STATUTORY RULES OF NORTHERN IRELAND

2015 No. 339

HEALTH AND SAFETY

The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015

Made - - - - *18th September 2015*

Coming into operation - *23rd October 2015*

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The Department of Enterprise, Trade and Investment ("the Department")(**a**), is designated for the purposes of section 2(2) of the European Communities Act 1972 ("the 1972 Act")(**b**) in relation to the control and regulation of genetically modified organisms(**c**).

The Department, being the Department concerned(**d**) makes the following Regulations in exercise of the powers conferred by section 2(2) of the 1972 Act and Articles 2(5), 17(1)to (5)(**e**), 40(2), 40(4), 54(1) and (2) and 55(2) of, and paragraphs 1(1), (2), (3), (4) and (5), 2, 3(1), 4, 5, 7(2), 8, 10, 12(1) and (3), 13, 14(1), 15, 16 and 19 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978(**f**)("the 1978 Order").

The Regulations give effect without modifications to proposals submitted to the Department by the Health and Safety Executive for Northern Ireland under Article 13(1A)(**g**) of the 1978 Order after the Executive had carried out consultations in accordance with Article 46(3)(**h**) of the 1978 Order.

PART 1

Interpretation and General

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015 and shall come into operation on 23rd October 2015.

Interpretation

2.—(1) In these Regulations—

"the 1978 Order" means the Health and Safety at Work (Northern Ireland) Order 1978;

"the 2001 Regulations" means the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001(**i**);

"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 the Department of the Environment and the Executive, acting jointly;

"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

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(**a**) Formerly the Department of Economic Development; *see* S.I. 1999/283 (N.I. 1), Article 3(5); that Department was formerly the Department of Manpower Services; *see* S.I. 1982/846 (N.I.11), Article 3
(**b**) 1972 c.68
(**c**) S.I. 1991/755
(**d**) *See* Article 2(2) of S.I. 1978/1039 (N.I. 9)
(**e**) Article 17 shall be read with S.I. 1992/1728 (N.I.17), Articles 3(2) and 4(2)
(**f**) S.I. 1978/1039 (N.I. 9); the general purposes of Part II referred to in Article 17(1) were extended by S.I. 1992/1728 (N.I. 17), Articles 3(1) and 4(1). Article 55(2) was amended by S.I. 1998/2795 (N.I. 18), Article 6(1) and Schedule 1, paragraph 19
(**g**) Article 13(1A) was substituted by S.I. 1998/2795 (N.I. 18), Article 4
(**h**) Article 46(3) was amended by S.I. 1998/2795 (N.I. 18), Article 6(1) and Schedule 1, paragraphs 8 and 18 and the Health Protection Agency Act 2004 (c.17), section 11 and Schedule 3 paragraph 10
(**i**) S.R. 2001 No.295. The 2001 Regulations and all amending instruments are revoked by these Regulations (see regulation 36).

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;

"the Executive" means the Health and Safety Executive for Northern Ireland;

"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;

"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 purpose of this definition—

(a) "human admixed embryo" has the same meaning as in the Human Fertilisation and Embryology Act 1990(**a**) 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(**b**);

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

(**a**) 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.

(**b**) OJ No L 287 5.11.2003, p. 1.

"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(**a**).

(2) 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.

(3) 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.

(4) The Interpretation Act (Northern Ireland) 1954(**b**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Application

3.—(1) These Regulations (except regulation 18) shall 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 shall 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(**c**)—

(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 Department of the Environment under Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991(**d**), or

(iii) a written consent given by the 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 the Council on the deliberate release into the environment of genetically modified organisms(**e**),

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

(**a**) 1971 c.80

(**b**) 1954 c.33 (N.I.)

(**c**) 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).

(**d**) S.I. 1991/1714 (N.I. 19)

(**e**) OJ No L 106, 17.04.2001, p1. Under Article 4.4 member States must designate a competent authority responsible for complying with the requirements of the Directive.

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

(i) a medicinal product for human or veterinary use marketed in accordance with 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(**a**);

(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(**b**); or

(iii) food products notified to the Commission in accordance with the provisions of Article 8.1, or feed products notified to the Commission in accordance with the provisions of Article 20.1, of Regulation (EC) No 1829/2003 of the European Parliament and the Council;

(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 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 shall not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

(4) Regulation 5 shall apply 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 shall not be required to include the steps set out in paragraph 3(i) to (k) of Part 2 of Schedule 3.

