STATUTORY INSTRUMENTS

2002 No. 2443

Genetically Modified Organisms (Deliberate Release) Regulations 2002

PART I

GENERAL

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) Regulations 2002 and shall come into force on 17 October 2002.

(2) Except for this regulation, regulation 38, insofar as it relates to the continental shelf, and regulation 2, insofar as it defines "the Act" for the purposes of regulation 38, these Regulations shall extend only to England and Wales.

(3) Except for this regulation, regulations 3, 4, 19(1), 29, 30, 33(2), 38 and 39 and regulation 2, insofar as it defines "the Act" for the purposes of the regulations referred to in this paragraph, these Regulations shall apply only to England.

Interpretation

2. In these Regulations—

"the Act" means the Environmental Protection Act 1990;

"the Advisory Committee on Releases to the Environment" means the committee appointed by the Secretary of State under section 124 of the Act;

"antibiotic resistance markers" means genes employed in the modification of an organism to make that organism express resistance to a particular antibiotic or antibiotics;

"application for consent to release" shall include any notification made under the First Simplified Procedure (crop plants) Decision;

[[F1]"approved product" means a product—

(a) permitted to be marketed in England by—

((i)) a consent granted by the Secretary of State under section 111(1) of the Act, or

((ii)) an authorisation under the Food and Feed Regulation, or

(b) which, immediately before exit day, was permitted to be marketed by a consent granted in accordance with Article 15(3), 17(6) or 18(2) of the Deliberate Release Directive or Article 13(2) or (4) of the 1990 Directive (a "pre-exit approved product");**]**

[[F2]"biological matter" means anything (other than an entity mentioned in the definition of organism) which consists of or includes—

(a) tissue or cells (including gametes or propagules) or subcellular entities, of any kind, capable of replication or of transferring genetic material, or

(b) genes or other genetic material, in any form, which are so capable,

and it is immaterial, in determining if something is or is not biological matter, whether it is the product of natural or artificial processes of reproduction or whether or not it has ever been part of a whole organism;**]**

F3 …

F4 …

[F5"the Deliberate Release Directive" means Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms as it applied immediately before exit day;**]**

"the 1990 Directive" means Council Directive 1990/220/EEC**M1** on the deliberate release into the environment of genetically modified organisms as amended by Commission Directive 1994/15/EC**M2** and Commission Directive 1997/35/EC**M3**;

"electronic communication" means the same as in the Electronic Communications Act 2000 **M4**;

"environmental risk assessment" means the environmental risk assessment required to be contained in an application for consent to release or market genetically modified organisms by regulation 11(1)(c) and regulation 16(2)(c), respectively;

"the First Simplified Procedure (crop plants) Decision" means Commission Decision 94/730/EC**M5****[F6**as it applies immediately before exit day**]**;

[F7"the Food and Feed Regulation" means Council Regulation (EC) No 1829/2003 on genetically modified food and feed;**]**

[F7"genetically modified feed" means—

(a) feed containing, consisting of or produced from genetically modified organisms; or

(b) genetically modified organisms for feed use;**]**

[F7"genetically modified food" means—

(a) food containing or consisting of genetically modified organisms;

(b) food produced from, or containing ingredients produced from, genetically modified organisms; or

(c) genetically modified organisms for food use;**]**

"genetically modified organisms" means a genetically modified organism or a combination of genetically modified organisms;

"higher plant" means a plant belonging to the taxonomic group*Spermatophytae* (*Gymnospermae* or*Angiospermae*);

[F2"human admixed embryo" has the same meaning as it has in the Human Fertilisation and Embryology Act 1990 by virtue of section 4A(6) and (11) of that Act;**]**

[F2"human embryo" means an embryo within the meaning given in the provisions of the Human Fertilisation and Embryology Act 1990 (apart from section 4A) by virtue of section 1(1) and (6) of that Act; and**]**

"local authority" means a county council, a district council, a London borough council, the Common Council of the City of London in its capacity as a local authority, and the Council of the Isles of Scilly;

"monitoring plan" means the plan required by regulation 16(2)(g);

[F2"organism" means any acellular, unicellular or multicellular entity (in any form and whether or not it is the product of natural or artificial processes of reproduction), other than humans,

human embryos or human admixed embryos; and, unless the context otherwise requires, the term also includes any article or substance consisting of or including biological matter;**]**

[[F8]"qualifying higher plant" means a higher plant which is a genetically modified organism but which has not been genetically modified other than to make modifications—

(a) that could have occurred naturally, or

(b) that could have been made using one or more of the techniques set out in regulation 5(2);**]**

"the register" means the public register kept by the Secretary of State under section 122 of the Act.

"the 1992 Regulations" means the Genetically Modified Organisms (Deliberate Release) Regulations 1992 [M6].

Textual Amendments

F1 Words in reg. 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(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Words in reg. 2 inserted (1.10.2009) by The Human Fertilisation and Embryology (Consequential Amendments and Transitional and Saving Provisions) Order 2009 (S.I. 2009/1892), art. 1(1)(b), **Sch. 3 para. 5** (with Sch. 4)

F3 Words in reg. 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(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F4 Words in reg. 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(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Words in reg. 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(2)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Words in reg. 2 inserted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(2)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F7 Words in reg. 2 inserted (8.10.2004) by The Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations 2004 (S.I. 2004/2411), regs. 1, **2(2)(b)**

F8 Words in reg. 2 inserted (11.4.2022) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 (S.I. 2022/347), regs. 1(1), **2(2)**

Marginal Citations

M1 OJ No L117, 8.5.1990, p. 15.

