STATUTORY INSTRUMENTS

2002 No. 2443

Genetically Modified Organisms (Deliberate Release) Regulations 2002

PART V

GENERAL PROVISIONS FOR CONSENTS

General provisions of consents to market

28. A consent to market genetically modified organisms granted by the Secretary of State under section 111(1) of the Act shall specify—

(a) the scope of the consent, including the identity of the genetically modified organisms to be marketed and their unique identifier,

(b) the period of validity of the consent,

(c) the conditions for marketing the product, including any specific conditions of use, handling and packaging of the genetically modified organisms, and conditions for the protection of particular ecosystems or environments or geographical areas as applicable,

(d) that the applicant shall make control samples available to the Secretary of State on request,

(e) the labelling requirements, in accordance with paragraph 8 of Schedule 3, which shall include a requirement to notify the Secretary of State of any new commercial name of the product after consent has been given, and

(f) monitoring requirements which shall be in accordance with the monitoring plan, and shall include the time period of the monitoring plan, an obligation that the applicant shall submit the reports of monitoring to the Commission and the competent authorities of the member States and, where appropriate, any obligations on any person selling the product or any user, which may include an obligation to provide information at an appropriate level on the location of the genetically modified organisms that are grown.

General conditions in consents to release or market

29.—(1) Section 112 of the Act (consents: limitations and conditions) is amended as follows.

(2) In subsection (1) (power of Secretary of State or National Assembly for Wales to impose limitations and conditions) at the end insert "for the purpose of ensuring that all appropriate measures are taken to avoid damage to the environment which may arise from the activity permitted by the consent".

(3) In subsection (5) (implied condition when releasing or marketing)—

(a) in paragraph (b) (obligation to notify Secretary of State or National Assembly for Wales of new information etc)—

(i) after "Secretary of State" insert "forthwith",

(ii) omit sub-paragraph (ii), and

(iii) after that sub-paragraph insert—

"(iii) any unforeseen event, occurring in connection with a release by him, which might affect the risks there are of damage to the environment being caused as a result of their being released;",

(b) for paragraph (c) (duty as regards preventing damage to environment) substitute—

"(c) take such measures as are necessary to prevent damage to the environment being caused as a result of the release or, as the case may be, the marketing of the organisms;", and

(c) after that paragraph insert—

"(d) notify the Secretary of State of the measures (if any) taken as a result of new information becoming available or an unforeseen event occurring as described in paragraph (b)(iii) above; and

(e) in a case where new information becomes available or an unforeseen event so occurs, revise the information contained in his application for a consent accordingly and supply the revised information to the Secretary of State.".

Proof of compliance with consent conditions

30. In section 119 of the Act (onus of proof as regards techniques and evidence) in subsection (1) (accused to prove use of best available techniques) after "the accused to prove" insert

"the matters described in subsection (1A) below.

(1A) The matters referred to in subsection (1) above are—

(a) in the case of an offence under section 118(1)(c) above consisting in a failure to comply with the general condition implied by section 112(5)(c) above—

(i) that no measures, other than the measures taken by him, were necessary to prevent damage being caused to the environment from the release or, as the case may be, marketing of the organisms, or

(ii) in a case where he took no measures, that no measures were necessary; and

(b) in any other case,".

New information on risks of damage from marketing genetically modified organisms

31.—(1) The Secretary of State shall immediately forward to the Commission and the competent authority or authorities of each member State any new information which becomes available to her which she considers could affect the assessment of the risk of damage being caused to the environment by marketing genetically modified organisms.

(2) Where an application for consent or for renewal of consent to market genetically modified organisms has been made to the Secretary of State and the information referred to in paragraph (1) becomes available to her before the application has been determined, she may seek to reach agreement with the Commission and the other member States pursuant to Articles 15(1) or 17(7) of the Deliberate Release Directive as applicable.

(3) Where an application for consent or for renewal of consent to market genetically modified organisms has been made to the Secretary of State and the information referred to in paragraph (1) becomes available to her after the consent has been granted or renewed, she shall within 60 days after receipt of the new information, forward to the Commission an assessment report prepared in accordance with Schedule 4 indicating whether the conditions of the consent should be varied, and, if so, how, or whether the consent should be revoked.

(4) The Secretary of State shall not forward an assessment report indicating that the consent to market genetically modified organisms as it relates to the protection of human health should be varied or revoked without the agreement of the Health and Safety Executive.

(5) Where the Secretary of State has indicated that the consent should be varied or revoked and either—

(a) no objection has been raised by a member State or by the Commission during a 60 day period beginning on the day the Commission circulated the assessment report, or

(b) an objection or objections have been raised by a member State or by the Commission but all outstanding issues have been resolved in accordance with Article 20(3) of the Deliberate Release Directive,

she shall vary or revoke the consent as proposed and inform the applicant, the competent authority or authorities of each member State and the Commission that she has done so within 30 days thereof.

(6) The Secretary of State shall only vary or revoke a consent to market genetically modified organisms under section 111(10) of the Act—

(a) where the information referred to in paragraph (1) has become available to her, and the procedure referred to in paragraphs (3) and (5) has been complied with, or

(b) in accordance with a decision adopted by the Commission under Article 18(1) or Article 23(2) of the Deliberate Release Directive.