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

Meaning of "work" and "at work" and modification of the 1978 Order

4.—(1) For the purpose of these Regulations and Part I of the 1978 Order, the meaning of "work" shall be extended to include any contained use and the meaning of "at work" shall be extended accordingly.

(2) Articles 4(1), (2) and (3) and 8 of the 1978 Order shall be modified in relation to contained use as follows—

(a) those Articles 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.

(**a**) OJ No L 136, 30.4.2004, p. 1 as amended by Regulation (EC) No 1901/2006 (OJ No L378 27.12.2006 p. 1), Regulation (EC) No 1394/2007 (OJ No L 324 , 10.12.2007 , p. 121), Regulation (EC) No 219/2009 (OJ No L87 31.3.2009, p. 109), Regulation (EC) No 470/2009 (OJ No L 152, 16.6.2009, p. 11), Regulation (EU) No 1235/2010 (OJ No L348, 31.12.2010, p 1) (which was corrected by Corrigendum, OJ No L 201, 27.7.2012, p 138) and Regulation (EU) No 1027/2012 (OJ No L 316, 14.11.2012, p38).

(**b**) OJ No L268 18.10.2003, p 1 as amended by Regulation (EC) No 1981/2006 (OJ No L368, 23.12.2006 p 99) and Regulation (EC) No 298/2008 (OJ No L 97 9.4.2008, p 64).

(3) Article 5(2) of the 1978 Order shall be modified in relation to contained use so as to have effect as if the reference in that Article—

(a) to a self-employed person were a reference to any person (except a student) undertaking contained use who is not an employer or an employee; and

(b) to that person's 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.

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 shall 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) shall 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 shall 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) shall 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 shall 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 shall—

(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 shall 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 shall be obtained from a genetic modification safety committee.

Notification of premises to be used for contained use

9.—(1) A user shall 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 shall—

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

Notification of class 2 contained use

10.—(1) A user shall 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 shall submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive shall 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 shall 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 shall 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 shall submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive shall 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 shall 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 shall 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 shall 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 shall 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 shall 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 shall submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive shall 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 shall 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 for connected programmes of work

13.—(1) The 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.

(2) The 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.

(3) 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 shall 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) shall 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 shall 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 shall 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 shall 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 shall 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) shall 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 shall 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 shall 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 shall 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 shall 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 shall apply the containment measures selected in the risk assessment for the contained use.

(2) A person responsible for the contained use shall 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 shall 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 shall 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 shall—

(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 shall—

(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 shall immediately inform the competent authority of the accident and shall 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 shall 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 Department of the Environment, the Executive shall request additional information under paragraph (1).

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

(4) The Executive shall 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 shall comply with that notice.

Exemption certificates

26.—(1) The 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) The competent authority shall 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 shall—

(a) ensure that any necessary measures are taken;

(b) immediately inform those EEA States which could be affected by the accident;

(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; and

(d) send to the European Commission—

(i) the information provided under regulation 22(a), (b) and (d);

(ii) information on the effectiveness of the measures taken in response to the accident; and

(iii) an analysis of the accident, including recommendations to limit its effects and to avoid similar accidents in the future.

Register of notifications

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

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

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

(a) in relation to each notification submitted under regulations 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 shall omit information from the register where—

(a) the information falls within one of the exceptions to disclosure in regulation 12(5) or 13(1) of the Environmental Information Regulations 2004(**a**);

(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 shall 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 shall 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.

Information not to be included in the register

29.—(1) No information shall be included in the register if and so long as, in the opinion of the Department of Enterprise, Trade and Investment, the inclusion in the register of that information, or information of that description, would be a breach of confidentiality.

(**a**) S.I. 2004/3391

(2) For the purpose of securing the exclusion from the register of information to which paragraph (1) applies, the Department of Enterprise, Trade and Investment 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 Department of Enterprise, Trade and Investment for its determination.

(3) No information referred to the Department of Enterprise, Trade and Investment under paragraph (2)(b) shall be included in the register unless the Department of Enterprise, Trade and Investment determines that it should be included.

(4) The competent authority shall notify the Department of Enterprise, Trade and Investment 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 Department of Enterprise, Trade and Investment 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 shall give written notice to the competent authority that they have done so.

