
STATUTORY INSTRUMENTS

1992 No. 3280

**The Genetically Modified Organisms
(Deliberate Release) Regulations 1992**

PART II

RELEASING ORGANISMS

Consent to release organisms

5.—(1) Subject to paragraphs (3) and (4), the cases and circumstances prescribed under section 111(1)(a) of the Act in relation to the release of any genetically modified organisms are any cases and circumstances other than the release of an approved product in accordance with the conditions and limitations to which the use of the product is subject.

(2) An application for a consent to release genetically modified organisms must be made in writing to the Secretary of State, and must be made either—

- (a) for one or more releases of one or more descriptions of genetically modified organisms on the same site for the same purpose within a limited period, or
- (b) for one or more releases of one description of genetically modified organisms on one or more sites for the same purpose within a limited period.

(3) Paragraph (1) shall not apply to a person who—

- (a) has notified the Health and Safety Executive, under regulation 5(1)(a) of the Genetic Manipulation Regulations 1989(1), of his intention to carry out an activity involving an intentional introduction into the environment, and
- (b) carries out the activity in accordance with that notification before 2nd May 1993.

(4) Paragraph (1) shall not apply to a person who releases a product which was marketed in the United Kingdom before 1st February 1993 and is not an approved product.

Information to be contained in application for consent to release

6.—(1) Subject to regulation 7 (Exemptions from regulation 6), the following is the information which an application for a consent to release genetically modified organisms must contain:—

- (a) the information prescribed in Schedule 1 to these Regulations, to the extent that such information is appropriate to the proposed release,
- (b) information on data or results from any previous release of the organisms, or of organisms of the same description, which has been carried out by the applicant, and information from any previous application for the release of the organisms, or of organisms of the same description, which the applicant has made to the Secretary of State in accordance with the Act and these Regulations or to another competent authority of a member State in accordance with Article 5 of the Deliberate Release Directive,

- (c) a statement evaluating the impacts and risks posed to human health and the environment by the release of the organisms,
 - (d) a statement whether the detailed description of the organisms and the details of the purpose for which the organisms will be released have been published, and the bibliographic reference for any information so published,
 - (e) a summary, in the format established by the Commission under Article 9(1) of the Deliberate Release Directive, of the information contained in the application.
- (2) The information prescribed in Schedule 1 shall be included in the application at the level of detail which is appropriate to the nature and scale of the proposed release.
- (3) Where the applicant considers, on the basis that it is not technically possible or it does not appear to the applicant to be necessary, that it is not appropriate for the application to contain the information prescribed in one or more of the paragraphs of Schedule 1, the application shall contain a statement of the reasons why the inclusion of the information is not appropriate.
- (4) The application must contain the description of the methods used to obtain the information contained in the application in accordance with paragraph (1) and a bibliographic reference, or, where standardised or internationally recognised methods are used, a reference to which method was used to obtain the information and its bibliographic references, together with the name of the body or bodies responsible for carrying out the studies.
- (5) The application may in addition contain 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.

Exemptions from regulation 6

7. An application for a consent to release genetically modified organisms need not contain the information prescribed in regulation 6(1)(a) and (b) if—
- (a) the information was contained either—
 - (i) in an application which was made by the same person in relation to a previous release of those organisms or of the same description of organisms, or
 - (ii) in an application which was made by some other person in relation to a previous release of those organisms or of the same description of organisms,
 - (b) the application refers to the previous application in which the information was contained, and
 - (c) where paragraph (a)(ii) applies, the application contains the agreement in writing of the person who made the previous application to a reference to that application being made.

Advertisement of application for consent to release

- 8.—(1) Subject to paragraph (2), a person who makes an application for a consent to release genetically modified organisms shall, not less than fourteen days and not more than twenty-eight days after acknowledgement of receipt of that application is sent to him by the Secretary of State, cause to be published in a newspaper or newspapers circulating in the areas likely to be affected by the proposed release a notice 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 general purpose of the release, and
 - (d) the foreseen dates of the release.

(2) Where the information on the location of the release which has been placed on the register kept by the Secretary of State under section 122 of the Act differs in its level of detail from that contained in the application for consent, the notice shall contain the level of detail regarding the location of the release which appears on the register.

(3) A person who makes an application for a consent to release genetically modified organisms shall, not less than fourteen days and not more than twenty-eight days after acknowledgement of receipt of that application is sent to him by the Secretary of State, give to the following persons notice that he has made the application and the information prescribed in paragraph (1)(a) to (d)—

- (a) the owner or owners of the site of the proposed release, if a person other than the applicant,
- (b) the local authority for the area of the proposed release,
- (c) the Nature Conservancy Council for England, Scottish Natural Heritage or the Countryside Council for Wales, as appropriate, according to whether the release will be in England, Scotland or Wales,
- (d) the Countryside Commission, if the release will be in England,
- (e) the Forestry Commission,
- (f) the National Rivers Authority or, if the release will be in Scotland, the river purification board or islands council for the area of the proposed release,
- (g) the water undertaker for the area of the proposed release or, if the release will be in Scotland, the regional or islands council for the area of the proposed release,
- (h) each member of the genetic modification safety committee established by the applicant under regulation 11 of the Genetically Modified Organisms (Contained Use) Regulations 1992(2).

General condition on consents to release organisms

9. In section 112 of the Act (Consents: limitations and conditions) there shall be substituted for paragraph (b) of subsection (5) the following paragraph—

- “(b) notify the Secretary of State of—
 - (i) any new information which becomes available with regard to any risks there are of damage to the environment being so caused, and
 - (ii) the effects of any releases by him for the assessment of any risks there are of damage to the environment being so caused by such organisms being released or marketed;”.