M2 OJ No L103, 22.4.1994, p. 20.

M3 OJ No L169, 27.6.1997, p. 72.

M4 2000 c. 7.

M5 OJ No L292, 12.11.1994, p. 31.

M6 SI 1992/3280 as amended by the Genetically Modified Organisms (Deliberate Release) Regulations 1993 (SI 1993/152), the Genetically Modified Organisms (Deliberate Release) Regulations 1995 (SI 1995/304), the Genetically Modified Organisms (Deliberate Release and Risk Assessment) (Amendment) Regulations 1997 (SI 1997/1900) and the Genetically Modified Organisms (Contained Use) Regulations 2000 (SI 2000/2831).

Purpose of Part VI of the Act and meaning of "genetically modified organisms" etc

3.—(1) Section 106 of the Act (purpose of Part VI of the Act and meaning of "genetically modified organisms" etc) is amended as follows.

(2) For subsection (1) substitute—

"(1) This Part has effect for the purpose of ensuring that all appropriate measures are taken to avoid damage to the environment which may arise from the escape or release from human control of genetically modified organisms.".

(3) In subsection (4) (definition of organism which is genetically modified) for paragraph (a) (modification of prescribed artificial technique) substitute—

"(a) have been artificially modified, or".

(4) After that subsection insert—

"(4A) Genes or other genetic material in an organism are "artificially modified" for the purposes of subsection (4) above if they are altered otherwise than by a process which occurs naturally in mating or natural recombination.

This subsection is subject to subsections (4B) and (4C) below.

(4B) For the purposes of subsection (4) above—

(a) genes or other genetic material shall be taken to be artificially modified if they are altered using such techniques as may be prescribed for the purposes of this paragraph;

(b) genes or other genetic material shall not be regarded as artificially modified by reason only of being altered by the use of such techniques as may be prescribed for the purposes of this paragraph.

(4C) An organism shall be taken not to be a genetically modified organism for the purposes of this Part if it is an organism of a prescribed description.

(4D) In subsections (4B) and (4C) above "prescribed" means prescribed by regulations made by the Secretary of State.".

(5) Subsections (5) and (6) are omitted.

Meaning of "damage to the environment" etc

4.—(1) Section 107 of the Act (meaning of "damage to the environment" etc) is amended as follows.

(2) For subsection (2) (meaning of "environment") substitute—

"(2) The "environment" includes land, air and water and living organisms supported by any of those media.".

(3) In subsection (3)(meaning of "damage to the environment") omit "to the living organisms supported by the environment".

(4) For subsection (6) (meaning of "harm") substitute—

"(6) "Harm" means adverse effects as regards the health of humans or the environment.".

(5) For subsection (9) (meaning of organism being under a person's "control") substitute—

"(9) Organisms of any description are under the "control" of a person where he keeps them contained by measures designed to limit their contact with humans and the environment and to prevent or minimise the risk of harm.".

(6) For subsection (11) (meaning of organism being "marketed") substitute—

"(11) Genetically modified organisms of any description are "marketed" by a person when products consisting of or including such organisms are placed on the market by being made available to other persons, whether or not for consideration.".

Techniques of genetic modification

5.—(1) Until the coming into force of the first regulations under section 106(4B)(a) [M7] of the Act, genes or other genetic material shall be taken, for the purposes of subsection (4) of that section, to be artificially modified if they are altered using any of the following techniques:

(a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

(b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

(c) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

(2) Until the coming into force of the first regulations under section 106(4B)(b) of the Act, genes or other genetic material shall not be regarded, for the purposes of subsection (4) of that section, as artificially modified by reason only of being altered by the use of any of the following techniques:—

(a) in vitro fertilisation,

(b) natural processes such as conjugation, transduction and transformation,

(c) polyploidy induction,

provided that such techniques do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques or methods other than—

(i) mutagenesis; or

(ii) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

(3) Until the coming into force of the first regulations under section 106(4C) of the Act, an organism shall be taken, for the purposes of Part VI of the Act, not to be a genetically modified organism if it is yielded from the techniques or methods listed in paragraph (2)(i) or (ii) provided that those techniques or methods did not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those made by techniques or methods listed in that paragraph.

Marginal Citations

M7 Section 106(4) is amended by regulation 3(3) and section 106(4A) to 106(4D) is inserted by regulation 3(4).

Environmental risk assessment

6.—(1) An environmental risk assessment contained in an application for consent to release or market genetically modified organisms shall—

(a) identify and evaluate the potential damage to the environment, whether direct or indirect, immediate or delayed, which may arise from the release or marketing of genetically modified organisms,

(b) be carried out in accordance with Annex II of the Deliberate Release Directive and contain the conclusions required in section D of that Annex,

(c) include bibliographic references and indications of the methods used where applicable.

(2) Where the genetically modified organisms contain antibiotic resistance markers, the environmental risk assessment shall include an examination of the particular risks of damage to the environment which may be posed by the deliberate release or marketing of those genetically modified organisms.

