Regulation, Risk Assessment and Placing on the Market of Genetically Modified Plants.

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Regulation:

The assessment of risk, to the environment and to human health arising from the release of any genetically modified crop, is a thorough and complex process governed by both national and EC regulations, and involving a number of overlapping but separate Acts and Directives. Within the EC genetically modified crops are regulated by EC Directive 90/220/EC although this regulation is currently undergoing revision (Directive 2001/18/EC from Oct 2002) As far as the UK is concerned this revision makes little or no practical difference to the risk assessment procedures already practised. The harmonisation and clarification of risk assessment adopted by Environment Ministers simply aims to bring all Member States into line with current best practice and provides a mechanism to monitor the use of an approved GM product following the granting of Part C marketing consent. The EC Directives are paralleled in national legislation. Using the UK as an example, releases of GM crops are covered by the UK Environmental Protection Act 1990 and are also subject to other relevant legislation including: Control of Pesticide Regulation 1986; Plant Varieties Act 1997; Food Safety Act 1990; Agriculture Act 1970; and Feeding Stuff Regulations 1995. These various regulations, separately and in conjunction, ensure that all aspects of any release are considered in depth on a case-by-case basis before any consent is granted. Consent for a research release (Part B consent) is the responsibility of each Member State of the EC for its own territory, and in the UK rests with the Secretary of State for the Environment, Department for the Environment, Food and Rural Affairs (Defra). However consent for marketing is the responsibility of the European Commission and involves all EC Member States (Part C consent).

Risk Assessment :

In the UK applications are considered on a case-by-case basis by the Advisory Committee for Releases to the Environment (ACRE), a statutory independent committee with expertise covering genetics, molecular biology, agronomy, human health and the environment. Any application involving food use, either directly or indirectly after processing, must also be considered by the Advisory committee on Novel Foods and Processes (ACNFP), a similar independent committee with expertise on all aspects of food and food products. Defra expert committees consider the use of any genetically modified materials in animal feeds.

Research Releases (Part B consent): To be granted approval for release and inclusion in food for research purposes an application must be cleared through all these stages. The consent, if granted by the Secretary of State, collates and includes all these

separate considerations and incorporates any conditions or any post release monitoring required. The applicant has to supply extensive data on both the inserted genetic material and the characteristics of the new genetically modified plant: the source of the insert; level of expression; interaction with the environment; effect on human health; management of the site and the release. All these are considered and summated by the applicant in a *Risk Assessment.* For crop plants, ACRE's consideration of the *Risk Assessment* focuses primarily on:

- Inserted genes may make the modified crop more persistent.
- Inserted genes may make the modified crop more invasive.
- Inserted genes may make the modified crop more undesirable to living organisms or the environment.
- Inserted genes may be transferred to other organisms.

Marketing (Part C consent): To be granted approval for marketing the applicant submits a dossier covering all the above issues to an EC Member State and, if that state's authorities are satisfied a favourable opinion will be forwarded to the EC. The full dossier is circulated to all EC member States for consideration. The collective opinions of all Member States are considered and an EC decision is reached based, if necessary on *qualified majority voting.* The EC Scientific Committee on Plants also considers this full dossier. This body, consisting of experts from across the whole EC, considers the whole body of data and issues a formal opinion. Having completed all of these stages, the EC decision is then communicated to the Member State, to whom the original application was made, for promulgation. When promulgated, that decision applies across the whole EC.

The potential impact of wide scale production of GM crops has been a major issue in Europe and an assessment of the potential adverse effects on the environment associated with the management of GM crops is now a requirement of EC legislation. In the UK these issues have been considered by a Sub-Group of ACRE set up to assess the likely immediate or delayed impact on the abundance and diversity of wildlife arising directly or indirectly from the management associated with the growing of GM crops. The principles proposed in the UK for this *extended risk assessment* are:

- This risk assessment applies to all GM crops at the time of application for general cultivation consent and will be applied in addition to all other standard risk assessments required under the EC Directives.
- Risk will be assessed relative to the range of current management practices for equivalent non-GM crops, and the land-use type most likely to be replaced by the new GM crop, and relative to the relevant UK Biodiversity Action Plan (BAP).
- Risk will be assessed for each particular crop and its associated management on the basis of experimental work, prediction from existing literature and post-release monitoring.
- The assessment should be sufficient to consider thoroughly the risks in the UK and include details adequate for other Member States, whether the application is submitted to the UK competent authority, or through another Member State.

- The risk assessment should consider that risks may vary across the range over which the crop will be grown, either as a result of differences in the wild life present, or because of differences in the management of the crop.

Commercialisation :

Finally, although having been cleared under the legislation covering genetically modification the crop can be grown, it still faces other regulatory hurdles before it can be commercialised and generally marketed. In the case of plant varieties, they must satisfy the relevant EC Directives (EC 70/457 and EC 98/95 and 96) and, in the UK, the Plant Varieties Act. If the GM crop is resistant to a specific herbicide, the application of that herbicide to that crop must be specifically approved, in the UK, under the Control of Pesticides Regulation. Currently this is a responsibility of each Member State, under its own legislation, but shortly there will be an EC Directive and a system similar to the Common Catalogue for seeds.

From all above it can be seen that the systems applied in the EC to examine, consider and authorise any release of a genetically modified crop is cautious, detailed and exhaustive.