

RISK MANAGEMENT AND EXPERTISE: UK: Strategies for Precautionary Commercialization of GM Crops

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Summary: As genetically modified (GM) products approach the market stage, the UK government and agro-food industry have faced a suspicious or hostile public. Since 1998 many retail chains have undertaken to exclude any GM-derived ingredients from their own-brand lines. This commercial blockage has intensified pressures for greater precaution, even for a moratorium on cultivating GM crops. Political protest has led to strategies for precautionary commercialization. Government and industry have cooperated to plan a "managed development" of GM crops. Across the agricultural supply chain, industry has devised voluntary guidelines to ensure segregation of GM crops and to limit the spread of GM herbicide-tolerance. In particular UK regulators seek to test the risk that broad-spectrum herbicide sprays could damage wildlife habitats; they have broadened the advisory expertise accordingly. These measures open up the precautionary content to further debate, at both national and EU levels. Market-stage precautions establish a means to test claims that GM crops are environmentally-friendly products. By translating public concerns into broader risk-assessment criteria, the UK procedure involves critics in potentially influencing standards of scientific evidence and environmental harm. This social process has become a prerequisite for legitimizing commercial use.

Keywords: genetically modified (GM) crops, precaution, European integration, single market, United Kingdom.

ARTICLE

In the UK, GM crops and food have become a prominent political issue, attracting new constituencies who criticize or oppose agricultural biotechnology. The intensified debate has presented new difficulties and opportunities for risk regulation.

This article analyses links among several developments: the intensified risk debate of the late 1990s; regulatory moves to broaden the environmental criteria; plans for market-stage precautions; and the commercial blockage of GM food. Finally the article locates this case study within the UK's changing role in EU environmental regulation.

New actors intensifying debate

For science-related policy in general, the government has been advised that "Openness will stimulate greater critical discussion of the scientific basis of policy proposals and bring to bear any conflicting scientific evidence which may have been overlooked [and] could in itself avoid greater controversy in the longer run" [1]. Since the early 1990s, under pressure from NGOs, biotechnology regulators have progressively enhanced public transparency, but this effort has not avoided controversy. NGOs have challenged the supposed neutrality of official experts, partly by using information disclosure, and partly by raising broader cause-effect uncertainties about potential harm.

As in other European countries, a turning point came in 1997, when US exports of Monsanto's GM soya became an ingredient in most processed foods. This provoked a widespread risk debate about GM crops overall. Half the people opposed their cultivation and did not want to eat GM food [2]. Consumer groups warned that GM crops could impose "irreversible mistakes" and "increased reliance on chemicals" [3]. They linked GM crops with harmful effects of intensive farming [4].

Monsanto ran an expensive publicity campaign, emphasizing the safety and benefits of GM crops, yet public opposition increased [5]. Indeed, Monsanto became the main target of public suspicion towards agricultural biotechnology. It even drew some criticism from other companies for discrediting the industry. The mass media both reflected and catalysed such negative attitudes, e.g. by challenging safety claims about GM products.

Since February 1999 the Genetic Engineering Alliance has demanded a "Five Year Freeze" on the commercial use, import or patenting of GM products. It has criticized shortcomings of the regulatory system and demanded public involvement in such decisions [6]. This alliance represents more than forty members, including consumer, environmental, development and quasi-governmental organizations.

Many critics have drawn analogies between regulatory failures in the "mad cow" scandal and the inherent limits of scientific expertise for making biotechnology safe. Greenpeace [7, 8] argues that some potential effects are "unpredictable" and "untestable". Other organizations have taken up emotive slogans which were coined by Greenpeace, e.g. "genetic pollution". According to Friends of the Earth, our countryside is being turned into "a genetic laboratory" for multinational companies. Representing organic farmers, in 1997 the Soil Association decided that GM crops could not be considered as "organic"; it has portrayed GM crops as an inherent threat, given the prospect that GM maize could spread "genetic contamination" to organic sweetcorn in nearby fields.