(7) No information notified under paragraph (5) shall be included in the register unless the Department of Enterprise, Trade and Investment determines that it should be included.

PART 5

Miscellaneous and General

Enforcement and civil liability

30.—(1) This regulation applies to the extent that any part of these Regulations are not health and safety regulations within the meaning of Article 17 of the 1978 Order.

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

(a) Articles 18 to 28 (approved codes of practice and enforcement) and Articles 31 to 39 (provisions as to offences) and Article 43 (civil liability) of the 1978 Order(**a**); and

(b) the Health and Safety (Training for Employment) Regulations (Northern Ireland) 1994(**b**).

(3) Every function of the Executive under any provision of the 1978 Order, 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 Order.

(4) Despite Article 31(1)(c) of the 1978 Order a failure to discharge a duty placed on the competent authority or the Executive by these Regulations shall not be an offence.

(5) Despite regulation 4 of the Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999(**c**), the enforcing authority for these Regulations shall be the Executive.

(**a**) S.I.1978/1039 (N.I.9); Articles 18 to 20 and 31 were amended by, and Article 34A was inserted by, S.I. 1998/2795 (N.I..18), Article 6(1) and Schedule 1

(**b**) S.R. 1994 No.1

(**c**) S.R. 1999 No.90

Appeals

31.—(1) A person responsible for contained use who is aggrieved by any of the following may appeal to the Department of Enterprise, Trade and Investment—

(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) Chapter I of the Schedule to the Deregulation (Model Appeal Provisions) Order (Northern Ireland) 1997(**a**) shall apply to any appeal made under this regulation.

(3) 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.

(4) 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).

Competent authority address

32. Anything required to be submitted or sent to the competent authority under these Regulations shall 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 will be deemed to have been made, granted or imposed under these Regulations—

(a) a notification made under any of regulations 9 to 13 of the 2001 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 2001 Regulations as if it were granted under regulation 11 of these Regulations;

(**a**) S.R. 1997 No.269

(c) an agreement by the competent authority under regulation 18(2) of the 2001 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 2001 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 2001 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 2001 Regulations shall 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 shall submit a notification to the competent authority in the following circumstances—

(a) the contained use was being undertaken in accordance with the 2001 Regulations before the date on which these Regulations come into operation;

(b) the appropriate containment level for the contained use is different under these Regulations to the appropriate containment level under the 2001 Regulations; and

(c) as a result the contained use is classified under these Regulations at a higher class than under the 2001 Regulations.

(4) The notification shall be submitted to the competent authority within the specified period.

(5) Subject to paragraphs (6) to (8) the notification shall be treated as a notification required under regulation 10(2) or 11(2) of these Regulations.

(6) The notification shall 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 shall 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 operation.

Consequential Amendments

34.—(1) The Health and Safety (Fees) Regulations (Northern Ireland) 2012(**a**) shall be amended as follows.

(2) In regulation 8—

(a) in the heading, for "2001" substitute "2015";

(b) in paragraph (1), after "a notifier" add "or applicant" and for "2001" substitute "2015";

(c) for paragraph (2) substitute—

(**a**) S.R. 2012 No.255

"(2) No fee shall be returned to a notifier where the notifier withdraws a notification under regulation 17 of the 2015 Regulations or the competent authority returns a notification under regulation 24(6) of the 2015 Regulations.";

(d) for paragraph (3) substitute–

"(3) In this regulation, "the 2015 Regulations" means the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015 and "notifier" and "competent authority" have the same meaning as in those Regulations.".

(3) In Schedule 6—

(a) in the heading, for "2001" substitute "2015";

(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)".

35.—(1) The REACH Enforcement Regulations 2008(**a**) shall be amended as follows.

(2) In Schedule 3, Part 3, paragraph 1(j) for the words "the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001" substitute "the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015".

Revocations

36. The following shall be revoked—

(a) the 2001 Regulations,

(b) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations (Northern Ireland) 2006(**b**), and

(**a**) S.I. 2008/2852
(**b**) S.R. 2006 No.524

(c) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations (Northern Ireland) 2010(**a**).

Sealed with the Official Seal of the Department of Enterprise, Trade and Investment on 18th September 2015.

