1999, p 2

184. Antibiotic-resistant marker genes should be phased out as swiftly as possible. Research needs to be conducted into how best to consider applications involving genes without proven track records of food use. We support the call for the accumulation and sharing of national data to assist regulators (paragraphs 75, 109-116).

185. Internal work at MAFF to prepare for the Food Standards Agency is poor substitute for its launch. We would be encouraged if legislation were to be brought forward in this Session (paragraphs 118-122).

186. Genetic modification does not concern a single product or variety but will soon affect the whole spectrum of agriculture. To require traceability for all agricultural commodities would be an exceedingly costly exercise for little benefit, especially when there is no anticipated risk to human health (paragraph 117).

Consumer choice

187. Once the regulatory process has ensured safety, the success or failure of the technology must be left to consumer choice in the marketplace. The two issues involved in providing choice are the supply of GM and non-GM products and labelling (paragraph 128).

188. Segregation must be driven by the market and not required by Government. Producers and manufacturers should however be under no illusion as to the climate of consumer opinion in Europe and it would be advisable for the immediate future for segregation to occur to facilitate consumer choice. The identity preservation system is to be commended. The crop and product must still be subject to the standard testing and labelling regimes as GM material has often been found in supposedly unmodified shipments (paragraphs 129-134).

189. We welcome the requirement for the explicit labelling of GM products in order to help provide consumer choice. We agree with the Commission and Government that only products where the transgene or its product are detectable should be labelled. To demand labelling where such detection is impossible would be meaningless. A Community list of products which do not require labelling is urgently required (paragraphs 135-139, 145).

190. Any ingredient or additive to a product should be identified as GM when the presence of GM material can be detected above an established threshold. No labelling should be required below the threshold. Additionally, if a finished product contains GM material above a threshold the product itself should be labelled.

191. The absence of a testing and thresholds policy is a serious gap in current European and domestic legislation. Until a Community policy is agreed we recommend that MAFF should issue interim guidelines. A workable but cautious threshold for GM presence would perhaps be 2 per cent. (paragraphs 136-139, 141-144).

192. Information supplementary to that provided on the label of GM foods must be available to the consumer. We recommend that Member State governments co-ordinate (but not necessarily be responsible for) the establishment within each State of a source of information regarding GM foods, to which the consumer may resort for information not provided on the product label. In the United Kingdom, this should as soon as possible fall under the remit of the proposed Food Standards Agency (paragraph 140).[37]

[37] Select Committee on the European Communities, Second Report, *EC Regulation of Genetic Modification in Agriculture,* 21 January 1999, HL 11, 1998-99

VIII The March 1999 Regulations

A. What the Government is trying to do

The News Release announcing the policy described its objectives:

> Food Safety Minister Jeff Rooker today announced the introduction of new powers aimed at enforcing an EC Regulation on the labelling of foodstuffs containing genetically modified soya or maize.
>
> And in a move in which the UK leads the way in Europe, the controls will also apply to restaurants, cafes, bakers and delicatessens. The new measures mean that outlets selling foods containing GM material that is not properly labelled may be prosecuted and fined up to £5,000.
>
> In a Parliamentary answer Mr Rooker said:
>
> "I have laid before Parliament this morning the Food Labelling (Amendment) Regulations 1999, which will come into force tomorrow. These provide the means for Local Authorities to be able to enforce the EC Regulation that requires all foods containing genetically modified soya or maize ingredients to be clearly labelled. This Regulation, which took effect last September, applies to all foods produced and labelled from that date.
>
> "The Government is determined that consumers should be able to choose whether or not to eat genetically modified foods. This includes foods sold in restaurants, cafes and takeaways and not just that available from supermarkets. The UK is the first member state in Europe to take steps to ensure that consumers eating out will have the same right to choose whether or not to consume foods containing GM ingredients as those buying from shops.
>
> "As a measure of how seriously the Government takes the right of consumers to have clear, reliable information about the GM content of the food they buy we have decided not to wait the customary 21 days for these Regulations to come into force but to make them fully effective from tomorrow."[38]

B. The effect of the Regulations

The EC Regulation 258/97, covering the approval of new GM products required that they be labelled, if the food or ingredients, were no longer equivalent to existing foods or ingredients (Article 8). However, it did not explain exactly when labelling was required nor did it deal with catering. The EC Regulation 1139/98, covering labelling of the soya and maize that had been approved before 258/97 came into force, made it clear that labelling would only be required when DNA or proteins resulting from genetic

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[38] MAFF News Release 95/99, *GM Labelling – Rooker puts new powers on the menu,* 18 March 1999

modification were present. Paragraphs 16 to 18 of the preamble deal with this important point.

