# GM SCIENCE REVIEW FIRST REPORT

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

PREPARED BY THE GM SCIENCE REVIEW PANEL (JULY 2003)

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# LIST OF ABBREVIATIONS

ACAF ACNFP	Advisory Committee on Animal Feedingstuffs (for the UK) Advisory Committee on Novel Foods and Processes (for the UK) Advisory Committee on Poleoses to the Environment (for the UK)
AFRC	Agriculture and Environment Biotechnology Commission
ARM	Antibiotic resistance marker
BA	British Association for the Advancement of Science
bn	Base pairs
Bt	Bacillus thuringiensis
CEC	Commission for Environmental Cooperation
crv	Cryptochrome
cv	Cultivar
DNA	Deoxyribonucleic acid
EEA	European Environment Agency
ENTRANSFOOD	European Network for Safety Assessment of Genetically Modified
	Food Crops
EU	European Union
EPA	Environmental Protection Agency (for the USA)
ESTO	Earth Science Technology Office
FAO	Food and Agriculture Organisation (of the United Nations)
FDA	Food and Drug Administration (for the USA)
FISH	Fluorescence in-situ hybridisation
FSA	Foods Standards Agency (for the UK)
FSE	Farm-scale evaluation
GM(O)	Genetically modified (organism)
GMHT	Genetically Modified Herbicide Tolerance
HGT	Horizontal gene transfer
ICSU	International Council of Scientific Unions
IFPRI	International Food Policy Research Institute
IgE	Immunoglobulin E
ILGRA	Interdepartmental Liaison Group on Risk Assessment (for the UK)
ILSI	International Life Sciences Institute
JRC	Joint Regulatory Commission (for the European Union)
mRNA	Messenger ribonucleic acid
OECD	Organisation for Economic Cooperation and Development
ORP	Open reading frame
PCR	Polymerase chain reaction
RT-PCR	Reverse transcriptase - polymerase chain reaction
SSSI	Site of Special Scientific Interest
UK	United Kingdom
UNCED	United Nations Conference on Environment and Development
USDA	US Department of Agriculture
WHO	World Health Organisation

A glossary of scientific and technical terms used in this report will be placed on the GM Science Review website (<u>http://www.gmsciencedebate.org.uk</u>) shortly after publication and a printed copy will be available on request.

## Annex I

# Questions about GM to be addressed by information (extract from Corr Willbourn report)

The foundation discussion workshops conducted by Corr Willbourn Research and Development as part of the GM public debate, allowed the general public to frame the issues for the programme of debate. The Corr Willbourn work has played a central role in setting the agenda of the Science Review process. The report that arose from this exercise can be viewed at: <u>http://www.gmnation.org.uk/docs/corrwillbourn.pdf</u>. It contains the following key questions about GM, framed by the public.

#### A Basic Information and Definitions

- A1 What is GM? How is it done? Where is it done / Does it have to be done in a lab?
- A2 What does it mean? How wide is its definition?
  - can everything with genes be modified / can it be done on humans?
  - is spraying crops with pesticides classed as genetic modification?
  - is it a speeding up of a natural process like the survival of the fittest?
- A3 Does it involve chemicals? Which ones and how?
- A4 When and how did it begin? How long has it been going on?
- A5 Does it work?

#### B Current Status of GM

- B1 How much is on the market? What percentage of foods on the market are GM? What crops are already genetically modified?
- B2 What new GM crops / foods are planned?
- B3 Who produces GM food?
- B4 Who eats GM food? Do the producers eat it?
- B5 Are we being fed GM foods without knowing it? Do we get told what is GM and what isn't in supermarkets? Do you have to label GM food as GM? How can we tell if it is a GM product / if we've eaten GM?

#### C Rationale

C1 Why do it? Why change what we've got? Is there a need for it? What can it be used for? Who is demanding GM/who says there's a need for it? Is it principally driven by profit? Is it driven by scientists seeing what they can do by playing with nature?

- C2 What are the real benefits? Who is benefiting and who will benefit?
- C3 Will it benefit <u>our</u> lives and how? What's in it for me?
- C4 Will it make life easier / give us better food / more nutritious or healthier food / food with a longer shelf life? Will it be cheaper (by how much and why?) or cost more?
- C5 What is the biggest advantage GM crops can bring the world?
- C6 Will it have medical benefits eg. a cure for diseases such as cancer?
- C7 Will it benefit the world's population, especially the Third World eg. problems of food and water supply?
- C8 What impact will GM crops have on alternative uses of crops eg. GM OSR for biofuels?

#### D Possible Risks to Health

- D1 Is it good for me or dangerous? How will it affect us? Are there negative effects / side effects / drawbacks to balance against the benefits?
- D2 Is it harmful? Could it be harmful in the future? What harm / damage could it do to the world? Do the people who do it know if it can harm us?
- D3 Could it harm me and my family? Could it harm future generations? Will eating GM foods undermine my health?
- D4 Could harm be caused by:
  - the chemicals used
  - cross-contamination
  - additives
  - mutations
  - altering the basic structure of things?
- D5 Could harm take the form of:
  - allergic reactions
  - new diseases
  - general negative effect on health?
- D6 Will they be able to cope with problems / treat any new diseases that arise?

