SCOTTISH STATUTORY INSTRUMENTS

2002 No. 541

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

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

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

19.—(1) Section 111 of the Act (consents required by certain persons) is amended as follows:–

(a) in subsection (6)–

(i) after the word "period" where it appears for the first time insert "and in such form and manner"; and

(ii) after the word "period" where it appears for the second time insert "and in the specified form and manner"; and

(b) after subsection (6) (power of Scottish Ministers to require further information) insert–

"(6ZA) A notice under subsection (6) 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 Scottish Ministers 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)(**1**) shall submit in writing to the Scottish Ministers a revised version of the original application for consent amended to take account of the new information.

Duties of the Scottish Ministers in relation to applications for consent to release

20. Following receipt of an application for consent to release genetically modified organisms the Scottish Ministers 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 in writing to the Scottish Ministers relating to any risks of damage being caused to the environment(**2**) 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 the Scottish Ministers;

(c) ensure that within thirty days of the date that the application was received by them a summary of that application in the format established by the Commission under Articles 11(1) and 30(2) 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;

(**1**) Section 111(6A) was added by S.I.1992/3280.
(**2**) As defined in section 107(2), (3) and (6) of the Act as amended by regulation 4(2) to (4).

(e) evaluate the risks of damage being caused to the environment by the proposed release having regard to the environmental risk assessment prepared in accordance with regulation 6; and

(f) take into account and give due weight to–

(i) any representations made to them before the end of the period specified in paragraph (b) relating to risks of damage being caused to the environment by the release; and

(ii) any comments made by the 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 Scottish Ministers on applications for consent to release

21.—(1) The Scottish Ministers shall not grant 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.

(2) The Scottish Ministers shall not determine an application 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 Scottish Ministers shall–

(a) communicate in writing their decision on an application for a consent to release genetically modified organisms to the applicant; and

(b) ensure that the Commission is informed of their decision,

before the end of a period of ninety days beginning with the day on which the application was received and shall include in any refusal of consent the reason for the decision.

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

(a) any period beginning with the day on which the Scottish Ministers give 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 Scottish Ministers; or

(b) any period of time during which the Scottish Ministers are considering representations submitted by any persons in accordance with regulation 20(b), provided that this consideration shall not prolong the ninety day period referred to in paragraph (3) by more than thirty 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 Scottish Ministers as soon as reasonably practicable after completion of the release and thereafter, at such intervals as the Scottish Ministers shall consider appropriate on the basis of the results of the environmental risk assessment.

(6) The Scottish Ministers shall ensure that the information submitted to them in accordance with paragraph (5) is sent to the Commission.

Variation or revocation of consents to release

22.—(1) The Scottish Ministers 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 them which they consider would affect the assessment of the risk of damage being caused to the environment by the release.

(2) The Scottish Ministers shall not revoke or vary a consent to release genetically modified organisms under section 111(10) of the Act as it relates to the protection of human health without the agreement of the Health and Safety Executive.

Duties of the Scottish Ministers in relation to applications for consent to market

23.—(1) On receipt of an application for consent to market genetically modified organisms the Scottish Ministers 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 Articles 13(2)(h) and 30(2) of the Deliberate Release Directive is forwarded immediately to the Commission and to the competent authorities of the other Member States;

(c) without delay 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 ninety days beginning with the day on which they received the application either–

(i) send to the applicant an assessment report prepared in accordance with Schedule 5 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 their decision, supported by an assessment report prepared in accordance with Schedule 5 which indicates that the genetically modified organisms should not be marketed; and

(e) once they are satisfied the application conforms to the requirements prescribed in regulation 16 and in any event no later than when they send their assessment report in accordance with subparagraph (d), ensure that a copy of the application is forwarded to the Commission.

(2) The Scottish Ministers shall ensure that–

(a) their assessment report;

(b) any further information they have received from the applicant pursuant to the service of a notice under section 111(6) of the Act(**3**); and

(c) any additional information on which they have based their assessment report,

are forwarded to the Commission–

(i) in the circumstances described in paragraph (1)(d)(i), before the end of a period of ninety days beginning with the day on which the Scottish Ministers received the application; and

(ii) in the circumstances described in paragraph (1)(d)(ii), no sooner than fifteen days from the date the Scottish Ministers sent the assessment report to the applicant and no later than 105 days from the date they 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 Scottish Ministers give 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 Scottish Ministers.

