STATUTORY RULES OF NORTHERN IRELAND

2003 No. 167

The Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

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

19.—(1) In Article 8 of the Order (consents required by certain persons) in paragraph (6) (power of Department to require further information) insert as a second sentence –

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

(2) An applicant for a consent to release or to market genetically modified organisms who notifies the Department of any information in accordance with Article 8(6A) of the Order (requirement for applicant to notify new information regarding risks of damage to the environment) shall submit in writing to the Department a revised version of the original application for consent amended to take account of the new information.

Duties of the Department in relation to applications for consent to release

20. Following receipt of an application for consent to release genetically modified organisms the Department 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 any risks of damage being caused to the environment by 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) within 30 days of the date the application was received by it forward to the Commission a summary of that application in the format established by the Commission under Article 11(1) of the Deliberate Release Directive;

(d) examine the application for its conformity with the requirements of the Order 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 Department on applications for consent to release

21.—(1) The Department shall not grant a consent to release genetically modified organisms under Article 8(1) of the Order as it relates to the protection of human health without the agreement of the Executive.

(2) The Department shall not grant or refuse consent to release genetically modified organisms before the end of a period of 60 days beginning on the day on which the application for consent was received.

(3) The Department shall communicate its decision on an application for a consent to release genetically modified organisms to the applicant and 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 Department gives notice in writing under Article 8(6) of the Order that further information in respect of the application is required and ending on the day on which that information is received by the Department; or

(b) any period of time during which the Department is considering representations submitted by any persons in accordance with regulation 20(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 Department as soon as reasonably practicable after completion of the release and thereafter, at such intervals as the Department shall consider appropriate on the basis of the results of the environmental risk assessment.

(6) The Department 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

22.—(1) The Department shall only vary or revoke a consent to release genetically modified organisms under Article 8(10) of the Order 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.

(2) The Department shall not revoke or vary a consent to release genetically modified organisms under Article 8(10) of the Order as it relates to the protection of human health without the agreement of the Executive.

Duties of the Department in relation to applications for consent to market

23.—(1) Following receipt of an application for a consent to market genetically modified organisms the Department shall –

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

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

(c) examine the application for its conformity with the requirements of the Order 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, and

(e) once it is satisfied it conforms to the requirements prescribed in regulation 16, and no later than when it sends its assessment report in accordance with paragraph (d), forward a copy of the application to the Commission.

(2) The Department shall forward to the Commission –

(i) its assessment report,

(ii) any further information it has received from the applicant pursuant to the service of a notice under Article 8(6) of the Order,

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

in the circumstances described in paragraph (1)(d)(i), before the end of a period of 90 days beginning with the day on which it received the application and, in the circumstances described in paragraph (1)(d)(ii), no sooner than 15 days from the date it sent the assessment report to the applicant and no later than 105 days from the date it received the application.

(3) The 90 day periods prescribed in paragraphs (1) and (2) shall not include any period beginning with the day on which the Department gives notice in writing under Article 8(6) of the Order that further information in respect of the application is required and ending on the day on which that information is received by the Department.

(4) Where the Department 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, it shall first consult the Executive and shall not forward its favourable opinion on the application as it relates to the protection of human health where the Executive has informed it that it does not fulfil the requirements of the Order and of these Regulations.

Decisions by the Department on applications for consents to market genetically modified organisms

24.—(1) The Department may grant an application for consent to market genetically modified organisms only where it has prepared an assessment report which indicates that the genetically modified organisms should be marketed and –

(a) no objection has been raised by 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 Member State or by the Commission but outstanding issues have been resolved in accordance with Article 15(l) 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 Member State or the Commission and the Commission has adopted a decision in accordance with Article 18(l) of the Deliberate Release Directive in favour of granting consent.

(2) The Department 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 45 day period of 105 days in paragraph (1)(b) 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 shall 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 any progeny of that genetically modified organism contained in a plant variety where that 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(**1**) and 2002/55/EC(**2**).

(6) For the purpose of granting consent to market a genetically modified organism contained in forest reproductive material, the period of any 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(**3**).

Duties of the Department on receiving applications for renewal of consent to market

25.—(1) On receipt of an application for renewal of consent to market genetically modified organisms the Department 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 Order 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 permitted 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) forward to the Commission a copy of the application and its assessment report.

(2) Where the Department 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, it shall first consult the Executive and shall not forward its favourable opinion on the application as it relates to the protection of human health where the Executive has informed it that it does not fulfil the requirements of the Order and of these Regulations.

Decisions by the Department on applications for renewal of consent to market genetically modified organisms

26.—(1) The Department may grant an application to renew a consent to market genetically modified organisms only where it has prepared an assessment report which indicates that the genetically modified organisms should continue to be permitted to be marketed and –

(a) no objection has been raised by 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 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

(**1**) O.J. No. L193, 20.7.2002, p. 1
(**2**) O.J. No. 193, 20.7.2002, p. 33
(**3**) Council Directive 1999/105/EC on the marketing of forest reproductive material (O.J. No. L11 15.1.2000, p. 17)

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

(2) The Department shall inform the competent authority or authorities of each Member State and the Commission of its decision to renew consent to market genetically modified organisms within 30 days of its renewal.

(3) The consent to market genetically modified organisms shall be given for a period of ten years unless the Department 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

27.—(1) The Department 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 placing on the market; and

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

(2) Where prior to 31st December 2004 in the case of placing on the market and 31st December 2008 in the case of release, an application is made for consent to release or place on the market genetically modified organisms containing antibiotic resistance markers, the Department shall evaluate the information in the environmental risk 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 placing on the market of the genetically modified organisms referred to in paragraph (1) within the time limits specified in that paragraph.