
WELSH STATUTORY INSTRUMENTS

2002 No. 3188

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

Part V

GENERAL PROVISIONS FOR CONSENTS

General provisions of consents to market genetically modified organisms

29. A consent to market genetically modified organisms granted by the National Assembly for Wales under section 111(1) of the Act shall specify—

- (a) the scope of the consent, including the identity of the genetically modified organisms to be marketed, and their unique identifier;
- (b) the period of validity of the consent;
- (c) the conditions for the marketing of the product, including any specific conditions of use, handling and packaging of the genetically modified organisms, and conditions for the protection of particular ecosystems or environments or geographical areas as applicable;
- (d) that the applicant shall make control samples available to the National Assembly for Wales on request;
- (e) the labelling requirements, in accordance with paragraph 8 of Schedule 3, which shall include a requirement to notify the National Assembly for Wales of any new commercial name of the product after consent has been given;
- (f) monitoring requirements which shall be in accordance with the monitoring plan, and shall include the time period of the monitoring plan, an obligation that the applicant shall submit the reports of monitoring to the Commission and the competent authorities of the Member States and, where appropriate, any obligations on any person selling the product or any user to provide information at an appropriate level on the location of the genetically modified organisms.

General conditions in consents to release or market genetically modified organisms

30.—(1) The amendments of section 112 of the Act (consents: limitations and conditions) made by the Genetically Modified Organisms (Deliberate Release) Regulations 2002 have effect in relation to Wales as follows.

(2) The amendment of subsection (1) made by regulation 29(2) of those Regulations, which inserts at the end of that subsection “for the purpose of ensuring that all appropriate measures are taken to avoid damage to the environment which may arise from the activity permitted by the consent”, also has effect in relation to Wales.

(3) The amendments of subsection (5) made by regulation 29(3)(a) and (b) of those Regulations, as described in paragraph (4), also have effect in relation to Wales.

(4) The amendments referred to in paragraph (3) are—

- (a) in subsection (5)(b)—
 - (i) after “Secretary of State” insert “forthwith”,
 - (ii) omit sub-paragraph (ii), and
 - (iii) after that sub-paragraph insert—
 - “(iii) any unforeseen event, occurring in connection with a release by him, which might affect the risks there are of damage to the environment being caused as a result of their being released;”, and
- (b) substitute for subsection (5)(c)—
 - “(c) take such measures as are necessary to prevent damage to the environment being caused as a result of the release or, as the case may be, the marketing of the organisms;”.

(5) The amendment of subsection (5) made by regulation 29(3)(c) of those Regulations, which inserts paragraphs (d) and (e), is modified by paragraph (6) and, as so modified, also has effect in relation to Wales.

(6) In paragraphs (d) and (e), as inserted by that regulation, after “the Secretary of State”, in both places where it occurs, insert “or, in relation to Wales, the National Assembly for Wales”.

(7) The text of paragraphs (d) and (e) of subsection (5), as inserted by that regulation and modified by paragraph (6), is—

- “(d) notify the Secretary of State or, in relation to Wales, the National Assembly for Wales of the measures (if any) taken as a result of new information becoming available or an unforeseen event occurring as described in paragraph (b) (iii) above; and
- (e) in a case where new information becomes available or an unforeseen event so occurs, revise the information contained in his application for a consent accordingly and supply the revised information to the Secretary of State or, in relation to Wales, the National Assembly for Wales.”.

Proof of compliance with consent conditions

31. The amendment of section 119(1) of the Act (“Onus of proof as regards techniques and evidence”) made by regulation 30 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002, which after “the accused to prove” inserts “the matters described in subsection (1A) below.

- “(1A) The matters referred to in subsection (1) above are—
 - (a) in the case of an offence under section 118(1)(c) above consisting in a failure to comply with the general condition implied by section 112(5)(c) above—
 - (i) that no measures, other than the measures taken by him, were necessary to prevent damage being caused to the environment from the release or, as the case may be, marketing of the organisms, or
 - (ii) in a case where he took no measures, that no measures were necessary; and
 - (b) in any other case,”

also has effect in relation to Wales.

New information on risks of damage to the environment

32.—(1) The National Assembly for Wales shall immediately forward to the Commission and the competent authority or authorities of each Member State any new information which becomes

available to it which it considers could affect the assessment of the risk of damage being caused to the environment by releasing or marketing genetically modified organisms.

(2) Where an application for consent or for renewal of consent to market genetically modified organisms has been made to the National Assembly for Wales and the information referred to in paragraph (1) becomes available to it before the application has been determined, it may seek to reach agreement with the Commission and the other Member States pursuant to Articles 15(1) or 17(7) of the Deliberate Release Directive as applicable.

(3) Where an application for consent or renewal of a consent to market genetically modified organisms has been made to the National Assembly for Wales and the information referred to in paragraph (1) becomes available to it after the consent has been granted or renewed, it shall ensure that an assessment report prepared in accordance with Schedule 4, indicating whether the conditions of the consent should be varied, and, if so, how, or whether the consent should be revoked, is forwarded to the Commission within 60 days of the date of receipt of the new information.

(4) Where the National Assembly for Wales has indicated that the consent should be varied and either—

- (a) no objection has been raised by a competent authority of any Member State or by the Commission during a 60 day period beginning on the day the Commission circulated the assessment report, or
- (b) an objection or objections have been raised by a competent authority of any Member State or by the Commission but all outstanding issues have been resolved in accordance with Article 20(3) of the Deliberate Release Directive,

it shall vary or revoke the consent as proposed and inform the applicant, the competent authority or authorities of each member State and the Commission that it has done so within 30 days thereof.

(5) The National Assembly for Wales shall only vary or revoke a consent to market genetically modified organisms under section 111(10) of the Act—

- (i) where the information referred to in paragraph (1) has become available to it, and the procedure referred to in paragraphs (3) and (4) have been complied with, or
- (ii) in accordance with a decision adopted by the Commission in accordance with Articles 18(1) or 23(2) of the Deliberate Release Directive.