
SCOTTISH STATUTORY INSTRUMENTS

2002 No. 541

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

PART I
GENERAL

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 and shall come into force on the day after the day on which they are made.

(2) These Regulations extend to Scotland only.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

“the Act” means the Environmental Protection Act 1990 ^{M1};

“the Advisory Committee on Releases to the Environment” means the committee appointed for the purposes of, and in accordance with, 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;

“approved product” means a product consisting of or including genetically modified organisms which is permitted to be marketed by a consent granted under section 111(1) of the Act or otherwise 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;

“the Commission” means the European Commission;

“community council” means a community council constituted under section 51 of the Local Government (Scotland) Act 1973 ^{M2};

“the Contained Use Directive” means Council Directive [1990/219/EEC](#)^{M3} on the contained use of genetically modified micro-organisms as amended by Commission Directive [1994/51/EC](#)^{M4} and Council Directive [1998/81/EC](#)^{M5};

[^{F1}“the Deliberate Release Directive” means Directive [2001/18/EC](#) of the European Parliament and the Council on the deliberate release into the environment of genetically modified organisms as amended by the Food and Feed Regulation and Council Regulation [\(EC\) No 1830/2003](#);

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the “1990 Directive” means Council Directive [1990/220/EEC](#)^{M6} on the deliberate release into the environment of genetically modified organisms as amended by Commission Directive [1994/15/EC](#)^{M7} and Commission Directive [1997/35/EC](#)^{M8};

“electronic communication” has the same meaning as in the Electronic Communications Act 2000^{M9};

“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 virtue of regulation 11(1)(c) and regulation 16(2)(c) respectively;

“the First Simplified Procedure (crop plants) Decision” means Commission Decision [1994/730/EC](#)^{M10}, as amended by the Deliberate Release Directive;

[^{F2}“the Food and Feed Regulation” means Council Regulation (EC) No 1829/2003 on genetically modified food and feed;]

[^{F2}“genetically modified feed” means–

- (a) feed containing or consisting of genetically modified organisms;
- (b) feed derived in whole or in part from, but not containing or consisting of genetically modified organisms; or
- (c) genetically modified organisms that may be used as feed or as a source material for the production of feed;]

[^{F2}“genetically modified food” means–

- (a) food containing or consisting of genetically modified organisms;
- (b) food, or food containing ingredients, derived in whole or in part from genetically modified organisms, but not containing or consisting of genetically modified organisms; or
- (c) genetically modified organisms that may be used as food or as a source material for the production of food;]

“the Food Standards Agency” means the Food Standards Agency established under section 1 of the Food Standards Act 1999^{M11};

“genetically modified organisms” means a genetically modified organism or a combination of genetically modified organisms;

“the Health and Safety Executive” means the Health and Safety Executive established under section 10 of the Health and Safety at Work etc. Act 1974^{M12};

“higher plant” means a plant belonging to the taxonomic group Spermatophyta (Gymnospermae or Angiospermae);

“local authority” means a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994^{M13};

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

“the register” means the public register kept by the Scottish Ministers under section 122 of the Act;

“Regulation 2309/93” has the same meaning as it has in Schedule 1;

“the 1992 Regulations” means the Genetically Modified Organisms (Deliberate Release) Regulations 1992^{M14}.

(2) Expressions used in these Regulations have, unless the contrary intention appears, the meaning which they bear in Part VI of the Act and in regulations 8, 9, 14, 15, 33 and 34

the prescribing of cases, circumstances, descriptions and matters shall be treated as being cases, circumstances, descriptions and matters prescribed in accordance with and under the Act.

- (3) In these Regulations, unless the context otherwise requires—
- (a) any reference to a numbered regulation or to a numbered Schedule or to a numbered Part is a reference to the regulation or Schedule or Part in these Regulations so numbered; and
 - (b) a reference to a numbered paragraph is a reference to the paragraph so numbered in the regulation or Schedule to which that reference occurs.

Textual Amendments

- F1** Words in reg. 2 substituted (15.11.2004) by [The Genetically Modified Organisms \(Deliberate Release\) \(Scotland\) Amendment Regulations 2004 \(S.S.I. 2004/439\)](#), regs. 1, **3(a)**
- F2** Words in reg. 2 inserted (15.11.2004) by [The Genetically Modified Organisms \(Deliberate Release\) \(Scotland\) Amendment Regulations 2004 \(S.S.I. 2004/439\)](#), regs. 1, **3(b)**

Marginal Citations

- M1** 1990 c.43.
- M2** 1973 c.65.
- M3** O.J. No. L 117, 8.5.90, p.1.
- M4** O.J. No. L 297, 18.11.94, p.29.
- M5** O.J. No. L 330, 5.12.98, p.13.
- M6** O.J. No. L 117, 8.5.90, p.15.
- M7** O.J. No. L 103, 22.4.94, p.20.
- M8** O.J. No. L 169, 27.6.97, p.72.
- M9** 2000 c.7.
- M10** O.J. No. L 292, 12.11.94, p.31.
- M11** 1999 c.28.
- M12** 1974 c.37.
- M13** 1994 c.39.
- M14** [S.I. 1992/3280](#), as amended by [S.I. 1993/152](#), 1995/304, 1997/1900 and 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 and meaning of “genetically modified organisms” etc.) is amended as follows.

- (2) For subsection (1) (purpose of Part VI) 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)—
- (a) insert after “this Part”—
“, subject to subsection (4C) below,”;
and
 - (b) for paragraph (a) (modification of prescribed artificial technique) substitute—
“(a) have been artificially modified, or”.
- (4) After subsection (4) insert—
- “(4A) subject to subsections (4B) and (4C) below, genes or other genetic material in an organism are “artificially modified” for the purposes of subsection (4) above if

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they are altered otherwise than by a process which occurs naturally in mating or natural recombination.

(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 Scottish Ministers.”.

(5) Subsections (5) (techniques which may be prescribed as genetic modification) and (6)(direct or indirect means of modification immaterial) 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 the living organisms supported by any of those media.”.

(3) In subsection (3)(meaning of “damage to the environment”) the words “to the living organisms supported by the environment” are omitted.

(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 that person keeps them contained by specific measure 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 “marketed”) substitute—

“(11) Genetically modified organisms of any description are “marketed” 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 made by the Scottish Ministers under section 106(4B)(a) (power to prescribe techniques, alteration by which shall be taken to be artificial modification) ^{M15} 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 made by the Scottish Ministers under section 106(4B)(b) (power to prescribe techniques, alteration by which shall not be taken to be artificial modification) of the Act, genes or other genetic material shall not be taken, for the purposes of subsection (4) of that section, to be artificially modified by reason only of being altered by the use of any of the following techniques:—

- (a) in vitro fertilisation;
- (b) natural processes including conjugation, transduction or 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 made by the Scottish Ministers under section 106(4C) (power to prescribe organisms which shall be taken not to be genetically modified) 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

M15 Section 106(4) is amended by regulation 3(3) and section 106(4A) to (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 or for renewal of consent to 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 the 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; and
- (c) include any 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.

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Communication with an applicant for consent

7.—(1) Notwithstanding paragraph (2), 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 or in written form, whether before or after consent is granted, the applicant shall submit that document both in writing and in an electronic form acceptable to the Scottish Ministers.

