

GENETICALLY MODIFIED FOODS

- *Benefits and Risks*
- *Regulation and Public Acceptance*

Genetically-Modified (GM) Foods have been in UK shops for some time. They have been clearly labelled as such, and commercially successful. Recently, however, changes in US agriculture mean that many of our processed foods already (or soon will) contain GM ingredients. This is causing problems for UK and EU regulators in deciding how such foods should be labelled, and may also contribute to trans-Atlantic tensions in agricultural trade.

POST has analysed recent developments in GM foods. This note summarises the report¹ and the issues of interest to Parliamentarians.

WHY GENETICALLY MODIFY FOODS?

Virtually all plants used in agriculture are genetically modified in the sense that they are the products of selective breeding programmes, and present-day crops are genetically far removed from their wild predecessors. Traditional breeding programmes are however somewhat 'hit and miss' and when the more precise techniques of genetic manipulation made it possible to introduce specific genes into plants, researchers turned their attention to how crops and foods might be improved by the new technology - e.g. by inserting genes to improve flavour or nutrition, increase yields, impart resistance to pests and diseases, or extend the conditions under which crops could be grown.

The full report describes the techniques involved, and how GM plants and foods have made their way from research in the laboratory, through development, field trials and the various regulatory systems, to reach the consumer's plate. The UK has many strong centres of research - in industry (e.g. Zeneca Plant Science), in research institutes (e.g. John Innes Centre), and universities where the support of both the BBSRC and MAFF is important. Many research ideas are now moving out of the laboratory into field trials (e.g. potatoes with increased starch content), but the use of GM foods has been quite limited in the UK until recently - vegetarian cheese uses an enzyme produced by a GM bacterium rather than from extracts of animal; and a paste from GM tomatoes is selling well.

But such products are only the beginning and, as outlined in the full report, GM plants and foods are set to make a major takeover of our diet and agriculture. The main GM plants on or nearing the market offer:

1. The full report "Genetically Modified Foods - Benefits and Risks, Regulation and Public Acceptance" (55 pp) is available from POST, 7 Millbank, London SW1P 3JA; free to Parliamentarians: external sales £12 (contact Parliamentary Bookshop on 0171-219-3890).

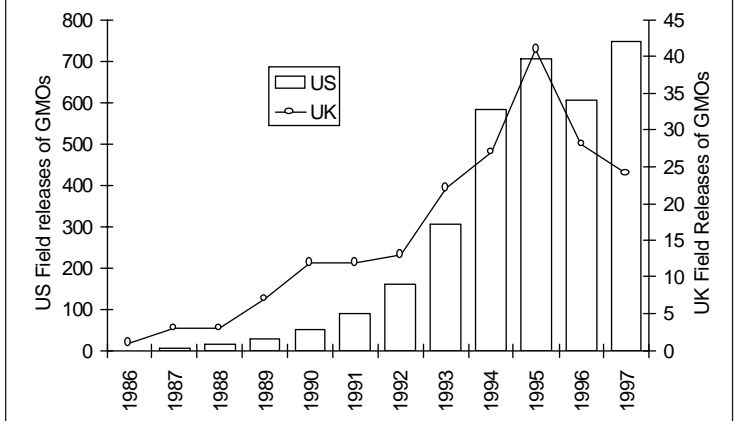


POST
REPORT
SUMMARY

115
May
1998

This is a summary of a 55-page report available from the PARLIAMENTARY OFFICE OF SCIENCE AND TECHNOLOGY (extension 2840).

Figure 1 FIELD TESTING OF GM PLANTS IN THE USA AND UK



- **Herbicide tolerance.** Crops such as soya beans, maize, oilseed rape and cotton are made resistant to a company's broad-spectrum herbicide (e.g. Monsanto's glyphosate, AgrEvo's glufosinate ammonium or Rhone-Poulenc's bromoxynil).
- **Insect resistance.** Crops are given genes of bacterial origin which produce proteins toxic to insects but harmless to plants and humans.
- **Altered ripening.** Fruit (e.g. tomatoes) can be modified to allow it to ripen without softening.
- **Altered fertility** - to produce hybrid seed by conventional breeding or to cause the crop to die before it can pollinate.

Now that earlier technical problems faced by scientists in modifying some crops are being overcome, the range of GM plants worldwide will soon extend to include many more commercially significant plants - for example, trials of plants such as aubergine, barley, broccoli, carrot, chicory, cranberry, grape, pea, pepper, raspberry, strawberry, sugarcane, sweetgum, sweetpotato, watermelon and wheat have all occurred in the last two years (see Figure 1).