J Kerr
A senior officer of the Department of Enterprise, Trade and Investment

(**a**) S.R. 2010 No.343

SCHEDULE 1

Regulation 2(1)

Classes of contained use

Class	*Description*
1	Contained use of no or negligible risk, for which containment level 1 is appropriate to protect human health and the environment.
2	Contained use of low risk, for which containment level 2 is appropriate to protect human health and the environment.
3	Contained use of moderate risk, for which containment level 3 is appropriate to protect human health and the environment.
4	Contained use of high risk, for which containment level 4 is appropriate to protect human health and the environment.

SCHEDULE 2

Regulation 2(1) and 3(1)

PART 1

Techniques constituting genetic modification

1. The techniques which constitute genetic modification referred to in sub-paragraph (a) of the definition of "genetic modification" in regulation 2(1) are—

(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 genetic material prepared outside the organism, including micro-injection, macro-injection and micro-encapsulation;

(c) cell fusion or hybridization 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.

PART 2

Techniques which are not considered to result in genetic modification

2. The following techniques are not considered to result in genetic modification provided that they do not involve the use of recombinant nucleic acid molecules or of genetically modified organisms made by techniques other than those listed in Part 3—

(a) in vitro fertilisation;

(b) natural processes including conjugation, transduction or transformation;

(c) polyploidy induction.

PART 3

Techniques to which these Regulations do not apply

3. These Regulations (except regulation 18) shall not apply to the following techniques of genetic modification, provided that they do not involve the use of recombinant nucleic acid molecules or of genetically modified organisms other than those made by one or more of the following techniques—

(a) mutagenesis;

(b) cell fusion (including protoplast fusion) of prokaryotic species which can exchange genetic material through homologous recombination;

(c) cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions;

(d) self-cloning, where the resulting organism is unlikely to cause disease or harm to humans, animals or plants.

4. In paragraph 3—

(a) "self-cloning" means the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent), whether or not altered by enzymic or mechanical processes, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by homologous recombination; and

(b) self-cloning may include the use of recombinant vectors, with an extended history of safe use in the particular organism, to manipulate and reinsert the nucleic acid sequences, but the vectors shall not consist of any genetic elements other than those designed for vector structure, vector replication, vector maintenance or marker genes.

SCHEDULE 3

Regulations 2(3), 3(4) and 5

PART 1

Matters to be taken into account in carrying out an assessment for the purposes of regulation 5

1. The following matters shall be taken into account in carrying out an assessment for the purposes of regulation 5—

(a) any potentially harmful effects, in particular those associated with—

(i) the recipient micro-organism;

(ii) the inserted genetic material (originating from the donor organism);

(iii) the vector;

(iv) the donor micro-organism (where that donor micro-organism is used during the contained use);

(v) the resulting genetically modified micro-organism;

(b) the characteristics of the contained use;

(c) the severity of the potentially harmful effects;

(d) the likelihood of the potentially harmful effects being realised;

(e) the disposal of waste and effluents.

2. In paragraph 1, "potentially harmful effects" includes—

(a) disease to humans including allergenic or toxic effects;

(b) disease to animals or plants;

(c) adverse effects resulting from the inability to treat disease or offer an effective prophylaxis;

(d) adverse effects resulting from establishment or dissemination of the genetically modified micro-organisms in the environment;

(e) adverse effects resulting from the natural transfer of genetic material to or from other organisms;

(f) adverse effects resulting from the likely interaction of the genetically modified micro-organism with other organisms at the premises where the contained use is to be conducted.

PART 2

Steps to be included when carrying out an assessment for the purposes of regulation 5

3. An assessment carried out for the purposes of regulation 5 shall include—

(a) identification of any harmful properties of the recipient and, where appropriate, the donor micro-organism;

(b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the existing properties of the recipient;

(c) recognition that, in general, only contained use which shows the following characteristics is appropriate for inclusion in class 1 as described in Schedule 1—

(i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants;

(ii) the nature of the vector and the insert is such that they do not endow the genetically modified micro-organism with a phenotype likely to cause disease to humans, animals or plants, or likely to cause deleterious effects on the environment; and

(iii) the genetically modified micro-organism is unlikely to cause disease to humans, animals or plants and is unlikely to have deleterious effects on the environment;

