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Overall Policy context

There are currently no GM crops grown commercially in the UK. Five years ago, the Government seemed intent on encouraging the GM industry, but were shaken by public and political concern over the wider implications. The most convincing arguments that emerged concerned the possible effects of GM commercial growing on local biodiversity and the problem of co-existence and protection of organic farmers. This is particularly significant in a densely populated country, one where protected conservation sites are often close to agricultural land, and equally one where organic and intensive agriculture farms are often physically close to each other. In 1998 the Government response was to secure a moratorium on any commercial or experimental growing of GTMO crops in the UK, by means of a voluntary agreement with industry, until it had completed a four-year experimental study on comparing biodiversity impacts of conventional and GMO crops. At the same time it established a stakeholder Commission, the Agriculture and Biotechnology Commission, to conduct a wide-ranging public debate on the ethics and concerns of GMOs. Both these exercises are now complete. Policy on co-existence and liability issues is still being developed (see below). No commercial growing is expected to be permitted until 2007 at the earliest, though an application for experimental growing of GMO potatoes resistant to potato blight was made only last month, the first such application for four years.

1. National regulatory approach.

Until 1986 the main regulatory initiatives on GMOs in the United Kingdom were concerned with risks in laboratories and other contained uses, with the controls based on health and safety at work legislation. In 1986 the Royal Commission on Environmental Pollution, an independent high level advisory body, published a major report on GMOs (13th report *The Release of Genetically Modified Organisms to the Environment*) which advocated a dedicated regulatory system based on consents for releases of GMOs into the environment. The Government accepted the main recommendations of the Royal Commission, and the core controls are contained in primary legislation, Part VI of the Environmental Protection Act 1990. Essentially this is based on a system of consents for imports or releases of GMO's and granted by central government. The 1990 Act remains

the core law, but regulations have been made under it implementing the subsequent EC Directives.

Consent regimes are a familiar tool in many areas of regulation, but the legal regime for GMOs contains two distinctive provisions which reflects the novelty of the technology, and the fact that key information may be held by industry rather than regulatory bodies. Consent holders are legally obliged to keep themselves informed of any risks of damages to the environment posed by the authorized activities, and where any new information comes to light concerning such risks they must inform central government.

2. Executive competences

Consents for releases into the environment are issued by central government department in England and Wales (Department of Food, Environment and Rural Affairs). and equivalent bodies in devolved administrations (Wales, Scotland and Northern Ireland). In assessing applications administrative arrangements have been established to involve consultation with other relevant statutory bodies including the Health and Safety Executive, Food Standards Agency, and English Nature (soon to be Natural England), the main statutory nature conservation body.

In addition, under the Environmental Protection Act 1990, the Government has established a statutory advisory committee, the Advisory Committee on Releases to the Environment (ACRE), whose function is to advise Government on environmental and human health implications of applications for consent releases. The Committee is an expert, scientific committee chaired by a leading academic rather than one involving stakeholders, and plays a key role in the evaluation of risk assessments. The Government has indicated that were the Committee to reach a negative conclusion on an application, it would always follow its advice. As far as I am aware, its advice has always been followed to date.

National aspects of Directive 1829/2003 (food and feedstuffs) and 1830/2003 are handled by an independent government agency, the Food Standards Authority, advised by another scientific committee, the Advisory Committee for Novel Foods and Processes.

3. Deliberate releases 2001/18/EC

(a) The precautionary principle is not explicitly expressed in the national legislation but according to current Government stated policy, *"In assessing applications every possible precaution is taken to ensure that human health and the environment are protected. Only if the risks are considered to be very low will the release be allowed to proceed*."

