STATUTORY INSTRUMENTS

2014 No. 1663

The Genetically Modified Organisms (Contained Use) Regulations 2014

PART 1

Interpretation and General

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) Regulations 2014 and come into force on 1st October 2014.

Interpretation

2.—(1) In these Regulations—

"the 1974 Act" means the Health and Safety at Work etc. Act 1974;

"the 2000 Regulations" means the Genetically Modified Organisms (Contained Use) Regulations 2000 [M1];

"accident" means an incident involving a significant and unintended release of genetically modified organisms in the course of a contained use which presents an immediate or delayed hazard to human health or to the environment;

"class" in relation to a contained use involving micro-organisms, means one of the four classes set out in Schedule 1;

"competent authority" means, in relation to premises situated in, or contained use taking place in—

(a) England and Wales, the Secretary of State and the Executive, acting jointly; or

(b) Scotland, the Scottish Ministers and the Executive, acting jointly,

and the expressions "competent authority as regards England and Wales" and "competent authority as regards Scotland" are to be construed accordingly;

"contained use" means an activity in which organisms are genetically modified or in which genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers, or any combination of such barriers, are used to limit their contact with, and to provide a high level of protection for, humans and the environment;

"emergency plan" means a plan required by regulation 21;

"emergency services" means the police, fire and ambulance services;

"genetic modification" in relation to an organism means the altering of the genetic material in that organism in a way that does not occur naturally by mating or natural recombination (or both) and within the terms of this definition—

(a) genetic modification occurs at least through the use of the techniques listed in Part 1 of Schedule 2; and

(b) the techniques set out in Part 2 of Schedule 2 are not considered to result in genetic modification,

and "genetically modified" is to be construed accordingly;

"joint competent authority" means the competent authority as regards England and Wales and the competent authority as regards Scotland acting jointly;

"larger GMO" means an organism which is genetically modified or is the subject of genetic modification which is not a micro-organism;

"micro-organism" means a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, and includes a virus, a viroid, and an animal or plant cell in culture;

"notifier" means, except in regulation 14, the person who submits or has submitted a notification to the competent authority under regulation 9(2), 10(2), 11(2), 12(2) or 33(3);

"organism" means a biological entity capable of replication or of transferring genetic material and includes a micro-organism, but does not include a human, human embryo or human admixed embryo and for the purposes of this definition—

(a) "human admixed embryo" has the same meaning as in the Human Fertilisation and Embryology Act 1990 [M2] by virtue of section 4A(6) and (11) of that Act; and

(b) "human embryo" has the same meaning as "embryo" in the Human Fertilisation and Embryology Act 1990 (apart from section 4A) by virtue of section 1(1) and (6) of that Act;

"person responsible for contained use" or "person responsible for the contained use" means—

(a) a person who has the authority to determine whether a particular contained use takes place; or

(b) a person who has control of the planning or conduct (or both) of that contained use,

and there may be more than one person responsible for the same contained use;

"premises" means both single buildings and a site made up of more than one building;

"risk assessment" means, in the context of contained use involving—

(a) genetically modified micro-organisms, an assessment carried out as required by regulation 5(1); or

(b) larger GMOs, an assessment carried out as required by regulation 6(1);

"transboundary movement" has the meaning assigned to it by Article 3 of Regulation (EC) No 1946/2003 of the European Parliament and the Council on transboundary movements of genetically modified organisms [M3];

"user" means a person who undertakes or proposes to undertake a contained use;

"working day" means any day other than a Saturday, a Sunday, Christmas Day or Good Friday, or a bank holiday specified in Schedule 1 to the Banking and Financial Dealings Act 1971 [M4].

(2) A reference in these Regulations to the competent authority is to be construed as a reference to the joint competent authority in relation to premises or contained use where the relevant notification is required to be submitted to the joint competent authority in accordance with regulation 9(5) or 13(1).

(3) In these Regulations—

(a) a reference to an appropriate containment level is a reference to the containment level assigned to a contained use involving micro-organisms in accordance with paragraphs 3(i) and 4 of Part 2 of Schedule 3;

(b) any reference to a contained use in a numbered class is a reference to a contained use involving micro-organisms which has been classified as belonging to the class of that number in accordance with paragraph 3(j) and (k) of Part 2 of Schedule 3.