(d) consideration of relevant EU legislation, including Directive (EC) No 2000/54 of the European Parliament and the Council on the protection of workers from risks related to exposure to biological agents at work(**a**), other classification schemes referring to plant and animal pathogens, and other international and national classification schemes for genetically modified micro-organisms;

(e) identification of the provisional level of risk associated with the genetically modified micro-organism;

(f) consideration of—

(i) the characteristics of the environment likely to be exposed;

(ii) the characteristics of the contained use involving micro-organisms;

(iii) any contained use of micro-organisms which cannot be controlled adequately by standard laboratory procedures, and which presents risks which require controls for each individual case;

(g) adjustment of the provisional level of risk in the light of the matters referred to in sub-paragraph (f);

(h) selection of the appropriate containment measures from those specified in the applicable table in Schedule 8 on the basis of the provisional level of risk as adjusted in accordance with sub-paragraph (g);

(**a**) OJ No L262, 17.10.2000, p21

(i) assignment of the contained use to the appropriate containment level, in accordance with paragraph 4;

(j) classification of the contained use in the class of the same number as that of the appropriate containment level;

(k) review and reconsideration of that classification in the light of the completed risk assessment.

4. To assign a contained use to the appropriate containment level for the purposes of paragraph 3(i), the person carrying out the risk assessment shall—

(a) first identify for each selected containment measure the column in the applicable table in Schedule 8 having the lowest number in which that selected containment measure is shown as being required, regardless of whether or not such requirement is subject to any qualification;

(b) then select the highest number of all the columns identified in accordance with sub-paragraph (a); and

(c) then assign the contained use to the containment level of that highest number.

5. In paragraph 4, "selected containment measure" means an appropriate containment measure selected in accordance with paragraph 3(h).

SCHEDULE 4

Regulation 6

PART 1

Matters to be taken into account in carrying out an assessment for the purposes of regulation 6

1. The following matters shall be taken into account in carrying out an assessment for the purposes of regulation 6—

(a) any potentially harmful effects, in particular those associated with—

(i) the recipient organism;

(ii) the inserted genetic material (originating from the donor organism);

(iii) the vector;

(iv) the donor organism;

(v) the resulting genetically modified organism;

(b) the characteristics of the contained use;

(c) the severity of the potentially harmful effects;

(d) the likelihood of the potentially harmful effects being realised.

2. In paragraph 1, "potentially harmful effects" includes—

(a) disease to humans including allergenic or toxic effects;

(b) acting as a human disease vector or reservoir;

(c) adverse effects to humans arising from change in behaviour or in physical nature;

(d) adverse effects arising from the inability to treat human disease or offer effective prophylaxis.

PART 2

Steps to be included when carrying out an assessment for the purposes of regulation 6

3. An assessment carried out for the purposes of regulation 6 shall include—

(a) identification of any harmful properties of the recipient and, where appropriate, the donor organism;

(b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the existing properties of the recipient;

(c) identification of the provisional level of risk associated with the genetically modified organisms;

(d) selection of containment and other protective measures on the basis of—

(i) the provisional level of risk; and

(ii) the characteristics of the contained use;

(e) adjustment of the level of risk in the light of the matters referred to in sub-paragraph (d);

(f) review and reconsideration of the containment and other protective measures in the light of the steps required by sub-paragraphs (a) to (e).

SCHEDULE 5 Regulations 9(2), 14(1) and 28(3)

Information required for a notification under regulation 9(2)

A notification required for the purposes of regulation 9(2) shall contain the following information—

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

(b) the name of the person with specific responsibility for the supervision and safety of contained use;

(c) information on the training and qualifications of that person;

(d) details of the arrangements for obtaining advice on risk assessments in accordance with regulation 8, including details of any genetic modification safety committee if established;

(e) the address of the premises where the contained use is to be carried out and a general description of the premises, together with, if required by regulation 9(6), the principal address of premises;

(f) the nature of the work to be undertaken;

(g) the class of any contained use involving micro-organisms;

(h) where the first contained use to be carried out in those premises is a class 1 contained use—

(i) a summary of the risk assessment of that contained use;

(ii) any advice received in relation to the risk assessment from a person or genetic modification safety committee in accordance with regulation 8;

(iii) information on waste management;

(iv) confirmation that the emergency services, and any body or authority liable to be affected by an accident to which any emergency plan relates, will be informed of the contents of the emergency plan and of any relevant revisions;

(i) where the first contained use to be carried out in those premises is a contained use involving larger GMOs and that contained use is not notifiable under regulation 12(2)—

(i) a copy of the risk assessment; and

(ii) confirmation that the emergency services, and any body or authority liable to be affected by an accident to which any emergency plan relates, will be informed of the contents of the emergency plan and of any relevant revisions.