(b) The scientific advisory body, ACRE, plays a critical role in the assessment process for releases in to the environment. Release applications received are of two types depending on their intended purpose. The so-called 'Part B' applications, which are mainly for research and development trials, are submitted within the UK with consent is given at a national level. 'Part C' applications (more correctly called 'notifications') for placing a GMO on the European Union market are initially assessed by one (lead) Member State in Europe which then forwards a summary to the Commission and other Member States for assessment. ACRE will provide advice to Government on both Part B and Part C applications (whether the UK is the lead or not), and it appears that the Government to date has always followed its advice. Summaries of the procedure and advice from ACRE, taken from its most recent annual report, (one where the UK was the lead, and one where the Netherlands was the lead) are contained in the Appendix.

In many instances, now, marketing applications are now being processed through Regulation 1829/2003 on the authorisation of genetically modified food since authorizations will encompass the cultivation of food crops connected with these uses. The scope of these regulations is the marketing of any GMO that is intended for use as food or feed, including the cultivation of crop plants that are intended for these uses. The Food Standards Agency leads on these applications in the UK while the role of ACRE is to advise on the environmental risk assessments provided with applications for cultivation.

(c) Enforcement of the provisions are currently delegated to the Health and Safety Executive (which enforcing via Inspectors most of workplace legislation) though the Government has been consulting on whether a more dedicated enforcement system may be required, should there be more extensive commercial growing of GM crops. As mentioned, the legislation imposes a duty of consent holders to keep themselves informed about risks, and to provide information to the Government on any new information that comes to light.

(d) Transparency

The scientific advisory body, ACRE, has a stated commitment of transparency and openness. Agendas of its meetings are published on its web-site in advance of each meeting and invite comments, and minutes of its meetings are similarly published. Its advice to Government on individual applications are published on the webs-site, and available on a public register. ACRE holds at last one open meeting a year. Nevertheless, in the early days of ACRE, there was criticisms that too many members, though expert, had links with the GMO industry. Government responded that the availability of expertise was limited, but recognized this was not satisfactory. Current members all appear to be academics or research scientists which perhaps indicates a maturing of the discipline.

Central Government maintains a public register of notices, applications, information supplied, consents granted, and any convictions for offences. In the original 1990 legislation on GMOs, the public register only contained details of applications, but these provisions were subsequently extended to include the wider information.

Regulations provide that the public must be given the opportunity to make representations, and the Secretary of State is obliged to take into account (though not necessarily) follow those representations in reaching his decision or evaluation.

These fairly formalistic and narrowly based provisions on transparency did not satisfy demands for a wider and more public policy debate on the implications of GM crop growing which reached a peak in the UK in the mid 1990's, and at a time when Government policy seemed to be highly supportive of GM technology generally. A key response of the Government was to establish a wide ranging Commission to lead a public debate on the issue - the Agriculture and Environment Biotechnology Commission. Chaired by an academic environmental lawyer, and consisting of members from both the GMO industry and strongly antagonistic NGOs, the Commission ran for five years, and was committed to transparency and openess of discussion. It proved more critical and questioning of current policies and procedures than the Government had expected, though probably assisted more in clarifying some of the basic arguments that securing any consensus. Nevertheless, holding genuine public debates on complex public policy issue is an expensive undertaking, and many consider that the Commission was underfunded for the tasks it had to achieve. Partly through the work of the Royal Commission on Environmental Pollution, there is a wide appreciation in the UK that while scientific expertise has an important role to play in regulatory regimes, it cannot deal with questions of values and ethics which underlie many aspects of decision making.

(e) There are no administrative appeal procedures concerning decisions on consents by Government, either for the applicant or third parties. Any challenge would have to be by way of judicial review questioning the legality of the decision (wholly unreasonable, or procedurally incorrect etc.). Standing rules on judicial review are liberal in the UK, and it is likely that any NGO with an interest in the GMOs would have standing to challenge in the courts. In 1999, an organic farmer was permitted to challenge by way of judicial review the Secretary of State's decision not to vary a consent granted for a trial of GMO modified maize two kilometres away[1]. The Court of Appeal, whilst not doubting the standing of the farmer to challenge, held that it was reasonable for the Secretary of State to

[1] R v Secretary of State for the Environment and Ministry of Agriculture, Fisheries and Food ex parte Watson [1999] Environmental Law Report 310

rely upon scientific advice that the risk of contamination was likely to be a minimal risk rather than a zero risk.

