WELSH STATUTORY INSTRUMENTS

2002 No. 3188

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

Part III

PLACING ON THE MARKET OF ORGANISMS AS OR IN PRODUCTS

Application for consent to market

17.—(1) An application for consent under section 111(1) of the Act must be made in writing to the National Assembly for Wales.

(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) the information prescribed in—

(i) Schedule 1 where the application is for consent to market any genetically modified higher plant, or

(ii) Schedule 2 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 organisms, or of the same combination of organisms which has been carried out by the applicant either inside or outside the European Community, and information from any previous application for consent to release the organisms, or the same combination of organisms, which the applicant has made to the National Assembly for Wales in accordance with the Act and these Regulations or to another competent authority in accordance with Article 6 of the Deliberate Release Directive;

(c) an environmental risk assessment prepared in accordance with regulation 7;

(d) subject to paragraph (3), the information prescribed in Schedule 3;

(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 3;

(i) a proposal for packaging;

(j) a summary of the application in the format established by the Commission under Article 13(2)(h) 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 a copy of that person's agreement in writing is contained in the application,

(b) an indication of the information submitted in the application, the disclosure of which might harm the competitive position of the applicant and which should therefore be treated as confidential, and

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

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

(5) Any indication in accordance with paragraph (3)(b) must be accompanied by verifiable justification.

(6) Where the applicant can demonstrate in his or her application to the satisfaction of the National Assembly for Wales that, on the basis of the results of any release in pursuance of and in accordance with a consent granted under section 111(1) of the Act under Part B of either the Deliberate Release Directive or the 1990 Directive, or on other substantive, reasoned scientific grounds, that the marketing and use of the product does not pose a risk of damage to the environment, he or she may propose not to supply part or all of the information prescribed in Part II of Schedule 3.