Communication with applicant for consent

7.—(1) Wherever an applicant for a consent or renewal of a consent to which these Regulations apply or a holder of such consent is required under these Regulations to submit any document in writing, he is required to submit that document in both a paper and in a commonly used electronic form.

(2) Wherever these Regulations require any communication from the Secretary of State to the applicant for a consent or renewal of a consent to be in writing, "writing" shall include an electronic communication.

(3) Any documents required by these Regulations to be in writing which do not fall within the provisions of paragraph (1) or (2) must be in paper form.

PART II

RELEASING ORGANISMS FOR ANY OTHER PURPOSE THAN MARKETING

Requirement for consent to release

8. The cases and circumstances prescribed for the purposes of section 111(1)(a) of the Act in relation to the release of any genetically modified organisms are all cases and circumstances in which genetically modified organisms are intended to be released.

[F9Exemption for approved products]

9. The cases and circumstances prescribed for the purposes of section 111(7) of the Act in which persons are exempt from the requirements of section 111(1)(a) of the Act, insofar as those requirements apply to the release of genetically modified organisms, are all cases and circumstances in which F10... an approved product is released in accordance with the conditions and limitations to which the use of the product is subject.

Textual Amendments

F9 Reg. 9 heading substituted (11.4.2022) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 (S.I. 2022/347), regs. 1(1), **2(3)**

F10 Words in reg. 9 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(3)**; 2020 c. 1, Sch. 5 para. 1(1)

[F11Exemption for release of qualifying higher plants

9A. The cases and circumstances prescribed for the purposes of sections 108(7) and 111(7) of the Act in which persons are exempt from the requirements of section 108(1)(a) of the Act (to carry out a risk assessment) and of section 111(1)(a) of the Act (to obtain consent) respectively, insofar as those requirements relate to releasing qualifying higher plants (which includes the import or acquisition of such plants for the purpose of release), are all cases and circumstances in which a person intends to release a qualifying higher plant, other than those in relation to the marketing of such qualifying higher plants.

Textual Amendments

F11 Regs. 9A, 9B inserted (11.4.2022) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 (S.I. 2022/347), regs. 1(1), **2(4)**

Notification requirement for release of qualifying higher plants

9B.—(1) The cases and circumstances prescribed for the purposes of section 108(1)(b) of the Act in which persons intending to release a genetically modified organism must give notice to the Secretary of State of that intention and such information as may be prescribed are all cases and circumstances in which a person intends to release a qualifying higher plant, other than those in relation to the marketing of such qualifying higher plants.

(2) A person to whom paragraph (1) applies must give that notice to the Secretary of State at least 20 days before the day on which the qualifying higher plant is released.

(3) A person to whom paragraph (1) applies must give the information set out in Schedule 3A to the Secretary of State in respect of their plans concerning the release of the qualifying higher plant ("the project") at the same time as giving notice in accordance with this regulation.**]**

Textual Amendments

F11 Regs. 9A, 9B inserted (11.4.2022) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 (S.I. 2022/347), regs. 1(1), **2(4)**

Applications for consent to release—general provisions

10.—(1) An application for a consent to release genetically modified organisms must be made in writing to the Secretary of State.

(2) Proposed releases of the same genetically modified organism or of a combination of genetically modified organisms on the same site or on different sites for the same purpose and within a defined period may be notified in a single application.

(3) Where an application for a consent to release genetically modified organisms is expressed to rely on the First Simplified Procedure (crop plants) Decision, in the event of any inconsistency in the requirements as to information to be provided under that Decision and the requirements as to information to be provided under these Regulations, the provisions of that Decision shall prevail.

Information to be contained in applications for consent to release

11.—(1) An application for a consent to release genetically modified organisms must contain—

(a) **[**F12subject to paragraph (1A),**]** the information prescribed in—

(i) Schedule 1, where the application is for consent to release any genetically modified higher plant, or

(ii) Schedule 2 in any other case,

F13...

(b) information on data or results from any previous release of the organisms, or of the same combination of organisms, which has been carried out by the applicant, and information from any previous application for the release of the organisms, or of the same combination of organisms, which the applicant has made to the Secretary of State pursuant to the Act or to another competent authority in accordance with Article 6 of the Deliberate Release Directive,

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

(d) a summary[F14]... of the information contained in the application **[**[F15], in the relevant format set out in the Annex to Council Decision 2002/813/EC**]**.

[[F16](e) summaries and results of studies referred to in the application, including an explanation of their relevance to the environmental risk assessment, as appropriate.**]**

[[F17](1A) The information specified in paragraph (1)(a) is only required to be provided if it is necessary for the completion of an environmental risk assessment in the context of a specific application, and the level of detail to be provided may vary according to the nature and the scale of the proposed deliberate release.**]**

(2) The application may contain—

(a) data or results from an application for consent to release genetically modified organisms previously made by some other person, provided that a copy of that person's agreement in writing is contained in the application, and

(b) any other information that the applicant considers relevant.