> (16) Whereas food and food ingredients produced from genetically modified soya beans (*Glycine max* L.) or from genetically modified maize (*Zea mays* L.), in which DNA resulting from genetic modification is present, are not equivalent and should therefore be subject to labelling requirements;
>
> (17) Whereas it is possible that protein or DNA resulting from genetic modification has been destroyed by successive stages of processing; whereas, in that case, foods and food ingredients should be considered equivalent for labelling purposes; whereas they should therefore not be subject to labelling requirements; whereas a list of such products should be drawn up;
>
> (18) Whereas, nevertheless, some processing methods may eliminate proteins; whereas the possibility cannot be excluded that such methods may be capable of being applied to food uses; whereas foods and food ingredients in which DNA resulting from genetic modification is not present but in which proteins resulting from genetic modification are present, cannot be considered to be equivalent; whereas, therefore, they should be subject to labelling requirements.

As well as providing for the enforcement of the EC Regulations 1139/98, the 1999 Regulations extend their provisions to unwrapped food and catering establishments. In such cases it is not necessary to label with the GMO particulars. Article 7 forming a new Article 4B of the 1996 Regulations, requires that:

> Alternative particulars are displayed…if there appears on a menu, notice, ticket or label which is readily discernible by an intending purchaser and which is located at the place at the premises where he chooses that food, indications to the effect that some of the food sold at those premises contains ingredients produced from genetically modified soya beans or maize, or both, as the case may be, and that further information is available from the staff.

At first sight, it looks as if a stricter regime is being imposed upon the soya and maize than upon those GM foods approved under Regulation 258/97, but that is slightly misleading. As noted above, only three foods or food ingredients have been approved in the UK, two of which are the soya and maize. The third is the tomato paste, which was approved under the pre-1997 voluntary system of labelling. This has been approved for particular containers and sale by a supermarket. It would be legally possible for a caterer to buy it and use it in food, but not to provide this information to consumers. However, MAFF does not consider this a likely possibility. Future approvals of GM food will include labelling/information requirement that will include the provision of information in catering, modelled on the system in the regulations.

IX What other countries are doing

A. EU countries

It is obvious that the regulation of GM food should be done on at least a Europe-wide basis because of the free trade in food. For crops, also the logic of the single market is that the same rules should apply throughout the Union. If food is approved under the terms of Council Regulation 258/97, then it can be sold throughout the Union. If a GM crop has been given consent for the deliberate release of genetically modified organisms, then that consent also applies throughout the Union, subject to a qualification explained below. Evidence by MAFF Officials to the House of Lords Select Committee explained the thinking.

> Since trial releases of GMOs are carried out in defined locations, it is appropriate that decisions about such releases are taken at national level, with some form of information exchange with other Member States. The marketing of GMO products however, presents a different scenario in which an approved product can be used anywhere in the EC. It is therefore appropriate in this case that decisions are taken collectively by the competent authorities using a procedure which allows each competent authority to review and reach a judgement on a marketing application in the light of its particular environment. Any procedure which removed this possibility would not give due attention to the property that organisms, unlike chemicals, are likely to behave differently in different environments.[39]

Article 16 of Directive 90/220 lays down the criteria by which a Member State can disallow the use of a seed that has been approved at EU level.

1 Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health ot the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member State of such action and give reasons for its decision.

2 A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 21.

There is a further final stage before a seed can be sold to and planted by farmers. In the UK such a seed needs to be on the national list. The testing for the national list, run by MAFF, checks for agronomic properties such as yield, checks that it is a distinct variety, that it is reasonably resistant to disease, has the properties claimed for it and so on. It does not include environmental checks. The UK could, therefore, ban an individual type of seed on environmental or health grounds under Article 16. It could also refuse to put a seed on the national list if it failed the necessary tests for efficiency. What it could not

[39] Select Committee on the European Communities, Second Report, *EC Regulation of Genetic Modification in Agriculture*, 21 January 1999, HL 11, 1998-99, written evidence, 15 July 1998

do, in terms of either EU or British law, would be to ban all GM seeds, regardless of their properties.

In practice, however, several countries have introduced unilateral measures to ban seeds approved at EU level. The measures have been challenged by the European Commission and may end in cases at the European Court of Justice.

GM Bt-resistant maize, produced by Novartis, was approved by the EU in December 1995. Apparently, the maize is unsuitable for planting in the UK, so the question of inclusion in the UK National List has not arisen. Several countries refused to accept this maize. Luxembourg and Austria banned the sale or planting of the Bt maize, while Italy and France banned their farmers from planting the modified seed. Luxembourg and Austria are likely to be taken to the European Court of Justice, but the ban has not yet been removed.

