THE REGULATION OF GENETICALLY MODIFIED FOOD

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Summary

This section reviews the two approaches which have been taken to the regulation of genetically modified organisms – product or process based regulation – as exemplified by the USA and Europe and replicated elsewhere. In Europe, a process based regulatory system, triggered by the use of genetic modification, exists for the release of GMOs to the environment. In the USA, a product based approach has been adopted which evaluates the risks according to the final product and whether genetic material

from plant pathogens has been used in the process. However, although the two systems are apparently based on different underlying assumptions about whether GMOs do or do not pose special risks to human health or the environment, when applied to a similar GMO both have similar data requirements. Differences exist in judgements on the importance of potential hazards and certain GMOs will not be evaluated under the US rules, if for example, they are created using physical methods (such as biolistics) rather than via a plant pathogen (*Agrobacterium*). Whether product or process based approaches are used influences attitudes to labelling. Product based approaches restrict labelling to situations where there is an alteration to the final food product considered to be to potential nutritional or health significance. The revised process-based labelling in Europe allows for products to be labelled if they have been produced from GMOs, even if there is no introduced DNA or protein in the final product. The international implications and tensions in relation to balancing the interests of free trade and environmental protection are also explored in the light of the trade dispute over GM products brought by the USA, Canada and Argentina against Europe.

1. Introduction

The use of genetically modified (GM) organisms to produce foods has caused considerable public concern in some parts of the world, notably the UK and the rest of Europe [see also - *Potential dangers of biotechnology in agriculture* and *Why genetic engineering causes concern?*]. Several GM crops, such as Roundup Ready soybeans, are being grown commercially and used in animal feed and in processed foods. GM microorganisms are being used to produce enzymes and food additives (such as vitamins) for use in food production. Although no food from GM animals is currently being sold, GM fish which have enhanced growth rates and other animals whose productivity has been increased using GM may be sold in the future.

The regulation of GM foods is intended to protect human health, the environment and consumer choice. Because of the controversy surrounding GM foods, the regulations have come under close scrutiny and there has been much dispute over their adequacy and scientific rationale. At the international level, two approaches to the safety assessment of GM products have evolved. In some countries (as exemplified by Europe), the means of production using GM has driven the regulatory framework. In other countries (the US in particular), the approach has been to evaluate the product according to its final characteristics rather than how it was produced. This difference is often referred to as process versus product regulation.

This difference is of more than academic interest as it has important implications for trade. The US, for example, has argued that regulations which demand labelling of GM foods (or seeds as their precursors) violates WTO rules that state that the means of production cannot be used to discriminate against a product (as a label conveying means of production might) and restrictions on trade can only be made on scientific safety grounds. This poses difficulties for those countries where consumer choice and labelling are seen as key requirements for GM food acceptance and where the risks of GM foods are viewed differently. However, the considerable scientific uncertainty surrounding GM foods and the performance of GM organisms in the environment

makes claims about their dangers or safety impossible to resolve absolutely in one way or another.

This section reviews the different approaches to the regulation of GM foods. It compares and contrasts the two main approaches to safety as seen in the US and Europe and then considers these in the wider context of international agreements. It outlines the disputes surrounding the regulations, particularly in relation to the product versus process debate, and explores the implications of these for the future of GM food. It considers all the stages at which the technology is regulated – in the laboratory (sometimes called 'contained use'), the release of GMOs to the environment, food and feed safety and labelling. Table 1 gives details of web sites where detailed information about the regulation of GMOs in different countries can be found.

Organisation	**Internet address**	**Type of Information provided**
European Union	http://ec.europa.eu/biotechnology/index_en.htm	Information on Europe's regulatory system
European Union	http://gmoinfo.jrc.it/	Details on application to test and market GMOs in Europe
GMO Compass	http://www.gmo-compass.org/eng/home/	General information on GM issues
Office of Biotechnology Activities	http://www.nih.gov/od/oba/	Rules governing contained use of GMOs in the US.
Organisation for Economic Cooperation and Development (OECD) – Biotrack online	http://www.oecd.org/department/0,2688,en_2649_34385_1_1_1_1_1,00.html	Information on environmental and food safety regulation of GMOs.
Cartagena Protocol on Biosafety – Biosafety Clearing House	http://bch.biodiv.org/	Information on GM regulation and biosafety reports internationally
US Regulatory Agencies	http://usbiotechreg.nbii.gov/	Unified US agency web site giving information on US system
Information Systems for	http://www.nbiap.vt.edu/	Database of field trials and