Textual Amendments

F12 Words in reg. 11(1)(a) inserted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), **4(a)(i)**

F13 Words in reg. 11(1)(a) omitted (29.9.2019) by virtue of The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), **4(a)(ii)**

F14 Words in reg. 11(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(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F15 Words in reg. 11(1)(d) inserted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F16 Reg. 11(1)(e) inserted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), **4(b)**

F17 Reg. 11(1A) inserted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), **4(c)**

Advertisement of applications for consent to release

12.—(1) Subject to paragraphs (2) and (3), a person who makes an application for a consent to release genetically modified organisms shall, not more than ten days after he sends that application to the Secretary of State, cause to be published in a national newspaper to be specified by the Secretary of State a notice containing the following information—

(a) the name and address of the applicant,

(b) the general description of the organisms to be released,

(c) the location and purpose of the release,

(d) the intended date or dates of the release,

(e) a statement that information about the application will be placed on the register by the Secretary of State within twelve days of her receipt of the application,

(f) the means by which that register can be inspected,

(g) a statement that the Secretary of State will consider any representations made to her relating to risks of damage to the environment posed by the release of the genetically modified organisms within a period which she shall specify in accordance with these Regulations

and shall immediately send a copy of the newspaper containing the advertisement to the Secretary of State.

(2) A notice published under paragraph (1) need not contain the information referred to in sub-paragraphs (c) and (d) of that paragraph insofar as the First Simplified Procedure (crop plants) Decision does not require that information to be submitted with the application and that information is not submitted with the application.

(3) An applicant for consent shall ascertain from the Secretary of State the level of detail on the location of the release which will be placed on the register and shall include the same level of detail in the notice to be published under paragraph (1).

(4) A person who makes an application for a consent to release genetically modified organisms shall, not more than ten days after he sends that application to the Secretary of State, give to the following persons notice in writing that he has made the application and shall include in such notice the information prescribed in paragraph (1)(a) to (g), save insofar as paragraph (2) permits such information to be excluded from the notice referred to in paragraph (1)—

(a) the local authority and any parish councils for the area or areas of each proposed release,

(b) the owner or owners of the site or sites of each proposed release, if a person other than the applicant,

[[F18](c) any person, or member of a genetic modification safety committee, from whom advice must be obtained under regulation 8 of the Genetically Modified Organisms (Contained Use) Regulations 2014,**]**

(d) the Association of National Park Authorities,

(e) English Nature [M8], and

(f) the Environment Agency,

and shall immediately send to the Secretary of State copies of the notices.

Textual Amendments

F18 Reg. 12(4)(c) substituted (1.6.2018) by The Environment, Food and Rural Affairs (Miscellaneous Amendments) (England) Regulations 2018 (S.I. 2018/575), regs. 1(2), **3(3)**

Marginal Citations

M8 See section 128 of the Environmental Protection Act 1990 (c.43) and section 73 of the Countryside and Rights of Way Act 2000 (c.37).

Transitional provisions for release

13. Where the Secretary of State has received an application for consent to release genetically modified organisms before 17 October 2002 pursuant to the 1992 Regulations and has not yet determined the application—

(a) the application shall be subject to the provisions of these Regulations,

(b) the applicant shall submit to the Secretary of State such further information, additional to that already provided in connection with the application, as is necessary in order to comply with the requirements of these Regulations by 17 January 2003,

(c) the application shall be treated as having been sent to the Secretary of State for the purposes of regulations 12(1) and (4) and as having been received by the Secretary of State for the purpose of regulation 20 on submission of the information required by paragraph (b), and

(d) if the information required by paragraph (b) has not been submitted by 17 January 2003, the Secretary of State may refuse to proceed with the application.

PART III

MARKETING ORGANISMS

Requirement for consent to market

14. The cases and circumstances prescribed for the purposes of section 111(1)(a) of the Act in relation to marketing genetically modified organisms are all cases and circumstances in relation to the marketing of genetically modified organisms.

Exempt activities

15.—**[**F19(1)**]** The cases and circumstances prescribed for the purposes of sections 108(7) and 111(7) of the Act in which persons are exempt from the requirements of section 108(1)(a) of the Act (to carry out a risk assessment) and of section 111(1)(a) of the Act (to obtain consent), respectively, insofar as they relate to marketing genetically modified organisms, are all cases and circumstances in which—

(a) an approved product is marketed for a use for which it has approval **[**F20and in accordance with the limitations and conditions to which the use of that product is subject**]**,

[F21(aa) a pre-exit approved product is marketed during the relevant period for a use for which it had approval before exit day and in accordance with the limitations and conditions to which the use of that product was subject before exit day,**]**

[F22(b) genetically modified organisms are made available for activities regulated under the Genetically Modified Organisms (Contained Use) Regulations 2014;**]**

(d) genetically modified organisms are made available to be used exclusively for deliberate releases complying with the requirements laid down in Part II,

[F23(e) a genetically modified organism is marketed which is contained in a medicinal product authorised under the Human Medicines Regulations 2012 or the Veterinary Medicines Regulations 2013 ;**]**

F24(f) . . . . . .

F25(g) . . . . . .

[F26(2) For the purposes of paragraph (1), "the relevant period", in relation to a pre-exit approved product, means the period beginning with exit day and ending on the day on which the consent concerned ceases to be valid.**]**

Textual Amendments

F19 Reg. 15 renumbered as reg. 15(1) (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F20 Words in reg. 15(a) inserted (8.10.2004) by The Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations 2004 (S.I. 2004/2411), regs. 1, **2(3)(a)**

F21 Reg. 15(1)(aa) inserted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(5)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F22 Reg. 15(1)(b) substituted for reg. 15(1)(b)(c) (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(5)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F23 Reg. 15(1)(e) substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(5)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F24 Reg. 15(f) omitted (13.2.2019) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(a), **2(2)(b)**

F25 Reg. 15(1)(g) 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(5)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F26 Reg. 15(2) inserted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(5)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

Applications for consent to market

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

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

(a) **[**F27subject to paragraph (2A)**]** the information prescribed in—

(i) **[**F28Schedule 1A**]** where the application is for consent to market any genetically modified higher plant, or

(ii) Schedule 2 in any other case,

F29...