(4) The measures in—

(a) Part 2 of Schedule 8 are to be applied in accordance with Part 1 of that Schedule; and

(b) Tables 1a, 1b and 1c in Part 2 of Schedule 8 are to be applied in accordance with the notes set out at the end of the table in question.

Marginal Citations

M1 S.I. 2000/2831. The 2000 Regulations and all its amending instruments are revoked by these Regulations (see regulation 35).

M2 1990 c. 37. Sections 1(1) and (6) were substituted by section 1(2) and (5) of the Human Fertilisation and Embryology Act 2008 (c. 22) and section 4A was inserted by section 4(2) of that Act.

M3 OJ No L 287, 5.11.2003, p1.

M4 1971 c. 80. Schedule 1 was amended by section 1 of the St Andrew's Day Bank Holiday (Scotland) Act 2007 (2007 asp.2).

Application

3.—(1) These Regulations (except regulation 18) do not apply to the genetic modification of organisms solely by any of the techniques referred to in Part 3 of Schedule 2 nor to any organisms so modified.

(2) These Regulations do not apply to any activity in which—

(a) genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used, where such organisms are, or are contained in, a product marketed in accordance with—

(i) the consent of any of the following granted under section 111(1) of the Environmental Protection Act 1990 [M5]—

(aa) the Secretary of State;

(bb) the Scottish Ministers, as regards Scotland;

(cc) the Welsh Ministers, as regards Wales;

(ii) a consent granted by the Northern Ireland Department of the Environment under article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991 [M6];

[F1](iii) . . . . . .

and, in each case, that activity is conducted in accordance with any conditions or limitations attached to that consent;

(b) genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used, where such organisms are, or are contained in—

[[F2](i) a medicinal product for veterinary use marketed in accordance with the Veterinary Medicines Regulations 2013;**][**[F3]or**]**

(ii) food or feed authorised in accordance with the provisions of Regulation (EC) No 1829/2003 of the European Parliament and the Council on genetically modified food and feed [M7][F4]...

[F5](iii) . . . . . [[F6]; or

(iv) a medicinal product for human use marketed in accordance with the Human Medicines Regulations 2012;]

(c) genetically modified organisms are released or marketed in cases or circumstances in which—

(i) the consent of any of the following is required under section 111(1) of the Environmental Protection Act 1990—

(aa) the Secretary of State;

(bb) the Scottish Ministers, as regards Scotland;

(cc) the Welsh Ministers, as regards Wales; or

(ii) the consent of the Northern Ireland Department of the Environment is required under article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991.

(3) Regulations 7, 9 to 17, 18(2) and (4), 19, 20, and 23 to 25 do not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

(4) Regulation 5 applies to the transport of genetically modified organisms by road, rail, inland waterway, sea or air, except that, in making the assessment required by regulation 5(1), the person undertaking that assessment is not required to include the steps set out in paragraph 3(i) to (k) of Part 2 of Schedule 3.

(5) These Regulations do not extend to Northern Ireland.

(6) In this regulation, "product" means a product consisting of, or containing, a genetically modified organism or a combination of genetically modified organisms.

Textual Amendments

F1 Reg. 3(2)(a)(iii) omitted (31.12.2020) by virtue of 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(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Reg. 3(2)(b)(i) substituted (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(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Word in reg. 3(2)(b)(i) inserted (31.12.2020) by The Health and Safety (Amendment) (EU Exit) Regulations 2018 (S.I. 2018/1370), regs. 1(1), **9(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F4 Words in reg. 3(2)(b)(ii) omitted (31.12.2020) by virtue of The Health and Safety (Amendment) (EU Exit) Regulations 2018 (S.I. 2018/1370), regs. 1(1), **9(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Reg. 3(2)(b)(iii) omitted (31.12.2020) by virtue of The Health and Safety (Amendment) (EU Exit) Regulations 2018 (S.I. 2018/1370), regs. 1(1), **9(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Reg. 3(2)(b)(iv) and word inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 12**; 2020 c. 1, Sch. 5 para. 1(1)