As the range of plants being modified has expanded, so too has the spectrum of modifications, and some of the main targets currently being developed include:

- resistance to bacteria, viruses or fungi;
- improving product quality (e.g. changing oil profiles, amino acid composition, carbohydrate metabolism, carotenoid content);
- changing the agronomic properties of plants (e.g. improving growth rates, tolerance to cold, drought, stress, changing nitrogen metabolism, maturation rates, yield, etc.).

Although many of these targets involve clear advantages to the consumer (e.g. improved taste or nutrition), the 'big business' is currently in GM crops such as maize, soya bean and oilseed rape, which have been modified to tolerate proprietary herbicides or resist insects. For instance, GM soya beans tolerant to glyphosate currently account for some 30% of the soya sown in the USA this year, and over 6 million acres of insect-resistant (Bt) maize were grown in 1997. Since Europe relies on US imports of these foods, this means that in practice, foods containing GM soya ingredients have been sold from 1997.

THE REGULATORY SYSTEM

The full report explains how the regulatory system has evolved (summarised in **Table 1**) and how responsibility shifts from one body to another as a GM plant moves from the research stage, through development and field trials, to marketing approvals for food use or use as seed. From the very beginning, both national and EU regulatory responsibilities have had to be resolved, and the resulting system is much more complex than its US equivalent. Combined with apparently greater public sensitivity to the issue of genetic modification in the EU as a whole, regulatory approvals in the EU can be protracted, and thus deployment of GM plants in agriculture is well behind that of the USA. Some of the EU initiatives (particularly that on labelling) have found it difficult to keep up with technology and events.

The means by which the EC resolves differences between Member States (MS) is also complex. Thus when a company applies for EU-wide marketing approval for a GM food, it need only apply to one MS. If approved, the details are circulated to the other MS which have 60 days to object. Objections are then considered by the Commission which may seek advice from its own scientific committees. Many of the applications have triggered objections (including some from the UK) and are described in the full report.

The regulatory system applies controls towards three primary ends - protection of the health of the consumer eating GM foods; protection of the environment from any effects of growing the food; and the provision of information to the consumer via labelling. The more important aspects of each of these areas (see full report for details) are summarised below.

Protecting the Health of the Consumer

The primary responsibility for ensuring the safety of GM foods is with MAFF advised by the Advisory Committee on Novel Foods and Processes (ACNFP). The two main considerations are the potential toxicity/allergenicity of the novel gene products, and the possible impact of the antibiotic resistance genes, still widely used as 'markers' at the research phase. Some of the

Table 1 THE UK AND EU REGULATORY SYSTEM

| Stage | UK Regs. | EC Directive / Action |
|--|--|---|
| Laboratory Research | HSE advised by ACGM | Directive 90/219 |
| Experimental Release ● growing plants outdoors, field trial and cultivation | DETR advised by ACRE | Directive 90/220 Details of all releases circulated to all EU States |
| Marketing ● consent to market GM food in EU | MAFF / DH advised by ACNFP, other committees | Marketing consents sent to all EU States - 60 days to object. |
| ● consent to market GM seed | MAFF | Directive 90/220 plus various seeds Directives. |
| ● Labelling | | Novel Food Regulation 1997 |

questions which ACNFP has had to address include:

- Do residues of Bt² toxin (to kill insects) in a GM maize pose any health risk?
- Could any of the modifications cause allergic reactions in some people?
- Could antibiotic resistance genes transfer from the plant into bacteria in the human or animal gut?

As explained in the full report, ACNFP assesses risks on a case-by-case basis. Overall, the risks have generally been estimated to be extremely small, but some evidence is inevitably circumstantial, leaving scope for uncertainty. Public faith in the regulatory process can thus be critical to public acceptance of the new product. The full report describes measures taken recently to improve openness and transparency and to ensure a wider representation of interested groups on ACNFP.

ACNFP's main reservations are over the antibiotic resistance genes which are often inserted as part of the early research and screening phases for GM plants. These genes persist into the plant and, in some cases, are even active so that the plant itself contains enzymes capable of inactivating specific antibiotics. ACNFP has pointed to the general undesirability of creating new opportunities for antibiotic resistance to spread - even if the probability of it doing so from plants is very low - and has urged the industry to develop alternatives. Some companies have responded, but progress is likely to be slow. One option would be for the regulatory authorities to identify the least safe practices and to discuss phase-out strategies with the industry. For instance, some genes (e.g. for ampicillin resistance) were considered particularly undesirable by ACNFP, and were allowed by the EC only after the UK objected.