(b) information on data or results from any previous release of the organisms, or of the same combination of organisms, which has been carried out by the applicant either inside or outside the **[**F30United Kingdom**]**, and information from any previous application for consent to release the organisms, or the same combination of organisms, which the applicant has made to the Secretary of State in accordance with the Act and these Regulations, F31...

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

(d) the information prescribed in Schedule 3,

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

(f) a proposed period for the consent which shall not exceed ten years,

(g) a monitoring plan prepared in accordance with Annex VII of the Deliberate Release Directive **[**F32, as read with the guidance notes set out in Commission Decision 2002/811/EC,**]** 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 3,

(i) a proposal for packaging,

(j) a summary of the application in the format **[**F33set out in the Annex to Commission Decision 2002/812/EC**]**.

[F34(k) in respect of each subset of information required in this paragraph—

(i) summaries and results of studies referred to in the application, including an explanation of their relevance to the environmental risk assessment, as appropriate,

(ii) details of studies referred to in the application, including materials and methods used or reference to standardised or internationally recognised methods and the name of the body or bodies responsible for carrying out those studies.**]**

[F35(2A) The information specified in paragraph (2)(a) is only required to be provided if it is necessary for the completion of an environmental risk assessment in the context of a specific application, and the level of detail to be provided may vary according to the nature and the scale of the proposed release resulting from the marketing of a genetically modified higher plant.**]**

(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 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 sub paragraphs (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 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 his application to the satisfaction of the Secretary of State, that, on the basis of the results of any release in pursuance of and in accordance with a consent under section 111(1) of the Act or under Part B of either the Deliberate Release Directive or the 1990 Directive, or on other substantive, reasoned scientific grounds, the marketing and use of the product do not pose a risk of damage to the environment, he may omit from the application part or all of the information prescribed in Part II of Schedule 3.

Textual Amendments

F27 Words in reg. 16(2)(a) inserted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), **5(a)(i)**

F28 Words in reg. 16(2)(a)(i) substituted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), **5(a)(ii)**

F29 Words in reg. 16(2)(a) omitted (29.9.2019) by virtue of The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), **5(a)(iii)**

F30 Words in reg. 16(2)(b) substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(6)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F31 Words in reg. 16(2)(b) 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(6)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F32 Words in reg. 16(2)(g) inserted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F33 Words in reg. 16(2)(j) substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(6)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F34 Reg. 16(2)(k) inserted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), **5(b)**

F35 Reg. 16(2A) inserted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), **5(c)**

Transitional provisions for marketing

F36 17. . . . . . .

Textual Amendments

F36 Reg. 17 omitted (13.2.2019) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(a), **2(3)**

Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

F37 17A. . . . . . .

Textual Amendments

F37 Reg. 17A omitted (13.2.2019) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(a), **2(3)**

Applications for renewal of consent to market

18.—(1) Where the Secretary of State has granted a consent to market genetically modified organisms under section 111(1) of the Act, any application to renew that consent shall be made in writing to the Secretary of State—

(a) before 17 October 2006 where the consent was granted before 17 October 2002, and

(b) no later than nine months before the expiry of the consent in all other cases.

(2) The application shall contain—

(a) a copy of the consent to market the genetically modified organisms,

(b) where applicable, a report on the results of the monitoring carried out in accordance with the requirements of regulation 28(f),

(c) any other new information which has become available with regard to the risks of the product causing damage to the environment,

(d) as appropriate, a proposal for amending or adding to the conditions of the existing consent, including the conditions concerning future monitoring, and a proposal for the time limitation of the new consent.

(3) Any consent to market genetically modified organisms granted by the Secretary of State under section 111(1) of the Act before 17 October 2002 for which no application for renewal under paragraph (1) has been received before 17 October 2006 shall be treated as having expired on that date.

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;

F38(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) F39...

Textual Amendments

F38 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)

F39 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 [M9].

[[F40](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 [F41]... 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.

[[F42](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.**]**

Textual Amendments

F40 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)**

F41 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)

F42 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

M9 *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,

F43(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**[**F44.**]**

F45(e) . . . . . .

F46(2) . . . . . .

(3) The 90 day **[**F47period**]** prescribed in **[**F48paragraph (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.

[F49(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)).**]**

Textual Amendments

F43 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)

F44 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)

F45 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)

F46 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)

F47 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)

F48 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)

F49 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.—**[**F50(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 F51... 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 **[**F52a 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 **[**F53the National Register in accordance with regulations 6 and 7 of the Forest Reproductive Material (Great Britain) Regulations 2002**]** .

Textual Amendments

F50 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)

F51 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)

F52 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)

F53 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,

F54(d) . . . . . .

F55(2) . . . . . .

Textual Amendments

F54 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)

F55 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.—**[**F56(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.**]**

[F57(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.

Textual Amendments

F56 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)

F57 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.

