SCOTTISH STATUTORY INSTRUMENTS

2002 No. 541

The Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002

PART III

MARKETING ORGANISMS

Applications for consent to market

16.—(1) An application for a consent to market genetically modified organisms under section 111(1) of the Act must be made in writing to the Scottish Ministers.

(2) An application for a consent to market genetically modified organisms which is not an application for renewal of consent must contain the following information:–

(a) subject to paragraph (4), the information prescribed in–

(i) Schedule 2 where the application is for consent to market any genetically modified higher plant; or

(ii) Schedule 3 in any other case,

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 same genetically modified organisms, or of the same combination of genetically modified organisms, which has been carried out by the applicant anywhere, and information from any previous application for consent to release the same genetically modified organisms, or the same combination of genetically modified organisms, which the applicant has made to any competent authority of any Member State (including the Scottish Ministers) in accordance with Article 6 of the Deliberate Release Directive or Article 5 of the 1990 Directive;

(c) an environmental risk assessment prepared in accordance with regulation 6;

(d) subject to paragraph (4), the information prescribed in Schedule 4;

(e) the proposed conditions for the marketing of the product, including specific conditions of use and handling;

(f) a proposed period for the consent which shall not exceed ten years;

(g) a monitoring plan prepared in accordance with Annex VII of the Deliberate Release Directive which shall include a proposal for the time period of the plan which may differ from the proposed period for the consent;

(h) a proposal for labelling which shall comply with the requirements laid down in Schedule 4;

(i) a proposal for packaging; and

(j) a summary of the application in the format established by the Commission under Articles 13(2)(h) and 30(2) of the Deliberate Release Directive.

(3) The application may in addition contain–

(a) data or results from an application for consent to release genetically modified organisms previously made by some other person, provided that if the data or results are confidential a copy of that person's agreement in writing is contained in the application; and

(b) any other information which the applicant considers relevant.

(4) The information provided in accordance with paragraph (2)(a) and (d) shall take into account the diversity of sites of use of the genetically modified organisms and shall include information on any data or results obtained from research and developmental releases concerning the impact of the release on human health and the environment.

(5) Where the applicant can demonstrate in the application by that person to the satisfaction of the Scottish Ministers that, on the basis of the results of any release in pursuance of and in accordance with a consent for a deliberate release granted by any competent authority of any Member State (including the Scottish Ministers) in accordance with Article 6(5) of the Deliberate Release Directive or Article 6(2) of the 1990 Directive, or on other substantive, reasoned scientific grounds, that the marketing and use of the product consisting of or including the genetically modified organisms do not pose a risk of damage to the environment, the applicant may omit from the application part or all of the information prescribed in Part II of Schedule 4.