GENETICALLY MODIFIED ORGANISMS: GENERAL ISSUES

Purpose

1. This paper, while focusing on the public dialogue on the commercialisation on GM crops and seeking the Committee's support for that in Wales, also provides an update on GM dossiers under negotiation in Europe and on Assembly GM consultations underway.

Summary

2. The Assembly Government is committed to operate the most restrictive policy possible in respect of GMOs within the framework of European legislation. This paper outlines the opportunity provided by the public debate on GM issues, describes the current state of play on a number of GM dossiers and on Assembly Government consultation exercises.

Timing

3. This paper is presented in order to brief Members on wider GM issues.

The Public Dialogue

4. Members will be aware, following their meeting with Professor Malcolm Grant and Professor Jeff Maxwell of AEBC on 28 October, that a UK public dialogue on the possible future commercialisation of GM crops is about to get underway. The dialogue is intended to have three strands – public debate, science review and cost benefits analysis.

5. More information can be found at the following websites:

- **Public Debate** http://www.gmpublicdebate.org.uk
  The aim of the public debate is to promote an innovative and effective programme of public debate on issues around GM in agriculture and the environment, in the context of the possible commercial growing of GM crops in the UK. We are in discussion with Professor Grant and his colleagues about the programme of activities for Wales.
- **Science Review http://www.gmsciencedebate.org.uk**
  Facilitated independently of Government by the British Association for the Advancement of Science, this review will provide a source of science-based information and opinion coupled with an opportunity to comment. We will ensure that there are meetings in Wales to engage the wider scientific community on issues of public interest and concern. We expect that a debate on gene-flow and separation distances will form a key part of the science debate in Wales.
- **Cost-Benefit Analysis** http://www.strategy.gov.uk/2002/gm/summ.shtml
  The objective of the analysis is to assess the full range of costs and benefits associated with the commercial growing of GM crops in the UK, including the effect on conventional and organic farming. Data will be collected on a regional and UK-wide basis. Welsh

organic and conventional farming will be included in the study.

EU Negotiations

6. A number of proposals relating to GMOs are currently being discussed in Europe. These are summarised below, together with the Assembly's stance on each:

- **Proposed Regulation on Food and Feed** http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/c_004/c_00420020107en00180051.pdf
  The proposal replaces the existing approval procedures for GM foods and introduces for the first time rules for the approval of GM animal feed. The proposal will place the European Food Authority (EFA), rather than individual Member States, at the centre of the approval process.

  The Assembly Government has raised concerns, at official and Ministerial level, about the centralisation of power in the Commission which this Regulation will bring about. In particular we have highlighted that the EFA, a body with limited environmental expertise, will be responsible for environmental risk assessment.

  As it is an EU regulation it will have direct effect in Wales, although the enforcement aspects may need to be implemented through domestic legislation.

  Negotiations on this Regulation are ongoing and discussion is included as an agenda item at the next EU Agriculture Council meeting on 26/27 November which the Minister will be attending.

- **Proposed Regulation on Traceability and Labelling of GMOs** http://europa.eu.int/comm/food/fs/gmo/biotech09_en.pdf
  The proposal is for a harmonised EU system for tracing and identifying genetically modified organisms (including food, feed and seeds) and products derived from them at all stages of their placing on the market. Each business operator would be required to pass on to the next operator in the supply chain information to the effect that a product contains, consists of, or is derived from, GMOs.

  Debate in Europe has centred around the scope of the Regulation, in particular whether products made from GMOs, but where no detectable GM DNA is present (e.g. highly refined oils) should be labelled; and over the permitted percentage threshold of adventitious presence of GMOs in a product before it has to be labelled as containing a GMO.

  In contributing to the UK line for negotiations the Assembly Government expressed support for the EC proposal and suggested that it should cover as wide a range of products as possible. This view was not supported by other

administrations and Whitehall departments and the formal UK position is to limit the scope of the Regulation to instances where detectable DNA is present. The European Parliament Environment Committee has taken a similar view to the Assembly Government and has tabled amendments which widen the scope of the Regulation. Discussion at the Environment Council on 17 October was inconclusive, with many Member States arguing for a wide scope.

This is a proposal for an EU regulation, which if it is approved, will have direct effect in Wales. However the enforcement aspects may need to be implemented through domestic legislation.

- **Proposed Directive on Environmental Liability**
  http://europa.eu.int/eur-lex/en/com/pdf/2002/en_502PC0017.pdf
  The proposed Directive applies to "environmental damage", when caused by certain EU regulated activities, for example:

  - biodiversity damage - damage seriously affecting the conservation status of EU designated habitats and species, and nationally designated sites;
  - water damage - damage adversely affecting the ecological or chemical status of waters covered by the EC Water Framework Directive (eg rivers and groundwater);
  - land damage - damage creating actual or potential harm to human health from soil contamination.