Environmental and Ecological Impacts

The lead department here is DETR advised by the Advisory Committee on Releases to the Environment (ACRE). The full report points to some potential environmental consequences of widespread use of GM plants - particularly 'selection' pressures which could

2. Bt toxin is a natural insect toxin found in the soil bacteria *Bacillus thuringiensis*.

encourage insects to develop resistance to Bt toxins, and possible spread of herbicide tolerance to close wild relatives of the crop involved. Regulators and industry point out that selection pressures are also present with non-GM plant agriculture, and argue that the risk of gene transfer is relatively small and controllable. Recent research, however, suggests that emergence of resistant insects and plants may be more likely than thought hitherto. Strategies to contain this do exist (e.g. refuges for non-resistant insects, and rotation of herbicide-tolerant and conventional crops), but concerns over GM crops' long-term effects remain. Evidence that companies are not always adhering to consent conditions designed to restrict spread of the modifying genes in field trials, also increases the perception that undesirable gene transfer may well occur. As the range of GM crops expands, there are also concerns that other crops or their close relatives could develop multiple herbicide tolerance.

Most recently, the emphasis of some companies on herbicide-tolerance has interacted with the wider debate over the role of pesticides in agriculture. Instead of seeking to reduce dependence on pesticides along with principles of sustainable agriculture, some conservation groups see herbicide-tolerant and insect resistant crops as providing a further intensification of agriculture, which is already under scrutiny for its adverse effects on natural biodiversity. Conservation groups are particularly concerned that the use of GM crops could remove what little food remains in modern arable fields for birds and wildlife, and have called for a moratorium on allowing GM crops to be grown commercially, during which period the effects of such crops on the environment and biodiversity should be fully tested. Such concerns have not affected the rapid increase in the use of GM crops in the USA.

Public Attitudes and Labelling

Attitudes towards GM foods vary considerably - at one end of the spectrum are those who see this as the technology to feed the world, and at the other end are groups who are opposed to such techniques in principle. Surveys (see full report) suggest that many European consumers do not reject GM foods out of hand - rather, they weigh the perceived benefits to themselves (e.g. is the product cheaper, tastier, healthier?) against the potential risks (e.g. could it harm the environment, human health or animal welfare?). In practice, this means that GM products where the perceived benefits accrue to the producer rather than the consumer are among the **least** readily accepted. Many consumers appear to view GM products derived from herbicide- and insect-resistant crops in this category.

The issue of labelling to inform consumer choice has been central to much of the public debate over GM foods. Here the lead is with the EU, and progress has

BOX 1 EU REGULATIONS ON LABELLING GM FOODS

EC Novel Foods and Novel Food Ingredients Regulation (258/97) provide for special labelling:

- if a GM food is judged not to be equivalent to the relevant existing (i.e. non-GM) food;
- if a GM food contains material that might give rise to health concerns (e.g. a protein from a known food allergen such as peanuts);
- if a GM food contains material that might give rise to ethical concerns (e.g. animal genes in vegetable products).

In addition, all foods which contain or consist of GM plants themselves should be labelled, although because segregation of GM and conventional products may not be possible, the Regulation recognises that a label stating that GMOs "*may be present*" would fulfil the labelling obligation.

been very slow. The Novel Food Regulation took some 8 years to develop and was finally introduced in May 1997. This put in place an EU-wide pre-market approval and labelling system (**Box 1**).

Because of these delays, the Regulation had already been overtaken by events in that GM soya and maize had already received marketing consents and were in use without labelling. A second regulation was thus needed in September 1997 to address this. Still being discussed however, are key details including what should be labelled and what the label should say. The Commission is currently considering these issues, and produced a proposal for a further Regulation in February 1998, which will be discussed in May.

The key questions here are why is the label there and what is it meant to convey? In practice, the only real difference in a GM food is that it has novel DNA (the inserted genes and related sequences) and the material produced by these genes (proteins). The Commission thus proposes that labelling will depend on whether or not novel DNA or novel protein can be detected in the product, leaving for future resolution exactly what detection methods are used and what levels would trigger a requirement to label.