SCHEDULE 6 Regulations 10(2), 11(2), 12(2), 14(1), 28(3) and 33(6)

Information required for a notification under regulations 10(2), 11(2) or 12(2)

A notification required for the purposes of regulation 10(2), 11(2) or 12(2) shall contain the following information except where it is required only for a specified regulation—

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

(b) any centre number allocated by the competent authority in respect of the premises at which the contained use is to be undertaken and the date of the notification required by regulation 9(2) relating to those premises;

(c) the name of the person with specific responsibility for supervision and safety of contained use;

(d) information on the training and qualifications of that person;

(e) the recipient or parental micro-organism to be used;

(f) the donor micro-organism to be used;

(g) where applicable, the host-vector system to be used;

(h) the source and intended function of the genetic material involved in the modification;

(i) the identity and characteristics of the genetically modified organism;

(j) the purpose of the contained use, including its expected results;

(k) for regulation 10(2) the approximate culture volumes to be used;

(l) for regulation 11(2) the culture volumes to be used;

(m) a description of the containment and other protective measures to be applied, including—

(i) information on waste management, including the type and form of wastes to be generated, their treatment, ultimate form and destination; and

(ii) for regulation 10(2) justification for not applying any containment measure at containment level 2;

(iii) for regulation 11(2), for class 3 contained use, justification for not applying any containment measure at containment level 3;

(iv) for regulation 11(2), for class 4 contained use, justification for not applying any containment measure at containment level 4;

(n) for regulations 10(2) and 11(2) a copy of the risk assessment;

(o) for regulations 10(2) and 11(2) the advice received in relation to that assessment from a genetic modification safety committee;

(p) for regulation 12(2) a copy of the risk assessment;

(q) information in relation to any accident prevention and emergency plans including—

(i) the information necessary for the competent authority to evaluate any emergency plan;

(ii) confirmation that the emergency services, and any body or authority liable to be affected by an accident to which any emergency plan relates, will be informed of the contents of the emergency plan and of any relevant revisions;

(iii) for regulation 11(2), in addition—

(aa) any specific hazards arising from the location of the installation;

(bb) the preventive measures applied, including safety equipment, alarm systems and containment methods;

(cc) procedures and plans for verifying the continuing effectiveness of the containment measures;

(dd) a description of the information provided to workers;

(r) for regulation 11(2) a description of the parts of the installation;

(s) for regulation 11(2) whether the genetically modified organism is likely to be subject to transboundary movement.

SCHEDULE 7

Regulation 18

General principles of good microbiological practice and of good occupational safety and hygiene

The general principles of good microbiological practice and of good occupational safety and hygiene are as follows—

(a) keeping workplace and environmental exposure to any genetically modified micro-organism to the lowest reasonably practicable level;

(b) exercising engineering control measures at source and supplementing these with appropriate personal protective clothing and equipment where necessary;

(c) testing adequately and maintaining control measures and equipment;

(d) testing, where necessary, for the presence of viable process organisms outside the primary physical containment;

(e) providing appropriate training of personnel;

(f) establishing a genetic modification safety committee, if required;

(g) formulating and implementing local codes of practice for the safety of personnel, as required;

(h) displaying biohazard signs where appropriate;

(i) providing washing and decontamination facilities for personnel;

(j) keeping adequate records;

(k) prohibiting in the work area eating, drinking, smoking, applying cosmetics or the storing of food for human consumption;

(l) prohibiting mouth pipetting;

(m) providing written standard operating procedures where appropriate to ensure safety;

(n) having effective disinfectants and specified disinfection procedures available in case of spillage of genetically modified micro-organisms;

(o) providing safe storage for contaminated laboratory equipment and materials where appropriate.

