STATUTORY INSTRUMENTS

2002 No. 2443

Genetically Modified Organisms (Deliberate Release) Regulations 2002

PART I

GENERAL

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) Regulations 2002 and shall come into force on 17 October 2002.

(2) Except for this regulation, regulation 38, insofar as it relates to the continental shelf, and regulation 2, insofar as it defines "the Act" for the purposes of regulation 38, these Regulations shall extend only to England and Wales.

(3) Except for this regulation, regulations 3, 4, 19(1), 29, 30, 33(2), 38 and 39 and regulation 2, insofar as it defines "the Act" for the purposes of the regulations referred to in this paragraph, these Regulations shall apply only to England.

Interpretation

2. In these Regulations—

"the Act" means the Environmental Protection Act 1990;

"the Advisory Committee on Releases to the Environment" means the committee appointed by the Secretary of State under section 124 of the Act;

"antibiotic resistance markers" means genes employed in the modification of an organism to make that organism express resistance to a particular antibiotic or antibiotics;

"application for consent to release" shall include any notification made under the First Simplified Procedure (crop plants) Decision;

"approved product" means a product permitted to be marketed by a consent granted under section 111(1) of the Act by a person other than the Secretary of State or otherwise in accordance with Article 15(3), 17(6) or 18(2) of the Deliberate Release Directive or Article 13(2) or (4) of the 1990 Directive;

"the Commission" means the European Commission;

"the Contained Use Directive" means Council Directive 90/219/EEC[M1] on the contained use of genetically modified micro-organisms as amended by Commission Directive 1994/51/EC[M2] and Directive 98/81/EC[M3];

"the Deliberate Release Directive" means Council Directive 2001/18/EC[M4] on the deliberate release into the environment of genetically modified organisms;

"the 1990 Directive" means Council Directive 1990/220/EEC[M5] on the deliberate release into the environment of genetically modified organisms as amended by Commission Directive 1994/15/EC[M6] and Commission Directive 1997/35/EC[M7];

"electronic communication" means the same as in the Electronic Communications Act 2000 [M8];

"environmental risk assessment" means the environmental risk assessment required to be contained in an application for consent to release or market genetically modified organisms by regulation 11(1)(c) and regulation 16(2)(c), respectively;

"the First Simplified Procedure (crop plants) Decision" means Commission Decision 94/730/EC[M9];

"genetically modified organisms" means a genetically modified organism or a combination of genetically modified organisms;

"higher plant" means a plant belonging to the taxonomic group*Spermatophytae* (*Gymnospermae* or*Angiospermae*);

"local authority" means a county council, a district council, a London borough council, the Common Council of the City of London in its capacity as a local authority, and the Council of the Isles of Scilly;

"monitoring plan" means the plan required by regulation 16(2)(g);

"the register" means the public register kept by the Secretary of State under section 122 of the Act.

"the 1992 Regulations" means the Genetically Modified Organisms (Deliberate Release) Regulations 1992 [M10].

Marginal Citations

M1 OJ No L117, 8.5.1990, p. 1.
M2 OJ No L297, 18.11.1994, p. 29.
M3 OJ No L330, 5.12.1998, p. 13.
M4 OJ No L106, 17.4.2001, p. 1.
M5 OJ No L117, 8.5.1990, p. 15.
M6 OJ No L103, 22.4.1994, p. 20.
M7 OJ No L169, 27.6.1997, p. 72.
M8 2000 c. 7.
M9 OJ No L292, 12.11.1994, p. 31.
M10 SI 1992/3280 as amended by the Genetically Modified Organisms (Deliberate Release) Regulations 1993 (SI 1993/152), the Genetically Modified Organisms (Deliberate Release) Regulations 1995 (SI 1995/304), the Genetically Modified Organisms (Deliberate Release and Risk Assessment) (Amendment) Regulations 1997 (SI 1997/1900) and the Genetically Modified Organisms (Contained Use) Regulations 2000 (SI 2000/2831).

Purpose of Part VI of the Act and meaning of "genetically modified organisms" etc

3.—(1) Section 106 of the Act (purpose of Part VI of the Act and meaning of "genetically modified organisms" etc) is amended as follows.

(2) For subsection (1) substitute—

"(1) This Part has effect for the purpose of ensuring that all appropriate measures are taken to avoid damage to the environment which may arise from the escape or release from human control of genetically modified organisms.".

(3) In subsection (4) (definition of organism which is genetically modified) for paragraph (a) (modification of prescribed artificial technique) substitute—

"(a) have been artificially modified, or".