(4) Where the Scottish Ministers intend to arrange for an assessment report which indicates that the genetically modified organisms to which an application relates should be permitted to be marketed to be forwarded to the Commission, they shall first consult the Health and Safety Executive

(**3**) Section 111(6) of the Act is amended by regulation 19(1).

and shall not arrange for their favourable opinion on the application as it relates to the protection of human health to be forwarded to the Commission where the Health and Safety Executive has informed them that it does not fulfil the requirements of the Act and of these Regulations.

Decisions by the Scottish Ministers on applications for consents to market

24.—(1) In the cases of subparagraphs (a) or (b), the Scottish Ministers may and in the case of subparagraph (c), the Scottish Ministers shall grant an application for consent to market genetically modified organisms only where they have prepared an assessment report which indicates that the genetically modified organisms should be marketed and–

(a) no reasoned objection has been raised by a Member State or by the Commission during a sixty day period beginning on the day the Commission circulated the assessment report;

(b) a comment or a reasoned objection has been raised by either 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 date the Commission circulated the assessment report; or

(c) an objection has been raised and maintained by a competent authority of any Member State or the Commission in accordance with Articles 15 or 20 of the Deliberate Release Directive 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 Scottish Ministers shall–

(a) inform the applicant; and

(b) ensure that the other Member States and the Commission are informed,

of any decision by the Scottish Ministers 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 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, notwithstanding paragraph (4), 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 Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species(**4**) and Council Directive 2002/55/EC on the marketing of vegetable seed(**5**).

(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, notwithstanding paragraph (4), 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(**6**).

(**4**) O.J. No. L 193, 20.7.02, p.1.
(**5**) O.J. No. L 193, 20.7.02, p.33.
(**6**) O.J. No. L 11, 15.1.00, p.17.

Duties on the Scottish Ministers 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 Scottish Ministers 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 5 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 their decision, supported by an assessment report which indicates that the genetically modified organisms should not continue to be marketed; and

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

(2) Where the Scottish Ministers intend to arrange for an assessment report which indicates that the genetically modified organisms to which an application relates should be permitted to be marketed to be forwarded to the Commission, they shall first consult the Health and Safety Executive and shall not arrange for their favourable opinion on the application as it relates to the protection of human health to be forwarded to the Commission where the Health and Safety Executive has informed them that it does not fulfil the requirements of the Act and of these Regulations.

Decisions by the Scottish Ministers on applications for renewals of consents to market

26.—(1) In the cases of subparagraphs (a) or (b), the Scottish Ministers may and in the case of subparagraph (c), the Scottish Ministers shall grant an application to renew a consent to market genetically modified organisms only where they have prepared an assessment report which indicates that the genetically modified organisms should continue to be marketed and–

(a) no reasoned objection has been raised by a Member State or by the Commission during a sixty day period beginning on the day the Commission circulated the assessment report;

(b) a reasoned objection has 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(7) and (8) of the Deliberate Release Directive within a seventy-five day period beginning on the day the Commission circulated the assessment report; or

(c) an objection has been raised and maintained by a competent authority of any Member State or the Commission in accordance with Articles 17 or 20 of the Deliberate Release Directive 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 Scottish Ministers shall–

(a) inform the applicant; and

(b) ensure that the other Member States and the Commission are informed,

of any decision by the Scottish Ministers to renew the consent to market genetically modified organisms within thirty days of its renewal.

(3) The renewed consent to market genetically modified organisms shall be given for ten years unless the Scottish Ministers consider that a shorter or longer period is justified, in which case they shall give their reasons therefor in writing.

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

Genetically modified organisms containing antibiotic resistance markers

27.—(1) The Scottish Ministers 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 Scottish Ministers 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 marketing of the genetically modified organisms referred to in paragraph (1) within the time limits specified in that paragraph.