
SCOTTISH STATUTORY INSTRUMENTS

2002 No. 541

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

PART II

RELEASING ORGANISMS FOR ANY OTHER PURPOSE THAN MARKETING

Requirement for consent to release

8. The cases and circumstances prescribed for the purposes of section 111(1)(a) of the Act in relation to the release of any genetically modified organisms are all cases and circumstances in which genetically modified organisms are intended to be released.

Exempt activities

9. The cases and circumstances prescribed for the purposes of section 111(7) of the Act in which persons are exempt from the requirements of section 111(1)(a) of the Act, insofar as those requirements apply to the release of genetically modified organisms, are all cases and circumstances in which an approved product is released in accordance with the conditions and limitations to which the use of the product is subject.

Applications for consent to release – general provisions

10.—(1) An application for a consent to release genetically modified organisms must be submitted in writing to the Scottish Ministers.

(2) The Scottish Ministers may accept that proposed releases of the same genetically modified organism or of a combination of genetically modified organisms on the same site or on different sites for the same purpose and within a defined period may be notified in a single application.

(3) Where an application for a consent to release genetically modified organisms is expressed to rely on the First Simplified Procedure (crop plants) Decision, in the event of any inconsistency in the requirements as to information to be provided under that Decision and the requirements as to information to be provided under these Regulations, the provisions of that Decision shall prevail.

Information to be contained in application for consent to release

11.—(1) An application for a consent to release genetically modified organisms must contain—

(a) the information prescribed in—

(i) Schedule 2, where the application is for consent to release 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 or application;

- (b) information on data or results from any previous release of the organisms, or the same combination of organisms, which has been carried out by the applicant, and information from any previous application for the release of the organisms, or of the same combination of 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; and
 - (d) a summary, in the format established by the Commission under Articles 11(1) and 30(2) of the Deliberate Release Directive, of the information contained in the application.
- (2) The application may contain—
- (a) data or results from an application for consent to release genetically modified organisms previously made by some other person, provided that where 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 is relevant.

Advertisement of applications for consent to release

12.—(1) Subject to paragraphs (2) and (3), a person who makes an application for a consent to release genetically modified organisms shall, not more than ten days after the applicant sends that application to the Scottish Ministers, cause to be published in any newspaper to be specified by the Scottish Ministers a notice approved by the Scottish Ministers containing the following information:—

- (a) the name and address of the applicant;
- (b) the general description of the organisms to be released;
- (c) the location and purpose of the release;
- (d) the intended date of the release;
- (e) a statement that information about the application will be placed on the register by the Scottish Ministers within 12 days of their receipt of the application;
- (f) the means by which the register can be inspected; and
- (g) a statement that the Scottish Ministers shall, within a period which they shall specify in accordance with these Regulations, have regard to any representations made to them in writing relating to risks of damage to the environment⁽¹⁾ posed by the release of the genetically modified organisms,

and that person shall—

- (i) immediately send to the Scottish Ministers confirmation that such information was placed in such newspaper and the date on which the information was published in the newspaper; and
- (ii) if requested to do so by the Scottish Ministers, send a copy of such newspaper containing the advertisement to them.

(2) A notice published under paragraph (1) need not contain the information referred to in subparagraphs (c) and (d) of that paragraph insofar as the First Simplified Procedure (crop plants) Decision does not require that information to be submitted with the application and that information is not submitted with the application.

⁽¹⁾ As defined in section 107(2), (3) and (6) of the Act as amended by regulation 4(2) to (4).

(3) An applicant for consent shall ascertain from the Scottish Ministers the level of detail on the location of the release which will be placed on the register and shall include the same level of detail in the notice to be published under paragraph (1).

(4) A person who makes an application for a consent to release genetically modified organisms shall, subject to paragraph (5), not more than ten days after that person sends that application to the Scottish Ministers, give to the following persons notice in writing that the application has been made and the information prescribed in paragraph (1)(a) to (g) (save insofar as paragraph (2) permits such information to be excluded from the notice referred to in paragraph (1)):-

- (a) the local authority and community council for the area of each proposed release;
- (b) the owner of the site of each proposed release, if such person is not the applicant;
- (c) each member of the genetic modification safety committee established by the applicant under regulation 16 of the Genetically Modified Organisms (Contained Use) Regulations 2000⁽²⁾ where relevant;
- (d) any National Park Authority designated under section 6 of the National Parks (Scotland) Act 2000⁽³⁾ for the area of each proposed release;
- (e) Scottish Natural Heritage established under section 1 of the Natural Heritage (Scotland) Act 1991⁽⁴⁾; and
- (f) such other body as the Scottish Ministers may notify the applicant that they consider appropriate,

and shall immediately send to the Scottish Ministers copies of the notices given under this paragraph.

(5) Notwithstanding paragraph (4), the applicant shall give any body which the Scottish Ministers consider appropriate, for the purposes of paragraph (4)(f), the notice referred to in paragraph (4) within ten days of receipt by the applicant of the notification of such body as the Scottish Ministers consider appropriate.

Transitional provisions in respect of applications to release

13. Where the Scottish Ministers, before the coming into force date of these Regulations, have received an application for consent to release genetically modified organisms pursuant to the 1992 Regulations and have not as at that date determined the application-

- (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, for the purposes of regulation 12(1) and (4), be treated as having been sent to the Scottish Ministers and shall, for the purposes of regulation 20, be treated as having been received by the Scottish Ministers on the date of submission of the information required by paragraph (b); and
- (d) 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.

(2) S.I.2000/2831.

(3) 2000 asp 10.

(4) 1991 c. 28.