Activists have sabotaged many field trials since 1997, including one near a prominent organic farm. In 1998 they formed a network, "Genetix Snowball", which quoted the UK Agriculture Minister: "The government is not in the driving seat", meaning that EU law was driving commercialization. In the name of "civil responsibility", activists "decontaminate" field sites by removing GM crops, while gaining mass-media attention and some local sympathy.

Under such pressures, industry has become more dependent upon government for the public acceptability of GM products. Yet official advisors have had difficulty in gaining public trust for safety claims. Alongside official information disclosure, Europe-wide expert disagreements have made the scientific issues more accessible to public debate. In this context, mass protest indicates a legitimacy crisis for GM crops.

Herbicide-tolerant crops in dispute

For herbicide-tolerant crops there has been a long-standing dispute over how to define the "adverse effects" or "environmental harm" which must be prevented under GMO legislation. In the UK the DETR (Department of the Environment, Transport and Regions) is the lead Competent Authority for GMO regulation under the 1990 Environmental Protection Act, which implements EC Directive 90/220. The DETR shares authority with MAFF (Ministry of Agriculture, Fisheries and Food) for any effects on agriculture.

From the early 1990s onwards, GMO regulators argued that the overall herbicide implications lay outside their remit, and that the new herbicide use would anyway require prior authorization from the pesticide authorities. As public criticism mounted, regulators elaborated their original argument: that "secondary effects" of herbicide usage would not be caused by the crop and so lie outside GMO regulation [9]. According to the regulators, as well as their Advisory Committee on Releases to the Environment, ACRE had "no legal basis to advise on possible secondary consequences arising from the use of herbicides" [10].

For the "agricultural environment", ACRE focused its assessment on how the herbicide-tolerance trait might affect weed-control measures. For the first such case in 1994, an oilseed rape tolerant to glufosinate (trade name Basta), ACRE considered whether gene flow might make glufosinate less effective for controlling weeds, e.g. in conventional oilseed rape or in following crops. Such an effect was deemed unlikely, though anyway acceptable on grounds that other weed-control methods would still be available [9, 11, 12]. This judgement provided a normative basis for EU-level market approval, which reiterated the UK argument [13].

During 1997-98 the previous basis of market approval came under criticism from more EU member states, emphasizing effects which were excluded from the original assessment. Similar objections gained force at home as well [14-16]. The government's conservation agencies emphasized risks of broad-spectrum herbicides, as grounds to delay commercial use of GM herbicide-tolerant crops until further research is completed. They warned that such herbicides would damage field-margin habitats essential for wildlife, thus threatening biodiversity; also that inadvertent hybridization could lead to adverse changes in herbicide usage [17].

Since the mid-1990s the DETR has funded large-scale trials on herbicide-tolerant oilseed rape. Initially these trials aimed to validate the assumptions in the original risk assessment, regarding gene flow and hybridization with weedy relatives. By 1998 the aims had been expanded, to inform the monitoring of commercial use. MAFF has funded studies which simulate commercial use of the product, to study the environmental effects of agricultural management; these continue in order to test how the best and worst herbicide usage could affect biodiversity near agricultural fields [18]. Both departments have emphasized that there is little evidence yet available for predicting such effects [19-21].

"Managed development" of GM crops

After the import of unlabelled GM soya provoked a hostile public reaction, the agricultural supply industry sought to be seen as acting responsibly whenever introducing GM crops into UK cultivation. Initially they devised plans for voluntarily segregating GM crops. This scheme would allow retailers to trace each consignment back to its farm source, so that any GM food products could be reliably labelled [22]. Later the industry added guidelines to minimize any spread of herbicide tolerance [23]. These voluntary guidelines were developed by the Supply Chain Initiative for Modified Agricultural Crops [24] - a group of individuals representing biotechnology companies, agricultural suppliers and farmers.

Faced with greater public protest, the Labour government was internally divided over regulatory policy. The UK has been a prime site for agricultural biotechnology - i.e. for R&D investment, for planned marketing of the initial GM crops, and for industry lobbying. Extending the policy of the previous Conservative government, the Cabinet Office promoted biotechnology as essential for attracting R&D investment and for enhancing economic competitiveness. The two Ministers responsible for safety regulation, however, sought to accommodate public protest through more stringent regulation.

