STATUTORY INSTRUMENTS

2002 No. 2443

Genetically Modified Organisms (Deliberate Release) Regulations 2002

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

Duty of the applicant after applying for consent to release or to market

19.—(1) In section 111 of the Act (consents required by certain persons) in subsection (6) (power of Secretary of State or the National Assembly for Wales to require further information) insert as a second sentence—

"A notice under this subsection must state the reasons for requiring the further information specified in the notice.".

(2) An applicant for a consent to release or to market genetically modified organisms who notifies the Secretary of State of any information in accordance with section 111(6A) of the Act (requirement for applicant to notify new information regarding risks of damage to the environment) shall submit in writing to the Secretary of State a revised version of the original application for consent amended to take account of the new information.

Duties of the Secretary of State in relation to applications for consent to release

20. Following receipt of an application for consent to release genetically modified organisms the Secretary of State shall—

(a) inform the applicant in writing of the date of receipt of the application,

(b) invite any person by means of a request placed on the register, to make representations to her relating to any risks of damage being caused to the environment by the release before the end of a period to be specified which shall not be less than 60 days from the date the application was received by her;

F1(c) . . . . . .

(d) examine the application for its conformity with the requirements of the Act and of these Regulations,

(e) evaluate the risks of damage being caused to the environment by the proposed release having regard to the environmental risk assessment, and

(f) take into account any representations relating to risks of damage being caused to the environment by the release made to her before the end of the period specified in accordance with paragraph (b) F2...

F1 Reg. 20(c) omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(7)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Words in reg. 20(f) omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(7)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Decisions by the Secretary of State on applications for consent to release

21.—(1) The Secretary of State shall not grant consent to release genetically modified organisms under section 111(1) of the Act as it relates to the protection of human health without the agreement of the Health and Safety Executive [M1].

[[F3](2) the Secretary of State shall not grant or refuse consent to release genetically modified organisms before the end of the period specified for representations in accordance with regulations 20(b) and (f) above and, if any comments referred to in regulation 20(f) are received within that period, before she has considered those comments.**]**

(3) The Secretary of State shall communicate her decision on an application for a consent to release genetically modified organisms to the applicant [F4]... before the end of a period of 90 days beginning with the day on which the application was received and shall include in any refusal of consent the reasons for the decision.

(4) The period prescribed in paragraph (3) shall not include—

(a) any period beginning with the day on which the Secretary of State gives notice in writing under section 111(6) of the Act that further information in respect of the application is required and ending on the day on which that information is received by the Secretary of State, or

(b) any period of time during which the Secretary of State is considering representations submitted by any persons in accordance with regulation 20(b), provided that this consideration shall not prolong the 90 day period referred to in paragraph (3) by more than 30 days.

(5) A consent to release genetically modified organisms shall require the applicant to send any information which might be relevant to assessing the risk of damage being caused to the environment, with, where appropriate, particular reference to any product which it is intended to market in the future, to the Secretary of State as soon as reasonably practicable after completion of the release and thereafter, at such intervals as the Secretary of State shall consider appropriate on the basis of the results of the environmental risk assessment.

[[F5](6) Information submitted in accordance with paragraph (5) must be provided in the format set out in the Annex to Commission Decision 2003/701/EC.**]**

F3 Reg. 21(2) substituted (8.10.2004) by The Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations 2004 (S.I. 2004/2411), regs. 1, **2(5)**

F4 Words in reg. 21(3) omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(8)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Reg. 21(6) substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(8)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Marginal Citations

M1 *See* section 10 of the Health and Safety at Work etc Act 1974 (c. 37).

Variation or revocation of consents to release

22.—(1) The Secretary of State shall only vary or revoke a consent to release genetically modified organisms under section 111(10) of the Act without the agreement of the holder of the consent where new information has become available to her which she considers would affect the assessment of the risk of damage being caused to the environment by the release.

(2) The Secretary of State shall not revoke or vary a consent to release genetically modified organisms under section 111(10) of the Act as it relates to the protection of human health without the agreement of the Health and Safety Executive.

Duties of the Secretary of State in relation to applications for consent to market

23.—(1) Following receipt of an application for consent to market genetically modified organisms the Secretary of State shall—

(a) inform the applicant in writing of the date of receipt of the application,

F6(b) . . . . . .

(c) examine the application for its conformity with the requirements of the Act and of these Regulations and, if necessary, request the applicant to supply additional information,

(d) before the end of a period of 90 days beginning with the day on which she received the application either—

(i) send to the applicant an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should be permitted to be marketed and under which conditions, or

(ii) refuse the application, stating reasons for her decision, supported by an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should not be marketed**[**F7**.]**

F8(e) . . . . . .

F9(2) . . . . . .

(3) The 90 day **[**F10period**]** prescribed in **[**F11paragraph (1)**]** shall not include any period beginning with the day on which the Secretary of State gives notice in writing under section 111(6) of the Act that further information in respect of the application is required and ending on the day on which that information is received by the Secretary of State.