The French Government suspended its planting approval for three varieties of Novartis maize containing the Bt gene in September 1998, following a Court action brought by Greenpeace in France. The French Court backed the Greenpeace claim that the product's submission for approval to the national register was incomplete and lacked information on antibiotic resistance that might be caused by planting the crop.[40] In December 1998, the Conseil d'Etat, France's highest administrative court upheld this decision, pending a ruling from the European Court of Justice. The objection appears to be because of procedural irregularities, rather than on safety grounds.[41] The Conseil d'Etat has referred to the European Court of Justice the interpretation of Directive 90/220 because of the overlapping procedures and decisions appropriate to national authorities or to Community authorities.[42]

The European Commission has decided to make an application to the European Court of Justice against Portugal for non-respect of Directives 90/220 and 90/219 relating to GMOs. In the case of Belgium, the Commission has sent a formal letter on a ruling by the European Court of Justice in July 1998 on the country's failure to adopt and notify national measures for transposing Directive 90/220. Further applications are being made against Greece and Portugal for failing to adopt national measures and notify the Commission of national measures for adopting Directive 97/35 (the second adaptation to technical progress of Directive 90/220.[43]

In other words, the legal position within the European Union is confusing. Several countries have delayed implementing EU legislation, while others fact legal challenges for having done so. The delays partly reflect the new technology and the difficulty of

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40 "France suspends GM maize authorisation", *Agra Europe*, 2 October 1998, EP/7

41 "France upholds ban on Novartis maize", *Reuter News Service*, 11 December 1998

42 "France asks EU Court to interpret GMO Directive", *Europe Environment*, 8 January 1999, p 1

43 "Serial infringements", *Europe Environment*, 8 January 1999, p 1

drafting laws in this area. However, there does appear to be so much hostility towards GM crops and food in public opinion that some governments are reluctant to implement laws allowing the use of the techniques.

B. The USA

The USA is the country that has made most advance in the growing of GM crops and in the approval of GM food. More than 25 agricultural biotechnology products have successfully progressed through the US regulatory system to commercialisation in the marketplace since 1990. Food is regulated by the Food and Drug Administration (FDA), pesticides regulated by the Environmental Protection Agency and plant pests by the US Department of Agriculture. Evidence to the House of Lords Select Committee on the European Communities from Mr Timothy Galvin of the US Department of Agriculture stressed the public approval of the US regulatory system, which was understood as being stable and predictable.

> **Chairman**
>
> 378. Is the situation in the US fairly stable? There is no pressure to change the regulatory system in any way to take into account considerations that hitherto have not been taken into account?
>
> A. More recently, there was a request by some consumer groups for the labelling of these products. There are some in the US who believe that we should do more to regulate these products or label them, but they tend to represent a minority. The overwhelming majority of the public accepts the procedures that we have in place. Part of the reason for that is that from the very start our process involved a period of public comment and review. Even to this day as specific products are reviewed and approved they are noted in our federal register so that there is an awareness on the part of those following this issue as to exactly what steps the federal agencies have taken to approve these products.
>
> **Lord Redesdale**
>
> 379. You referred to labelling. In supermarkets in the United Kingdom every genetically modified product is labelled. Are you saying that in the US some products are not labelled as such?
>
> A. That is correct.
>
> 380. Consumers are not aware that they are eating genetically modified products?
>
> A. Not in each and every case, but they are aware that these products have been approved and are available in the marketplace.
>
> The Committee returned to the topic in more detail a few questions later:
>
> **Lord Rathcavan**
>
> 387. Could you deal in more detail with your labelling philosophy? The FDA state that the "Food, Drug and Cosmetic Act does not require disclosure in labelling of information solely on the basis of consumer desire to know." Do you

consider that the consumer has the right to know? Perhaps you can illustrate this to us? I am not familiar with the practical example in the US of, say, how tomato paste is labelled if it is a 100 per cent GM product. In the case of certain products of which soya is a material ingredient, such as a pizza, does that also involve particular labelling?

A. First, perhaps I may explain the general policy that underlies the labelling requirements in the US. Labelling policy falls under the Federal Food, Drug and Cosmetic Act. Essentially, it requires that the labelling of products should be truthful and not misleading and it should include the common or usual name of the food. Perhaps more importantly, it requires labelling only if the end product is materially different in some respect. Our FDA has concluded after a careful review that inherently there is nothing in these genetically modified products that makes them materially different from their conventional counterparts. Therefore, we do not as a general matter of policy require that these products be labelled. If however, in future there is a particular genetically modified product that is materially different from its conventional counterpart, it has to be labelled. Two specific examples: Our FDA has required that oil derived from genetically engineered canola plants that have high levels of laurate be labelled as "high laurate canola oil", and that oil from soybean plants modified to express high oleic acid content be labelled as "high oleic soybean oil". Both of these products are significantly different in composition and use than the conventional products. However, in neither case was the product label required to state that the oil was produced through genetic modification. Similar labelling requirements were imposed on specific sunflower and safflower varieties, even though those varieties were developed through conventional mutagenesis.