(2) A reference in these Regulations to anything done in writing or produced in written form which does not fall within the provisions of paragraph (1) includes a reference to an electronic communication which has been recorded and is consequently capable of being reproduced.

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.

Exempt activities

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 an approved product is released in accordance with the conditions and limitations to which the use of the product is subject.

Applications for consent to release – general provisions

10.—(1) An application for a consent to release genetically modified organisms must be submitted in writing to the Scottish Ministers.

(2) The Scottish Ministers may accept that 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 application for consent to release

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

(a) the information prescribed in—

(i) Schedule 2, where the application is for consent to release any genetically modified higher plant; or

(ii) Schedule 3 in any other case,

to the extent that such information is appropriate to the nature and scale of the release or application;

- (b) information on data or results from any previous release of the organisms, or 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 any competent authority of any Member State (including the Scottish Ministers) in accordance with Article 6 of the Deliberate Release Directive or Article 5 of the 1990 Directive;
 - (c) an environmental risk assessment prepared in accordance with regulation 6; and
 - (d) a summary, in the format established by the Commission under Articles 11(1) and 30(2) of the Deliberate Release Directive, of the information contained in the application.
- (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 where the data or results are confidential a copy of that person’s agreement in writing is contained in the application; and
 - (b) any other information which the applicant considers is relevant.

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 the applicant sends that application to the Scottish Ministers, cause to be published in any newspaper to be specified by the Scottish Ministers a notice approved by the Scottish Ministers 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 of the release;
- (e) a statement that information about the application will be placed on the register by the Scottish Ministers within 12 days of their receipt of the application;
- (f) the means by which the register can be inspected; and
- (g) a statement that the Scottish Ministers shall, within a period which they shall specify in accordance with these Regulations, have regard to any representations made to them in writing relating to risks of damage to the environment ^{M16} posed by the release of the genetically modified organisms,

and that person shall—

- (i) immediately send to the Scottish Ministers confirmation that such information was placed in such newspaper and the date on which the information was published in the newspaper; and
- (ii) if requested to do so by the Scottish Ministers, send a copy of such newspaper containing the advertisement to them.

(2) A notice published under paragraph (1) need not contain the information referred to in subparagraphs (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 Scottish Ministers 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).

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(4) A person who makes an application for a consent to release genetically modified organisms shall, subject to paragraph (5), not more than ten days after that person sends that application to the Scottish Ministers, give to the following persons notice in writing that the application has been made and 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 community council for the area of each proposed release;
- (b) the owner of the site of each proposed release, if such person is not the applicant;
- (c) each member of the genetic modification safety committee established by the applicant under regulation 16 of the Genetically Modified Organisms (Contained Use) Regulations 2000 ^{M17} where relevant;
- (d) any National Park Authority designated under section 6 of the National Parks (Scotland) Act 2000 ^{M18} for the area of each proposed release;
- (e) Scottish Natural Heritage established under section 1 of the Natural Heritage (Scotland) Act 1991 ^{M19}; and
- (f) such other body as the Scottish Ministers may notify the applicant that they consider appropriate,

and shall immediately send to the Scottish Ministers copies of the notices given under this paragraph.

(5) Notwithstanding paragraph (4), the applicant shall give any body which the Scottish Ministers consider appropriate, for the purposes of paragraph (4)(f), the notice referred to in paragraph (4) within ten days of receipt by the applicant of the notification of such body as the Scottish Ministers consider appropriate.

Marginal Citations

M16 As defined in section 107(2), (3) and (6) of the Act as amended by regulation 4(2) to (4).

M17 S.I. 2000/2831.

M18 2000 asp 10.

M19 1991 c.28.

Transitional provisions in respect of applications to release

13. Where the Scottish Ministers, before the coming into force date of these Regulations, have received an application for consent to release genetically modified organisms pursuant to the 1992 Regulations and have not as at that date determined the application-

- (a) the application shall be subject to the provisions of these Regulations;
- (b) the applicant shall submit in writing to the Scottish Ministers 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 the date occurring three months after the coming into force date of these Regulations;
- (c) the application shall, for the purposes of regulation 12(1) and (4), be treated as having been sent to the Scottish Ministers and shall, for the purposes of regulation 20, be treated as having been received by the Scottish Ministers on the date of submission of the information required by paragraph (b); and
- (d) if the information required by paragraph (b) has not been submitted in writing by the date occurring three months after the coming into force date of these Regulations, the Scottish Ministers 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. 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 [^{F3}and in accordance with the limitations and conditions to which the use of that product is subject];
- (b) genetically modified micro-organisms are made available for activities regulated under the Contained Use Directive (including culture collections);
- (c) genetically modified organisms other than micro-organisms referred to in paragraph (b) are made available to be used exclusively for activities where appropriate stringent containment measures based on the same principles of containment as laid down in the Contained Use Directive are used to limit their contact with and to provide a high level of safety for the general population and the environment;
- (d) genetically modified organisms are made available to be used exclusively for deliberate releases complying with the requirements laid down in Part II;
- (e) a genetically modified organism authorised under Regulation 2309/93 [^{F4}or Regulation (EC) No. 726/2004 of the European Parliament and the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency] is marketed;
- [^{F5}(f) a novel food or novel food ingredient within the meaning of Council Regulation (EC) No. 258/97, as amended by the Food and Feed Regulation and Council Regulation 1882/2003, is marketed; and]
- [^{F6}(g) genetically modified food or feed authorised under the Food and Feed Regulation is marketed.]

Textual Amendments

- F3** Words in reg. 15(a) added (15.11.2004) by [The Genetically Modified Organisms \(Deliberate Release\) \(Scotland\) Amendment Regulations 2004 \(S.S.I. 2004/439\)](#), regs. 1, **4(a)**
- F4** Words in reg. 15 inserted (20.11.2005) by [The Medicines \(Marketing Authorisations Etc.\) Amendment Regulations 2005 \(S.I. 2005/2759\)](#), reg. 1(b), **Sch. para. 9**
- F5** Reg. 15(f) substituted (15.11.2004) by [The Genetically Modified Organisms \(Deliberate Release\) \(Scotland\) Amendment Regulations 2004 \(S.S.I. 2004/439\)](#), regs. 1, **4(b)**
- F6** Reg. 15(g) added (15.11.2004) by [The Genetically Modified Organisms \(Deliberate Release\) \(Scotland\) Amendment Regulations 2004 \(S.S.I. 2004/439\)](#), regs. 1, **4(c)**

Applications for consent to market

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

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

- (a) subject to paragraph (4), the information prescribed in—
 - (i) Schedule 2 where the application is for consent to market any genetically modified higher plant; or
 - (ii) Schedule 3 in any other case,to the extent that such information is appropriate to the nature and scale of the release which may result from the marketing;
- (b) information on data or results from any previous release of the same genetically modified organisms, or of the same combination of genetically modified organisms, which has been carried out by the applicant anywhere, and information from any previous application for consent to release the same genetically modified organisms, or the same combination of genetically modified organisms, which the applicant has made to any competent authority of any Member State (including the Scottish Ministers) in accordance with Article 6 of the Deliberate Release Directive or Article 5 of the 1990 Directive;
- (c) an environmental risk assessment prepared in accordance with regulation 6;
- (d) subject to paragraph (4), the information prescribed in Schedule 4;
- (e) the proposed conditions for the marketing of the product, including specific conditions of use and handling;
- (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 which shall include a proposal for the time period of the plan which may differ from the proposed period for the consent;
- (h) a proposal for labelling which shall comply with the requirements laid down in Schedule 4;
- (i) a proposal for packaging; and
- (j) a summary of the application in the format established by the Commission under Articles 13(2)(h) and 30(2) of the Deliberate Release Directive.