(4) After that subsection insert—

"(4A) Genes or other genetic material in an organism are "artificially modified" for the purposes of subsection (4) above if they are altered otherwise than by a process which occurs naturally in mating or natural recombination.

This subsection is subject to subsections (4B) and (4C) below.

(4B) For the purposes of subsection (4) above—

(a) genes or other genetic material shall be taken to be artificially modified if they are altered using such techniques as may be prescribed for the purposes of this paragraph;

(b) genes or other genetic material shall not be regarded as artificially modified by reason only of being altered by the use of such techniques as may be prescribed for the purposes of this paragraph.

(4C) An organism shall be taken not to be a genetically modified organism for the purposes of this Part if it is an organism of a prescribed description.

(4D) In subsections (4B) and (4C) above "prescribed" means prescribed by regulations made by the Secretary of State.".

(5) Subsections (5) and (6) are omitted.

Meaning of "damage to the environment" etc

4.—(1) Section 107 of the Act (meaning of "damage to the environment" etc) is amended as follows.

(2) For subsection (2) (meaning of "environment") substitute—

"(2) The "environment" includes land, air and water and living organisms supported by any of those media.".

(3) In subsection (3)(meaning of "damage to the environment") omit "to the living organisms supported by the environment".

(4) For subsection (6) (meaning of "harm") substitute—

"(6) "Harm" means adverse effects as regards the health of humans or the environment.".

(5) For subsection (9) (meaning of organism being under a person's "control") substitute—

"(9) Organisms of any description are under the "control" of a person where he keeps them contained by measures designed to limit their contact with humans and the environment and to prevent or minimise the risk of harm.".

(6) For subsection (11) (meaning of organism being "marketed") substitute—

"(11) Genetically modified organisms of any description are "marketed" by a person when products consisting of or including such organisms are placed on the market by being made available to other persons, whether or not for consideration.".

Techniques of genetic modification

5.—(1) Until the coming into force of the first regulations under section 106(4B)(a) [M11] of the Act, genes or other genetic material shall be taken, for the purposes of subsection (4) of that section, to be artificially modified if they are altered using any of the following techniques:

(a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

(b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

(c) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

(2) Until the coming into force of the first regulations under section 106(4B)(b) of the Act, genes or other genetic material shall not be regarded, for the purposes of subsection (4) of that section, as artificially modified by reason only of being altered by the use of any of the following techniques:—

(a) in vitro fertilisation,

(b) natural processes such as conjugation, transduction and transformation,

(c) polyploidy induction,

provided that such techniques do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques or methods other than—

(i) mutagenesis; or

(ii) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

(3) Until the coming into force of the first regulations under section 106(4C) of the Act, an organism shall be taken, for the purposes of Part VI of the Act, not to be a genetically modified organism if it is yielded from the techniques or methods listed in paragraph (2)(i) or (ii) provided that those techniques or methods did not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those made by techniques or methods listed in that paragraph.

Marginal Citations

M11 Section 106(4) is amended by regulation 3(3) and section 106(4A) to 106(4D) is inserted by regulation 3(4).

Environmental risk assessment

6.—(1) An environmental risk assessment contained in an application for consent to release or market genetically modified organisms shall—

(a) identify and evaluate the potential damage to the environment, whether direct or indirect, immediate or delayed, which may arise from the release or marketing of genetically modified organisms,

(b) be carried out in accordance with Annex II of the Deliberate Release Directive and contain the conclusions required in section D of that Annex,

(c) include bibliographic references and indications of the methods used where applicable.

(2) Where the genetically modified organisms contain antibiotic resistance markers, the environmental risk assessment shall include an examination of the particular risks of damage to

the environment which may be posed by the deliberate release or marketing of those genetically modified organisms.

Communication with applicant for consent

7.—(1) Wherever an applicant for a consent or renewal of a consent to which these Regulations apply or a holder of such consent is required under these Regulations to submit any document in writing, he is required to submit that document in both a paper and in a commonly used electronic form.

(2) Wherever these Regulations require any communication from the Secretary of State to the applicant for a consent or renewal of a consent to be in writing, "writing" shall include an electronic communication.

(3) Any documents required by these Regulations to be in writing which do not fall within the provisions of paragraph (1) or (2) must be in paper form.

Status:
Point in time view as at 17/10/2002.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to Genetically Modified Organisms (Deliberate Release) Regulations 2002. Any changes that have already been made by the team appear in the content and are referenced with annotations.