SCHEDULE 8

Regulations 2(2) and 19(1)

PART 1

General

1. In this Schedule—

"GMMs" means genetically modified micro-organisms;

"HEPA" means High Efficiency Particulate Air;

"inactivation" means the complete or partial destruction of GMMs so as to ensure that any contact between the GMMs and humans or the environment is limited to an extent commensurate with the risks identified in the risk assessment and to provide a high level of protection for humans and the environment;

"plant growth facilities" means a structure, whether permanent or impermanent, designed and used principally for growing plants in a controlled and protected environment.

2. For the purposes of this Schedule where in the final column of Table 1b or 1c, a measure is specified as—

(a) a modification, it is to be read in substitution for the relevant measure in Table 1a;

(b) additional, it is to be read as an addition to the measures in Table 1a, and any measure which has been substituted for a measure in Table 1a, in accordance with paragraph 2(a).

3. For the purposes of this Schedule—

(a) Table 1a describes containment measures applicable to contained use involving micro-organisms in laboratories;

(b) Table 1a, read with Table 1b, describes containment measures applicable to contained use involving micro-organisms in plant growth facilities;

(c) Table 1a, read with Table 1c, describes containment measures applicable to contained use involving micro-organisms in animal units;

(d) Table 2 describes containment measures applicable to contained use involving micro-organisms in premises other than those referred to in Tables 1a, 1b and 1c.

PART 2

Containment measures

Table 1a

Containment measures applicable to contained use involving micro-organisms in laboratories

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
Facilities					
1	Laboratory suite: isolation[(1)]	not required	not required	required	required
2	Laboratory: sealable for fumigation	not required	not required	required	required
Equipment					
3	Surfaces impervious to water, resistant to acids, alkalis, solvents, disinfectants and decontam-ination agents and easy to clean	required for any bench	required for any bench	required for any bench and floor	required for any bench, floor, ceiling and walls

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
4	Entry to laboratory via airlock[2]	not required	not required	required where and to extent the risk assessment shows it is required	required
5	Negative pressure relative to the pressure of the immediate surroundings	not required	not required	required except for activities where transmission does not occur by the airborne route	required
6	Extract and input air from the laboratory must be HEPA filtered	not required	not required	HEPA filters required for extract air except for activities where transmission does not occur by the airborne route	HEPA filters required for input and extract air[3]
7	Micro-biological safety cabinet /enclosure	not required	required where and to extent the risk assessment shows it is required	required, and all procedures with infective materials required to be contained within a cabinet/ enclosure	required, and all procedures with infective materials required to be contained within a cabinet/ enclosure
8	Autoclave	required on site	required in the building	required in the laboratory suite[4]	double ended autoclave required in laboratory
System of work					
9	Access restricted to authorised personnel only	not required	required	required	required (via airlock key procedure)
10	Biohazard sign on door	not required	required	required	required
11	Specific measures to control aerosol dissem-ination	not required	required so as to minimise	required so as to prevent	required so as to prevent
12	Shower	not required	not required	required where and to extent the risk assessment shows it is required	required

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
13	Protective clothing	suitable protective clothing required	suitable protective clothing required	suitable protective clothing required; footwear required where and to extent the risk assessment shows it is required	complete change of clothing and footwear required before entry and exit
14	Gloves	not required	required where and to extent the risk assessment shows they are required	required	required
15	Efficient control of disease vectors (e.g. rodents and insects) which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required	required	required
Waste					
16	Inactivation of GMMs in effluent from hand-washing sinks and showers and similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
17	Inactivation of GMMs in contaminated material and waste	required by validated means where and to extent the risk assessment shows it is required	required by validated means	required by validated means, with waste inactivated within the laboratory suite	required by validated means, with waste inactivated within the laboratory
Other measures					
18	Laboratory to contain its own equipment	not required	not required	required, so far as is reasonably practicable	required
19	An observation window or alternative is to be present so that occupants can	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
	be seen				
20	Safe storage of GMMs	required where and to extent the risk assessment shows it is required	required	required	secure storage required
21	Written records of staff training	not required	required where and to extent the risk assessment shows it is required	required	required

(1) "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.

(2) Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

(3) Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.