In October 1998 the Environment Minister announced that there would be a "managed development" of GM crops. Their commercial introduction would be accompanied by farm-scale monitoring for ecological effects [25]. Moreover, henceforth ACRE would assess "indirect effects", e.g. any resultant changes in agronomic practice and the subsequent effects on biodiversity.

During the first commercial use of glufosinate-tolerant oilseed rape, regulators would seek evidence that the herbicide sprays do not cause more harm than present practices. Re-interpreting GMO legislation, biotechnology regulators would now act as if their remit already included the herbicide effects. To clarify the statutory remit at EU level, the Environment Minister also advocated that Directive 90/220 be amended so that the risk assessment includes "indirect effects", *i.e.* effects from "changes in use or management" of the product [25-27].

The Environment Minister later clarified that commercial cultivation should not begin until farm-scale field trials adequately test any harm caused by broad-spectrum herbicides - implicitly, at least not until the year 2002. Funded by the DETR, the trials are designed to compare the effects of spraying GM and non-GM crops and any consequent effect in nearby fields [28]. These trials follow relevant points of the SCIMAC guidelines; however, the conservation agencies warned that farmers could still "eliminate all wildlife from their fields", even while strictly following the guidelines.

There remain difficulties in obtaining meaningful results from the farm-scale trials, for several reasons. The scientific methods have been challenged by some environmentalists [29]. They have questioned several key features, e.g. the chosen measures of biodiversity, the presumed extrapolation from sample species to biodiversity, and differences between controlled trials and realistic commercial farming; these weaknesses suggest "that some motivation other than science" is driving the trials [30]. Anti-biotechnology pressure groups have deterred some farmers from allowing the use of their land. Activists have "decontaminated" many trials.

Meanwhile the official expertise has been broadened to fulfill ACRE's broader remit. When re-appointing the committee in 1999, regulators sought expertise in farmland systems, wildlife

biodiversity and ecological practice: "We cannot neatly pigeonhole the potential impact as occurring in either the agricultural or non-agricultural environment" (DETR interview, 13.11.98). According to one advisor, monocultural systems are more fragile than diverse ones, so a GM crop could plausibly cause a "changing balance" in agricultural environments (ACRE member, interview, 04.11.98). Such views contrast with the mid-1990s, when UK regulators sharply demarcated between the "agricultural" and "non-agricultural" environment, while inquiring whether the latter might suffer an "ecological imbalance" from GMOs.

The extra precautionary measures involve new science-policy issues. The government's conservation agencies have advocated a careful "science-based approach", with more research and enforceable safeguards before permitting commercial use [31]. Such science involves value judgements about the basis for comparing GM with non-GM crops, given that the herbicide effects vary with the crop-protection method [26, 32, 33].

At least initially, the DETR set "no standard with which to judge environmental harm" [34]. In practice, the farm-scale trials took conventional, chemical-intensive agriculture as the appropriate norm for comparison [35]. By contrast, others proposed that government should adopt a more stringent norm or even steer crop choices towards a more sustainable agriculture. According to a House of Commons report, for example, the government should influence GM crop R&D towards applications which "contribute to the mitigation of the environmental impacts of agriculture", and should establish an extra advisory committee for these strategic issues [36].

In response to criticisms, the government established an Agriculture and Environment Biotechnology Commission (AEBEC) in order to complement ACRE, e.g. by identifying gaps in the regulatory framework. Among other aspects, it was intended to advise government on "setting the general direction for the role of GMOs in agriculture, defining which impacts will and will not be acceptable, and identifying the potential for biotechnology to contribute to sustainable agricultural practices" [37, 38]. Interpreted broadly, this remit would mean debating the environmental norms which underlie risk assessment, market-stage precautions and crop R&D priorities.

GM food safety

GM food remains contentious, though rarely because of specific hazards, and for reasons marginal to the risk-assessment procedure. There has been little expert disagreement, though a few scientists claim that the GM process generates unpredictable risks in food. Consumer NGOs cast doubt on safety assessments in general, e.g. on grounds that these products of a novel technology have not yet had a long-term large-scale use [39].

