WELSH STATUTORY INSTRUMENTS

# 2002 No. 3188

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

## Part IV

## DUTIES AFTER THE MAKING OF APPLICATIONS

**Duty of the applicant after applying for consent to release or to market**

**20.**—(1) The amendment of section 111 of the Act (consents required by certain persons) made by regulation 19(1) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002, which inserts as a second sentence in subsection (6) the following—

> "A notice under this subsection must state the reasons for requiring the further information specified in the notice.",

also has effect in relation to Wales.

(2) An applicant for a consent to release or to market genetically modified organisms who notifies the National Assembly for Wales of any information in accordance with section 111(6A) of the Act (requirement for applicant to notify new information regarding risks of damage to the environment) shall submit in writing to the National Assembly for Wales a revised version of the original application for consent amended to take account of the new information.

**Duties of the National Assembly for Wales on receiving applications for consent to release**

**21.** Following receipt of an application for consent to release genetically modified organisms the National Assembly for Wales shall—

(a) inform the applicant in writing of the date of receipt of the application;

(b) invite any person by means of a request placed on the register, to make representations to it relating to the release before the end of a period to be specified which shall not be less than sixty days from the date the application was received by it;

(c) ensure that within 30 days a summary of that application in the format established by the Commission under Article 11(1) of the Deliberate Release Directive is forwarded to the Commission;

(d) examine the application for its conformity with the requirements of the Act and of these regulations;

(e) evaluate the risks of damage being caused to the environment by the proposed release having regard to the environmental risk assessment; and

(f) take into account any representations relating to risks of damage being caused to the environment by the release made to it before the end of the period specified in accordance with paragraph (b) and any comments made by a competent authority or authorities of other Member States following the circulation to them by the Commission of the summary referred to in paragraph (c).

### Decisions by the National Assembly for Wales on applications for consent to release

**22.**—(1) The National Assembly for Wales shall not grant a consent to release genetically modified organisms under section 111(1) of the Act as it relates to the protection of human health without the agreement of the Health and Safety Executive(**1**).

(2) The National Assembly for Wales shall not grant or refuse consent to release genetically modified organisms before the end of a period of sixty days beginning on the day on which the application for consent was received.

(3) The National Assembly for Wales shall communicate its decision on an application for a consent to release genetically modified organisms to the applicant and shall ensure that its decision is communicated to the Commission before the end of a period of 90 days beginning with the day on which the application was received and shall include in any refusal of consent the reasons for the decision.

(4) The period prescribed in paragraph (3) shall not include—

(a) any period beginning with the day on which the National Assembly for Wales gives notice in writing under section 111(6) of the Act that further information in respect of the application is required and ending on the day on which that information is received by the National Assembly for Wales, or

(b) a period of time during which the National Assembly for Wales is considering representations submitted by any persons in accordance with regulation 21(b), provided that this consideration shall not prolong the 90 day period referred to in paragraph (3) by more than 30 days.

(5) A consent to release genetically modified organisms shall require the applicant to send any information which might be relevant to assessing the risk of damage being caused to the environment, with, where appropriate, particular reference to any product which it is intended to market in the future, to the National Assembly for Wales after completion of the release and thereafter, at such intervals as the National Assembly for Wales shall consider appropriate on the basis of the results of the environmental risk assessment.

(6) The National Assembly for Wales shall send to the Commission the information submitted to it in accordance with paragraph (5).

### Variation or revocation of a consent to release genetically modified organisms

**23.** The National Assembly for Wales shall only vary or revoke a consent to release genetically modified organisms under section 111(10) of the Act without the agreement of the holder of the consent where new information has become available to it which it considers would affect the assessment of the risk of damage being caused to the environment by the release.

### Duties of the National Assembly for Wales in relation to applications for consent to market genetically modified organisms

**24.**—(1) Following receipt of an application for consent to market genetically modified organisms the National Assembly for Wales shall—

(a) inform the applicant in writing of the date of receipt of the application;

(b) ensure that a summary of that application in the format established by the Commission under Article 13(2)(h) of the Deliberate Release Directive is forwarded immediately to the Commission and to the competent authorities of the Member States;

(**1**) *See* section 10 of the Health and Safety at Work etc. Act 1974 (c. 37).

(c) examine the application for its conformity with the requirements of the Act and of these Regulations and, if necessary, request the applicant to supply additional information;

(d) before the end of a period of 90 days beginning with the day on which it received the application either—

(i) send to the applicant an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should be permitted to be marketed and under which conditions, or

(ii) refuse the application, stating reasons for its decision, supported by an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should not be marketed;

(e) ensure that a copy of the application is forwarded to the Commission when satisfied it conforms to the requirements prescribed in regulation 15 and no later than when it sends its assessment report in accordance with paragraph (d).

(2) The National Assembly for Wales shall ensure that—

(i) its assessment report,

(ii) any further information it has received from the applicant pursuant to the service of a notice under section 111(6) of the Act,

(iii) any additional information on which it has based its assessment report,

are forwarded to the Commission in the circumstances described in regulation 24(1)(d)(i), before the end of a period of ninety days beginning with the day on which it received the application and, in the circumstances described in regulation 24(1)(d)(ii), no sooner than fifteen days from the date it sent the assessment report to the applicant and no later than one hundred and five days from the date it received the application.

(3) The ninety day periods prescribed in paragraphs (1) and (2) shall not include any period beginning with the day on which the National Assembly for Wales gives notice in writing under section 111(6) of the Act that further information in respect of the application is required and ending on the day on which that information is received by the National Assembly for Wales.

