

STATUTORY INSTRUMENTS

2014 No. 1663

The Genetically Modified Organisms (Contained Use) Regulations 2014

PART 5

Miscellaneous and General

Enforcement

30.—(1) This regulation applies to the extent that any part of these Regulations are not health and safety regulations within the meaning of section 15 of the 1974 Act.

(2) The following provisions apply to the whole of these Regulations as if they were health and safety regulations for the purposes of that Act—

(a) sections 16 to 26^{M1} (approved codes of practice and enforcement) and sections 33 to 42^{M2} (provisions as to offences) of the 1974 Act; and

(b) the Health and Safety (Training for Employment) Regulations 1990^{M3}.

(3) Every function of the Executive under any provision of the 1974 Act, or under health and safety regulations, is exercisable in relation to these Regulations as if the whole of these Regulations were health and safety regulations for the purposes of that Act.

(4) Despite section 33(1)(c) of the 1974 Act a failure to discharge a duty placed on the competent authority or the Executive by these Regulations is not an offence.

(5) Despite regulation 3 of the Health and Safety (Enforcing Authority) Regulations 1998^{M4}, the enforcing authority for these Regulations is the Executive.

Marginal Citations

M1 Section 16 of the 1974 Act was amended by paragraph 9 of Schedule 3 to the [Railways Act 2005](#) (c. 14) and paragraphs 4 and 5 of Schedule 7 to the [Health and Social Care Act 2012](#) (c. 7). Section 18 was amended by Schedules 15 and 18 to the [Employment Protection Act 1975](#) (c. 71), **paragraph 10(3)** of Schedule 3 and Part 1 of Schedule 13 to the [Railways Act 2005](#) and paragraphs 1 and 6 of Schedule 12 to the [Energy Act 2013](#) (c. 32). Section 20 was amended by paragraph 49 of Schedule 27 to the [Civil Partnership Act 2004](#) (c. 33). Section 22 was amended by Schedule 3 to the [Consumer Protection Act 1987](#) (c. 43). Section 23 was amended in relation to England and Wales by paragraph 44 of Schedule 1 to the [Fire and Rescue Services Act 2004](#) (c. 21) and [S.I. 2005/1541](#). In relation to Scotland section 23 was amended by [S.S.I. 2005/383](#), [S.S.I. 2006/475](#) and paragraph 49 of Schedule 7 to the [Police and Fire Reform \(Scotland\) Act 2012](#) (asp. 8). Section 24 was amended by section 1(2) (a) of the [Employment Rights \(Dispute Resolution\) Act 1998](#) (c. 8). Section 25A was inserted by paragraph 3 of Schedule 3 to the [Consumer Protection Act 1987](#) (c. 43). In addition sections 16, 17 and 18 were amended by [S.I. 2008/960](#).

M2 Section 33 was amended by Schedules 15 and 18 to the [Employment Protection Act 1975](#), Part 1 of the Schedule to the [Forgery and Counterfeiting Act 1981](#) (c. 45), **Schedule 3** to the [Consumer](#)

Protection Act 1987, sections 4(5) and (6) of, and Schedule 2 to, the [Offshore Safety Act 1992 \(c. 15\)](#) and section 1(1) of the [Health and Safety \(Offences\) Act 2008 \(c. 20\)](#). Section 34 was amended by [S.I. 2008/960, paragraph 25](#) of Schedule 21 to the [Coroners and Justice Act 2009 \(c. 25\)](#) and, in its application to Scotland, by paragraph 51 of Schedule 9 to the [Criminal Procedure \(Scotland\) Act 1975 \(c. 21\)](#) and paragraph 18 of Schedule 7 to the [Gas Act 1986 \(c. 44\)](#). Section 36 has been modified by [S.I. 2007/1353](#) to the effect that references to the Crown are treated as including references to the National Assembly for Wales Commission. Section 38 was amended by paragraph 30(7) of Schedule 22 to the [Environmental Act 1995 \(c. 25\)](#) and [S.I. 2013/755](#). Section 36 was amended by paragraph 2(2) and (3) of Schedule 3 to the [Health and Safety \(Offences\) Act 2008](#).

M3 [S.I. 1990/1380](#).

M4 [S.I. 1998/494](#), to which there are amendments not relevant to these Regulations.

Appeals

31.—(1) A person responsible for contained use who is aggrieved by any of the following may appeal to the appropriate person—

- (a) a decision by the competent authority—
 - (i) to refuse to provide a written agreement requested under regulation 10(6);
 - (ii) to refuse consent for a class 3 or class 4 contained use notified under regulation 11(2);
 - (iii) to refuse to provide written agreement under regulation 19(2)(c) that a particular containment measure need not be applied for a specific activity;
 - (iv) to refuse to grant an exemption certificate under regulation 26(1) or to revoke such a certificate;
 - (v) to impose a condition or a time limit on an exemption certificate issued under regulation 26(1);
- (b) an instruction concerning the cessation of a contained use under regulation 16(3);
- (c) a request for additional information by the Executive under regulation 24(1);
- (d) a notice from the competent authority under regulation 25.