GM food is regulated by the MAFF Additives and Novel Foods (ANF) section. It has established a Joint Food Safety and Standards Group with the Department of Health, thereby avoiding the isolation which contributed to the BSE crisis. Together the two departments host the Advisory Committee on Novel Foods and Processes (ACNFP). Regulators have interpreted the statutory criteria more stringently than before.

For many years the ACNFP has included a consumer representative, whose presence has influenced how the committee worked: "Eventually the scientists learned how to ask questions which would concern consumers, though we missed the public concern about Monsanto's GM soybean being mixed with other soybeans", according to the former chairman (Prof. Derek Burke, interview,

28.05.98). The consumer representative has influenced the burden of evidence for safety: "We cannot expect the public to take a strictly scientific view of safety issues", remarked a scientist on the committee (interview, 10.05.98).

A recurring issue has been antibiotic-resistance marker (ARMs) genes, amidst wider concern about excessive use of antibiotics in farm animals. When a GM crop is consumed as food or feed, an ARM hypothetically could transfer to gut pathogens, thus jeopardizing use of the antibiotic as a clinical agent. Citing that risk, advisors have asked companies not to include ARMs in unprocessed products.

In particular the committee opposed approval of the Ciba/Novartis maize, which included an ampicillin-resistance gene with a microbial promotor. Accepting that advice, the UK government voted against the product in 1996 but eventually declared the product to be safe, citing favourable advice from an EU-level committee. When the Netherlands proposed a GM potato for animal feed uses under Directive 90/220, the ACNFP advised against approval, while requesting more data on the presence of the amikacin-resistance gene in the processed starch. A similar response came from the UK government and the EU-level Scientific Committee on Plants.

The Novel Food Regulation provides a simplified procedure for products which are claimed to have "substantial equivalence" with a familiar non-GM counterpart (EC, 1997). UK regulators decided that a GM food may qualify for "substantial equivalence" only if the GM crop undergoes more extensive field testing, e.g. for genetic stability (ACNFP member, interview, 11.05.98). Moreover, MAFF accepts "substantial equivalence" only for highly processed products, containing no intact DNA. If a product does not satisfy these criteria, then it must undergo a more cumbersome procedure under the Regulation: "All other ingredients derived from GM crops... should be given a full safety evaluation, as they may not have been subjected to the processing associated with highly refined products...", according to MAFF [40]. A similar approach was adopted by the EU-level Standing Committee on Foodstuffs [41].

Since the Novel Food Regulation came into force in May 1997, most applications for GM food have been submitted to the UK, which thereby became the EU-wide rapporteur. Those UK-based applications, all for fully processed foods, have gained favourable advice from the ACNFP and have met no objections from other member states. However, its precautionary risk assessment has not gained public confidence.

GM food blockage

Despite early demands for comprehensive labelling, UK regulators advocated EU-wide approval of Monsanto's GM soybean without requiring a "GM" label [42]. As in other European countries, this product first entered the UK food chain as a common ingredient for processed foods in 1997. The food industry faced protests at its failure to provide labelling and non-GM alternatives. Local supermarkets were targeted by Friends of the Earth, among other local groups. Critics denounced biotechnology companies for "force-feeding" consumers GM food, as if we were guinea pigs in an "uncontrolled experiment".

To accommodate consumer demands, the UK food processing and retail sectors had already agreed on voluntarily labelling food as "GM" if it contains GM protein [43]. According to the British Retail Consortium, supermarket chains would simply apply a "GM" label to all protein-based products from countries where the corresponding GM crop is cultivated - firstly from North America, then

Argentina as well. Consumer groups protested at being denied a true choice, in two senses: that they would have no "non-GM" alternatives, and that there would be no "GM" label on highly processed products. According to UK retailers, they had no reliable way to obtain adequate non-GM supplies.

In May 1998 a different scenario was opened up by a minor supermarket chain, Iceland [44]. In Brazil and Canada it found suppliers of non-GM soybeans, though these were not claimed to be 100% GM-free. Iceland also introduced negative labelling, while repeating Greenpeace claims about risks of GM food. In effect, Iceland stimulated the development of a dual market, defined by labelling.

