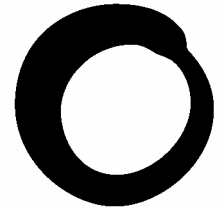


Briefing Note



**Friends of
the Earth**

The GM regulatory process

Before any genetically modified (GM) plant can be grown in the UK, or a GM food sold on the market, there are several regulatory hurdles that it must pass through. GM legislation originates in Europe and is implemented in the UK under domestic laws. The Department of the Environment, Food and Rural Affairs (DEFRA) is the lead agency and the devolved administrations of Scotland, Wales and Northern Ireland have powers in this area. Currently, new directives are being developed by the European Union (EU) to introduce traceability for GM foods and increased labelling requirements. International agreements, such as the Convention on Biological Diversity, and the World Trade Organisation also influence the regulation of GM food and crops.

Contained Use

The initial experimental phases of developing GMOs take place in laboratories, industrial production plants or greenhouses. This is regulated by the Contained Use Directive, (90/219/EEC), which is under the control of the Health and Safety Executive in the UK.

The release of GMOs into the environment

Part B: experimental releases

Once a GM organism has been developed in the laboratory, research may be continued in field trials. The new Deliberate Release Directive, (2001/18/EEC), which came into force in October 2002, controls the growing of GM crops in the open. An application is made to DEFRA under Part B of the Directive, which covers release for research and development purposes.

Part C: commercial releases

If a company decides that a GMO is ready for commercial use, an application can be made for commercial approval to place it on the market across the EU. This is covered by Part C of the Deliberate Release Directive. It also covers consent for imports of GMOs from non-EU countries for use in food processing or animal feed.

To obtain commercial consent the GM crop must satisfy the necessary risk assessments and there must be agreement from all the EU member states. In the UK, the Advisory Committee on Releases to the Environment (ACRE) advises the Government whether, in its opinion, an application meets the requirements of the Directive. Twelve GM plants, including soya, oilseed rape and maize, already have Part C approval in the EU. There have been no new approvals since 1999. Several member states, including France and Italy, blocked new consents because issues to do with traceability and labelling had not been resolved.

Pesticide Approval

In the case of GM herbicide tolerant crops, the herbicide used must also satisfy legislation controlling the use of pesticides. Approval is given by the Pesticides Safety Directorate of DEFRA. So far approvals have only been given for experimental use.

Approval of GM foods

If a GM food is to be sold on the market it must also meet the requirements of the Novel Food Regulation, (258/97/EEC), which assesses the safety of GM foods. Once again, EU member states must agree and in the UK the responsibility for examining GM food and feed safety falls to the Food Standards Agency (FSA). The Advisory Committee on Novel Foods and Processes assesses the safety of a GM food, including whether it is 'substantially equivalent' to its non-GM counterpart. If a GM crop is to be used in animal feed, it is assessed by the Advisory Committee on Animal Feedingstuffs although there is currently no regulation to control this.

The FSA is also responsible for the labelling of GM foods. Foods with over 1% of detectable GM DNA or protein present need to be labelled. Rules to strengthen these requirements are currently being developed.

The National Seed List

If a GM plant has obtained Part C marketing consent, it must be placed on the UK's National List of Agricultural Plant Varieties, known as the Seed List, before seeds can be sold to farmers. To get onto this list, any new seeds, GM or not, must show that they are distinct, uniform and stable and are a clear improvement over existing varieties. If a seed is placed on the national list of another EU member state, it can be placed on the EU's 'Common Catalogue' of varieties and sold in all EU countries.

No GM seeds have yet appeared on the UK's Seed List. The first GM seed, Chardon LL maize, was proposed in 2000. This was challenged by Friends of the Earth and many other groups and member of the public under the right to hold a public hearing.

Government advisory committees involved in the regulatory process

Committee	Department	Responsibility
Advisory Committee on Genetic Modification	Health and Safety Executive	Advises on all aspects of human and environmental safety of contained use (e.g. in the laboratory) of GMOs
Advisory Committee on Releases into the Environment	DEFRA	Advises on the environmental safety of proposed releases, marketing of GMOs, and related issues
Advisory Committee on Novel Foods and Processes	Food Standards Agency	Advises on the safety of novel foods such as those derived from GMOs
Advisory Committee on Animal Feedingstuffs	Food Standards Agency	Advises on the safety and use of animal feeds
Advisory Committee on Pesticides	DEFRA	Advises the Government on the use of pesticides and herbicides
Agriculture and Environment Biotechnology Commission	Department of Trade and Industry	Advises the Government on strategic developments in agricultural biotechnology and environmental implications

For further information on the regulatory process contact the GM Unit at DEFRA, Ashdown House, 123 Victoria Street, London SW1E 6DE. Tel: 020 7944 3409. Email: gm@defra.gsi.gov.uk

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