(f) The legislation provides for criminal offences covering all the core areas of the statutory controls (failure to obtain a consent, breach of a consent, making false statements etc.), with the possibility of imprisonment or unlimited fines. Criminal liability can be imposed on companies as well as individuals. Liability is strict in the sense that no criminal intention or recklessness need be proved, though it is a defence to show that the accused took all reasonable precautions to avoid commission of the offence. In 1999 Monsanto were prosecuted for failing to provide sufficient safety barriers for trial crops, and although there was no proven damage, fined £17000 (fairly high in comparative terms for similar regulatory offences).

Where an offence has been committed, the court may also order the defendant to take remedial steps in relation to any harm caused by the commission of the offence. In addition, the Government may also take steps to remedy the harm and recover the costs from the offender. The exercise of these remedial powers, though, are dependent on there first being a conviction of an offence. The 2003 report on liability issues (see para 7) suggested that there should also be an independent power to remediate and recover costs - this is likely to be implemented in the context of implementation of the Environmental Liability Directive.

4) (a) Risk Assessment

The approach adopted to risk assessment is largely based on equivalence, meaning that the GM variety is not thought to pose any greater risk than the release of its non-GM equivalent. According to the Advisory Committee on Releases to the Environment,

"*In accordance with the precautionary principle, the following general principles should be followed when carrying out the environmental risk assessment:*

- *identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;*
- *the risk assessment should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;*
- *the risk assessment should be carried out on a case by case basis; this implies that the required information may vary depending on the type of the GMOs concerned, their intended use and the potential receiving environment, taking into account, i.a., GMOs already in the environment;*
- *if new information on the GMO and its effects on human health and the environment becomes available, the environmental risk assessment should be re-examined in order to:*
  - *determine whether the risk level has changed;*
  - *determine whether there is a need to amend the risk management.*"

Strictly the potential societal benefits are not formally considered as part of the risk assessment process, though informally I have been told by those involved that this might influence the process, even if not explicitly so. - for example, a GMO product proposed to lower risks of cancer might be treated more generously than one simply designed to prolong shelf life of a product. The approach in the UK is very much to handle GMO on a case by case basis, and the local environment, special sensitivities etc. would be taken into account in the assessment, and reflected in consent conditions where appropriate.

The approach adopted towards risk assessment has been subject to some sustained criticism. Concerns over the possible effect of GM crops on wider biodiversity lead the Government in 2001 to set up a four year experimental study to evaluate the impact of crop management practices on farmland ecology where conventional and GM varieties of four crops were grown on more than 270 split fields across Britain. The results of what was described as the largest world experiment on farm-scale evaluation were published in 2005, and demonstrated that three of the GM crops grown (spring and winter oilseed rape, sugar beet, and maize) had significant effects on biodiversity. One GM crop, maize, came through with better results, though this was largely because conventional maize growing proved equally detrimental. As the Secretary of State noted, *"We have nothing like the influence over the growing and management of conventional crops that we have over GM, even though the effects may be just as far reaching."*

The scientific advisory body, ACRE, is now considering the implications of its evaluation trials for its own risk assessment processes. It has tended to use conventional crops as a base line against which to evaluate and compare risks, but is being challenged as to what should be the most appropriate base-line. The Agriculture and Biotechnology Commission suggested that conventional cropping was a somewhat arbitrary base line, and that organic agriculture might be more appropriate.

(b) GM Food and Feed (Reg 1829/03)

The core national body handling the procedures under Reg 1829/03 is an independent Government agency, the Food Standards Agency (FSA). Where applications involve cultivation of crops, the FSA seeks the advice of the Advisory Committee on Releases to the Environment. Under its first Chairman, the Food Standards Agency perhaps unwisely for its political credibility engaged in debate as to whether organic foods were healthier than non-organic, and firmly concluded they were not. Nevertheless, the FSA has engaged in exceptional transparent processes, with all its board meetings fully open to the public and discussion unrehearsed.