Biotechnology		commercialised crops in USA and internationally

Table 1: Sites on the World Wide Web where details about the regulation of GMOs in different countries may be found

2. Process versus product regulation and the risks of GMOs

Whether GMOs are regulated according to the process of genetic modification or the characteristics of the final product has been important in determining whether new laws are needed, as in the case of process based approaches, or existing laws are extended as in the case of product based approaches. The key difference is whether there is an acceptance that the process itself brings new risks to human health and the environment or not. Product based regulation has been strongly favoured by the biotechnology industry because it means that no stigma is attached to the process of GM. In practice, although there may be different emphasis placed on the particular risks involved, product based regulation does consider the method of production albeit less explicitly than process based regulation.

Before looking at the regulations that cover GM food, it is worth briefly reviewing the kinds of adverse effects that may arise as a result of their production and use as it is these kinds of effect that the regulations are trying to avoid.

2.1. The risks of genetically modified organisms to the environment

The risks of releasing GMOs to the environment can be split into those directly attributable to the genetic modification or the altered characteristic and those secondary impacts which arise from the use of the GMO [see also BG6.58.4.10 - *Biotechnology and agro-biodiversity*]. These are summarised below but in addition there is a potential for there to be unanticipated effects which will only be specified with the benefit of hindsight. Direct effects could occur:

- if there is gene transfer from the GMO to native flora or fauna – leading to new pests as a result of hybridisation;
- unexpected behaviour of the GMO in the environment if it escapes its intended use and becomes a pest;
- disruption of natural communities – through competition or interference;
- food web effects through harm to non-target species – for example, if the host range of a virus was increased it may affect beneficial as well as the targeted species or there may be secondary effects of the insect toxin contained in a crop on the food web;
- harmful effects on ecosystem processes – if products of GMOs interfere with natural biochemical cycles;
- squandering natural biological resources if, for example, the use of a genetic modification to bring pest resistance in many different species induces the emergence of resistance and loss of efficacy.

Indirect effects may cause:

- continuation of intensive agricultural systems – as a result of the requirement for high levels of external inputs;
- impacts on biodiversity as a consequence of changes in agricultural practice – for example by altering patterns of herbicide use, effects on flora may be seen;
- cumulative environmental impacts from multiple releases and interactions;
- alterations in agricultural practices, for example, to manage any direct environment impacts such the evolution of insect, herbicide or disease resistance in weeds.

2.2. The risks of genetically modified organisms to the human health

The possible adverse effects of eating GM foods can be summarised as:

- new allergens being formed through the inclusion of novel proteins which trigger allergic reactions at some stage;
- antibiotic resistance genes used as 'markers' in the GM food being transferred to gut microorganisms and intensifying problems with antibiotic-resistant pathogens;
- the creation of new toxins through unexpected interactions between the product of the GM and other constituents for example.

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Biographical Sketch

Sue Mayer is the Executive Director and a founder member of GeneWatch UK an independent policy research group based in Derbyshire that monitors developments in genetic engineering, Sue has Degrees in Veterinary Science and Pharmacology and a PhD in Veterinary Cell Biology from Bristol University. She has worked in veterinary practice, as a University lecturer and manager of the RSPCA's Seal Assessment Unit. From 1990 to 1995 she was Director of Science at Greenpeace UK where she was involved in developing policy and campaigns on patenting and the release of genetically engineered organisms. In 1994, she spent a sabbatical year at the Centre for the Study of Environmental Change at Lancaster University looking at issues of risk and continues to be an honorary research fellow there. From October 1995, she was a freelance consultant on science and policy issues, working for a wide range of clients including the Whale and Dolphin Conservation Society, Unilever, Sainsbury's, the Consumer's Association and Greenpeace before establishing GeneWatch UK in January 1998. She is also a member of the UK Health and Safety Executive's Scientific Advisory Committee on Genetic Modification (Contained Use), the Biotechnology and Biological Sciences Research Council's Science and Society Panel, and chair of the Greenpeace UK Board.