
WELSH STATUTORY INSTRUMENTS

2002 No. 3188

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

Part I

General

Citation, commencement and application

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 and shall come into force on 31st December 2002.

(2) These Regulations apply in relation to Wales.

Interpretation

2.—(1) In these Regulations—

“the Act” (“*y Ddeddf*”) means the Environmental Protection Act 1990;

“the Advisory Committee on Releases to the Environment” (“*y Pwyllgor Ymgynghorol ar Ollyngiadau i'r Amgylchedd*”) means the Committee appointed by the National Assembly for Wales under section 124 of the Act;

“antibiotic resistance markers” (“*marcwyr ymwrthedd gwrthfotig*”) 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” (“*cais am ganiatâd i ollwng*”) shall include any notification made under the First Simplified Procedure (crop plants) Decision;

“approved product” (“*cynnyrch wedi'i gymeradwyo*”) means a product permitted to be marketed by a consent granted by the National Assembly for Wales under section 111(1) of the Act or 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” (“*y Comisiwn*”) means the European Commission;

“the Contained Use Directive” (“*y Gyfarwyddeb Defnydd Amgaeëdig*”) means Council Directive [90/219/EEC](#)(1) on the contained use of genetically modified micro-organisms as last amended by Council Decision [2001/204/EC](#)(2);

“the Deliberate Release Directive” (“*y Gyfarwyddeb Gollwng Bwriadol*”) means Directive [2001/18/EC](#) of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms(3);

(1) OJNo. L117, 8.5.1990, p.1.

(2) OJ No. L73, 15.03.2001, p.32—34

(3) OJ No. L106, 17.4.2001, p.1.

“the 1990 Directive” (“*Cyfarwyddeb 1990*”) means Council Directive [90/220/EEC](#)(4) on the deliberate release into the environment of genetically modified organisms as amended by Commission Directive [1994/15/EC](#)(5) and Commission Directive [1997/35/EC](#)(6);

“electronic communication” (“*cyfathrebiad electronig*”) means the same as in the Electronic Communications Act 2000(7);

“environmental risk assessment” (“*asesiad risg amgylcheddol*”) means the environmental risk assessment required to be contained in an application for consent to release or market genetically modified organisms by regulation 12(1)(c) and regulation 17(2)(c) respectively;

“the First Simplified Procedure (crop plants) Decision” means Commission Decision [94/730/EC](#)(8);

“genetically modified organisms” (“*organeddau a addaswyd yn enetig*”) means a genetically modified organism or a combination of genetically modified organisms;

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

“local authority” (“*awdurdod lleol*”) means the council of a county or county borough;

“monitoring plan” (“*cynllun monitro*”) means the plan required by regulation 17(2)(g);

“the register” (“*y gofrestr*”) means the public register kept by the National Assembly for Wales under section 122 of the Act;

“the 1992 Regulations” (“*Rheoliadau 1992*”) means the Genetically Modified Organisms (Deliberate Release) Regulations 1992(9).

(2) In these Regulations—

- (a) any reference to a numbered regulation or to a numbered Schedule is a reference to the regulation or Schedule 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 in which that reference occurs.

Designation of competent authority

3. The National Assembly for Wales shall be the competent authority in relation to Wales for the purposes of the Deliberate Release Directive.

Purpose of Part VI of the Act and meaning of “genetically modified organisms” etc.

4.—(1) The amendments of section 106 of the Act (purpose of Part VI of the Act and meaning of “genetically modified organism” etc.) made by the Genetically Modified Organisms (Deliberate Release) Regulations 2002 have effect in relation to Wales as follows:

(2) The amendment made by regulation 3(2) of those Regulations, which substitutes for subsection (1) the following—

“(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.”,

also has effect in relation to Wales.

(4) OJ No. L117, 8.5.90, p.15.

(5) OJ No. L103, 22.4.94, p.20.

(6) OJ No. L169, 27.6.97, p.72.

(7) 2000 c. 7.

(8) OJ No. L292, 12.11.1994, p.31.

(9) [S.I. 1992/3280](#). The functions of the Secretary of State under these regulations were transferred to the National Assembly for Wales under Article 3 and Schedule 1 to the National Assembly for Wales (Transfer of Functions) Order 2000 ([S.I. 2000/253](#)).

(3) The amendment of subsection (4) made by regulation 3(3) of those Regulations, which substitutes for paragraph (a) the following—

“(a) have been artificially modified, or”,
also has effect in relation to Wales.

(4) The amendment made by regulation 3(4) of those Regulations (which inserts subsections (4A) to (4D)) is modified by paragraph (5) and, as so modified, also has effect in relation to Wales.

(5) In subsection (4D), as inserted by that regulation, after “the Secretary of State” insert “or, in relation to Wales, the National Assembly for Wales”.

(6) The text of subsections (4A) to (4D), as inserted by that regulation and modified by paragraph (5), is—

“(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 or, in relation to Wales, the National Assembly for Wales.”.

(7) The amendment made by regulation 3(5) of those Regulations (which omits subsections (5) and (6)) also has effect in relation to Wales.

Meaning of “damage to the environment” etc.

5.—(1) The amendments of section 107 of the Act (meaning of “damage to the environment” etc.) made by regulation 4 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002, as described in paragraph (2), also have effect in relation to Wales.

(2) The amendments referred to in paragraph (1)—

(a) substitute for subsection (2) (meaning of “environment”)—

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

(b) in subsection (3) (meaning of “damage to the environment”) omit “to the living organisms supported by the environment”,

(c) substitute for subsection (6) (meaning of “harm”)—

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

(d) substitute for subsection (9) (meaning of organism being under a person’s “control”)—

“(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.”, and

(e) substitute for subsection (11) (meaning of organism being “marketed”)—

“(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

6.—(1) Until the coming into force of the first regulations under section 106(4B)(a)(10) 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; and
- (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 or 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 paragraphs (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.

Environmental risk assessment

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

(10) Section 106(4) is amended by regulation 3(3) and section 106(4A) to 106(4D) is inserted by regulation 3(4) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002, and are given effect in Wales subject to further modification by regulation 4 of these Regulations.

- (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; and
 - (c) include any bibliographic reference 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

8.—(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, whether before or after consent is granted, he or she 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 National Assembly for Wales 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) above must be in paper form.