PART V

GENERAL PROVISIONS FOR CONSENTS

General provisions of consents to market

28. A consent to market genetically modified organisms granted by the Secretary of State under section 111(1) of the Act shall specify—

(a) the scope of the consent, including the identity of the genetically modified organisms to be marketed and their unique identifier,

(b) the period of validity of the consent,

(c) the conditions for marketing 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 Secretary of State on request,

(e) the labelling requirements, in accordance with paragraph 8 of Schedule 3, which shall include a requirement to notify the Secretary of State 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 **[**F58monitoring reports in the relevant format set out in the Annexes to Commission Decision 2009/770/EC**]** and, where appropriate, any obligations on any person selling the product or any user, which may include an obligation to provide information at an appropriate level on the location of the genetically modified organisms that are grown.

Textual Amendments

F58 Words in reg. 28(f) substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(13)**; 2020 c. 1, Sch. 5 para. 1(1)

General conditions in consents to release or market

29.—(1) Section 112 of the Act (consents: limitations and conditions) is amended as follows.

(2) In subsection (1) (power of Secretary of State or National Assembly for Wales to impose limitations and conditions) at the end 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 subsection (5) (implied condition when releasing or marketing)—

(a) in paragraph (b) (obligation to notify Secretary of State or National Assembly for Wales of new information etc)—

(i) after "Secretary of State" insert " forthwith ",

(ii) omit sub-paragraph (ii), and

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

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

and

(c) after that paragraph insert—

"(d) notify the Secretary of State of the measures (if any) taken as a result of new information becoming available or an unforeseen event occurring as described in paragraph (b)(iii) above; 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 Secretary of State.".

Proof of compliance with consent conditions

30. In section 119 of the Act (onus of proof as regards techniques and evidence) in subsection (1) (accused to prove use of best available techniques) after "the accused to prove" insert

"the matters described in subsection (1A) below.

(1A) The matters referred to in subsection (1) above are—

(a) in the case of an offence under section 118(1)(c) above consisting in a failure to comply with the general condition implied by section 112(5)(c) above—

(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, marketing of the organisms, or

(ii) in a case where he took no measures, that no measures were necessary; and

(b) in any other case,".

[F59 Variation or revocation of a consent to market

31.—(1) The Secretary of State may only vary or revoke a consent to market 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 which the Secretary of State considers would affect the assessment of the risk of damage being caused to the environment by the release.

(2) The Secretary of State must not revoke or vary a consent to market 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.**]**

Textual Amendments

F59 Reg. 31 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(14)**; 2020 c. 1, Sch. 5 para. 1(1)

PART VI

SAFEGUARD

Safeguard

32.—(1) The Secretary of State may serve a prohibition notice under section 110 of the Act to prohibit an act which is authorised by a consent granted by her under section 111(1) of the Act or by a consent granted in respect of **[**F60marketing a pre-exit approved**]** product only if her opinion that doing such an act would involve a risk of causing damage to the environment is based on detailed grounds as the result of either—

(a) new or additional information made available since the date of the consent which affects the environmental risk assessment in respect of that product; or

(b) a reassessment of existing information in respect of that product on the basis of new or additional scientific information.

(2) Where, in the circumstances described in paragraph (1), the Secretary of State considers that the risk of damage being caused to the environment is severe she shall serve a prohibition notice requiring such measures to be taken as she may consider appropriate and once any work required by the notice has been carried out she shall enter details of it on the register.

F61(3) . . . . . .

F61(4) . . . . . .

F61(5) . . . . . .

(6) References in this regulation to the Secretary of State exercising a function under section 110 of the Act shall, in any case to which section 126(3) of the Act applies, be treated as references to the Secretary of State and the Food Standards Agency M10 acting jointly.

Textual Amendments

F60 Words in reg. 32(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(15)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F61 Reg. 32(3)-(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(15)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Marginal Citations

M10 See section 1 of the Food Standards Act 1999 (c.28).

PART VII

CONFIDENTIALITY

Confidentiality

33.—(1) For the purposes of section 123(7) of the Act the following descriptions of information are also information which the public interest requires to be included in the register notwithstanding that it may be commercially confidential—

(a) the location of the release of the genetically modified organisms to which the information relates,

(b) the intended use of the genetically modified organisms to which the information relates,

(c) the environmental risk assessment,

(d) the methods and plans for monitoring and for responding to an emergency in relation to the genetically modified organisms to which the information relates,

(e) the name and address of the holder of a consent to which a prohibition notice or other information relates.

(2) In section 123 of the Act (exclusion from register of certain information) in subsection (7) (particulars included even if commercially confidential)—

(a) after "section 122(1)(a)," insert " (c), ",

(b) in paragraph (b) for "the description" substitute " the general description ", and

(c) paragraphs (c) and (e) are omitted.

PART VIII

REGISTER OF INFORMATION

Information to be included in the register

34.—(1) The register shall contain the particulars set out in paragraphs **[**F62(1A)**]** to (10).

[F63(1A) In relation to a notice given under section 108(1)(b) of the Act, the content of that notice and the information given under regulation 9B(3), except information falling within paragraphs 3 to 5 of Schedule 3A.**]**

(2) In relation to a prohibition notice served by the Secretary of State under section 110 of the Act—

(a) the name and address of the person on whom the notice is served,

(b) the description of the genetically modified organisms in relation to which the notice is served,

(c) the location at which the genetically modified organisms are proposed to be released,

(d) the purpose for which the genetically modified organisms are proposed to be released or marketed,

(e) the reason for the service of the notice,

(f) any date specified in the notice as the date on which the prohibition is to take effect.