Marginal Citations

M5 1990 c. 43. The functions of the Secretary of State under section 111(1) are exercisable in relation to Scotland by the Scottish Ministers, by virtue of section 53 of the Scotland Act 1998 (c. 46). The functions of the Secretary of State under section 111(1) are exercisable in relation to Wales by the Welsh Ministers. Those functions were originally conferred on the National Assembly for Wales under S.I. 1999/672, which was an Order in Council made under section 22 of the Government of Wales Act

1998 (c. 38). Functions which had been conferred on the Assembly under an Order in Council under section 22 were transferred to the Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32).

M6 S.I. 1991/1714 (N.I.19).

M7 OJ No L 268 18.10.2003, p1 as amended by Regulation (EC) No 1981/2006 (OJ No L 368, 23.12.2006, p[99) and Regulation (EC) No 298/2008 (OJ No L 97 9.4.2008, p64).

Meaning of "work" and "at work" and modification of the 1974 Act

4.—(1) For the purpose of these Regulations and Part 1 of the 1974 Act, the meaning of "work" is extended to include any contained use and the meaning of "at work" is extended accordingly.

(2) Sections 2(1), (2) and (3) and 7 of the 1974 Act are modified in relation to contained use as follows—

(a) those sections have effect as if a reference to—

(i) an employer includes a reference to an educational establishment providing a course of study; and

(ii) an employee includes a reference to a student undertaking contained use in that educational establishment to the extent that the contained use is under the control of that educational establishment.

(3) Section 3(2) of the 1974 Act is modified in relation to contained use so as to have effect as if the reference in that section—

(a) to a self-employed person **[**F7who conducts an undertaking of a prescribed description**]** were a reference to any person (except a student) undertaking contained use who is not an employer or an employee; and

(b) to **[**F8the undertaking**]** includes a reference to that contained use.

(4) In this regulation—

"educational establishment" means a university, college, school or similar educational or technical institute; and

"student" means any person studying at an educational establishment.

Textual Amendments

F7 Words in reg. 4(3)(a) inserted (1.10.2015) by The Deregulation Act 2015 (Health and Safety at Work) (General Duties of Self-Employed Persons) (Consequential Amendments) Order 2015 (S.I. 2015/1637), art. 1, **Sch. para. 12(a)**

F8 Words in reg. 4(3)(b) substituted (1.10.2015) by The Deregulation Act 2015 (Health and Safety at Work) (General Duties of Self-Employed Persons) (Consequential Amendments) Order 2015 (S.I. 2015/1637), art. 1, **Sch. para. 12(b)**

PART 2

Risk Assessment and Notification of Contained Use

Risk assessment of contained use involving micro-organisms

5.—(1) Before any contained use involving micro-organisms is commenced, a person responsible for the contained use must ensure that a suitable and sufficient assessment of the risks to human health and the environment created by the contained use is carried out.

(2) The assessment required by paragraph (1) must take into account the matters set out in Part 1, and include the steps set out in Part 2, of Schedule 3.

Risk assessment of contained use involving larger GMOs

6.—(1) Before any contained use involving larger GMOs is commenced, a person responsible for the contained use must ensure that a suitable and sufficient assessment of the risks to human health created by the contained use is carried out.

(2) The assessment required by paragraph (1) must take into account the matters set out in Part 1, and include the steps set out in Part 2, of Schedule 4.

Review and recording of risk assessments

7.—(1) A person responsible for contained use must ensure that the risk assessment is reviewed immediately where—

(a) there is reason to suspect that the risk assessment is no longer valid; or

(b) there has been a significant change in the contained use to which the risk assessment relates.

(2) A person responsible for contained use must—

(a) keep a record of the risk assessment and any review of the risk assessment, for at least 10 years from the date the contained use stops; and

(b) make the record available to the competent authority when requested to do so.

Advice from a genetic modification safety committee

8.—(1) Subject to paragraph (2), a person responsible for contained use must obtain advice on a risk assessment from either—

(a) a person; or

(b) a genetic modification safety committee,

with expertise in risk assessment relating to contained use.

