STATUTORY INSTRUMENTS

1992 No. 3280

The Genetically Modified Organisms (Deliberate Release) Regulations 1992

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

Duty of the applicant after applying for consent

13.—(1) In section 111 of the Act (Consents required by certain persons), after subsection (6) there shall be inserted the following subsection—

> "(6A) Where an applicant for consent for releasing or marketing genetically modified organisms becomes aware, before his application is either granted or rejected, of any new information with regard to any risks there are of damage to the environment being caused as a result of the organisms being released or marketed, he shall notify the Secretary of State of that new information forthwith."

(2) In section 118(1)(e) of the Act (Offences), after the words "section 108(5) or (6)" there shall be inserted the words "or section 111(6A)".

Duties of the Secretary of State on receiving applications for consent to release

14.—(1) The Secretary of State shall within 30 days of receiving an application for a consent to release genetically modified organisms forward to the Commission a summary of that application in the format established by the Commission under Article 9(1) of the Deliberate Release Directive.

(2) The Secretary of State shall—

(a) examine an application for a consent to release genetically modified organisms for its conformity with the requirements of the Act and of these Regulations,

(b) evaluate the risks posed by the proposed release,

(c) if necessary, carry out such tests or inspections as may be necessary for control purposes,

(d) where appropriate, take into account any comments made by the competent authority or authorities of member States following the circulation to them by the Commission of the summary referred to in paragraph (1) above, and

(e) record his conclusions in writing.

Decisions by the Secretary of State on applications for consent to release

15.—(1) The Secretary of State shall not grant a consent to release genetically modified organisms as it relates to the protection of human health without the agreement of the Health and Safety Executive.

(2) The Secretary of State shall communicate his decision on an application for a consent to release genetically modified organisms to the applicant before the end of a period of 90 days beginning with the day on which the application was received.

(3) The period prescribed in paragraph (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 with the day on which that information is received by the Secretary of State.

(4) The Secretary of State shall inform the competent authority or authorities of each member State and the Commission of his decision on each application for consent to release genetically modified organisms.

(5) The Secretary of State shall not revoke or vary a consent to release genetically modified organisms as it relates to the protection of human health without the agreement of the Health and Safety Executive.

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 require ments 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 applicationas 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

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.