SCOTTISH STATUTORY INSTRUMENTS

2002 No. 541

The Genetically Modified Organisms (Deliberate Release) (Scotland) 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 (including culture collections);

(c) genetically modified organisms other than micro-organisms referred to in 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 Regulation 2309/93 is marketed;

(f) a novel food or novel food ingredient within the scope of Regulation ECNo. 258/1997 of the European Parliament and of the Council(**1**) as amended by Commission Regulation (EC) No. 1852/2001(**2**) is marketed.

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.

(**1**) O.J. No. L 43, 14.2.97, p.1
(**2**) O.J. No. L 253, 21.9.01, p.17.

(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.

Transitional provision in respect of applications to market

17. Where the Scottish Ministers have received an application for consent to market genetically modified organisms before the coming into force date of these Regulations pursuant to the 1992 Regulations and have 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 in writing to the Scottish Ministers 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 the date occurring three months after the coming into force date of these Regulations;

(c) the application shall be treated as having been received by the Scottish Ministers for the purposes of regulation 23 on the date of submission of the information required by paragraph (b);

(d) if, by the coming into force date of these Regulations, the information required by regulation 16(2) of the 1992 Regulations has been forwarded to the Commission, the Scottish Ministers shall ensure that the information is supplemented and, if they consider it necessary, revised on the receipt by the Scottish Ministers of the further information required by paragraph (b) in the light of their obligations under these Regulations; and

(e) if the information required by paragraph (b) has not been submitted in writing by the date occurring three months after the coming into force date of these Regulations, the Scottish Ministers may refuse to proceed with the application.

Applications for renewal of consent to market

18.—(1) Where a consent has been granted under section 111(1) of the Act to market genetically modified organisms which were first marketed in Scotland, any application to renew that consent shall be made in writing to the Scottish Ministers–

(a) before 17th October 2006 where the consent was granted before the coming into force date of these Regulations; or

(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 the consent to market was granted–

(i) after the coming into force date of these Regulations, a report on the results of the monitoring carried out in accordance with the requirements of regulation 28(f); or

(ii) before that date, a report on the results of any monitoring carried out on the relevant product;

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

(d) as appropriate, a proposal for amending, complementing 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 first marketed in Scotland which was granted under section 111(1) of the Act before the coming into force date of these Regulations and for which no application for renewal under paragraph (1) has been received by the Scottish Ministers before 17th October 2006 shall be treated as having expired on that date.

(4) Any consent to market genetically modified organisms marketed in Scotland which was granted under section 111(1) of the Act before the coming into force date of these Regulations and for which an application for renewal under paragraph (1) is refused shall be treated as having expired on 17th October 2006 or the date of refusal of the application, whichever is the later.