  It does not provide redress for private interests affected by an environmental incident such as personal injury, property damage or loss or economic loss, as remedies for these fall to private law.

  The deliberate release of GMOs is referred to as an activity that can lead to environmental damage as defined by the Directive.

Assembly Consultations

7. The Assembly Government has recently undertaken or is undertaking the following consultations on GM-related issues:

- **Adventitious Presence**
  http://www.wales.gov.uk/subienvironment/content/consultations/gmo/gmo-seeds-e.htm
  The Assembly Government will continue to press for levels of adventitious presence of GMOs in certified seed to be set at the lowest practicable level and for strict regulations to be brought forward at the EU level.

  This consultation ended in September and a summary of responses to

consultation is in preparation.

- **Changes to Representations and Hearings Under National Listing**
  http://www.wales.gov.uk/subienvironment/content/consultations/nlwp&h-procedures/letter-e.htm
  The National List system implements EC Directives and is concerned with the agricultural qualities of candidate varieties. It is effectively a quality control mechanism to ensure that the varieties available to UK agriculture meet certain minimum criteria. As far as GM varieties are concerned, they must already have GM approvals for release into the environment or marketing under Directive 90/220/EEC before they enter the National List system. Before they are proposed for addition to the National List they must also have a marketing approval under the GM release directive and authorisation under the Novel Foods regulation where appropriate.

  The current procedures for making Written Representations and requesting a Hearing about seeds issues were introduced following the UK's accession to the EC and were aimed at National List applicants and the seeds industry as those primarily affected by proposed decisions. They pre-dated GM plant varieties and were never intended to deal with GM safety issues. In1990, (when GMOs including GM crops had become an issue) the EC introduced separate legislation, Directive 90/220/EEC, under which decisions on the safety of GM releases had to be taken before releases into the environment could be permitted. These decisions are taken on the basis of independent, expert advice e.g. in the UK from ACRE and from the ACNFP.

8. Of relevance to the consultation exercise on Representations and Hearings is the recently concluded **Chardon Hearing**, and Members may find the following update helpful:

The EC Common Catalogue Directives require that agricultural and vegetable species be tested before listing in order to ensure consistent quality across the Community. Listing is undertaken on a National basis before being approved for listing on the EC Common Catalogue, which allows unrestricted marketing in the EU.

The National Listing process allows for "any person affected" to make written representations and to be heard. This system was established to allow plant breeders to contest the listing of a variety, for example, to contend that the variety was not distinct from a variety they had created.

It was not originally intended to be a forum for discussing safety or risk assessment issues associated with genetic modification. A GM variety has already been assessed for its impact on human health and the environment under

the deliberate release Directive before it reaches National Listing. Instead, it is simply being assessed for its value for cultivation and use (VCU) and its distinctiveness, uniformity and stability (DUS). These are measures of its marketability as a commercial product.

Chardon LL (a genetically transformed maize variety) was proposed for addition to the National List in March 2000. That proposal triggered 227 written representations and 67 requests for a Hearing from individuals and organisations. The bulk of the evidence submitted to the Hearing, conducted by Alun Alesbury, focused on GM safety issues, which are the responsibility of ACRE (Advisory Committee on Releases into the Environment) or the ACNFP (Advisory Committee on Novel Foods and Processes).

The Hearing closed on 13 June 2002 and Alun Alesbury is expected to submit his report, which contains a factual digest of the evidence, later this month. The statutory advisory bodies have yet to submit their advice to Ministers on the GM evidence presented in the written representations and put to the Hearing.

Chardon LL has already been entered on the Dutch National List and should the Commission decide to include it in the Common Catalogue there would be no barrier to its being marketed in the UK, apart from the voluntary moratorium on planting GM crops.

Following receipt of the Alesbury report and ACRE/ACNFP advice, Ministers will be required to come to a joint decision on the National Listing of Chardon LL.

9. Key Issues relating to the Public Dialogue

- ARD Committee engaging with the UK public dialogue on the possible future commercialisation of GM crops.
- Public meetings will be held in Wales.
- With other devolved administrations, Assembly is contributing towards the cost of funding the public debate.
- Assembly represented at workshops looking at all three strands of the public dialogue.
- Professor Jeff Maxwell, AEBC member, represents Devolved Administrations' interests on the Steering Board.
- Science Review facilitated independently of Government by the British Association for the Advancement of Science.
- Cost-benefit analysis will assess impacts on organic and conventional farming in Wales.

Action for ARD

10. To note the issues set out above, and indicate its support for the public debate in Wales.

Contact Point

11. Plant Health and Biotechnology Branch, Countryside Division.