(4) Where the National Assembly for Wales intends to submit to the Commission an assessment report which indicates that the genetically modified organisms to which an application relates should be permitted to be marketed, the National Assembly for Wales shall first consult the Health and Safety Executive and shall not forward a favourable opinion on the application as it relates to the protection of human health where the Health and Safety Executive has informed the National Assembly for Wales that it does not fulfil the requirements of the Act and of these Regulations.

**Decisions by the National Assembly for Wales on applications for consent to market genetically modified organisms**

**25.**—(1) The National Assembly for Wales may only grant an application for consent to market genetically modified organisms where it has prepared an assessment report which indicates that the genetically modified organisms should be permitted to be marketed and either—

(a) no objection has been raised by a competent authority of a 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 either a competent authority of a Member State or by the Commission but all outstanding issues have been resolved in accordance with Article 15(1) of the Deliberate Release Directive within a 105 day period beginning on the day the Commission circulated the assessment report, or

(c) an objection has been raised by a competent authority of a Member State or the Commission and the Commission has adopted a decision in accordance with Article 18(1) of the Deliberate Release Directive in favour of granting consent.

(2) The National Assembly for Wales shall inform the competent authority or authorities of each Member State and the Commission of its decision to grant consent to market genetically modified organisms within thirty days of its grant.

(3) For the purpose of calculating the final forty-five day period of the one hundred and five days in sub-paragraph (1)(b) above no period during which further information is awaited from the applicant shall be taken into account.

(4) Subject to paragraphs (5) and (6), a consent to market genetically modified organisms may be given for a maximum period of ten years beginning with the day on which the consent is issued.

(5) For the purpose of granting consent to market a genetically modified organism or a progeny of that genetically modified organism contained in a plant variety where the plant variety is intended only for the marketing of its seeds under the relevant Community provisions the period of the first consent shall end at the latest ten years after the date of the first inclusion of the first plant variety containing the genetically modified organism on an official national catalogue of plant varieties in accordance with Directives 2002/53/EC(**2**) and 2002/55/EC(**3**) as amended.

(6) For the purpose of granting consent to market a genetically modified organism contained in forest reproductive material, the period of the first consent shall end at the latest ten years after the date of the first inclusion of basic material containing the genetically modified organism on an official national register of basic material in accordance with Council Directive 1999/105/EC(**4**).

**Duties on the National Assembly for Wales on receiving applications for renewal of consent to market genetically modified organisms**

**26.**—(1) Following receipt of an application for renewal of consent to market genetically modified organisms the National Assembly for Wales shall—

(a) inform the applicant in writing of the date of receipt of the application;

(b) examine the application for its conformity with the requirements of the Act and of these Regulations and, if necessary, request the applicant to supply additional information;

(c) either—

(i) send to the applicant an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should continue to be marketed and under which conditions, or

(ii) refuse the application, stating reasons for its decision, supported by an assessment report which indicates that the genetically modified organisms should not continue to be marketed;

(d) ensure that a copy of the application and its assessment report is forwarded to the Commission.

(2) Where the National Assembly for Wales intends to submit to the Commission an assessment report which indicates that the genetically modified organisms to which an application relates should be permitted to be marketed, the National Assembly for Wales shall first consult the Health and Safety Executive and not forward a favourable opinion on the application as it relates to the protection of human health where the Health and Safety Executive has informed the National Assembly for Wales that it does not fulfil the requirements of the Act and of these Regulations.

(**2**) OJNo. L193, 20.7.2002, p.1.
(**3**) OJ No. L193, 20.7.2002 p.33.
(**4**) Council Directive 1999/105/EC on the marketing of forest reproductive material OJ No. L11, 15.1.2000, p. 17.

**Decisions by the National Assembly for Wales on applications for renewals of consents to market genetically modified organisms**

**27.**—(1) The National Assembly for Wales may only grant an application to renew a consent to market genetically modified organisms when it has prepared an assessment report which indicates that the genetically modified organisms should continue to be marketed 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 has circulated the assessment report, or

(b) an objection or objections have been raised by either a competent authority of any Member State or by the Commission but all outstanding issues have been resolved in accordance with Article 17(8) of the Deliberate Release Directive within a 75 day period beginning on the day the Commission circulated the assessment report, or

(c) an objection has been raised by a competent authority of any Member State or the Commission and the Commission has adopted a decision in accordance with Article 18(1) of the Deliberate Release Directive in favour of granting consent.

(2) The National Assembly for Wales shall ensure that the competent authority or authorities of each Member State and the Commission are informed of its decision to renew consent to market genetically modified organisms within thirty days of its renewal.

(3) The renewed consent to market genetically modified organisms may be given for a maximum of 10 years unless the National Assembly for Wales considers that a shorter or longer period is justified, in which case it shall give its reasons in writing.

(4) The applicant may continue to market the genetically modified organisms under the conditions specified in the original consent until a final decision has been taken on the application.

**Genetically modified organisms containing antibiotic resistance markers**

**28.**—(1) The National Assembly for Wales shall not grant a consent to an application for the release or marketing of genetically modified organisms containing antibiotic resistance markers which may have adverse effects on human health and the environment after—

(i) 31st December 2004 in the case of marketing, and

(ii) 31st December 2008 in the case of release.

(2) Where prior to 31st December 2004 in the case of marketing and 31st December 2008 in the case of release, an application is made for consent to release or market genetically modified organisms containing antibiotic resistance markers, the National Assembly for Wales shall evaluate the information in the environmental assessment accompanying the application, taking into particular consideration those antibiotic resistance markers in use for medical or veterinary treatment, with a view to identifying and phasing out the release or marketing of the genetically modified organisms referred to in paragraph (1) within the time limits specified in that paragraph.