#### E Other Possible Effects

- E1 Could jobs be lost?
- E2 What will happen to ordinary farmers?
- E3 How will farming in the UK progress and compete?
- E4 What could be the effects of the commercialisation of GM crops in the UK?
  - on UK science?
  - will it increase our dependence on industrialised farming methods?
  - will it increase our dependence on lower diversity and chemical dependent farming?
- E5 Could corporations end up controlling the food chain?
- E6 Could world climate change be affected? What does the future hold re food, energy, environment etc?
- E7 What effect might GM have on the environment? Is it destroying nature as we know it? What will the effect be on natural (non-GM?) crops / wildlife?
- E8 What about pesticide harm?

#### F Regulation and Monitoring of Safety

- F1 Is it safe and how do I know that it is safe? What proof is there that it is safe? What tests are in place? Are all foods fully tested?
- F2 What research has been carried out into the effects on health of modified foods that are already available? What research is being carried out into the potential long term effects?
- F3 What are the real experiences of US farmers and consumers?
- F4 Who funds and carries out the research? How much corporate funding is there? Is the research independent? Should it be?
- F5 What controls and regulations / legislation are in place?
- F6 Who is the regulator and are they independent? Do we need one?

#### G Boundaries

- G1 Will there be boundaries around what can be changed? How far will they go?
- G2 Where will it stop? eg. Will we get lettuces the size of houses? Will it lead to the cloning of all animals?
- G3 What are the long-term aims of all this research into GM?

#### H Trust and Confidence

- H1 Why is there so much disagreement about the benefits and risks of GM?
- H2 Is everything we hear about GM from the people developing the technology?
- H3 Can we get unbiased and impartial information and from whom? Who can you believe or trust? Can scientists be neutral? What is the involvement and attitude of farmers, producers, environmentalists, supermarkets, Government?
- H4 Why does the Government think that the commercialisation of GM crops should go ahead (in concrete terms)? Why did it feel it necessary to decide on sites for FSEs without local consultation?
- H5 Will we be given the full picture? Do we know what happens behind the scenes?
- H6 If problems arise, will we get honest answers from Government? Will Government present research findings properly and fairly?
- H7 Who will be liable for contamination from the commercialisation of GM crops (or any other form of damage?)?

#### J Moral / Ethical Issues

- J1 Is it right for man to be tampering with nature? Are we playing God?
- J2 What legacy are we leaving future generations?
- J3 The involvement of the Third World: Is Africa being used as a dumping ground? If the Third World needs GM, then why use it in the West? Will it really help the poor or is it about making the rich richer?
- J4 Need to confront more basic problems: Why don't we acknowledge that we waste too much food rather than search for perfect food? Will GM distract us from looking at proven solutions to current farming problems?
- J5 How democratic is it to patent genes?

## Review process undertaken by ACRE in assessing applications for the deliberate release of a GMO in England



## Annex III

### Description of the regulatory frameworks

#### The Deliberate Release Directive (2001/18/EC)

The release<sup>1</sup> and marketing<sup>2</sup> of genetically modified organisms (GMOs)<sup>3</sup> in the EU are controlled under a EU-wide regime. The essential point about this legal framework is that releases and marketing of GMOs can only take place in the EU with explicit consent of the regulatory authorities. The aim of the legislation is to protect human health and the environment across the EU from any adverse effects that may be caused by the deliberate release into the environment of GMOs. To achieve this objective the directive sets out a system by which GMOs have to be approved on safety grounds and, to this end, each GMO is subjected to a science-based risk assessment. The EU Directive covers both small-scale trials for research and development (so called part B consents) and consent to place on the market in Europe (part C consents). GM Products on the market can be withdrawn if there is information that indicates that a GMO will be harmful.

In the UK, all of this information is evaluated and weighed by the Advisory Committee on Releases to the Environment (ACRE), an independent, expert scientific committee. On this basis, the committee advises whether there are any significant risks associated with the GMO release. The committee operates in an open and transparent way and its work can be viewed on their website<sup>4</sup>. Annex I shows the review process undertaken by ACRE in assessing applications.

#### GM food and feed

Comparable legislation covers GM food and Feed Safety. The Novel Food Regulation (258/97) introduced a statutory pre-market approval system for novel foods throughout the EU which is directly applicable and legally binding in all Member States. These regulations cover a range of novel foodstuffs and by definition all foods and food ingredients containing, or consisting of, GMOs or produced from GMOs are novel.

The protocols for the safety assessment of GM foods are based upon a decision tree approach, which was developed by Advisory Committee on Novel Foods and Processes (ACNFP) prior to the current regulation and which has been endorsed by FAO and WHO. This assessment ensures an integrated, stepwise, case-by-case, evidence-based approach. The safety assessment uses the concept of substantial equivalence. This is not an end

<sup>&</sup>lt;sup>1</sup> A GMO is 'released' if someone deliberately allows it to pass from their control into the environment. A GMO would 'escape' if it passed unintentionally from a person's control into the environment.