In response to Iceland's success, more and more supermarket chains used the same source to obtain non-GM soya supplies for their own-brand product lines, though they did not apply negative labelling. Reportedly the non-GM lines were sold as fast as they could be supplied. Some retail chains extended their positive "GM" label to all GM-based products, e.g. lecithin and oil, even though these contain no protein or DNA and so require no labelling by law. MAFF published a list of companies which could supply non-GM soya or maize.

Meanwhile the EU clarified that any food with detectable GM DNA or protein must be labelled as "contains GM" [45]. The new rule probably motivated supermarket chains to provide more non-GM alternatives. In early 1999 more supermarkets - and even some food processors - announced that they would use no GM ingredients in their own-brand lines [46].

In these ways, public protest and labelling law together generated a non-GM food market, despite earlier claims that segregation would be impossible. Industry intended labelling rules to provide consumer choice, to avoid negative labelling, and to avoid connotations of risk. Nevertheless labelling and segregation became a surrogate for concerns not accommodated by the regulatory procedure, e.g. distrust of safety claims, resentment at dependence on expertise, and hostility towards the biotechnology-agrochemical industry.

CONCLUSION

precautionary commercialization?

As genetically modified (GM) products approach the market stage, the UK government and agro-food industry have faced a suspicious or hostile public. Protest has led to strategies for precautionary commercialization of GM crops. Indeed, the eventual acceptability of commercial use depends upon extending precautionary measures.

NGOs have targeted GM food, partly in order to deter commercial cultivation of GM crops. In response to public protest, UK retail chains eventually undertook to exclude GM-derived ingredients from their own-brand lines. This commercial blockage has intensified pressures for greater precaution, even for a moratorium on cultivating GM crops.

As constituencies more hostile to GM crops entered the risk debate, regulators broadened their statutory boundaries and expert advisory body. Government and industry have cooperated to plan a "managed development" of GM crops, partly to contain political demands for a moratorium. Across the agricultural supply chain, industry has devised voluntary guidelines to ensure segregation of GM crops and to limit the spread of GM herbicide-tolerance. Beyond the scope of those guidelines,

debate also continues over the prospect that broad-spectrum herbicide sprays could damage wildlife habitats. As the DETR attempts to regulate this risk, controversy continues on how to set the appropriate baseline for monitoring and evaluating harm.

Biotechnology illustrates general tension of Europeanizing UK environmental regulation. For many regulatory sectors, other member states have sought a greater role for EU environmental policymaking as the counterpart to market liberalisation. The UK has accepted such a role for the EU, while demanding and accommodating clearer environmental standards within the single market. The UK has sought greater subsidiarity, or else a more consistent compliance in order to equalize the regulatory burden upon industry across EU member states [47].

Since 1990 the government has used "the precautionary principle" to manage uncertainty about the potential for irreversible environmental harm from various substances, including GMOs. Given the "uncertainty about when uncertainty disappears", the principle has provided a flexible basis for extending or relaxing restrictions [48]. For GMOs in particular, UK officials advocated precautionary legislation as a means to avert various threats - public distrust, trade barriers within Europe, and an "ecological imbalance" potentially caused by GMOs.

All those dynamics acquire an extra twist in this case. By the late 1990s a legitimacy crisis (especially in the UK) jeopardized all commercial use of GM crops, not simply the internal market. Seizing this opportunity, the DETR re-interpreted the EU risk-assessment criteria to encompass all the herbicide implications, as already proposed by some member states. The DETR also supported EU-level statutory changes so that Directive 90/220 would regulate the effects of agricultural practices in cultivating GM crops. This change could mean a more stringent implementation across the EU.

Alongside such criteria, market-stage precautions provide a more credible means to test claims that GM crops are environmentally-friendly products. In practice, industry has acknowledged its dependence upon such measures. NGOs have found more opportunities to demand public accountability - for the effects of GM crops, the environmental standards, and even the basic technological choices.

Such measures open up the precautionary content to further debate. By translating public concerns into broader risk-assessment criteria, the UK procedure involves critics in potentially influencing standards of scientific evidence and environmental harm. This social process, not simply the empirical results, has become a prerequisite for legitimizing commercial use of GM crops.

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