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SCOTTISH STATUTORY INSTRUMENTS

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**2002 No. 541**

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

**PART III**

**MARKETING ORGANISMS**

**Applications for consent to market**

**16.**—(1) An application for a consent to market genetically modified organisms under section 111(1) of the Act must be made in writing to the Scottish Ministers.

(2) An application for a consent to market genetically modified organisms which is not an application for renewal of consent must contain the following information:—

- [<sup>F1</sup>(a) the information prescribed in Part 2 of schedule 2, where the application is for consent to market any genetically modified higher plant, or schedule 3 in any other case, to the extent that such information is—
- (i) appropriate to the nature and scale of the release or application, and
  - (ii) in the case of schedule 2, relevant and necessary for the purposes of the environmental risk assessment referred to in sub-paragraph (c), in view especially of the characteristics of the genetically modified organism and of the scale and conditions of the release or of its intended conditions of use,
- (aa) where the application is for consent to market a genetically modified higher plant, summaries and results of studies referred to in the application for consent to market, including an explanation of their relevance to the environmental risk assessment referred to in sub-paragraph (c), where applicable,
- (ab) where the application is for consent to market a genetically modified higher plant, detailed information on the studies referred to in the application for consent to market, including—
- (i) a description of the methods and materials used or the reference to standardised or internationally recognised methods, and
  - (ii) the name of the body or bodies responsible for carrying out the studies,]

(b) information on data or results from any previous release of the same genetically modified organisms, or of the same combination of genetically modified organisms, which has been carried out by the applicant anywhere, and information from any previous application for consent to release the same genetically modified organisms, or the same combination of genetically modified organisms, which the applicant has made [<sup>F2</sup>under section 111(1) of the Act (in relation to any part of the United Kingdom)];

(c) an environmental risk assessment prepared in accordance with regulation 6;

(d) subject to paragraph (4), the information prescribed in Schedule 4;

(e) the proposed conditions for the marketing of the product, including specific conditions of use and handling;

*Status: Point in time view as at 31/12/2020.*

*Changes to legislation: There are currently no known outstanding effects for the The Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002, Section 16. (See end of Document for details)*

- (f) a proposed period for the consent which shall not exceed ten years;
- (g) a monitoring plan prepared in accordance with [F<sup>3</sup>schedule 5A] which shall include a proposal for the time period of the plan which may differ from the proposed period for the consent;
- (h) a proposal for labelling which shall comply with the requirements laid down in Schedule 4;
- (i) a proposal for packaging; and
- (j) a summary of the application in the format [F<sup>4</sup>set out in the Annex to Commission Decision 2002/812/EC].
- (3) The application may in addition contain—
- (a) data or results from an application for consent to release genetically modified organisms previously made by some other person, provided that if the data or results are confidential a copy of that person’s agreement in writing is contained in the application; and
- (b) any other information which the applicant considers relevant.
- (4) The information provided in accordance with paragraph (2)(a) and (d) shall take into account the diversity of sites of use of the genetically modified organisms and shall include information on any data or results obtained from research and developmental releases concerning the impact of the release on human health and the environment.
- (5) Where the applicant can demonstrate in the application by that person to the satisfaction of the Scottish Ministers that, on the basis of the results of any release in pursuance of and in accordance with a consent for a deliberate release granted [F<sup>5</sup>under section 111(1) of the Act or a consent under Part B of either] the Deliberate Release Directive or F<sup>6</sup>... the 1990 Directive, or on other substantive, reasoned scientific grounds, that the marketing and use of the product consisting of or including the genetically modified organisms do not pose a risk of damage to the environment, the applicant may omit from the application part or all of the information prescribed in Part II of Schedule 4.

#### Textual Amendments

- F1** Reg. 16(2)(a)-(ab) substituted for reg. 16(2)(a) (15.3.2019) by The Genetically Modified Organisms (Deliberate Release etc.) (Miscellaneous Amendments) (Scotland) Regulations 2019 (S.S.I. 2019/86), regs. 1(1), 8
- F2** Words in reg. 16(2)(b) substituted (31.12.2020) by The Genetically Modified Organisms (EU Exit) (Scotland) (Amendment) Regulations 2019 (S.S.I. 2019/57), regs. 1(2)(b), 3(7)(a)(i); 2020 c. 1, Sch. 5 para. 1(1)
- F3** Words in reg. 16(2)(g) substituted (31.12.2020) by The Genetically Modified Organisms (EU Exit) (Scotland) (Amendment) Regulations 2019 (S.S.I. 2019/57), regs. 1(2)(b), 3(7)(a)(ii); 2020 c. 1, Sch. 5 para. 1(1)
- F4** Words in reg. 16(2)(j) substituted (31.12.2020) by The Genetically Modified Organisms (EU Exit) (Scotland) (Amendment) Regulations 2019 (S.S.I. 2019/57), regs. 1(2)(b), 3(7)(a)(iii); 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in reg. 16(5) substituted (31.12.2020) by The Genetically Modified Organisms (EU Exit) (Scotland) (Amendment) Regulations 2019 (S.S.I. 2019/57), regs. 1(2)(b), 3(7)(b)(i); 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in reg. 16(5) omitted (31.12.2020) by virtue of The Genetically Modified Organisms (EU Exit) (Scotland) (Amendment) Regulations 2019 (S.S.I. 2019/57), regs. 1(2)(b), 3(7)(b)(ii); 2020 c. 1, Sch. 5 para. 1(1)

**Status:**

Point in time view as at 31/12/2020.

**Changes to legislation:**

There are currently no known outstanding effects for the The Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002, Section 16.