(2) Where the risk assessment indicates that the contained use is classified as class 2 or above the advice must be obtained from a genetic modification safety committee.

Notification of premises to be used for contained use

9.—(1) A user must not use premises for contained use unless the premises have been notified to the competent authority in accordance with this regulation.

(2) Before premises are used for contained use for the first time, a person responsible for the contained use must—

(a) submit a notification to the competent authority containing the information specified in Schedule 5; and

(b) have received an acknowledgement of receipt of the notification from the Executive.

(3) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) A single notification may include more than one premises.

(5) Where a notification includes more than one premises and at least one of those premises is situated in England or Wales and at least one of those premises is situated in Scotland the notification must be submitted to the joint competent authority.

(6) The notifier must nominate one address which is to be the principal address for the purposes of a notification under paragraph (4) or (5).

Notification of class 2 contained use

10.—(1) A user must not undertake a contained use involving micro-organisms classified as class 2 unless the provisions of this regulation have been complied with.

(2) A person responsible for the contained use must submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) Where the premises in the notification have not previously been notified for class 2 or a higher class of contained use, a user may undertake the class 2 contained use if—

(a) 45 days have elapsed since the acknowledgement of receipt was received, provided that the competent authority has not informed the notifier that the class 2 contained use may not be undertaken; or

(b) the competent authority has agreed in writing that the class 2 contained use may commence sooner.

(5) Where the premises in the notification have—

(a) previously been notified for class 2 contained use; or

(b) already been granted consent for class 3 or class 4 contained use,

a user may undertake the class 2 contained use if the notifier has received the acknowledgement of receipt.

(6) Where a notifier submits a notification for a class 2 contained use which is to be undertaken for the second or subsequent time at the premises in the notification, the notifier may request that the competent authority provide a written agreement that the contained use may be undertaken.

(7) The competent authority must make a decision and, if they agree, provide the written agreement requested under paragraph (6), within 45 days of the date on which the acknowledgement of receipt was sent to the notifier.

Notification of class 3 or class 4 contained use

11.—(1) A user must not undertake a contained use involving micro-organisms classified as class 3 or class 4 unless written consent for that contained use has been granted by the competent authority.

(2) A person responsible for the contained use must submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) Where the premises in the notification have not previously been notified for class 3 or class 4 contained use, the competent authority must inform the notifier, in writing, of its decision to grant or refuse consent for the class 3 or class 4 contained use, within 90 days of the date on which the acknowledgement of receipt was sent to the notifier.

(5) Where the premises in the notification have previously been notified for class 3 or class 4 contained use and all relevant conditions of existing consents have been complied with, the competent authority must inform the notifier, in writing, of its decision to grant or refuse consent for the class 3 or class 4 contained use, within 45 days of the date on which the acknowledgement of receipt was sent to the notifier.

(6) Before granting consent, the competent authority must ensure that an emergency plan has been prepared where the risk assessment shows an emergency plan is required.

(7) Before deciding whether to grant or refuse consent, the competent authority must take into account any representations made to it by any person within 30 days of the date on which the acknowledgement of receipt was sent to the notifier.

(8) A consent granted under this regulation may be granted subject to conditions.

Notification of contained use involving larger GMOs

12.—(1) A user must not undertake a contained use involving larger GMOs unless the provisions of this regulation have been complied with.

(2) A person responsible for the contained use must submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) A user may undertake the contained use if—

(a) 45 days have elapsed since the acknowledgement of receipt was received, provided that the competent authority has not informed the notifier that the contained use may not be undertaken; or

(b) the competent authority has agreed in writing that the contained use may commence sooner.

(5) This regulation does not apply to a contained use which results in a larger GMO that poses no greater risk to humans than its unmodified parental organism.

Single notifications to the joint competent authority and for connected programmes of work

13.—(1) Where a notification is required under regulation 10(2), 11(2) or 12(2) in respect of a contained use which is to take place in premises that fall within regulation 9(5) the notifier must submit the notification for that contained use to the joint competent authority.