Until the technical details are resolved, many inconsistencies will remain. For instance, some label only those foods which contain the GM protein (not the DNA) which means that products containing oil or sugars/starches from GM maize (e.g. soft drinks) and soya (e.g. margarines) do not need to be labelled, while those containing proteins (e.g. semolina, tofu, soya milk) do. On the other hand, if low levels of GM DNA were the yardstick, more such products might need labelling (e.g. DNA is found in food starches, but not in oil). Because GM soya and maize are not segregated at source in the USA, most major UK retailers will label products containing soya protein as "*containing genetically-modified soya*", irrespective of whether this is actually the case. However, at least one supermarket chain (Iceland) has announced that it has secured a full traceable non-GM source of soya, and will not be using

GM derivatives in its own brand products, and others (Sainsbury and Tesco) have managed to eliminate GM soya from most of their own brand products.

This situation appears unsatisfactory in several respects. Food retailers are applying labels which cannot be used to find out whether the product contains GM soya and how much. Some products from the same GM raw material are labelled, others not. And by labelling everything which may contain some soya or maize (some 60% of processed food contains soya), the consumer has no choice to exercise (except in so far as some retailers guarantee a GM-free source of soya or maize).

The whole issue **could benefit from the regulatory activities of the EU being more in step**, so that the details on labelling requirements could be known before another part of the Commission issued marketing consents to use the GM product in food. As to the future, one option would be to continue with the current (science-based) approach, and to clarify what methods should be used to detect and define GM foods, and to develop more specific labelling. Another is based on the argument that consumers should have a right to choose between GM and non-GM versions of a product which would involve the introduction of **traceability and segregation** of ingredients throughout the whole food chain. Whether or not this is a realistic prospect (e.g. given GATT rules enforced by the World Trade Organisation and sensitivities over EU-US agricultural trade) remains to be seen.

ISSUES OVERVIEW

Biotechnology is widely seen as a major source of economic benefit for countries with a strong science base, and GM foods and plants are a primary research target. The success of industry depends on a favourable regulatory and consumer environment, and over-regulation in this area within the EU could lead to further dominance by US companies, and EU companies relocating to more favourable regulatory environments outside the EU. National and EU regulatory policies have thus sought to ensure adequate protection for the consumer and the environment without placing such a burden on industry that innovation in Europe is stifled. At the same time however, too light a regulatory touch could fuel some of the public's concerns over the potential risks associated with new plants and foods. Here the key principles of labelling and choice have an important role to play in achieving the right balance.

The overall regulatory regime had, until last year, led to the first GM foods being successful in the UK and non-controversial - consumers had a choice and could see benefits. The rapid growth in GM herbicide-tolerant and insect-resistant soya and maize crops in agriculture in the USA has however driven a 'coach and horses' through the steady approach previously seen in

the UK. There are two issues here - the first is that US authorities have effectively deregulated GM soya and maize, so there is no segregation at source and European food manufacturers thus receive mixed product. But second is that it is easy to portray the modifications involved as benefitting only the companies which successfully tie the GM crop to a specific herbicide, with no advantage to the consumer in nutritional quality, taste or price. While scientific assessment judges any additional risks to human health to be very small, uncertainties remain. Research on risk perception suggests that such situations (where there are no perceived benefits to balance even minute levels of perceived risk) often lead to consumer resistance, particularly when denied a choice between GM and non-GM products.

Some companies' concentration on herbicide-tolerant crops has also acted as a 'lightning rod' for more generalised concerns over the role of intensive agriculture within the rural environment. This has led to concerns that there might be a 'backlash' against GM products in general to the particular disadvantage of European companies who would face extra difficulties in their own home market in getting new products established.

GM applications in food and agriculture thus raise a number of questions of relevance to Parliamentarians.

- Firstly, there is the reaction of UK consumers to developments and how to improve public representation within the regulatory framework.
- Secondly, the negative reaction to the current focus on herbicide tolerance and insect resistance is spilling over into hostility to the technique itself, threatening UK investment in this area, and the creation of wealth from previous investments in R&D.
- Thirdly, the UK's own position is heavily constrained in this area - not only is this an area of EU competence, from the point of view of both food safety and environmental impact, but any action taken across borders impacts substantially on the global agreements on trade.
- Current practice in the EU is leading to inconsistencies between the different functions, typified by the granting of marketing consents before labelling policy is resolved. The means of resolving disagreements between MS has also proved to be somewhat cumbersome.
- Finally, even within the UK, the specific terms of reference allocated to the various agencies involved mean that some of the more general issues such as the role of GM crops in agriculture and the effects on the rural environment, and of general consumer anxiety over the principle of clear and meaningful labelling, have no obvious forum for resolution.