388. You do not label GM tomato paste?

A. It is just tomato paste. That is because the FDA has reviewed the product and concluded that the genetically modified version is not materially different from the conventional product.

Chairman

389. It is for the FDA to decide whether or not labelling is required?

A. Correct.

390. If, for example, an anti-freeze gene from a flounder or other fish is inserted into a plant would labelling be required?

A. That could be an example, but I would have to address that question to our FDA.

391. If there were a modification that reduced or increased fat content would that require labelling?

A. That sort of information is disclosed on the so-called nutritional panel on the side of the label. That covers fat and protein content but there is no specific mention of the fact that the product is genetically modified.

Lord Rathcavan

392. To return to the tomato paste, from our observation it is a different product compared to standard tomato paste. Although your FDA may say that it does not require labelling, in practice do manufacturers of that product choose to identify it as a different product—as a GM paste?

A. Our companies do not voluntarily disclose the fact that it is genetically modified. They are free to do that. We would support that sort of voluntary disclosure, but that is not something that the companies have chosen to do. However, if it is a flavour savour tomato, for example, they will sell that product with that sort of advertising so that people know it is a special tomato which is more shelf stable and so on. They do other things to advertise the fact that this tomato has special characteristics.

393. It is identified as a different product, not as a genetically modified product?

A. Correct.

Lord Redesdale

394. Is that because such labelling would be detrimental to the sale of that product?

A. I do not know. You would have to put that question to the manufacturers. For whatever reason, they have not chosen to put that on the label. It is likely that they would do so if they thought there was great consumer concern in the US about whether or not the product had been genetically modified.

395. Has there been any campaigning against supermarkets who sell unlabelled genetically modified products?

A. There have been some but it is only a distinct minority who are in favour of this kind of labelling.

Lord Willoughby de Broke

396. Are there any consumer organisations represented on the regulatory agencies - the FDA, EPA and Food and Drug Administration - who monitor GM organisms?

A. No. The agencies are wholly comprised of government officials. We have scientific advisory committees. I do not have a list of their membership. I would be happy to provide that information for the record. It may be that some of the consumer groups have representatives on those committees. But the consumer groups are free to comment at various stages, even at the stage of developing regulations or as public notice is given that various products are approved or are about to be approved.

Chairman

397. Is it your view that a labelling requirement can constitute a barrier to trade?

A. It could depending on how it is constructed. For example, on the basis of the new labelling policy that has been issued by the EU it is not clear to us at this

point what level of testing may be required. If the US sent a shipload of soybeans to Europe would each bin or hold of the ship have to be sampled individually or would there be one sample for the whole ship? It is not clear how intensive that sampling has to be, or what sampling methods will be sanctioned. Until all sorts of operational details are worked out we have concerns that this policy may constitute a barrier to trade.

Lord Willoughby de Broke

398. This brings us to the question of segregation. Our impression is that the US is opposed to segregation. Is that correct, or do you accept that segregation should be decided by consumer choice? Has the US Government made any attempt to prevent segregation either at home or abroad?

A. What we are opposed to in the US is mandatory segregation. We have not made any attempt to discourage segregation to the extent that if a seller wants voluntarily to segregate a commodity we are not opposed to it. If a seller can find a certain market niche by advertising a product as GMO-free or whatever he is free to do that. We would support that as a voluntary measure. But in the case of mandatory segregation the issue for us is whether or not the end product is materially different. We have reviewed that issue very carefully in the US and have concluded that these products are not materially different from their conventional counterparts. We do not believe therefore that segregation is necessary. We also believe that on a broad scale segregation is impractical given the way that major commodities are produced in the US. Typically, our farmers harvest all their corn or soybeans together, put them in the same bins and move them to the same terminal elevators. It would be difficult and more costly if farmers segregated products according to whether or not they were conventional or genetically modified. However, increased segregation is occurring in the US but not as a result of whether or not the products are genetically modified; rather, it occurs because today farmers are more interested in producing certain commodities with special characteristics. In the case of corn, farmers are producing more higher oil, waxy or white corn that meet specific end-user requirements. That corn is then segregated and identity preserved in the marketplace. But typically it also commands a premium in the marketplace because it offers special characteristics. If a farmer is offered that premium for producing a different product then he is happy to segregate and give it the special handling and attention that it requires.[44]

[44] Select Committee on the European Communities, Second Report, *EC Regulation of Genetic Modification in Agriculture,* 21 January 1999, HL 11, 1998-99, Evidence of 8 July 1998