(2) A competent authority, or where paragraph (1) applies the joint competent authority, may accept a single notification submitted under regulation 10(2), 11(2) or 12(2) in respect of a connected programme of work undertaken at—

(a) one premises; or

(b) more than one premises.

(3) A competent authority, or where paragraph (1) applies the joint competent authority, may accept a single notification submitted under regulation 10(2), 11(2) or 12(2) in respect of a single contained use undertaken at more than one premises.

(4) In this regulation—

"connected programme of work" means a series of activities involving contained use which form a coherent and integrated programme.

Changes of circumstances relating to notifications

14.—(1) Full details in writing must be sent immediately to the competent authority of—

(a) any change in the information specified in paragraph (a), (d) or (e) of Schedule 5 in relation to premises previously notified in accordance with regulation 9(2);

(b) any new building—

(i) added to premises previously notified in accordance with regulation 9(2); and

(ii) under the notifier's control;

(c) premises notified under regulation 9(2) that will no longer be used for contained use;

(d) any cessation, for the time being, of all contained use at premises notified under regulation 9(2);

(e) any cessation of a contained use notified in accordance with regulation 10(2), 11(2) or 12(2);

(f) any recommencement of contained use at premises in respect of which the notifier had previously given details of a cessation under sub-paragraph (d);

(g) any use of additional premises in connection with a single contained use where a single notification for that contained use was accepted by the competent authority under regulation 13(3);

(h) any change in the information specified in paragraph (b) or (c) of Schedule 5 as provided by the original notifier in accordance with regulation 9(2);

(i) any change in the information specified in paragraph (c) or (d) of Schedule 6 as provided by the original notifier in accordance with regulation 10(2), 11(2) or 12(2).

(2) Where—

(a) a notifier has informed the competent authority of additional premises under paragraph (1)(g); and

(b) that information, taken together with the notification for that single contained use accepted under regulation 13(3), provides all the information required for notification of those premises under regulation 9(2),

the provision of that information will be treated as notification of those premises for the purposes of regulation 9(2).

(3) The details required by paragraph (1) must be provided by—

(a) the original notifier;

(b) a person responsible for the premises notified under regulation 9(2); or

(c) a person responsible for the contained use notified under regulation 10(2), 11(2) or 12(2).

(4) In this regulation—

"notifier" means the person who sends the details required by paragraph (1) to the competent authority; and

"original notifier" means the person who submitted the notification of the premises under regulation 9(2) or the contained use under regulation 10(2), 11(2) or 12(2).

Duty to notify significant changes affecting risks

15.—(1) Where, after submitting a notification, a notifier—

(a) makes a change in the premises or the contained use to which the notification relates which may have significant consequences for the risks arising from the contained use; or

(b) becomes aware of any new information which may have significant consequences for the risks arising from the contained use,

the notifier must immediately send to the competent authority full details in writing of the change or the new information.

(2) As long as the change or new information does not affect the class of the contained use, the notifier need not submit a further notification under regulation 10(2), 11(2) or 12(2), and the change or new information will be treated as a modification of the original notification.

Action of notifier and user on receipt of request for additional information

16.—(1) If additional information relating to a notification is requested by the Executive under regulation 24(1), a user must not commence the contained use that is the subject of the notification until the competent authority has given its approval in writing.

(2) Subject to paragraphs (3) and (4), if the contained use has commenced before the Executive requests additional information, a user may not continue the contained use until the competent authority has given its approval in writing.

(3) The Executive may give the notifier instructions concerning the cessation of the contained use and the notifier and any user undertaking the contained use must comply with the instructions.

(4) Subject to any instructions, the notifier or user may continue the contained use only to the extent necessary to store or destroy all genetically modified organisms resulting from the contained use.

Withdrawal of notification

17. A notifier may withdraw a notification by giving written notice to the competent authority, provided that the contained use to which the notification related has not commenced.

PART 3

Conduct of Contained Use

Principles of occupational and environmental safety

18.—(1) A user who undertakes a contained use involving micro-organisms must ensure that the risks to human health and the environment arising from the contained use are reduced to the lowest level that is reasonably practicable.