The implementing national regulations provide for a range of criminal offences, and enforcement at a local level is delegated from the FSA to local authorities and at entry points to Port Health authorities. At present the FSA has acknowledged that most checks are based on documentary evidence with very little sampling and analysis due to the costs involved. For products where no DNA or protein is present, analytical methods cannot be used to detect GM presence.

EFSA. There seems to be a general view running through both official documentation and NGOs that the EFSA needs to be far more transparent. The Food Standards Agency, for example, in its 2005 response to the Commission Questionnaire of National Authorities commented that *"It is essential to maintain a high degree of openness and we urge EFSA to ensure that information is placed in the public domain as soon as practicable, and that any claims for confidentiality are carefully scrutinized. We also support the publication of EFSDA opinion available for defined period of public consultation before any decision for authorization is made.....It is not yet clear how any comments to the Commission as described in Articles 6(7) and 18(7) of regulation 1829/2003 will be handled. Will the applicant and/or EFSA be invited to comment? Will the comments be made public?"*

5) Co-existence

Policy debates concerning co-existence, particularly with organic crops, and designing appropriate regimes for handling this continue, and are as yet unresolved. In 2004, the Government announced that farmers wishing to grown GM crops would have to comply with a code of practice based on ensuring that non-GM crops were not contaminated beyond 0.9% (reflecting the EU Directive on traceability and labelling). However, a legal opinion commissioned by NGOs questioned whether the 0.9% figure was legally relevant in the context of co-existence measures, and that it might be contrary to EU legislation concerning the labelling of organic products. The main UK private certifier of organic products, the Soil Association, adopts a standard of 0.1% contamination, the practical limit of detection, and is one to which most retailers are working. The dispute as what level can be described as "adventitious and technically unavoidable" continues.
It also raises a more fundamental question as to the extent to which a private certifier body (but one which commands a wide degree of public respect) can in effect impose higher standards on society.

A number of local authorities have declared "GMO free zones" but these are political actions have no legal standing since local authorities have no powers to control or regulate agricultural practices.

The Government is also considering what sort of compensation measures should be in place to those farmers who have suffered loss as a result of GM contamination. The 2003 report of the Agriculture and Environment Biotechnology Commission on liability (see para 7 below) suggested a number of models, included a government compensation scheme, but in 2004 the Government indicated that any such scheme would have to funded by the GM sector itself rather than Government or producers of non-GM crops. (see further para 7 below)

6) Food Labelling

The EC Regulation was implemented in the UK under the Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004. This provides for various criminal penalties for non-compliance including fines of up to £5000 and imprisonment of up to 3 months. Enforcement is by local authority trading standards officers, but the Food Standards Agency has acknowledged that local authorities are unlikely to possess sufficient equipment for detailed testing.

7) Liability

The 1986 Report of the Royal Commission on Environmental Pollution considered that the application of existing general legal principles of liability (in the UK largely based on case law jurisprudence) to GMOs were so riddled with uncertainties that it would be preferable to have a dedicated statutory system based on strict liability. The Government did not accept this part of the Commission's report, and considered that, until proven otherwise, existing liability principles should be sufficient. In 2003 the Advisory Committee on Releases to the Environment published a special report on liability, *GM Crops? Coexistence and Liability* which considered the issues in a lot more detail, but again concluded that there needed to be a dedicated statutory regime, though recognized that a number of the issues that needed to be address could be incorporated within the implementation of the EC Directive on Environmental Liability. The Government is still considering the detailed legislation needed to implement the Directive, with public consultation procedures about to take place. There are no reported cases to date concerning civil liability arising from GMOs.

In July this year, the Government issued a consultation document on co-existence and possible liability issues. Various options are discussed, but the Government has made a policy commitment that any compensation scheme should not be funded by the Government or the non-GMO sector.

