STATUTORY INSTRUMENTS

1992 No. 3280

The Genetically Modified Organisms (Deliberate Release) Regulations 1992

PART III

MARKETING ORGANISMS

Consent to market products

10.—(1) The cases and circumstances prescribed under section 111(1)(a) of the Act in relation to the marketing of any genetically modified organisms are any cases and circumstances other than the marketing of a product in accordance with a written consent given by another competent authority of a member State in accordance with Article 13(4) of the Deliberate Release Directive.

(2) An application for a consent to market genetically modified organisms must be made in writing to the Secretary of State, and must be made either—

(a) where the product has not previously been marketed in pursuance of and in accordance with a consent granted by the Secretary of State under section 111(1) of the Act or a written consent given by another competent authority of a member State in accordance with Article 13(4) of the Deliberate Release Directive, or

(b) where the product is intended for a use for which it has not previously been marketed in pursuance of and in accordance with a consent granted by the Secretary of State under section 111(1) of the Act or a written consent given by another competent authority of a member State in accordance with Article 13(4) of the Deliberate Release Directive.

Information to be contained in application for consent to market

11.—(1) The following is the information which an application for a consent to market genetically modified organisms must contain:—

(a) the information prescribed in Schedule 1 to these Regulations, to the extent that such information is appropriate to the nature and scale of the release which may result from the marketing,

(b) information on data or results from any previous release of the organisms, or of organisms of the same description, which have been carried out by the applicant, and information from any previous application for consent to release the organisms, or organisms of the same description, which the applicant has made to the Secretary of State in accordance with the Act and these Regulations or to another competent authority of a member State in accordance with Article 5 of the Deliberate Release Directive,

(c) subject to paragraph (5), the information prescribed in Schedule 2 to these Regulations,

(d) a summary, in the format established by the Commission under Article 12(3) of the Deliberate Release Directive, of the information contained in the application.

(2) The information prescribed in Schedule 1 shall be included in the application at the level of detail which is appropriate to the nature and scale of the release which may result from the marketing, and shall take into account the diversity of sites of use of the product, including—

(a) information on data and results obtained from research and developmental releases concerning the ecosystems which could be affected by the use of the product, and

(b) an assessment of any risks for human health or the environment related to the genetically modified organisms contained in the product, including information obtained from the research and development stage on the impact of the release on the environment.

(3) Where the applicant considers, on the basis that it is not technically possible or it does not appear to the applicant to be necessary, that it is not appropriate for the application to contain the information prescribed in one or more of the paragraphs of Schedule 1, the application shall contain a statement of the reasons why the inclusion of the information is not appropriate.

(4) The application must contain the description of the methods used to obtain the information prescribed in Schedule 1 and a bibliographic reference or, where standardised or internationally recognised methods are used, a reference to which method was used to obtain the information and its bibliographic references, together with the name of the body or bodies responsible for carrying out the studies.

(5) Where the applicant considers, on the basis of the results of any release in pursuance of and in accordance with a consent granted by the Secretary of State under section 111(1) of the Act or a written consent given by another competent authority of a member State in accordance with Article 13(4) of the Deliberate Release Directive, or on substantive, reasoned scientific grounds, that the placing on the market and use of the product do not pose a risk to human health or the environment, he may propose not to supply the information prescribed in Part II of Schedule 2.

(6) The application may in addition contain data or results from an application for consent to market genetically modified organisms previously made by some other person, provided that a copy of that person's agreement in writing is contained in the application.

Transitional provision for marketing

12. Regulation 10(1) shall not apply to a person who markets a product which—

(a) was marketed by him in the United Kingdom before 1st February 1993, and

(b) is not an approved product,

until 1st February 1995.