
STATUTORY INSTRUMENTS

1992 No. 3280

**The Genetically Modified Organisms
(Deliberate Release) Regulations 1992**

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

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

16.—(1) The Secretary of State shall examine an application for consent to market genetically modified organisms for its conformity with the requirements of the Act and of these Regulations, giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product.

(2) Before the end of a period of 90 days beginning with the day on which he receives an application for consent to market genetically modified organisms the Secretary of State shall either—

- (a) forward to the Commission—
 - (i) the application,
 - (ii) a summary of the application in the format established by the Commission under Article 12(3) of the Deliberate Release Directive,
 - (iii) a statement of the conditions under which he proposes to consent to the marketing of the product,
 - (iv) where acceded to by the Secretary of State, details of any proposal by the applicant under regulation 11(5) not to comply with any of the requirements of regulation 11(1)(c), and
 - (v) his favourable opinion on the application, or
- (b) inform the applicant that the proposal does not fulfil the requirements of the Act and of these Regulation and is rejected.

(3) The Secretary of State shall not forward his favourable opinion on the application as it relates to the protection of human health where the Health and Safety Executive has informed him that it does not fulfil the requirements of the Act and of these Regulations.

(4) The period prescribed in paragraph (2) shall not include any period beginning with the day on which the Secretary of State gave notice in writing under section 111(6) of the Act that further information in respect of the application is required and ending with the day on which that information is received by the Secretary of State.

(5) The Secretary of State shall immediately inform the competent authority or authorities of each member State and the Commission of any other information he receives from the applicant before or after the granting of the consent.

(6) Where no objection has been raised by a competent authority of a member State the Secretary of State shall, within a period of 60 days beginning with the day on which the documents referred to in paragraph (2)(a) were forwarded to the competent authority or authorities of the member States

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by the Commission, grant consent to market the genetically modified organisms and inform the competent authority or authorities of the member States and the Commission that he has done so.

(7) Where an objection has been raised by a competent authority of a member State and the Commission has taken a favourable decision under Article 13(3) of the Deliberate Release Directive, the Secretary of State shall grant consent to market the genetically modified organisms and inform the competent authority or authorities of the member States and the Commission that he has done so.

(8) The Secretary of State shall not revoke or vary a consent to market genetically modified organisms as it relates to the protection of human health without the agreement of the Health and Safety Executive, and shall immediately inform the competent authority or authorities of each member State and the Commission of any decision to revoke or vary a consent.