(2) The measures to be taken in order to comply with the duty under paragraph (1) must include the general principles of good microbiological practice and of good occupational safety and hygiene set out in Schedule 7.

(3) A user who undertakes a contained use involving larger GMOs must ensure that the risks to human health arising from the contained use are reduced to the lowest level that is reasonably practicable.

(4) For contained use involving larger GMOs, the general principles set out in Schedule 7 must be applied to the extent that they are appropriate.

Containment and control measures for contained use involving micro-organisms

19.—(1) A user who undertakes a contained use involving micro-organisms must apply the containment measures set out in the applicable table in Part 2 of Schedule 8, where and to the extent required in the column of the appropriate containment level.

(2) A user need not apply a containment measure required for the appropriate containment level where—

(a) the risk assessment, or any review of the risk assessment, shows that the containment measure is not necessary or practicable for a specific activity;

(b) the notifier of the contained use has provided justification in writing to the competent authority; and

(c) the notifier has received the written agreement of the competent authority that the containment measure need not be applied.

(3) A person responsible for the contained use must review the containment measures applied—

(a) at suitably regular intervals; and

(b) immediately, if that person suspects that—

(i) the containment measures are no longer adequate;

(ii) the class assigned to the contained use in the risk assessment is no longer appropriate; or

(iii) in the light of new scientific or technical knowledge, the risk assessment is no longer valid.

Containment and control measures for contained use involving larger GMOs

20.—(1) A user who undertakes a contained use involving larger GMOs must apply the containment measures selected in the risk assessment for the contained use.

(2) A person responsible for the contained use must review the containment measures applied—

(a) at suitably regular intervals; and

(b) immediately, if that person suspects that—

(i) the containment measures are no longer adequate; or

(ii) in the light of new scientific or technical knowledge, the risk assessment is no longer valid.

Emergency plans

21.—(1) Where an assessment carried out under regulation 5(1) shows that, as a result of any reasonably foreseeable accident—

(a) the health or safety of persons outside the premises in which the contained use is undertaken is liable to be seriously affected; or

(b) there is a risk of serious damage to the environment from the contained use,

a person responsible for the contained use must ensure that, before the contained use commences, a suitable emergency plan is prepared with a view to securing the health and safety of those persons or the protection of the environment or both.

(2) Where an assessment carried out under regulation 6(1) shows that, as a result of any reasonably foreseeable accident, the health or safety of persons outside the premises in which the contained use is undertaken is liable to be seriously affected, a person responsible for the contained

use must ensure that, before the contained use commences, a suitable emergency plan is prepared with a view to securing the health and safety of those persons.

(3) An emergency plan must—

(a) include the measures to be taken in the event of an accident to which the plan relates; and

(b) be reviewed and, where necessary, revised at suitably regular intervals.

(4) A person responsible for the contained use which is the subject of an emergency plan must—

(a) inform the emergency services, and any body or authority liable to be affected by an accident to which the plan relates, of the contents of the plan and of any relevant revisions; and

(b) make information about the plan and any such revisions publicly available.

Information relating to accidents

22. If an accident occurs, a person responsible for the contained use must immediately inform the competent authority of the accident and must provide the following information—

(a) the circumstances of the accident;

(b) the identity and quantity of the genetically modified organisms concerned;

(c) any information necessary to assess the effects of the accident on the health of the general population and, in the case of a genetically modified micro-organism, on the environment; and

(d) any measures taken in response to the accident.

PART 4

Duties and Powers of the Competent Authority

Duties of competent authority on receiving a notification

23. The competent authority must examine a notification and accompanying documentation submitted under regulation 9(2), 10(2), 11(2) or 12(2) for—

(a) conformity with the requirements of these Regulations;

(b) the accuracy and completeness of the information provided;

(c) the adequacy and correctness of the risk assessment or summary of the risk assessment;

(d) the adequacy of the waste management and emergency response measures;

(e) in the case of a notification submitted under regulation 10(2) or 11(2), the correctness of the class assigned to the contained use; and

(f) the inclusion of an emergency plan where the risk assessment indicates that such a plan is necessary.

