SCOTTISH STATUTORY INSTRUMENTS

2019 No. 86

The Genetically Modified Organisms (Deliberate Release etc.) (Miscellaneous Amendments) (Scotland) Regulations 2019

Amendment to the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002

12. After regulation 26, insert—

"**Demand for the adjustment of geographical scope of consent or authorisation in respect of cultivation of genetically modified organisms**

26A.—(1) The Scottish Ministers may, in respect of any relevant application, demand that the geographical scope of any resulting consent or authorisation is adjusted to exclude all or any part of Scotland for the purposes of cultivating a genetically modified organism.

(2) A demand under paragraph (1) must be communicated by the Scottish Ministers to the Commission within 45 days at the latest of—

(a) the date of circulation of the assessment report by the Commission under Article 14(2) of the Deliberate Release Directive, or

(b) the date of receipt of the opinion of the European Food Safety Authority under Article 6(6), or Article 18(6) of the Food and Feed Regulation.

(3) In this regulation, "relevant application" means an application for any of the following—

(a) consent to place on the market a genetically modified organism under—

(i) section 111(1) of the Act, or

(ii) otherwise under Part C of the Deliberate Release Directive,

(b) renewal of consent to place on the market genetically modified organisms under—

(i) regulation 18, or

(ii) otherwise under Part C of the Deliberate Release Directive,

(c) an authorisation to place on the market genetically modified organisms under Article 5 or 17 of the Food and Feed Regulation, or

(d) renewal of authorisation to place on the market genetically modified organisms under Article 11 or 23 of the Food and Feed Regulation.

(4) A relevant application includes an application made to a competent authority other than the Scottish Ministers(**1**) or Food Standards Scotland(**2**).

(**1**) Under Directive 2001/18 of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms (OJ L 106/17.4.2001), Part C, where an applicant intends to place a genetically modified organism on the market that person may notify the competent authority, as designated for the purposes of Article 4(4) of that Directive, of any member State. In addition, such a person may notify a competent authority in another part of the United Kingdom in accordance with the applicable legislation there.

(**2**) The Food and Feed Regulation (as defined in regulation 2(1) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 S.S.I. 2002/541) is implemented by the Genetically Modified Food (Scotland) Regulations 2004 (S.S.I 2004/432) in relation to food and by the Genetically Modified Animal Feed (Scotland) Regulations 2004

Request for reintegration following exclusion from geographical scope

26B.—(1) The Scottish Ministers may request that all or any part of Scotland be reintegrated by being included in a consent (including a renewed consent) or authorisation from which it is excluded following a demand under regulation 26A(1).

(2) A request under paragraph (1) is made by notifying—

(a) in the case of a consent under the Deliberate Release Directive, the competent authority which issued the consent, or

(b) in the case of an authorisation under the Food and Feed Regulation, the Commission.”.

(S.S.I. 2004/433) in relation to animal feed. Regulation 3 of S.S.I. 2004/432 (as amended by S.S.I. 2015/100) designates Food Standards Scotland as the national competent authority in Scotland for the purposes of receiving applications for the authorisation of new genetically modified organisms in relation to food. Regulation 3 of S.S.I. 2004/433 (as amended by S.S.I. 2015/100), designates Food Standards Scotland as the national competent authority in Scotland for receiving applications for the authorisation of new genetically modified organisms in relation to feed. Under the Food and Feed Regulation a person may make an application for authorisation to place on the market a genetically modified organism for food use or for food to the national competent authority of any member State (Article 5 refers). In addition, such a person may make such an application to the national competent authority in another part of the United Kingdom in accordance with the applicable legislation there.