<sup>&</sup>lt;sup>2</sup> GMOs of any description are 'marketed' when products consisting of or including such organisms are placed on the market.

<sup>&</sup>lt;sup>3</sup> Techniques of genetic modification include recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.

<sup>&</sup>lt;sup>4</sup> <u>www.defra.gov.uk/environment/acre</u>

point but a comparative approach used to identify significant differences between the new food and its traditional counterpart, which are then the subject of further investigation. Arrangements are subject to review in light of developments in science and technology, for example new applications of GM and improved analytical methods.

In the UK two Advisory Committees are at the forefront of this activity – these are Advisory Committee on Novel Foods and Processes (ACNFP) and Advisory Committee on Animal Feeding stuffs (ACAF). Both Committees are made up of independent experts appointed solely for their particular expertise and experience. They do not represent any sector, organisation or government department. Likewise, both Committees are committed to a policy of openness and publish agenda, minutes, reports and dossiers on their respective websites.

Under the Novel Foods Regulation (258/97), companies wishing to market a novel food in the EU are required to submit an application to the Competent Authority in the Member State where they first tend to market the product. Since 1 April 2000 the Food Standards Agency has been the UK Competent Authority.

# Key UK decisions/actions in the Directive 2001/18 Part C (marketing) procedure



#### Notes

- (1) The centre boxes show key stages of the Part C procedure. The boxes on either side indicate key decisions/actions the UK must take, depending on whether or not we are the 'lead member state' (if we are, our involvement is greater and we must take decisions earlier).
- (2) Currently, Defra leads on 2 Part C applications, and other member states lead on another 17.
- (3) The timescales given below are maxima set by the Directive: in practice things could happen *faster*, but they could also happen *slower* because the clock can stop if there is a justified request for more information from a member state or the Commission.
- (4) UK decisions are taken in consultation with devolved administrations (DAs).
- (5) Defra and DAs get expert scientific advice principally from the Advisory Committee on Releases to the Environment (ACRE).

# Annex V

### European Commission proposals on GM food and feed

The European Commission published two proposals for new legislation concerning genetically modified organisms (GMOs) in July 2001, one covering Food and Feed and the other, on Traceability and Labelling of GMOs. These proposals were issued in response to the current impasse in the approval process for consents to release GMOs into the environment, to address the lack of specific legislative controls on GM animal feed, to revise the approval regime for GM food and feed and extend the current labelling requirements.

This proposed GM food and feed regulation will replace the existing approval procedures for GM foods, as contained in Regulation 258/97 and introduce for the first time rules for the approval of GM animal feed and a harmonised procedure for the scientific assessment and authorisation of GMOs and GM food and feed. It would be a uniform and transparent Community procedure for all marketing applications, whether they concern the GMO itself or the food and feed derivatives.

The proposal will place the European Food Safety Authority (EFSA), rather than individual Member States, at the centre of the approval process. EFSA will carry out the scientific risk assessment covering both the environmental risk and human and animal health safety assessment. On the basis of the opinion of EFSA, the Commission will draft a proposal for granting or refusing authorisation.

The proposal includes labelling provisions that will require labelling of all GM food and feed products derived from GMOs, regardless of the presence or absence of GM material in the final food or feed product. This is an extension to the existing labelling rules and means highly processed products such as oils and glucose syrup, alcoholic drinks, made using GM grain and foods sold in restaurants, which had been cooked in oil derived from GM crops would require labelling. Honey produced by bees foraging nectar from GM crops would also have to be labelled.

Foods produced using processing aids which have been obtained with the help of GM technology (e.g. the enzyme chymosin derived from a GM microorganism, which is used extensively to make hard cheeses) and products from animals fed GM animal feed will continue to be exempt from the labelling requirements.

The proposal agreed at Common Position includes threshold at levels of 0.9%, for GM material in food and feed that has an EU authorisation, and 0.5%, for material not yet authorised but that has a favourable EU risk evaluation (or safety assessment) for accidental present GM-derived material in non-GM supplies below which labelling is not required. The 0.5% threshold will last for three years.

Political agreement was reached on the proposal on 28 November 2002 at the EU Agriculture Council. The proposal was agreed by a qualified majority vote. Common position was adopted on 17 March 2003.

The proposal has now returned to the European Parliament for its second reading with the plenary session due in July 2003. Depending on the outcome of the plenary the proposal may be adopted in late 2003 with Member States implementing the new Regulations within six months of adoption. Alternatively the proposal may go through the conciliation process.

# Annex VI

Further information available on the GM Science Review website

(http://www.gmsciencedebate.org.uk/default.htm)

GM Science Review Panel: http://www.gmsciencedebate.org.uk/panel/default.htm

GM Science Review Panel meetings: http://www.gmsciencedebate.org.uk/panel/default.htm#Meetings

GM Science Review open meetings: http://www.gmsciencedebate.org.uk/meetings/default.htm

Contributions to the GM Science Review website: <u>http://www.gmsciencedebate.org.uk/topics/forum/default.htm</u>