(3) Subject to paragraph (4), in relation to an application for a consent under section 111(1) of the Act—

(a) the name and address of the applicant,

(b) a general description of the genetically modified organisms in relation to which the application is being made,

(c) the location at which the genetically modified organisms are proposed to be released, to the extent that this information is notified to the Secretary of State,

(d) the purpose for which the genetically modified organisms are proposed to be released (including any future use to which they are intended to be put) or, in relation to a consent to market, the purpose for which they will be marketed,

(e) the intended dates of the release,

(f) the environmental risk assessment,

(g) the methods and plans for monitoring the genetically modified organisms and for responding to an emergency, and

(h) a summary of any advice the Secretary of State has received from the Advisory Committee on Releases to the Environment as to whether an application for release of **[**F64, or to market,**]** genetically modified organisms should be granted or rejected, and either—

(i) the conditions or limitations in accordance with which that committee has advised that the consent should be granted, or

(ii) a summary of the reasons why that committee has advised that the consent should not be granted.

[F65(i) the summary of the information contained in the application required by regulation 11(1)(d) or, as the case may be, of the application required by regulation 16(2)(j).**]**

[F66(3A) Subject to paragraph (4) and to the information concerned not being confidential, in relation to an application for a consent under section 111(1) of the Act to market genetically modified organisms—

(a) the name and address of the person who is responsible for the marketing, whether manufacturer, importer or distributor;

(b) the proposed commercial name of the product;

(c) the names of the genetically modified organisms in the product, including the scientific and common names of, where appropriate, the parental, recipient and donor organisms;

(d) the unique identifiers of the genetically modified organisms in the product;

(e) an application reference code assigned by the Secretary of State;

(f) the information included in the application as specified at paragraphs 3 and 7 of Schedule 3;

(g) information about stored samples of the genetically modified organisms, including the type of material, its genetic characterisation and stability, the amount of repository material, and the conditions of appropriate storage and shelf-life.**]**

(4) Where the Secretary of State is or becomes aware that information regarding the genetically modified organisms or the purpose for which they will be released or marketed has been published which is more detailed than that which would satisfy the requirements of paragraph (3), she shall enter so much of that more detailed information on the register as she shall consider appropriate.

(5) In relation to consents granted under section 111(1) of the Act—

(a) a copy of the consent, and a reference to the application in respect of which it was granted,

(b) any information supplied to the Secretary of State in accordance with conditions imposed on the consent,

(c) the fact that the consent has been varied or revoked, the contents of the notice by which the consent was varied or revoked, and a copy of the varied consent,

(d) a summary of any advice the Secretary of State has received from the Advisory Committee on Releases to the Environment as to whether a consent to release genetically modified organisms should be varied or revoked.

(6) The following information concerning the risk of damage being caused to the environment by genetically modified organisms—

(a) any information provided to the Secretary of State in accordance with section 111(6A) or 112(5)(b)(i) of the Act,

(b) any information relating to an unforeseen event occurring in connection with a release of a genetically modified organism which might affect the risks there are of damage being caused to the environment notified to the Secretary of State in accordance with section 112(5)(b)(iii) of the Act.

(7) A copy of any consent to market genetically modified organisms granted **[**F67before exit day**]** by a competent authority of another member State.

[F68(7A) A copy of any assessment report produced in accordance with regulation 23(1)(d) or regulation 25(1)(c).**]**

(8) The location of any genetically modified organisms grown in England pursuant to a consent to market insofar as that information is supplied to the Secretary of State in accordance with the monitoring requirements imposed on the consent.

(9) Any decision adopted **[**F69before exit day by the European**]** Commission in accordance with Article 18 of the Deliberate Release Directive.

(10) In relation to convictions for any offence under section 118 of the Act—

(a) the name and address of the person convicted,

(b) the description of any genetically modified organisms in relation to which the conviction was obtained,

(c) the offence which was committed,

(d) the penalty imposed and any order made by the court under section 120 of the Act.

Textual Amendments

F62 Word in reg. 34(1) substituted (11.4.2022) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 (S.I. 2022/347), regs. 1(1), **2(5)(a)**

F63 Reg. 34(1A) inserted (11.4.2022) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 (S.I. 2022/347), regs. 1(1), **2(5)(b)**

F64 Words in reg. 34(3)(h) inserted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(16)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F65 Reg. 34(3)(i) inserted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(16)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F66 Reg. 34(3A) inserted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(16)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F67 Words in reg. 34(7) inserted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(16)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F68 Reg. 34(7A) inserted (31.12.2020) by The Food and Farming (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/759), regs. 1(b), **9(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F69 Words in reg. 34(9) substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(16)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

Keeping the register

35.—[[F70](A1) The information prescribed in regulation 34(1A) must be placed on the register within twelve days of receipt by the Secretary of State of the notice.**]**

(1) The information prescribed in regulation 34(2) shall be placed on the register within twelve days of the prohibition notice being served.

(2) The information prescribed in paragraphs (a) to (g) **[**[F71]and (i)**]** of regulation 34(3) shall be placed on the register within twelve days of the receipt by the Secretary of State of the application for consent to release or market.