(3) The application may in addition contain—

- (a) data or results from an application for consent to release genetically modified organisms previously made by some other person, provided that if the data or results are confidential a copy of that person's agreement in writing is contained in the application; and
- (b) any other information which the applicant considers relevant.

(4) The information provided in accordance with paragraph (2)(a) and (d) shall take into account the diversity of sites of use of the genetically modified organisms and shall include information on any data or results obtained from research and developmental releases concerning the impact of the release on human health and the environment.

(5) Where the applicant can demonstrate in the application by that person to the satisfaction of the Scottish Ministers that, on the basis of the results of any release in pursuance of and in accordance with a consent for a deliberate release granted by any competent authority of any Member State (including the Scottish Ministers) in accordance with Article 6(5) of the Deliberate Release Directive or Article 6(2) of the 1990 Directive, or on other substantive, reasoned scientific grounds, that the marketing and use of the product consisting of or including the genetically modified organisms do

not pose a risk of damage to the environment, the applicant may omit from the application part or all of the information prescribed in Part II of Schedule 4.

Transitional provision in respect of applications to market

17. Where the Scottish Ministers have received an application for consent to market genetically modified organisms before the coming into force date of these Regulations pursuant to the 1992 Regulations and have not yet determined that application, or in a case where the Commission is required to take a decision in accordance with Article 13(3) of the 1990 Directive, that decision has not yet been taken—

- (a) the application shall be subject to the provisions of these Regulations;
- (b) the applicant shall submit in writing to the Scottish Ministers 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 the date occurring three months after the coming into force date of these Regulations;
- (c) the application shall be treated as having been received by the Scottish Ministers for the purposes of regulation 23 on the date of submission of the information required by paragraph (b);
- (d) if, by the coming into force date of these Regulations, the information required by regulation 16(2) of the 1992 Regulations has been forwarded to the Commission, the Scottish Ministers shall ensure that the information is supplemented and, if they consider it necessary, revised on the receipt by the Scottish Ministers of the further information required by paragraph (b) in the light of their obligations under these Regulations; and
- (e) if the information required by paragraph (b) has not been submitted in writing by the date occurring three months after the coming into force date of these Regulations, the Scottish Ministers may refuse to proceed with the application.

[^{F7}Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

17A.—(1) Subject to paragraph (2), the marketing of traces of a genetically modified organism or combination of genetically modified organisms in products intended for direct use as food or feed or for processing shall be exempted 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) provided that the conditions set out in article 47 of the Food and Feed Regulation are met.

(2) Paragraph (1) shall cease to have effect on 18th April 2007.]

Textual Amendments

F7 [Reg. 17A](#) inserted (15.11.2004) by [The Genetically Modified Organisms \(Deliberate Release\) \(Scotland\) Amendment Regulations 2004 \(S.S.I. 2004/439\)](#), regs. 1, 5

Applications for renewal of consent to market

18.—(1) Where a consent has been granted under section 111(1) of the Act to market genetically modified organisms which were first marketed in Scotland, any application to renew that consent shall be made in writing to the Scottish Ministers—

- (a) before 17th October 2006 where the consent was granted before the coming into force date of these Regulations; or
- (b) no later than nine months before the expiry of the consent in all other cases.

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(2) The application shall contain—

- (a) a copy of the consent to market the genetically modified organisms;
- (b) where the consent to market was granted—
 - (i) after the coming into force date of these Regulations, a report on the results of the monitoring carried out in accordance with the requirements of regulation 28(f); or
 - (ii) before that date, a report on the results of any monitoring carried out on the relevant product;
- (c) any other new information which has become available with regard to the risks of the product causing damage to the environment; and
- (d) as appropriate, a proposal for amending, complementing 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 first marketed in Scotland which was granted under section 111(1) of the Act before the coming into force date of these Regulations and for which no application for renewal under paragraph (1) has been received by the Scottish Ministers before 17th October 2006 shall be treated as having expired on that date.

(4) Any consent to market genetically modified organisms marketed in Scotland which was granted under section 111(1) of the Act before the coming into force date of these Regulations and for which an application for renewal under paragraph (1) is refused shall be treated as having expired on 17th October 2006 or the date of refusal of the application, whichever is the later.

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

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

19.—(1) Section 111 of the Act (consents required by certain persons) is amended as follows:—

- (a) in subsection (6)—
 - (i) after the word “period” where it appears for the first time insert “ and in such form and manner ”; and
 - (ii) after the word “period” where it appears for the second time insert “ and in the specified form and manner ”; and
- (b) after subsection (6) (power of Scottish Ministers to require further information) insert—

“(6ZA) A notice under subsection (6) 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 Scottish Ministers 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)^{M20} shall submit in writing to the Scottish Ministers a revised version of the original application for consent amended to take account of the new information.

Marginal Citations

M20 Section 111(6A) was added by S.I. 1992/3280.

Duties of the Scottish Ministers in relation to applications for consent to release

20. Following receipt of an application for consent to release genetically modified organisms the Scottish Ministers 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 in writing to the Scottish Ministers relating to any risks of damage being caused to the environment^{M21} by the release before the end of a period to be specified which shall not be less than sixty days from the date the application was received by the Scottish Ministers;
- (c) ensure that within thirty days of the date that the application was received by them a summary of that application in the format established by the Commission under Articles 11(1) and 30(2) of the Deliberate Release Directive is forwarded to the Commission;
- (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 prepared in accordance with regulation 6; and
- (f) take into account and give due weight to—
 - (i) any representations made to them before the end of the period specified in paragraph (b) relating to risks of damage being caused to the environment by the release; and
 - (ii) any comments made by the competent authority or authorities of other Member States following the circulation to them by the Commission of the summary referred to in paragraph (c).

Marginal Citations

M21 As defined in section 107(2), (3) and (6) of the Act as amended by regulation 4(2) to (4).

Decisions by the Scottish Ministers on applications for consent to release

21.—(1) The Scottish Ministers 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.

[^{F8}(2) The Scottish Ministers shall not grant or refuse consent to release genetically modified organisms before the end of the period specified for representations and comments in accordance with regulation 20(b) and (f) and if any comments referred to in regulation 20(f) are received within that period, before they have considered those comments.]

(3) The Scottish Ministers shall—

- (a) communicate in writing their decision on an application for a consent to release genetically modified organisms to the applicant; and
- (b) ensure that the Commission is informed of their decision,

before the end of a period of ninety days beginning with the day on which the application was received and shall include in any refusal of consent the reason for the decision.

