STATUTORY INSTRUMENTS

2002 No. 2443

Genetically Modified Organisms (Deliberate Release) Regulations 2002

PART III

MARKETING ORGANISMS

Requirement for consent to market

14. The cases and circumstances prescribed for the purposes of section 111(1)(a) of the Act in relation to marketing genetically modified organisms are all cases and circumstances in relation to the marketing of genetically modified organisms.

Exempt activities

15. The cases and circumstances prescribed for the purposes of sections 108(7) and 111(7) of the Act in which persons are exempt from the requirements of section 108(1)(a) of the Act (to carry out a risk assessment) and of section 111(1)(a) of the Act (to obtain consent), respectively, insofar as they relate to marketing genetically modified organisms, are all cases and circumstances in which—

(a) an approved product is marketed for a use for which it has approval,

(b) genetically modified micro-organisms are made available for activities regulated under the Contained Use Directive,

(c) genetically modified organisms other than micro-organisms falling within paragraph (b) are made available to be used exclusively for activities where appropriate stringent containment measures based on the same principles of containment as laid down in the Contained Use Directive are used to limit their contact with and to provide a high level of safety for the general population and the environment,

(d) genetically modified organisms are made available to be used exclusively for deliberate releases complying with the requirements laid down in Part II,

(e) a genetically modified organism authorised under Council Regulation (EEC) No. 2309/93(**1**), as amended by Commission Regulation EC No 649/98(**2**), is marketed, or

(f) a novel food or novel food ingredient within the scope of Regulation EC No. 258/97 of the European Parliament and of the Council(**3**) is marketed.

Applications for consent to market

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

(**1**) OJ No L214, 24.8.1993, p. 1.
(**2**) OJ No L88, 24.3.1998, p. 7.
(**3**) OJ No L43, 14.2.1997, p. 1.

(2) An application for a consent to market genetically modified organisms which is not an application for renewal of a 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 Secretary of State 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 6,

(d) 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, and

(b) 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 organisms 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) Where the applicant can demonstrate in his application to the satisfaction of the Secretary of State, that, on the basis of the results of any release in pursuance of and in accordance with a consent under section 111(1) of the Act or under Part B of either the Deliberate Release Directive or the 1990 Directive, or on other substantive, reasoned scientific grounds, the marketing and use of the product do not pose a risk of damage to the environment, he may omit from the application part or all of the information prescribed in Part II of Schedule 3.

Transitional provisions for marketing

17. Where the Secretary of State has received an application for consent to market genetically modified organisms before 17 October 2002 pursuant to the 1992 Regulations and has not yet

determined that application, or, in a case where the Commission is required to take a decision in accordance with Article 13(3) of the 1990 Directive, that decision has not yet been taken—

(a) the application shall be subject to the provisions of these Regulations,

(b) the applicant shall submit to the Secretary of State such further information, additional to that already provided in connection with the application, as is necessary in order to comply with the requirements of these Regulations by 17 January 2003,

(c) the application shall be treated as having been received by the Secretary of State for the purposes of regulation 23 on submission of the information required by paragraph (b),

(d) if, by 17 October 2002, the Secretary of State has forwarded to the Commission the information required by regulation 16(2) of the 1992 Regulations, she shall supplement it and, if she considers it to be necessary, revise it on receipt of the further information required by paragraph (b) in the light of her obligations under these Regulations, and

(e) if the information required by paragraph (b) has not been submitted by 17 January 2003, the Secretary of State may refuse to proceed with the application.

Applications for renewal of consent to market

18.—(1) Where the Secretary of State has granted a consent to market genetically modified organisms under section 111(1) of the Act, any application to renew that consent shall be made in writing to the Secretary of State—

(a) before 17 October 2006 where the consent was granted before 17 October 2002, and

(b) no later than nine months before the expiry of the consent in all other cases.

(2) The application shall contain—

(a) a copy of the consent to market the genetically modified organisms,

(b) where applicable, a report on the results of the monitoring carried out in accordance with the requirements of regulation 28(f),

(c) any other new information which has become available with regard to the risks of the product causing damage to the environment,

(d) as appropriate, a proposal for amending or adding to the conditions of the existing consent, including the conditions concerning future monitoring, and a proposal for the time limitation of the new consent.

(3) Any consent to market genetically modified organisms granted by the Secretary of State under section 111(1) of the Act before 17 October 2002 for which no application for renewal under paragraph (1) has been received before 17 October 2006 shall be treated as having expired on that date.