STATUTORY RULES OF NORTHERN IRELAND

2003 No. 167

The Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003

PART V

GENERAL PROVISION FOR CONSENTS TO MARKET

General provisions of consents to market genetically modified organisms

28. A consent to market genetically modified organisms granted by the Department under Article 8(1) of the Order shall specify –

(a) the scope of the consent, including the identity of the genetically modified organisms to be placed on the market, and their unique identifier;

(b) the period of validity of the consent;

(c) the conditions for the placing on the market 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 Department on request;

(e) the labelling requirements, in accordance with paragraph 8 of Schedule 3, which shall include a requirement to notify the Department 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 the information at an appropriate level on the location of the genetically modified organisms that are grown.

General conditions in consents to release or market genetically modified organisms

29.—(1) Article 9 of the Order (consents: limitations and conditions) is amended as follows.

(2) In paragraph (1) (power of Department to impose limitations and conditions) after the words "as he may think fit" 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 paragraph (5) (implied condition when releasing or marketing) –

(a) in sub-paragraph (b) (obligation to notify Department of new information etc) –

(i) after "Department" insert "forthwith",

(ii) omit head (ii), and

(iii) after that head 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 sub-paragraph (c) (duty as regards preventing damage to environment) substitute –

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

(c) after that sub-paragraph insert –

"(d) notify the Department of the measures (if any) taken as a result of new information becoming available or an unforeseen event occurring as described in sub-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 Department.".

Proof of compliance with consent condition

30. In Article 16 of the Order (onus of proof as regards techniques and evidence) in paragraph (1) (accused to prove use of best available techniques) after "the accused to prove" insert

"the matters described in paragraph (1A).

(1A) The matters referred to in paragraph (1) are –

(a) in the case of an offence under Article 15(1)(c) consisting in a failure to comply with the general condition implied by Article 9(5)(c) –

(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, placing on the market 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 Department shall immediately forward to the Commission and the competent authority or authorities of each Member State any new information which becomes available to it which it considers could affect the assessment of the risk of the damage being caused to the environment by releasing or placing on the market genetically modified organisms.

(2) Where an application for consent or for renewal of consent to place on the market genetically modified organisms has been made and the information referred to in paragraph (1) becomes available to the Department before the consent has been granted or renewed, the Department may seek to reach agreement with the Commission and 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 place on the market genetically modified organisms has been made and the information referred to in paragraph (1) becomes available to the Department after the consent has been granted or renewed, it shall within 60 days after receipt of the new information, forward to the Commission an assessment report indicating whether the conditions of the consent should be varied, and, if so, how, or whether the consent should be revoked.

(4) The Department shall not forward an assessment report indicating that the consent to place on the market genetically modified organisms as it relates to the protection of human health should be varied without the agreement of the Executive.

(5) Where the Department has indicated that the consent should be varied 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 outstanding issues have been resolved in accordance with Article 20(3) of the Deliberate Release Directive;

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

(6) The Department shall only vary or revoke a consent to market genetically modified organisms under Article 8(10) of the Order –

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

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