(3) The information prescribed in regulation 34(3)(h) shall be placed on the register within twelve days of the consent being granted or refused.

[[F72](3A) The information prescribed in regulation 34(3A) shall be placed on the register within twelve days of receipt by the Secretary of State of the application for consent to market.**]**

(4) The information prescribed in regulation 34(5)(a) shall be placed on the register within twelve days of the consent being granted.

(5) The information prescribed in regulation 34(5)(b) and (d) shall be placed on the register within twelve days of its receipt by the Secretary of State.

(6) The information prescribed in regulation 34(5)(c) shall be placed on the register within 14 days of the consent being revoked or varied.

(7) The information prescribed in regulations 34(6) and 34(10) shall be placed on the register within 14 days of its receipt by the Secretary of State.

[[F73](7A) The information prescribed in regulation 34(7A) shall be placed on the register within twelve days of its production.**]**

[F74](8) . . . . . .

(9) The information prescribed in regulation 34(8) shall be placed on the register within 14 days of its receipt by the Secretary of State.

[F75](10) . . . . . .

Textual Amendments

F70 Reg. 35(A1) inserted (11.4.2022) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 (S.I. 2022/347), regs. 1(1), **2(6)**

F71 Words in reg. 35(2) inserted (31.12.2020) by The Food and Farming (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/759), regs. 1(b), **9(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F72 Reg. 35(3A) inserted (31.12.2020) by The Food and Farming (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/759), regs. 1(b), **9(5)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F73 Reg. 35(7A) inserted (31.12.2020) by The Food and Farming (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/759), regs. 1(b), **9(5)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F74 Reg. 35(8) 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(17)**; 2020 c. 1, Sch. 5 para. 1(1)

F75 Reg. 35(10) 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(17)**; 2020 c. 1, Sch. 5 para. 1(1)

Publication of representations

36.—(1) The Secretary of State shall, within a period of 28 days after granting consent to or rejecting an application for the release of genetically modified organisms, make available to the public by whatever means she shall consider appropriate details of where and when paper copies of representations received may be inspected.

(2) Paragraph (1) shall not require copies of representations to be made publicly available where they contain confidential information and the person making the representations has asked the Secretary of State to treat that information as confidential.

PART IX

MISCELLANEOUS

Revocations

37. The regulations set out in Schedule 5 are revoked in respect of England to the extent specified in that Schedule.

Application of Part VI of the Act to territorial sea and continental shelf

38. In section 127(2) of the Act (definitions etc) in subsection (2) (application to territorial sea and continental shelf)—

(a) for "applies to the territorial sea adjacent to Great Britain," substitute " applies to the territorial sea adjacent to England as it applies in England ", and

(b) for the words from "to any" to the end substitute " applies to any area for the time being designated under section 1(7) of the Continental Shelf Act 1964 [M11] as it applies in England ".

Marginal Citations

M11 1964 c. 29.

Application of Part VI of the Act: England and Wales

39. After section 163 of the Act insert—

"**163A Application of Part VI: England and Wales**

163A

(1) The amendments made to the provisions of Part VI by the 2002 Regulations, other than the amendment of section 127(2) as it relates to the continental shelf, have effect in relation to England only, and accordingly, in the application of that Part in relation to Wales, the provisions listed in subsection (2) below continue to have effect without the amendments made by the 2002 Regulations.

(2) The provisions referred to in subsection (1) above are—

(a) section 106(1) and (4) to (6);

(b) section 107(2), (3), (6), (9) and (11);

(c) section 111(6);

(d) section 112(1) and (5);

(e) section 119(1);

(f) section 123(7);

(g) section 127(2) in so far as it relates to the territorial sea.

(3) In this section "the 2002 Regulations" means the Genetically Modified Organisms (Deliberate Release) Regulations 2002.".

Michael Meacher
Minister of State,
Department for Environment, Food and Rural Affairs

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 :

- Sch. 3 para. 7 words omitted by S.I. 2019/88 reg. 3(18)(c) (This amendment not applied to legislation.gov.uk. Reg. 3(18)(c) omitted (29.9.2019) by virtue of S.I. 2019/1252, regs. 1(1), 9)
- reg. 23(1)(b) substituted by S.I. 2019/88 reg. 3(9)(a)(i) (This amendment not applied to legislation.gov.uk. Reg. 3(9)(a) omitted immediately before IP completion day by virtue of S.I. 2019/759, regs. 1(a), 11)
- reg. 23(1)(e) substituted by S.I. 2019/88 reg. 3(9)(a)(ii) (This amendment not applied to legislation.gov.uk. Reg. 3(9)(a) omitted immediately before IP completion day by virtue of S.I. 2019/759, regs. 1(a), 11)
- reg. 23(4) omitted by S.I. 2019/88 reg. 3(9)(d) (This amendment not applied to legislation.gov.uk. Reg. 3(9)(d) omitted immediately before IP completion day by virtue of S.I. 2019/759, regs. 1(a), 11)
- reg. 24(1)-(4) substituted by S.I. 2019/88 reg. 3(10)(a) (This amendment not applied to legislation.gov.uk. Reg. 3(10)(a) omitted immediately before IP completion day by virtue of S.I. 2019/759, regs. 1(a), 11)

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