SCOTTISH STATUTORY INSTRUMENTS

2002 No. 541

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

PART V

GENERAL PROVISION FOR CONSENTS

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.