Requests for additional information

24.—(1) For the purpose of carrying out an examination of a notification in accordance with regulation 23 the Executive may, on behalf of the competent authority, request the notifier to provide such additional information relating to the notification as it may specify.

(2) If requested to do so by the Secretary of State or the Scottish Ministers, the Executive must request additional information under paragraph (1).

(3) A request for additional information must be made in writing.

(4) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of receipt of all of the additional information.

(5) The period of time beginning with the date on which the Executive requests additional information and ending with the date on which the Executive receives all of that additional information 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).

(6) The competent authority may return a notification to the notifier where—

(a) the Executive has requested additional information;

(b) the notifier has not provided all the additional information requested within six months of the date on which the Executive sent the request; and

(i) contained use has not commenced at the premises to which a notification made under regulation 9(2) relates; or

(ii) the contained use referred to in the notification has not commenced.

Powers of competent authority in relation to contained use

25. The competent authority may at any time by notice in writing to a notifier—

(a) set a time limit for, or impose conditions with regard to, a particular contained use;

(b) require the notifier and any user to suspend, terminate or not to commence a particular contained use;

(c) revoke or vary a consent granted to the notifier under regulation 11,

and the notifier and any user undertaking the contained use must comply with that notice.

Exemption certificates

26.—(1) A competent authority may, by a certificate in writing, exempt—

(a) any person or class of persons; or

(b) any genetically modified organism or class of genetically modified organisms,

from all or any of the requirements of, or prohibitions imposed by, these Regulations.

(2) An exemption may be granted subject to conditions and to a time limit and may be revoked by a certificate in writing at any time.

(3) A competent authority must not grant an exemption unless, having regard to the circumstances of the case and in particular to—

(a) the conditions, if any, that it proposes to attach to the exemption; and

(b) any relevant requirements imposed by or under any enactments,

it is satisfied about the matters referred to in paragraph (4).

(4) The matters are—

(a) that the health or safety of persons who are likely to be affected by the exemption will not be prejudiced in consequence of it; and

(b) where the exemption relates to a contained use involving a micro-organism, that the environment will not be prejudiced in consequence of the exemption.

Duties of competent authority on receipt of information about accidents

27. Where the competent authority is informed of an accident in accordance with regulation 22, it must—

(a) ensure that any necessary measures are taken; **[**F9and**]**

F10(b) . . . . . .

(c) collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit their effects F11...

F12(d) . . . . . .

Textual Amendments

F9 Word in reg. 27(a) inserted (31.12.2020) by The Health and Safety (Amendment) (EU Exit) Regulations 2018 (S.I. 2018/1370), regs. 1(1), **9(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F10 Reg. 27(b) omitted (31.12.2020) by virtue of The Health and Safety (Amendment) (EU Exit) Regulations 2018 (S.I. 2018/1370), regs. 1(1), **9(3)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F11 Word in reg. 27(c) omitted (31.12.2020) by virtue of The Health and Safety (Amendment) (EU Exit) Regulations 2018 (S.I. 2018/1370), regs. 1(1), **9(3)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F12 Reg. 27(d) omitted (31.12.2020) by virtue of The Health and Safety (Amendment) (EU Exit) Regulations 2018 (S.I. 2018/1370), regs. 1(1), **9(3)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

Register of notifications

28.—(1) This regulation is subject to regulation 29.

(2) The competent authority must maintain a register of every notification submitted under regulations 9 to 12.

(3) Subject to paragraph (4) the register must contain—

(a) in relation to each notification submitted under regulation 9(2), 10(2), 11(2) or 12(2)—

(i) the name, address and telephone number and any fax number and any e-mail address of the notifier;

(ii) the date on which the Executive acknowledged receipt of the notification; and

(iii) where the competent authority receives details of a matter referred to in sub-paragraphs (a) to (g) of regulation 14(1), or in regulation 15(1), confirmation that such details have been received;

(b) in relation to each notification submitted under regulation 10(2), 11(2) or 12(2), the date of any cessation of the contained use to which the notification related;

(c) in relation to each notification submitted under regulation 9(2)—

(i) the information specified in paragraphs (d) to (g) and (h)(ii) and (iii) of Schedule 5;