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

- (a) any period beginning with the day on which the Scottish Ministers give notice in writing under section 111(6) of the Act that further information in respect of the application is

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required and ending on the day on which that information is received by the Scottish Ministers; or

- (b) any period of time during which the Scottish Ministers are considering representations submitted by any persons in accordance with regulation 20(b), provided that this consideration shall not prolong the ninety day period referred to in paragraph (3) by more than thirty 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 Scottish Ministers as soon as reasonably practicable after completion of the release and thereafter, at such intervals as the Scottish Ministers shall consider appropriate on the basis of the results of the environmental risk assessment.

(6) The Scottish Ministers shall ensure that the information submitted to them in accordance with paragraph (5) is sent to the Commission.

Textual Amendments

- F8** [Reg. 21\(2\)](#) substituted (15.11.2004) by [The Genetically Modified Organisms \(Deliberate Release\) \(Scotland\) Amendment Regulations 2004 \(S.S.I. 2004/439\)](#), regs. 1, 6

Variation or revocation of consents to release

22.—(1) The Scottish Ministers 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 them which they consider would affect the assessment of the risk of damage being caused to the environment by the release.

(2) The Scottish Ministers 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 Scottish Ministers in relation to applications for consent to market

23.—(1) On receipt of an application for consent to market genetically modified organisms the Scottish Ministers shall—

- (a) inform the applicant in writing of the date of receipt of the application;
- (b) ensure that a summary of that application in the format established by the Commission under Articles 13(2)(h) and 30(2) of the Deliberate Release Directive is forwarded immediately to the Commission and to the competent authorities of the other Member States;
- (c) without delay 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 ninety days beginning with the day on which they received the application either—
 - (i) send to the applicant an assessment report prepared in accordance with Schedule 5 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 their decision, supported by an assessment report prepared in accordance with Schedule 5 which indicates that the genetically modified organisms should not be marketed; and
 - (e) once they are satisfied the application conforms to the requirements prescribed in regulation 16 and in any event no later than when they send their assessment report in accordance with subparagraph (d), ensure that a copy of the application is forwarded to the Commission.
- (2) The Scottish Ministers shall ensure that—
- (a) their assessment report;
 - (b) any further information they have received from the applicant pursuant to the service of a notice under section 111(6) of the Act ^{M22}; and
 - (c) any additional information on which they have based their assessment report,
- are forwarded to the Commission—
- (i) in the circumstances described in paragraph (1)(d)(i), before the end of a period of ninety days beginning with the day on which the Scottish Ministers received the application; and
 - (ii) in the circumstances described in paragraph (1)(d)(ii), no sooner than fifteen days from the date the Scottish Ministers sent the assessment report to the applicant and no later than 105 days from the date they received the application.
- (3) The ninety day periods prescribed in paragraphs (1) and (2) shall not include any period beginning with the day on which the Scottish Ministers give 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 Scottish Ministers.
- (4) Where the Scottish Ministers intend to arrange for an assessment report which indicates that the genetically modified organisms to which an application relates should be permitted to be marketed to be forwarded to the Commission, they shall first consult the Health and Safety Executive and shall not arrange for their favourable opinion on the application as it relates to the protection of human health to be forwarded to the Commission where the Health and Safety Executive has informed them that it does not fulfil the requirements of the Act and of these Regulations.

Marginal Citations

M22 [Section 111\(6\)](#) of the Act is amended by regulation 19(1).

Decisions by the Scottish Ministers on applications for consents to market

24.—(1) In the cases of subparagraphs (a) or (b), the Scottish Ministers may and in the case of subparagraph (c), the Scottish Ministers shall grant an application for consent to market genetically modified organisms only where they have prepared an assessment report which indicates that the genetically modified organisms should be marketed and—

- (a) no reasoned objection has been raised by a Member State or by the Commission during a sixty day period beginning on the day the Commission circulated the assessment report;
- (b) a comment or a reasoned objection has been raised by either a Member State or by the Commission but all outstanding issues have been resolved in accordance with Article 15(1) of the Deliberate Release Directive within a 105 day period beginning on the date the Commission circulated the assessment report; or
- (c) an objection has been raised and maintained by a competent authority of any Member State or the Commission in accordance with Articles 15 or 20 of the Deliberate Release

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Directive and the Commission has adopted a decision in accordance with Article 18(1) of the Deliberate Release Directive in favour of granting consent.

(2) The Scottish Ministers shall—

- (a) inform the applicant; and
- (b) ensure that the other Member States and the Commission are informed,

of any decision by the Scottish Ministers to grant consent to market genetically modified organisms within thirty days of its grant.

(3) For the purpose of calculating the final forty five day period of the 105 days in paragraph (1) (b), no period during which further information is awaited from the applicant shall be taken into account.

(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 under the relevant Community provisions the period of the first consent shall, notwithstanding paragraph (4), end at the latest ten years after the date of the first inclusion of the first plant variety containing the genetically modified organism on an official national catalogue of plant varieties in accordance with Council Directive [2002/53/EC](#) on the common catalogue of varieties of agricultural plant species ^{M23} and Council Directive [2002/55/EC](#) on the marketing of vegetable seed ^{M24}.

(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, notwithstanding paragraph (4), end at the latest ten years after the date of the first inclusion of basic material containing the genetically modified organism on an official national register of basic material in accordance with Council Directive [1999/105/EC](#) ^{M25}.

Marginal Citations

M23 O.J. No. L 193, 20.7.02, p.1.

M24 O.J. No. L 193, 20.7.02, p.33.

M25 O.J. No. L 11, 15.1.00, p.17.

Duties on the Scottish Ministers 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 Scottish Ministers 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 5 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 their decision, supported by an assessment report which indicates that the genetically modified organisms should not continue to be marketed; and

(d) ensure that a copy of the application and their assessment report is forwarded to the Commission.

(2) Where the Scottish Ministers intend to arrange for an assessment report which indicates that the genetically modified organisms to which an application relates should be permitted to be marketed to be forwarded to the Commission, they shall first consult the Health and Safety Executive and shall not arrange for their favourable opinion on the application as it relates to the protection of human health to be forwarded to the Commission where the Health and Safety Executive has informed them that it does not fulfil the requirements of the Act and of these Regulations.

Decisions by the Scottish Ministers on applications for renewals of consents to market

26.—(1) In the cases of subparagraphs (a) or (b), the Scottish Ministers may and in the case of subparagraph (c), the Scottish Ministers shall grant an application to renew a consent to market genetically modified organisms only where they have prepared an assessment report which indicates that the genetically modified organisms should continue to be marketed and—

- (a) no reasoned objection has been raised by a Member State or by the Commission during a sixty day period beginning on the day the Commission circulated the assessment report;
- (b) a reasoned objection has been raised by either a competent authority of any Member State or by the Commission but all outstanding issues have been resolved in accordance with Article 17(7) and (8) of the Deliberate Release Directive within a seventy-five day period beginning on the day the Commission circulated the assessment report; or
- (c) an objection has been raised and maintained by a competent authority of any Member State or the Commission in accordance with Articles 17 or 20 of the Deliberate Release Directive and the Commission has adopted a decision in accordance with Article 18(1) of the Deliberate Release Directive in favour of granting consent.

(2) The Scottish Ministers shall—

- (a) inform the applicant; and
- (b) ensure that the other Member States and the Commission are informed,

of any decision by the Scottish Ministers to renew the consent to market genetically modified organisms within thirty days of its renewal.