(2) The appropriate person may direct that an appeal be determined on their behalf by one or more persons appointed for that purpose.

(3) The appropriate person may pay such remuneration and allowances to an appointed person as the appropriate person may determine.

(4) An appointed person may decide the procedure to be followed on the appeal and may give such directions as are appropriate to give effect to the determination of the appeal.

(5) Where an appeal is brought under this regulation—

- (a) the following remain valid pending the final determination of the appeal—
 - (i) a decision of the competent authority referred to in paragraph (1)(a);
 - (ii) a request for additional information made under regulation 24(1);
- (b) the following are not suspended pending the final determination of the appeal—
 - (i) the operation of regulation 16 and any instructions given under regulation 16(3);
 - (ii) a notice issued under regulation 25.

(6) The period of time beginning with the date on which an appeal is lodged and ending with the date on which that appeal is determined will not be taken into account in calculating the period of days referred to in regulation 10(4), 10(7), 11(4), 11(5) or 12(4).

(7) In this regulation,

“appointed person” means the person appointed by the appropriate person to determine an appeal;

“appropriate person” means—

- (a) the Secretary of State, in the case of—
 - (i) an appeal under paragraph (1)(a) or (d) against a decision of, or a notice issued by, the competent authority as regards England and Wales; or
 - (ii) an appeal under paragraph (1)(b) or (c) against a request or instruction relating to—
 - (aa) the undertaking or proposed undertaking of a contained use; or
 - (bb) premises which are the subject of a notification under regulation 9(2), in England or Wales;
- (b) the Secretary of State and the Scottish Ministers, acting jointly, in the case of—
 - (i) an appeal under paragraph (1)(a) or (d) against a decision of, or a notice issued by, the competent authority as regards Scotland or the joint competent authority; or
 - (ii) an appeal under paragraph (1)(b) or (c) against a request or instruction relating to—
 - (aa) the undertaking or proposed undertaking of a contained use; or
 - (bb) premises which are the subject of a notification under regulation 9(2) or 9(5), in Scotland.

Competent authority address

32. Anything required to be submitted or sent to a competent authority under these Regulations must be sent to the Executive at the address published for this purpose on its website which may be, or include, an address for submission by electronic means.

Saving and transitional provisions

33.—(1) Subject to paragraph (3) the following continue to have effect and are deemed to have been made, granted or imposed under these Regulations—

- (a) a notification made under any of regulations 9 to 13 of the 2000 Regulations, provided that the notification complied with the provisions of those Regulations, as if the notification had been made by a notifier under the corresponding regulation of these Regulations;
- (b) a consent granted by the competent authority under regulation 11 of the 2000 Regulations as if it were granted under regulation 11 of these Regulations;
- (c) an agreement by the competent authority under regulation 18(2) of the 2000 Regulations that a specific containment measure need not be applied to a contained use, as if it were made under regulation 19(2) of these Regulations;
- (d) a request for additional information made under regulation 14(2) of the 2000 Regulations, as if it were made under regulation 24(1) of these Regulations;
- (e) a condition, limit of time or other requirement imposed by the competent authority under regulation 15(1) of the 2000 Regulations, as if it were imposed under regulation 25 of these Regulations.

(2) Every record required to be kept under regulation 8(2) of the 2000 Regulations must be kept in the same manner and for the same period as specified in that regulation as if the requirement were imposed under regulation 7(2) of these Regulations.

(3) A person responsible for contained use involving micro-organisms must submit a notification to the competent authority in the following circumstances—

- (a) the contained use was being undertaken in accordance with the 2000 Regulations before the date on which these Regulations come into force;
 - (b) the appropriate containment level for the contained use is different under these Regulations to the appropriate containment level under the 2000 Regulations; and
 - (c) as a result the contained use is classified under these Regulations at a higher class than under the 2000 Regulations.
- (4) The notification must be submitted to the competent authority within the specified period.
- (5) Subject to paragraphs (6) to (8) the notification must be treated as a notification required under regulation 10(2) or 11(2) of these Regulations.
- (6) The notification must contain the information in Schedule 6 that is specified for the new class of contained use, unless the competent authority exempts the notifier from some or all of the requirements of Schedule 6.
- (7) Where a notification is submitted for a contained use that requires consent as class 3 or class 4 contained use, the competent authority must inform the notifier of its decision whether or not to grant consent within 90 days of receipt of the notification.
- (8) The contained use referred to in paragraph (3) may continue provided that—
- (a) the notification is submitted within the specified period;
 - (b) the risk assessment shows no increase in the risks to human health or the environment created by the contained use;
 - (c) the competent authority does not require the notifier to suspend or terminate the contained use under regulation 25 of these Regulations; and
 - (d) the competent authority has not refused consent for the contained use.
- (9) In this regulation—
“specified period” means the 90 days beginning with the date on which these Regulations come into force.