[F12(4) Where the assessment report referred to in paragraph (1)(d) indicates that the genetically modified organisms to which an application relates should be permitted to be marketed, the Secretary of State must invite any person, by means of a request placed on the register, to make representations on the assessment report, which must be received by the Secretary of State within a period of 30 days beginning with the day on which the request is placed on the register (which must not be earlier than the day on which the assessment report is placed on the register under regulation 35(7A)).**]**

F6 Reg. 23(1)(b) omitted (31.12.2020) by virtue of The Food and Farming (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/759), regs. 1(b), **9(2)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F7 Word in reg. 23(1)(d)(ii) substituted (31.12.2020) by The Food and Farming (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/759), regs. 1(b), **9(2)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F8 Reg. 23(1)(e) omitted (31.12.2020) by virtue of The Food and Farming (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/759), regs. 1(b), **9(2)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F9 Reg. 23(2) omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(9)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F10 Word in reg. 23(3) substituted (31.12.2020) by The Food and Farming (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/759), regs. 1(b), **9(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F11 Words in reg. 23(3) substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(9)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F12 Reg. 23(4) substituted (31.12.2020) by The Food and Farming (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/759), regs. 1(b), **9(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Decisions by the Secretary of State on applications for consent to market

24.—**[**F13(1) The Secretary of State must not grant an application for consent to market genetically modified organisms under section 111(1) of the Act as it relates to the protection of human health without the agreement of the Health and Safety Executive.

(2) Where the Secretary of State invites representations on an assessment report relating to an application for consent to market genetically modified organisms—

(a) the Secretary of State must not determine whether to grant or refuse the application before the period for making representations under regulation 23(4) has ended and the Secretary of State has considered any representations made in accordance with that regulation;

(b) the Secretary of State must, within 105 days after the end of the period for making representations under regulation 23(4)—

(i) determine the application, and

(ii) notify the applicant in writing of the decision to grant or refuse the application, and the reasons for the decision.

(3) The period referred to in paragraph (2)(b) does not include any period beginning with the day on which the Secretary of State gives notice in writing under section 111(6) of the Act that further information in respect of the application is required and ending on the day on which that information is received by the Secretary of State.**]**

(4) Subject to paragraphs (5) and (6), a consent to market genetically modified organisms shall be given for a maximum period of ten years beginning with the day on which the consent is issued.

(5) For the purpose of granting consent to market a genetically modified organism or any progeny of that genetically modified organism contained in a plant variety where that plant variety is intended only for the marketing of its seeds F14... the period of the first consent shall end at the latest ten years after the date of the first inclusion of the first plant variety containing the genetically modified organism on **[**F15a National List in accordance with regulation 3 of the Seeds (National Lists of Varieties) Regulations 2001**]** .

(6) For the purpose of granting consent to market a genetically modified organism contained in forest reproductive material, the period of the first consent shall end at the latest ten years after the date of the first inclusion of basic material containing the genetically modified organism on **[**F16the National Register in accordance with regulations 6 and 7 of the Forest Reproductive Material (Great Britain) Regulations 2002**]** .

F13 Reg. 24(1)-(3) substituted (31.12.2020) by The Food and Farming (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/759), regs. 1(b), **9(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F14 Words in reg. 24(5) omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(10)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F15 Words in reg. 24(5) substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(10)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F16 Words in reg. 24(6) substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(10)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Duties of the Secretary of State on receiving applications for renewal of consent to market

25.—(1) On receipt of an application for renewal of consent to market genetically modified organisms the Secretary of State shall—

(a) inform the applicant in writing of the date of receipt of the application,

(b) examine the application for its conformity with the requirements of the Act and of these Regulations and, if necessary, request the applicant to supply additional information,

(c) either—

(i) send to the applicant an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should continue to be permitted to be marketed and under which conditions, or

(ii) refuse the application, stating reasons for her decision, supported by an assessment report which indicates that the genetically modified organisms should not continue to be marketed,

F17(d) . . . . . .

F18(2) . . . . . .

F17 Reg. 25(1)(d) omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(11)**; 2020 c. 1, Sch. 5 para. 1(1)

F18 Reg. 25(2) omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(11)**; 2020 c. 1, Sch. 5 para. 1(1)

Decisions by the Secretary of State on applications for renewal of consent to market

26.—**[**F19(1) The Secretary of State must not grant an application for the renewal of a consent under section 111(1) of the Act to market genetically modified organisms as it relates to the protection of human health without the agreement of the Health and Safety Executive.**]**

[F20(2) The Secretary of State must communicate a decision on an application to renew a consent to market genetically modified organisms to the applicant as soon as possible and must include in any refusal of a consent the reasons for that decision.**]**

(3) The consent to market genetically modified organisms shall be given for a period of ten years unless the Secretary of State considers that a shorter or longer period is justified, in which case she shall give her reasons in writing.

(4) The applicant may continue to market the genetically modified organisms under the conditions specified in the original consent until a final decision has been taken on the application.

F19 Reg. 26(1) substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(12)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F20 Reg. 26(2) substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(12)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Genetically modified organisms containing antibiotic resistance markers

27.—(1) The Secretary of State shall not grant a consent to an application for the release or marketing of genetically modified organisms containing antibiotic resistance markers which may have adverse effects on human health and the environment after—

(i) 31 December 2004 in the case of marketing, and

(ii) 31 December 2008 in the case of release.

(2) Where prior to 31 December 2004 in the case of marketing and 31 December 2008 in the case of release, an application is made for consent to release or market genetically modified organisms containing antibiotic resistance markers, the Secretary of State shall evaluate the information in the environmental risk assessment accompanying the application, taking into particular consideration those antibiotic resistance markers in use for medical or veterinary treatment, with a view to identifying and phasing out the release or marketing of the genetically modified organisms referred to in paragraph (1) within the time limits specified in that paragraph.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to Genetically Modified Organisms (Deliberate Release) Regulations 2002. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

– Blanket amendment words substituted by S.I. 2011/1043 art. 3-68-10