SCOTTISH STATUTORY INSTRUMENTS

2002 No. 541

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

PART V

GENERAL PROVISION FOR CONSENTS

General provisions of consents to market

28. A consent to market genetically modified organisms granted by the Scottish Ministers 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 Scottish Ministers on request;

(e) the labelling requirements, in accordance with paragraph 8 of Schedule 4, which shall include a requirement to notify the Scottish Ministers 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 of it, 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 on consents to release or market genetically modified organisms

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

(2) In subsection (1) (power of Scottish Ministers 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 Scottish Ministers of new information etc.)–

(i) before the word "of" where it appears for the second time insert "forthwith";

(ii) omit subparagraph (ii); and

(iii) after that subparagraph 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 Scottish Ministers forthwith 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); 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 Scottish Ministers in such form and manner as they may specify.".

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 Scottish Ministers shall ensure that any new information which becomes available to them which they consider could have consequences for the risks of damage being caused to the environment by marketing the genetically modified organisms shall be forwarded immediately to the Commission and the competent authority of each Member State.

(2) Where an application for consent or for renewal of consent to market genetically modified organisms has been made to the Scottish Ministers and the information referred to in paragraph (1) becomes available to them before the application has been determined, the Scottish Ministers may arrange to seek 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) Subject to paragraph (4), where an application for consent or for renewal of consent to market genetically modified organisms has been made to the Scottish Ministers and the information referred to in paragraph (1) becomes available to them after the consent has been granted or renewed, the Scottish Ministers shall within sixty days after receipt of the new information, ensure that there is forwarded to the Commission an assessment report prepared in accordance with Schedule 5 indicating whether the conditions of the consent should be varied and if so, how, or whether the consent should be revoked.

(4) The Scottish Ministers shall not arrange for an assessment report to be forwarded if that assessment report indicates 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 Scottish Ministers have indicated that the consent should be varied or revoked and either–

(a) no reasoned objection has been raised by a Member State or by the Commission during a sixty day period beginning on the day the Commission circulated the assessment report; or

(b) a reasoned objection has 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,

they shall vary or revoke the consent as proposed and they shall inform the applicant, and ensure that the other Member States and the Commission are informed, that they have done so within thirty days of the sixty day period specified in subparagraph (a) or of the resolution referred to in subparagraph (b), as the case may be.

(6) The Scottish Ministers 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 them 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 Articles 18(1) or 23(2) of the Deliberate Release Directive.