(ii) if applicable, the fact that the competent authority has been informed of an accident at those premises under regulation 22;

(d) in relation to each notification submitted under regulation 10(2), the information specified in paragraphs (e) to (k) and (m)(i) and (ii) of Schedule 6;

(e) in relation to each notification submitted under regulation 11(2)—

(i) the information specified in paragraphs (e) to (j), (1), (m)(i),(iii) and (iv) and (r) of Schedule 6;

(ii) if applicable, confirmation that consent for the contained use has been granted under regulation 11(4) or 11(5);

(f) in relation to each notification submitted under regulation 12(2), the information specified in paragraphs (e) to (j) and (m)(i) of Schedule 6.

(4) The competent authority must omit information from the register where—

(a) the information falls within one of the exceptions to disclosure in—

(i) regulation 12(5) or 13(1) of the Environmental Information Regulations 2004 [M8]; or

(ii) regulation 10(5) or 11(1) of the Environmental Information (Scotland) Regulations 2004 [M9];

(b) the notifier has requested that the competent authority treat the information as confidential; and

(c) the competent authority has decided that the information is to be kept confidential.

(5) The competent authority may not keep the following information confidential if it was submitted in accordance with the requirements of regulation 9(2), 10(2) or 11(2)—

(a) the general characteristics of any genetically modified micro-organisms, the name and address of the notifier, and the location of use;

(b) the class of contained use and the containment measures;

(c) the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.

(6) Information must be entered in the register within 14 days of its receipt by the competent authority.

(7) The competent authority may remove from the register details of—

(a) premises which are no longer used for contained use, ten years after being informed of this under regulation 14(1)(c);

(b) premises where all contained use has ceased for the time being, ten years after being informed of this under regulation 14(1)(d), provided that no notice of recommencement under regulation 14(1)(f) has been received;

(c) a contained use that has ceased, ten years after being informed of this under regulation 14(1)(e).

(8) A copy of the register must be made available for inspection to members of the public by the Executive, by such means as it considers appropriate, which may include publication on its website.

Marginal Citations

M8 S.I. 2004/3391.

M9 S.S.I. 2004/520.

Information not to be included in the register

29.—(1) No information may be included in the register if and so long as, in the opinion of the Secretary of State, the inclusion in the register of that information, or information of that description, would be contrary to the interests of national security.

(2) For the purpose of securing the exclusion from the register of information to which paragraph (1) applies, the Secretary of State may give the competent authority directions—

(a) specifying information, or descriptions of information, to be excluded from the register; or

(b) specifying descriptions of information to be referred to the Secretary of State for his or her determination.

(3) No information referred to the Secretary of State under paragraph (2)(b) may be included in the register unless the Secretary of State determines that it should be included.

(4) The competent authority must notify the Secretary of State of any information it excludes from the register in accordance with directions given to it under paragraph (2).

(5) A person may give a written notice to the Secretary of State specifying information which appears to that person to be information to which paragraph (1) may apply and stating why it should not be included in the register.

(6) If a person gives a written notice under paragraph (5), at the same time that person must give written notice to the competent authority that they have done so.

(7) No information notified under paragraph (5) may be included in the register unless the Secretary of State determines that it should be included.

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 [M10] (approved codes of practice and enforcement) and sections 33 to 42 [M11] (provisions as to offences) of the 1974 Act; and

(b) the Health and Safety (Training for Employment) Regulations 1990 [M12].

(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 [M13], the enforcing authority for these Regulations is the Executive.

Marginal Citations

M10 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.

M11 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.

M12 S.I. 1990/1380.

M13 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.

[F13Transitional 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.**]**

Textual Amendments

F13 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 [M14] 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) ";

(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

M14 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 [M15];

(c) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005 [M16];

(d) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010 [M17].

Marginal Citations

M15 S.I. 2002/63.

M16 S.I. 2005/2466.

M17 S.I. 2010/2840.

Signed by authority of the Secretary of State for Work and Pensions

Mike Penning
Minister of State

Department for Work and Pensions

Changes to legislation:
There are currently no known outstanding effects for the The Genetically Modified Organisms (Contained Use) Regulations 2014.