APPENDIX

Extract for 2005 Annual Report of Advisory Committee on Releases to the Environment illustrating summary of its responses on two applications

2.2.1 C/NL/04/02 Notification for Part C consent from Florigene Ltd to market the carnation "Florigene moonlite" In April 2005 ACRE considered this marketing notification (C/NL/04/02) from Florigene Ltd for carnations modified for flower colour. It had been given a favourable opinion by the Netherlands Competent Authority (who lead on this notification). This GM carnation line (123-3-38) is modified with hf1 and dfr genes from petunia, which confer a violet colouring to the petals and the SuRB (ALS) gene from tobacco which confers resistance to sulfonylurea herbicides. ACRE was asked to consider the notification in the light of the assessment report by the Dutch competent authority and the scope of this notification which is for import and marketing of cut flowers to the EU. ACRE considered that the data provided on molecular characterisation were adequate given the scope of this notification. The full sequence of the transformation vector is known and PCR based evidence indicated that a complete copy of the tetracycline gene present on the backbone of the vector is not present. The committee considered that the PCR detection method provided is event specific. The notifier has provided no sequence information for the DNA flanking the insertion site however the committee considered the toxicity tests provided as a substitute for this information to be adequate given the scope of this notification and the fact that carnation is not generally consumed as a food crop. The notifier has indicated that this plant could be a periclinal chimera with only the L1 layer containing the transgene. If this is the case the committee observed that the risk of gene flow would be further reduced since the transgene would not be present in the germ line of the plant.

The environmental risk assessment examined the toxicity and allergenicity of the plants and the potential for gene flow and weediness of the plant. The committee discussed the possibility that consumers might take leaf or stem cuttings from the cut flowers and cultivate these plants. Since the risk of gene flow has been identified as low and no other adverse environmental effects are indicated ACRE was satisfied that no risks have been identified that require further information. In terms of the post-market monitoring, ACRE agreed that for this GMO, casespecific monitoring was not required since no environmental risks were highlighted in the environmental risk assessment. The committee was content that the general surveillance plan was proportionate to the scope of the notification. In conclusion, ACRE agreed with the Dutch competent authority's assessment that consent for this application should be issued. ACRE's advice was agreed and the UK opinion supporting the application was forwarded to the Commission on 4 May 2005.

At its October 2005 meeting, ACRE reviewed the further information submitted by Florigene in response to comments from Member States on its application to market a carnation genetically modified for petal colour. Further information was provided on the molecular characterisation and detection, the environmental risk assessment, allergenicity and toxicity and the post-market monitoring plan. After consideration of the revised risk assessment the committee found no reason to alter its previous conclusion that the risk of carnation establishment from this import was negligible. The committee discussed potential risks associated with the disposal of the cut flowers through landfill or composting and concluded that these were no greater than those associated with other cut carnation varieties. ACRE considered that the further information did not alter its previous advice, which was that the import and distribution of this GM carnation poses no greater risk to human health or the environment compared with its non-GM counterparts. This latest advice was agreed by circulation and was published on ACRE's website.

2.2.7 C/GB/02/M3/3 NK603 x MON810 maize (Monsanto Europe S.A.)

This application was received by the UK Competent Authority in April 2002, and was accepted under Directive 2001/18/EC in December 2002. ACRE considered this notification at various meetings in 2003 and in January 2004. The committee also sought advice from the ACAF GM sub-group on animal feed matters. This application is for consent to market maize genetically modified for herbicide tolerance and insect resistance (NK603 x MON810) and the scope is for importation and processing only (not cultivation). This GM maize is a conventionally bred hybrid derived from crossing two genetically modified parental lines. ACRE asked for detailed arrangements for general surveillance to be provided and recommended annual monitoring reports in its advice issued on 30 January 2004. As the lead competent authority for this notification the UK submitted a favourable opinion in March 2004. Following EU wide consultation, some member states raised objections. Monsanto's response to these objections was tabled at ACRE's February 2005 meeting. In the light of this further information provided by Monsanto, member states submitted updated opinions on this notification. The information provided did not alter ACRE's favourable assessment.