
STATUTORY INSTRUMENTS

2002 No. 2443

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

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

Duties of the Secretary of State in relation to applications for consent to market

23.—(1) Following receipt of an application for consent to market genetically modified organisms the Secretary of State 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 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 she 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 her 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 she is satisfied it conforms to the requirements prescribed in regulation 16, and no later than when she sends her assessment report in accordance with paragraph (d), forward a copy of the application to the Commission.

(2) The Secretary of State shall forward to the Commission—

- (a) her assessment report,
- (b) any further information she has received from the applicant pursuant to the service of a notice under section 111(6) of the Act, and
- (c) any additional information on which she has based her assessment report,

in the circumstances described in regulation 23(d)(i), before the end of a period of 90 days beginning with the day on which she received the application and, in the circumstances described in regulation 23(d)(ii), no sooner than 15 days from the date she sent the assessment report to the applicant and no later than 105 days from the date she 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 Secretary of State 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 Secretary of State.

(4) Where the Secretary of State 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, she shall first consult the Health and Safety Executive and shall not forward her favourable opinion on the application as it relates to the protection of human health where the Health and Safety Executive has informed her that it does not fulfil the requirements of the Act and of these Regulations.