(3) The renewed consent to market genetically modified organisms shall be given for ten years unless the Scottish Ministers consider that a shorter or longer period is justified, in which case they shall give their reasons therefor in writing.

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

Genetically modified organisms containing antibiotic resistance markers

27.—(1) The Scottish Ministers 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) 31st December 2004 in the case of marketing; and
- (ii) 31st December 2008 in the case of release.

(2) Where prior to 31st December 2004 in the case of marketing and 31st 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 Scottish Ministers 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

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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 PROVISION FOR CONSENTS

General provisions of consents to market

28. A consent to market genetically modified organisms granted by the Scottish Ministers 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 Scottish Ministers on request;
- (e) the labelling requirements, in accordance with paragraph 8 of Schedule 4, which shall include a requirement to notify the Scottish Ministers of any new commercial name of the product after consent has been given; and
- (f) monitoring requirements which shall be in accordance with the monitoring plan, and shall include the time period of the monitoring plan, an obligation that the applicant shall submit the reports of monitoring to the Commission and the competent authorities of the Member States and, where appropriate, any obligations on any person selling the product or any user of it, which may include an obligation to provide information at an appropriate level on the location of the genetically modified organisms that are grown.

General conditions on consents to release or market genetically modified organisms

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

(2) In subsection (1) (power of Scottish Ministers 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 Scottish Ministers of new information etc.)—
 - (i) before the word “of” where it appears for the second time insert “ forthwith ”;
 - (ii) omit subparagraph (ii); and
 - (iii) after that subparagraph 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 Scottish Ministers forthwith 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); 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 Scottish Ministers in such form and manner as they may specify.”.

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.”.

New information on risks of damage from marketing genetically modified organisms

31.—(1) The Scottish Ministers shall ensure that any new information which becomes available to them which they consider could have consequences for the risks of damage being caused to the environment by marketing the genetically modified organisms shall be forwarded immediately to the Commission and the competent authority of each Member State.

(2) Where an application for consent or for renewal of consent to market genetically modified organisms has been made to the Scottish Ministers and the information referred to in paragraph (1) becomes available to them before the application has been determined, the Scottish Ministers may arrange to seek agreement with the Commission and the other Member States pursuant to Articles 15(1) or 17(7) of the Deliberate Release Directive as applicable.

(3) Subject to paragraph (4), where an application for consent or for renewal of consent to market genetically modified organisms has been made to the Scottish Ministers and the information referred to in paragraph (1) becomes available to them after the consent has been granted or renewed, the Scottish Ministers shall within sixty days after receipt of the new information, ensure that there is forwarded to the Commission an assessment report prepared in accordance with Schedule 5 indicating whether the conditions of the consent should be varied and if so, how, or whether the consent should be revoked.

(4) The Scottish Ministers shall not arrange for an assessment report to be forwarded if that assessment report indicates that the consent to market genetically modified organisms as it relates to the protection of human health should be varied or revoked without the agreement of the Health and Safety Executive.

(5) Where the Scottish Ministers have indicated that the consent should be varied or revoked and either–

(a) no reasoned objection has been raised by a Member State or by the Commission during a sixty day period beginning on the day the Commission circulated the assessment report; or

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- (b) a reasoned objection has been raised by a Member State or by the Commission but all outstanding issues have been resolved in accordance with Article 20(3) of the Deliberate Release Directive,

they shall vary or revoke the consent as proposed and they shall inform the applicant, and ensure that the other Member States and the Commission are informed, that they have done so within thirty days of the sixty day period specified in subparagraph (a) or of the resolution referred to in subparagraph (b), as the case may be.

(6) The Scottish Ministers shall only vary or revoke a consent to market genetically modified organisms under section 111(10) of the Act—

- (a) where the information referred to in paragraph (1) has become available to them and the procedure referred to in paragraphs (3) and (5) has been complied with; or
- (b) in accordance with a decision adopted by the Commission under Articles 18(1) or 23(2) of the Deliberate Release Directive.

PART VI SAFEGUARD

Safeguard

32.—(1) The Scottish Ministers may serve a prohibition notice under section 110 of the Act to prohibit an act which is authorised by a consent granted in respect of an approved product only if their 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 Scottish Ministers consider that the risk of damage being caused to the environment is severe they shall serve a prohibition notice requiring such measures to be taken as they may consider appropriate and once any work required by the notice has been carried out they shall enter details of that work on the register.

(3) In cases to which paragraphs (1) and (2) apply, the Scottish Ministers shall ensure that the Commission and the other Member States are immediately informed of the Scottish Ministers' actions and that at the same time—

- (a) the reasons for taking such actions;
- (b) the results of the review by the Scottish Ministers of the environmental risk assessment;
- (c) the opinion of the Scottish Ministers as to whether the conditions of the consent should be varied, and, if so, how, or whether the consent should be revoked; and
- (d) where appropriate, the new information on which their decision to take action was based,

are provided to the Commission and the other Member States.

(4) A prohibition notice served under section 110 of the Act in accordance with this regulation shall be subject to any decision adopted by the Commission in accordance with Article 23(2) of the Deliberate Release Directive.

(5) Upon receipt of notification of a decision by the Commission to which paragraph (4) refers, the Scottish Ministers shall send a copy of it to the holder of the consent to which the decision relates and shall at the same time withdraw any prohibition notice which is inconsistent with that decision.

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

PART VII

CONFIDENTIALITY

Confidentiality

33.—(1) For the purposes of section 123(7) of the Act (exclusion from the register of certain information) 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 organism to which the information relates;
- (b) the intended use of the genetically modified organism 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; and
- (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), after the word “the” where it appears for the first time insert “ general ”; 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 (2) to (10).

(2) In relation to a prohibition notice served by the Scottish Ministers 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; and
- (f) any date specified in the notice as the date on which the prohibition is to take effect.

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(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 Scottish Ministers;
- (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 Scottish Ministers have received from the Advisory Committee on Releases to the Environment as to whether an application for release of 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.

(4) Where the Scottish Ministers are or become 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), they shall enter so much of that more detailed information on the register as they 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 Scottish Ministers 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, where applicable, a copy of the varied consent; and
- (d) a summary of any advice the Scottish Ministers have 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 genetically modified organisms released or grown pursuant to a consent, or proposed to be released or grown pursuant to a consent, as the case may be:—

- (a) any information provided to the Scottish Ministers 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 Scottish Ministers in accordance with section 112(5)(b)(iii) ^{M26} of the Act.

(7) A copy of any consent to market genetically modified organisms granted by a competent authority of another Member State.

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

(9) Any decision adopted by the Commission in accordance with Article 18 of the Deliberate Release Directive and such decisions are prescribed as matters relating to Part VI of the Act for the purposes of section 122(1)(h) of the Act.

(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 date on which the offence was committed;
- (e) the date on which the person was convicted; and
- (f) the penalty imposed and any order made by the court under section 120 of the Act (power of the court to order cause of offence to be remedied).

Marginal Citations

M26 Section 112(5)(b)(iii) has been inserted by regulation 29(3)(iii).

Keeping the register

35.—(1) The information on the register shall be made available to the public by such means as the Scottish Ministers shall consider appropriate.