[^{F1}Transitional provision in relation to the withdrawal of the United Kingdom from the European Union

33A.—(1) Subject to paragraphs (2) and (3), these Regulations do not apply to any activity which is covered by a written consent given by a competent authority of an EEA State in accordance with Article 15(3), 17(6) or 18(2) of Directive (EC) No 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms.

(2) The written consent referred to in paragraph (1) must be valid immediately before IP completion day.

(3) Any activity covered by the consent referred to in paragraph (1) must be conducted in accordance with any obligations, conditions or limitations attached to that consent.

(4) Subject to paragraphs (5) and (6), these Regulations do not apply to any genetically modified organisms which are cultured, stored, transported, destroyed, disposed of or used, where such organisms are, or are contained in, a medicinal product for human or veterinary use marketed in accordance with an authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

(5) The marketing authorisation referred to in paragraph (4) must be valid immediately before IP completion day.

(6) Any marketing authorisation referred to in paragraph (4) must be conducted in accordance with any obligations, conditions, restrictions, requirements or limitations attached to that authorisation.]

F1 Reg. 33A inserted (31.12.2020) by [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/720\)](#), reg. 1(2), [Sch. 1 para. 40\(3\)](#) (as amended by [S.I. 2020/1567](#), reg. 1(2), [Sch. 1 para. 19](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Consequential amendments

34.—(1) The Health and Safety (Fees) Regulations 2012 ^{M5} are amended as follows.

(2) In regulation 13—

- (a) in the heading, for “2000” substitute “ 2014 ”;
- (b) in paragraph (1), for “2000” substitute “ 2014 ”;
- (c) for paragraph (2) substitute—

“(2) No fee is to be returned to a notifier where the notifier withdraws a notification under regulation 17 of the 2014 Regulations or the competent authority returns a notification under regulation 24(6) of the 2014 Regulations.”;

- (d) in paragraph (3) in both instances, for “2000” substitute “ 2014 ”.

(3) In regulation 24(16)(b) for “2000” substitute “ 2014 ”.

(4) In Schedule 10—

- (a) in the heading, for “2000” substitute “ 2014 ”;
- (b) in column 1 of the table—
 - (i) for paragraph (a) substitute “ Notification of premises to be used for contained use for the first time under regulation 9(2) ”;
 - (ii) for paragraph (b) substitute “ Notification of class 2 contained use under regulation 10(2) ”;
 - (iii) for paragraph (c) substitute “ Notification of premises to be used for contained use for the first time under regulation 9(2) at the same time as notification of class 2 contained use under regulation 10(2) ”;
 - (iv) for paragraph (d) substitute “ Notification of class 3 contained use under regulation 11(2) ”;
 - (v) for paragraph (e) substitute “ Notification of premises to be used for contained use for the first time under regulation 9(2) at the same time as notification of class 3 contained use under regulation 11(2) ”;
 - (vi) for paragraph (f) substitute “ Notification of class 4 contained use under regulation 11(2) ”;
 - (vii) for paragraph (g) substitute “ Notification of premises to be used for contained use for the first time under regulation 9(2) at the same time as notification of class 4 contained use under regulation 11(2) ”;
 - (viii) for paragraph (h) substitute “ Notification of contained use under regulation 12(2) ”;
 - (ix) for paragraph (i) substitute “ Notification of premises to be used for contained use for the first time under regulation 9(2) at the same time as notification of contained use under regulation 12(2) ”;

Changes to legislation: There are currently no known outstanding effects for the The Genetically Modified Organisms (Contained Use) Regulations 2014, PART 5. (See end of Document for details)

- (x) for paragraph (j) substitute “ Notification of a change or new information affecting risks under regulation 15(1) ”;
- (xi) in paragraph (k) for “18(2)” substitute “19(2)” and for “9(1), 10(1), 11(1) or 12(1)” substitute “ 9(2), 10(2), 11(2) or 12(2) ”.

Marginal Citations

M5 [S.I. 2012/1652](#) as amended by [S.I. 2013/448](#), 2013/1512 and 2013/1948.

Revocations

35. The following are revoked—

- (a) the 2000 Regulations;
- (b) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002 ^{M6};
- (c) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005 ^{M7};
- (d) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010 ^{M8}.

Marginal Citations

M6 [S.I. 2002/63](#).

M7 [S.I. 2005/2466](#).

M8 [S.I. 2010/2840](#).

Changes to legislation:

There are currently no known outstanding effects for the The Genetically Modified Organisms (Contained Use) Regulations 2014, PART 5.