
SCOTTISH STATUTORY INSTRUMENTS

2002 No. 541

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

PART I
GENERAL

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 and shall come into force on the day after the day on which they are made.

(2) These Regulations extend to Scotland only.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

“the Act” means the Environmental Protection Act 1990(1);

“the Advisory Committee on Releases to the Environment” means the committee appointed for the purposes of, and in accordance with, 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 consisting of or including genetically modified organisms which is permitted to be marketed by a consent granted under section 111(1) of the Act 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;

“community council” means a community council constituted under section 51 of the Local Government (Scotland) Act 1973(2);

“the Contained Use Directive” means Council Directive 1990/219/EEC(3) on the contained use of genetically modified micro-organisms as amended by Commission Directive 1994/51/EC(4) and Council Directive 1998/81/EC(5);

(1) 1990 c. 43.

(2) 1973 c. 65.

(3) O.J. No. L 117, 8.5.90, p.1.

(4) O.J. No. L 297, 18.11.94, p.29.

(5) O.J. No. L 330, 5.12.98, p.13.

“the Deliberate Release Directive” means Directive [2001/18/EC](#) of the European Parliament and the Council⁽⁶⁾ on the deliberate release into the environment of genetically modified organisms;

the “1990 Directive” means Council Directive [1990/220/EEC](#)⁽⁷⁾ on the deliberate release into the environment of genetically modified organisms as amended by Commission Directive [1994/15/EC](#)⁽⁸⁾ and Commission Directive [1997/35/EC](#)⁽⁹⁾;

“electronic communication” has the same meaning as in the Electronic Communications Act 2000⁽¹⁰⁾;

“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 virtue of regulation 11(1)(c) and regulation 16(2)(c) respectively;

“the First Simplified Procedure (crop plants) Decision” means Commission Decision [1994/730/EC](#)⁽¹¹⁾, as amended by the Deliberate Release Directive;

“the Food Standards Agency” means the Food Standards Agency established under section 1 of the Food Standards Act 1999⁽¹²⁾;

“genetically modified organisms” means a genetically modified organism or a combination of genetically modified organisms;

“the Health and Safety Executive” means the Health and Safety Executive established under section 10 of the Health and Safety at Work etc. Act 1974⁽¹³⁾;

“higher plant” means a plant belonging to the taxonomic group Spermatophyta (Gymnospermae or Angiospermae);

“local authority” means a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994⁽¹⁴⁾;

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

“the register” means the public register kept by the Scottish Ministers under section 122 of the Act;

“Regulation 2309/93” has the same meaning as it has in Schedule 1;

“the 1992 Regulations” means the Genetically Modified Organisms (Deliberate Release) Regulations 1992⁽¹⁵⁾.

(2) Expressions used in these Regulations have, unless the contrary intention appears, the meaning which they bear in Part VI of the Act and in regulations 8, 9, 14, 15, 33 and 34 the prescribing of cases, circumstances, descriptions and matters shall be treated as being cases, circumstances, descriptions and matters prescribed in accordance with and under the Act.

(3) In these Regulations, unless the context otherwise requires—

- (a) any reference to a numbered regulation or to a numbered Schedule or to a numbered Part is a reference to the regulation or Schedule or Part in these Regulations so numbered; and
- (b) a reference to a numbered paragraph is a reference to the paragraph so numbered in the regulation or Schedule to which that reference occurs.

(6) O.J. No. L 106, 17.4.01, p.1.

(7) O.J. No. L 117, 8.5.90, p.15.

(8) O.J. No. L 103, 22.4.94, p.20.

(9) O.J. No. L 169, 27.6.97, p.72.

(10) 2000 c. 7.

(11) O.J. No. L 292, 12.11.94, p.31.

(12) 1999 c. 28.

(13) 1974 c. 37.

(14) 1994 c. 39.

(15) S.I.1992/3280, as amended by S.I. 1993/152, 1995/304, 1997/1900 and 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 and meaning of “genetically modified organisms” etc.) is amended as follows.

(2) For subsection (1) (purpose of Part VI) 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)—

(a) insert after “this Part”—

“, subject to subsection (4C) below,”; and

(b) for paragraph (a) (modification of prescribed artificial technique) substitute—

“(a) have been artificially modified, or”.

(4) After subsection (4) insert—

“(4A) subject to subsections (4B) and (4C) below, 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.

(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 Scottish Ministers.”.

(5) Subsections (5) (techniques which may be prescribed as genetic modification) and (6) (direct or indirect means of modification immaterial) 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 the living organisms supported by any of those media.”.

(3) In subsection (3) (meaning of “damage to the environment”) the words “to the living organisms supported by the environment” are omitted.

(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 that person keeps them contained by specific measure 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 “marketed”) substitute—

“(11) Genetically modified organisms of any description are “marketed” 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 made by the Scottish Ministers under section 106(4B)(a) (power to prescribe techniques, alteration by which shall be taken to be artificial modification)(16) 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 made by the Scottish Ministers under section 106(4B)(b) (power to prescribe techniques, alteration by which shall not be taken to be artificial modification) of the Act, genes or other genetic material shall not be taken, for the purposes of subsection (4) of that section, to be artificially modified by reason only of being altered by the use of any of the following techniques:—

- (a) in vitro fertilisation;
- (b) natural processes including conjugation, transduction or 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 made by the Scottish Ministers under section 106(4C) (power to prescribe organisms which shall be taken not to be genetically modified) 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).

(16) Section 106(4) is amended by regulation 3(3) and section 106(4A) to (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 or for renewal of consent to 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 the 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; and
- (c) include any 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 an applicant for consent

7.—(1) Notwithstanding paragraph (2), 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 or in written form, whether before or after consent is granted, the applicant shall submit that document both in writing and in an electronic form acceptable to the Scottish Ministers.

(2) A reference in these Regulations to anything done in writing or produced in written form which does not fall within the provisions of paragraph (1) includes a reference to an electronic communication which has been recorded and is consequently capable of being reproduced.