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

(3) The information prescribed in regulation 34(3) (a) to (g) shall be placed on the register within twelve days of receipt by the Scottish Ministers of the application for consent to release or market.

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

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

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

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

(8) The information prescribed in regulations 34(6) and 34(10) shall be placed on the register within fourteen days of its receipt by the Scottish Ministers.

(9) The information prescribed in regulation 34(7) shall be placed on the register within fourteen days of its receipt by the Scottish Ministers.

(10) The information prescribed in regulation 34(8) shall be placed on the register within fourteen days of its receipt by the Scottish Ministers.

(11) The information prescribed in regulation 34(9) shall be placed on the register within fourteen days of the decision having been notified to the Scottish Ministers.

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(12) The information prescribed in regulation 34(10) in relation to any particular conviction shall be removed from the register when that conviction is spent within the meaning of the Rehabilitation of Offenders Act 1974 ^{M27}.

Marginal Citations

M27 1974 c.53.

Publication of representations

36.—(1) Subject to paragraph (2), the Scottish Ministers shall, within a period of twenty eight days after granting consent to or rejecting an application for the release of genetically modified organisms, make available to the public by whatever means they shall consider appropriate details of where, when and how 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 representation has asked the Scottish Ministers to treat that information as confidential.

PART IX

CONSEQUENTIAL AND OTHER AMENDMENTS AND REVOCATIONS

Consequential and other amendments – agency arrangements

37. The Scotland Act 1998 (Agency Arrangements) (Specification) (No. 2) Order 2002 ^{M28} shall be amended in accordance with Schedule 6.

Marginal Citations

M28 S.I. 2002/800.

Revocations

38. The Regulations set out in column 1 of Schedule 7 are revoked to the extent specified in the corresponding entry in relation to those Regulations in column 3 of that Schedule.

St Andrew's House, Edinburgh

ROSS FINNIE
A member of the Scottish Executive

Changes to legislation:

There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Genetically Modified Organisms (Deliberate Release) (Scotland) 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. 1 inserted by [S.S.I. 2019/57 sch. 1](#)
- Sch. 1 omitted by [S.S.I. 2019/86 reg. 17](#)
- Sch. 2 substituted by [S.S.I. 2019/86 reg. 18](#)
- sch. 2 para. 13 words substituted by [S.S.I. 2019/57 reg. 3\(25\)\(a\)](#)
- sch. 2 para. 14(b) words substituted by [S.S.I. 2019/57 reg. 3\(25\)\(b\)](#)
- Sch. 3 para. 12(a) word substituted by [S.S.I. 2023/374 Sch. 2 para. 2\(6\)](#)
- sch. 3 para. 12(a) words substituted by [S.S.I. 2019/57 reg. 3\(26\)](#)
- Sch. 4 para. 1 substituted by [S.S.I. 2019/86 reg. 19\(a\)](#)
- Sch. 4 para. 7 substituted by [S.S.I. 2019/86 reg. 19\(b\)](#)
- sch. 4 para. 7 word substituted by [S.S.I. 2019/57 reg. 3\(27\)\(d\)](#)
- sch. 4 para. 2 words omitted by [S.S.I. 2019/57 reg. 3\(27\)\(b\)](#)
- sch. 4 para. 5 words omitted by [S.S.I. 2019/57 reg. 3\(27\)\(c\)](#)
- sch. 4 para. 8 words omitted by [S.S.I. 2019/57 reg. 3\(27\)\(e\)](#)
- sch. 4 para. 1 words substituted by [S.S.I. 2019/57 reg. 3\(27\)\(a\)](#)
- sch. 4 para. 11 words substituted by [S.S.I. 2019/57 reg. 3\(27\)\(f\)](#)
- sch. 4 para. 14 words substituted by [S.S.I. 2019/57 reg. 3\(27\)\(g\)](#)
- sch. 5 para. 6 words omitted by [S.S.I. 2019/57 reg. 3\(28\)](#)
- reg. 2(1) words inserted by [S.S.I. 2019/57 reg. 3\(2\)\(d\)](#)
- reg. 2(1) words inserted by [S.S.I. 2019/86 reg. 3\(a\)](#)
- reg. 2(1) words omitted by [S.S.I. 2019/57 reg. 3\(2\)\(b\)](#)
- reg. 2(1) words omitted by [S.S.I. 2019/57 reg. 3\(2\)\(c\)](#)
- reg. 2(1) words omitted by [S.S.I. 2019/86 reg. 3\(g\)](#)
- reg. 2(1) words substituted by [S.S.I. 2015/100 art. 2Sch. para. 8](#)
- reg. 2(1) words substituted by [S.S.I. 2019/57 reg. 2\(2\)](#)
- reg. 2(1) words substituted by [S.S.I. 2019/57 reg. 3\(2\)\(a\)](#)
- reg. 2(1) words substituted by [S.S.I. 2019/86 reg. 3\(b\)](#)
- reg. 2(1) words substituted by [S.S.I. 2019/86 reg. 3\(c\)](#)
- reg. 2(1) words substituted by [S.S.I. 2019/86 reg. 3\(d\)](#)
- reg. 2(1) words substituted by [S.S.I. 2019/86 reg. 3\(e\)](#)
- reg. 2(1) words substituted by [S.S.I. 2019/86 reg. 3\(f\)](#)
- reg. 6(1)(b) words substituted by [S.S.I. 2019/57 reg. 3\(3\)\(a\)](#)
- reg. 6(1)(b) words substituted by [S.S.I. 2019/57 reg. 3\(3\)\(b\)](#)
- reg. 9 words inserted by [S.S.I. 2019/57 reg. 2\(3\)\(a\)](#)
- reg. 9 words inserted by [S.S.I. 2019/57 reg. 3\(4\)](#)
- reg. 9 words substituted by [S.S.I. 2019/57 reg. 2\(3\)\(b\)](#)
- reg. 9 words substituted by [S.S.I. 2019/57 reg. 2\(3\)\(c\)](#)
- reg. 11(1)(b) words inserted by [S.S.I. 2019/57 reg. 3\(5\)\(a\)\(i\)](#)
- reg. 11(1)(b) words omitted by [S.S.I. 2019/57 reg. 3\(5\)\(a\)\(ii\)](#)
- reg. 11(1)(b) words substituted by [S.S.I. 2019/57 reg. 2\(4\)](#)
- reg. 11(1)(d) words inserted by [S.S.I. 2019/57 reg. 3\(5\)\(b\)\(ii\)](#)
- reg. 11(1)(d) words omitted by [S.S.I. 2019/57 reg. 3\(5\)\(b\)\(i\)](#)
- reg. 12(4)(c) substituted by [S.S.I. 2019/86 reg. 5](#)
- reg. 13 omitted by [S.S.I. 2019/86 reg. 6](#)
- reg. 16(2)(b) words substituted by [S.S.I. 2019/57 reg. 3\(7\)\(a\)\(i\)](#)
- reg. 16(2)(g) words substituted by [S.S.I. 2019/57 reg. 3\(7\)\(a\)\(ii\)](#)
- reg. 16(2)(j) words substituted by [S.S.I. 2019/57 reg. 3\(7\)\(a\)\(iii\)](#)
- reg. 16(5) words omitted by [S.S.I. 2019/57 reg. 3\(7\)\(b\)\(ii\)](#)
- reg. 16(5) words substituted by [S.S.I. 2019/57 reg. 3\(7\)\(b\)\(i\)](#)
- reg. 17 omitted by [S.S.I. 2019/86 reg. 9\(a\)](#)

