
SCOTTISH STATUTORY INSTRUMENTS

2002 No. 541

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

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

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⁽¹⁾; and
 - (c) any additional information on which they have based their assessment report,
- are forwarded to the Commission—

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

- (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 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.