- reg. 17A omitted by S.S.I. 2019/86 reg. 9(b)
- reg. 20(c) omitted by S.S.I. 2019/57 reg. 3(8)(a)
- reg. 20(f) substituted by S.S.I. 2019/57 reg. 3(8)(b)
- reg. 21(2) words omitted by S.S.I. 2019/57 reg. 3(9)(a)(i)
- reg. 21(2) words omitted by S.S.I. 2019/57 reg. 3(9)(a)(ii)
- reg. 21(3) substituted by S.S.I. 2019/57 reg. 3(9)(b)
- reg. 21(6) substituted by S.S.I. 2019/57 reg. 3(9)(c)
- reg. 23 substituted by S.S.I. 2019/57 reg. 3(10)
- reg. 24 substituted by S.S.I. 2019/57 reg. 3(11)
- reg. 24(1) words substituted by S.S.I. 2019/86 reg. 10(a)
- reg. 24(4) words inserted by S.S.I. 2019/57 reg. 2(6)(a)
- reg. 24(5) words inserted by S.S.I. 2019/86 reg. 10(b)(i)
- reg. 24(5) words inserted by S.S.I. 2019/86 reg. 10(b)(ii)
- reg. 24(6) words inserted by S.S.I. 2019/86 reg. 10(c)
- reg. 25(1)(b) word inserted by S.S.I. 2019/57 reg. 3(12)(a)(i)
- reg. 25(1)(c) full stop substituted for word by S.S.I. 2019/57 reg. 3(12)(a)(ii)
- reg. 25(1)(c)(i) words substituted by S.S.I. 2019/57 reg. 2(7)(a)(i)
- reg. 25(1)(c)(ii) words inserted by S.S.I. 2019/57 reg. 2(7)(a)(ii)
- reg. 25(1)(d) omitted by S.S.I. 2019/57 reg. 3(12)(a)(iii)
- reg. 25(2) omitted by S.S.I. 2019/57 reg. 3(12)(b)
- reg. 26(1) substituted by S.S.I. 2019/57 reg. 3(13)(a)
- reg. 26(2) substituted by S.S.I. 2019/57 reg. 3(13)(a)
- reg. 26(4) words substituted by S.S.I. 2019/57 reg. 2(8)(a)
- reg. 28(f) words substituted by S.S.I. 2019/57 reg. 3(16)
- reg. 31 substituted by S.S.I. 2019/57 reg. 3(20)
- reg. 32(1) words inserted by S.S.I. 2019/86 reg. 15
- reg. 32(1) words substituted by S.S.I. 2019/57 reg. 3(21)(a)
- reg. 32(3)-(5) omitted by S.S.I. 2019/57 reg. 3(21)(b)
- reg. 32(6) words substituted by S.S.I. 2015/100 art. 2Sch. para. 8
- reg. 34(3)(g) word omitted by S.S.I. 2019/57 reg. 3(22)(a)(i)
- reg. 34(3)(h) word inserted by S.S.I. 2019/57 reg. 3(22)(a)(ii)
- reg. 34(3)(h) word substituted by S.S.I. 2019/57 reg. 2(15)(a)(ii)
- reg. 34(3)(h) words substituted by S.S.I. 2019/57 reg. 2(15)(a)(i)
- reg. 34(7) word substituted by S.S.I. 2019/57 reg. 2(15)(b)
- reg. 34(7) word substituted by S.S.I. 2019/57 reg. 3(22)(c)(ii)
- reg. 34(7) words inserted by S.S.I. 2019/57 reg. 3(22)(c)(i)
- reg. 34(7) words inserted by S.S.I. 2019/57 reg. 3(22)(c)(iii)
- reg. 34(9) words substituted by S.S.I. 2019/57 reg. 3(22)(e)
- reg. 35(3) words inserted by S.S.I. 2019/57 reg. 3(23)(a)
- reg. 35(9) omitted by S.S.I. 2019/57 reg. 3(23)(d)
- reg. 35(11) omitted by S.S.I. 2019/57 reg. 3(23)(d)

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

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Pt. 6A inserted by S.S.I. 2019/86 reg. 16
- Sch. 1 para. 6(4)(a)(i) word substituted by S.S.I. 2023/374 Sch. 2 para. 2(4)
- Sch. 1 para. 6(4)(b)(i) word substituted by S.S.I. 2023/374 Sch. 2 para. 2(5)
- sch. 1 para. 6(4)(a)(ii) words inserted by S.S.I. 2022/361 reg. 14(2)(ii)
- sch. 1 para. 6(4)(a)(i) words substituted by S.S.I. 2022/361 reg. 14(2)(i)
- sch. 2 para. 42 words substituted by S.S.I. 2019/57 reg. 3(25)(c)
- sch. 2 para. 43 words substituted by S.S.I. 2019/57 reg. 3(25)(c)
- sch. 2 para. 46 words substituted by S.S.I. 2019/57 reg. 3(25)(c)
- sch. 2 para. 53 words substituted by S.S.I. 2019/57 reg. 3(25)(d)

- sch. 2 para. 54(h)(i) words substituted by S.S.I. 2019/57 reg. 3(25)(e)(i)
- sch. 2 para. 54(h)(ii) words substituted by S.S.I. 2019/57 reg. 3(25)(e)(ii)
- sch. 5A inserted by S.S.I. 2019/57 sch. 2
- reg. 11(1)(a)(aa) substituted for reg. 11(1)(a) by S.S.I. 2019/86 reg. 4
- reg. 15(1) reg. 15 renumbered as reg. 15(1) by S.S.I. 2019/86 reg. 7(a)
- reg. 15(1) word omitted by S.S.I. 2019/57 reg. 2(5)(b)(ii)
- reg. 15(1) word substituted by S.S.I. 2019/57 reg. 2(5)(a)
- reg. 15(1) words omitted by S.S.I. 2019/57 reg. 2(5)(b)(i)
- reg. 15(1) words substituted by S.S.I. 2019/57 reg. 2(5)(c)
- reg. 15(1)(a) words inserted by S.S.I. 2019/57 reg. 3(6)(a)(i)
- reg. 15(1)(a) words substituted by S.S.I. 2019/57 reg. 2(5)(d)(i)
- reg. 15(1)(a) words substituted by S.S.I. 2019/57 reg. 2(5)(d)(ii)
- reg. 15(1)(b) words substituted by S.S.I. 2019/57 reg. 3(6)(a)(iii)
- reg. 15(1)(c) omitted by S.S.I. 2019/57 reg. 3(6)(a)(iv)
- reg. 15(1)(d) word inserted by S.S.I. 2019/57 reg. 3(6)(a)(v)
- reg. 15(1)(e) substituted by S.S.I. 2019/57 reg. 3(6)(a)(vi)
- reg. 15(1)(e) word inserted by S.S.I. 2019/86 reg. 7(c)
- reg. 15(1)(e) words substituted by S.S.I. 2019/86 reg. 7(b)
- reg. 15(1)(f) and word omitted by S.S.I. 2019/86 reg. 7(d)
- reg. 15(1)(g) omitted by S.S.I. 2019/57 reg. 3(6)(a)(vii)
- reg. 15(1)(aa) inserted by S.S.I. 2019/57 reg. 3(6)(a)(ii)
- reg. 15(2) inserted by S.S.I. 2019/86 reg. 7(e)
- reg. 15(2) substituted by S.S.I. 2019/57 reg. 3(6)(b)
- reg. 16(2)(a)-(ab) substituted for reg. 16(2)(a) by S.S.I. 2019/86 reg. 8
- reg. 24(7)-(11) inserted by S.S.I. 2019/86 reg. 10(d)
- reg. 24(7) words substituted by S.S.I. 2019/57 reg. 2(6)(b)
- reg. 24(9) words substituted by S.S.I. 2019/57 reg. 2(6)(c)
- reg. 26(5)-(8) inserted by S.S.I. 2019/86 reg. 11
- reg. 26(5) substituted by S.S.I. 2019/57 reg. 3(13)(b)
- reg. 26(5) words substituted by S.S.I. 2019/57 reg. 2(8)(b)
- reg. 26(6) words substituted by S.S.I. 2019/57 reg. 2(8)(c)
- reg. 26(7) substituted for reg. 26(7)(8) by S.S.I. 2019/57 reg. 3(13)(c)
- reg. 26A26B inserted by S.S.I. 2019/86 reg. 12
- reg. 26A substituted by S.S.I. 2019/57 reg. 3(14)
- reg. 26A(1) words substituted by S.S.I. 2019/57 reg. 2(9)
- reg. 26B substituted by S.S.I. 2019/57 reg. 3(15)
- reg. 26B(1) substituted by S.S.I. 2019/57 reg. 2(10)
- reg. 29A29B inserted by S.S.I. 2019/86 reg. 13
- reg. 29A(1) words omitted by S.S.I. 2019/57 reg. 3(17)(a)(iii)
- reg. 29A(1)(a) word substituted by S.S.I. 2019/57 reg. 2(11)(a)(i)
- reg. 29A(1)(a) words substituted by S.S.I. 2019/57 reg. 2(11)(a)(ii)
- reg. 29A(1)(b) words substituted by S.S.I. 2019/57 reg. 3(17)(a)(i)
- reg. 29A(1)(c) full stop substituted for comma by S.S.I. 2019/57 reg. 3(17)(a)(ii)
- reg. 29A(2) omitted by S.S.I. 2019/57 reg. 3(17)(b)
- reg. 29A(3)(a) words substituted by S.S.I. 2019/57 reg. 2(11)(b)(i)
- reg. 29A(3)(b) word substituted by S.S.I. 2019/57 reg. 2(11)(b)(ii)
- reg. 29A(3)(c) word inserted by S.S.I. 2019/57 reg. 3(17)(c)
- reg. 29A(5) word inserted by S.S.I. 2019/57 reg. 3(17)(d)(ii)
- reg. 29A(5) word substituted by S.S.I. 2019/57 reg. 3(17)(d)(i)
- reg. 29A(6) word substituted by S.S.I. 2019/57 reg. 3(17)(e)
- reg. 29A(6) words inserted by S.S.I. 2019/57 reg. 2(11)(c)
- reg. 29A(7) words inserted by S.S.I. 2019/57 reg. 2(11)(d)
- reg. 29A(7)(a)(v) words omitted by S.S.I. 2019/57 reg. 3(17)(f)(i)
- reg. 29A(7)(b) word inserted by S.S.I. 2019/57 reg. 3(17)(f)(ii)
- reg. 29A(7)(b) word substituted by S.S.I. 2023/374 Sch. 2 para. 2(2)
- reg. 29A(7)(e) word substituted by S.S.I. 2023/374 Sch. 2 para. 2(3)
- reg. 29A(7)(e) words substituted by S.S.I. 2019/57 reg. 3(17)(f)(iii)
- reg. 29A(9)(a) omitted by S.S.I. 2019/57 reg. 3(17)(g)

- reg. 29A(11) words substituted by S.S.I. 2019/57 reg. 2(11)(e)
- reg. 29A(11) words substituted by S.S.I. 2019/57 reg. 3(17)(h)
- reg. 29A(12)(a) word inserted by S.S.I. 2019/57 reg. 2(11)(f)(i)
- reg. 29A(12)(a) words inserted by S.S.I. 2019/57 reg. 2(11)(f)(ii)
- reg. 29A(12)(a) words omitted by S.S.I. 2019/57 reg. 3(17)(i)
- reg. 29B(1)(a) words inserted by S.S.I. 2019/57 reg. 2(12)(a)(i)
- reg. 29B(1)(a) words inserted by S.S.I. 2019/57 reg. 2(12)(a)(ii)
- reg. 29B(1)(a) words substituted by S.S.I. 2019/57 reg. 2(12)(a)(iii)
- reg. 29B(1)(b) words inserted by S.S.I. 2019/57 reg. 2(12)(b)
- reg. 29B(1)(c) words substituted by S.S.I. 2019/57 reg. 3(18)(a)
- reg. 29B(2) words substituted by S.S.I. 2019/57 reg. 3(18)(b)
- reg. 30A inserted by S.S.I. 2019/86 reg. 14
- reg. 30A(1)(a)(i) word omitted by S.S.I. 2019/57 reg. 2(13)(a)(i)(bb)
- reg. 30A(1)(a)(i) word substituted by S.S.I. 2019/57 reg. 2(13)(a)(i)(aa)
- reg. 30A(1)(a)(i) words omitted by S.S.I. 2019/57 reg. 3(19)
- reg. 30A(1)(a)(iii) inserted by S.S.I. 2019/57 reg. 2(13)(a)(iii)
- reg. 30A(1)(a)(ii) word inserted by S.S.I. 2019/57 reg. 2(13)(a)(ii)
- reg. 30A(1)(b) words substituted by S.S.I. 2019/57 reg. 2(13)(b)(i)
- reg. 30A(1)(b) words substituted by S.S.I. 2019/57 reg. 2(13)(b)(ii)
- reg. 30A(1)(c) words substituted by S.S.I. 2019/57 reg. 2(13)(c)
- reg. 30A(1)(d) words substituted by S.S.I. 2019/57 reg. 2(13)(d)
- reg. 32B(1)(d) words substituted by S.S.I. 2019/57 reg. 2(14)(a)(i)
- reg. 32B(1)(d) words substituted by S.S.I. 2019/57 reg. 2(14)(a)(ii)
- reg. 32B(1)(e) words substituted by S.S.I. 2019/57 reg. 2(14)(b)
- reg. 34(3)(i) inserted by S.S.I. 2019/57 reg. 3(22)(a)(iii)
- reg. 34(3A) inserted by S.S.I. 2019/57 reg. 3(22)(b)
- reg. 34(7A) inserted by S.S.I. 2019/57 reg. 3(22)(d)
- reg. 35(3A) inserted by S.S.I. 2019/57 reg. 3(23)(b)
- reg. 35(7A) inserted by S.S.I. 2019/57 reg. 3(23)(c)