(4) Where the autoclave is outside the laboratory in which the contained use is being undertaken, but within the laboratory suite, there must be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

Table 1b

Containment measures applicable to contained use involving micro-organisms in plant growth facilities (to be read with Table 1a as indicated in paragraph 3(b) of Part 1)

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
Facilities						
1	Permanent structure(1)	required where and to extent the risk assessment shows it is required	required	required	required	modification
Equipment						
2	Entry via a separate room with two interlocking doors	not required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required (via airlock key procedure)	additional
3	Control of contaminated run-off water	required where and to extent the risk assessment shows it is required	required so as to minimise run-off	required so as to prevent run-off	required so as to prevent run-off	additional

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
System of work						
4	Effective control of disease vectors such as insects, rodents and arthropods which could disseminate GMMs	required	required	required	required	additional
5	Effective control of pollen, seeds and other plant material which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required so as to minimise dissem-ination	required so as to prevent dissem-ination	required so as to prevent dissem-ination	additional
6	Procedures for transfer of living material between the plant growth facilities, protective structure and laboratory shall control dissemination of GMMs	required so as to minimise dissem-ination	required so as to minimise dissem-ination	required so as to prevent dissem-ination	required so as to prevent dissem-ination	additional

(1) A permanent structure refers to a fixed structure with walls, a roof and a floor. Where the permanent structure is a greenhouse, that structure shall also have a continuous waterproof covering and self-closing lockable outer doors, and be located on a site designed to prevent the entry of surface run-off water.

Table 1c

Containment measures applicable to contained use involving micro-organisms in animal units (to be read with Table 1a as indicated in paragraph 3(c))

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
Facilities						
1	Isolation of animal unit(1)	required where and to extent the risk assessment shows it is required	required	required	required	modification
2	Animal facilities(2)	required where and	required	required	required	additional

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
	separated by lockable doors	to extent the risk assessment shows it is required				
3	Animal facilities (cages, etc.) designed to facilitate decontamin-ation (waterproof and easily washable material)	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required	required	additional
4	Floor, walls and ceiling easily washable	required where and to extent the risk assessment shows it is required	required for floor	required for floor and walls	required for floor, walls and ceiling	modification
5	Appropriate filters on isolators or isolated rooms(3)	not required	required where and to extent the risk assessment shows it is required	required	required	additional
6	Appropriate barriers at the room exit, and at drains or ventilation duct work	required	required	required	required	additional
7	Animals kept in appropriate containment facilities, such as cages, pens or tanks but not isolators	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	additional
8	Animals kept in isolators	not required	required where and to extent the risk assessment shows it is required	required	required	modification

(1) "animal unit" means a building, or separate area within a building, containing an animal facility and other areas including changing rooms, showers, autoclaves and food storage areas.

(2) "animal facility" means a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures on animals.
(3) "isolators" means transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

Table 2

Containment measures applicable to contained use involving micro-organisms in premises other than those referred to in Tables 1a, 1b and 1c

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
General					
1	Viable micro-organisms shall be contained in a system which separates the process from the workplace and wider environment (closed system)	required where and to extent the risk assessment shows it is required	required	required	required
2	Closed systems located within a controlled area	not required	required where and to extent the risk assessment shows it is required	required	required
3	Control of exhaust gases from the closed system	not required	required so as to minimise release	required so as to prevent release	required so as to prevent release
4	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	required where and to extent the risk assessment shows it is required	required so as to minimise release	required so as to prevent release	required so as to prevent release
5	Inactivation of bulk culture fluids before removal from the closed system	required where and to extent the risk assessment shows it is required	required by validated means	required by validated means	required by validated means
6	Seals shall be designed so as to minimise or prevent release	not required	required so as to minimise release	required so as to prevent release	required so as to prevent release
7	The controlled area designed to	required where and to extent	required where and to	required	required

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
	contain spillage of the entire contents of the closed system	the risk assessment shows it is required	extent the risk assessment shows it is required		
8	The controlled area sealable to permit fumigation	not required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required
9	Biohazard signs posted	not required	required	required	required
Equipment					
10	Entry via airlock	not required	not required	required where and to extent the risk assessment shows it is required	required
11	Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean	required for any bench	required for any bench	required for any bench and floor	required for any bench, floor, ceilings and walls
12	Specific measures to ventilate adequately the controlled areas in order to minimise air contamination	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required
13	The controlled area maintained at an air pressure negative to the immediate surroundings	not required	not required	required where and to extent the risk assessment shows it is required	required
14	Extract and input air from the controlled area must be HEPA filtered	not required	not required	required for extract air; required where and to extent the risk assessment shows they are required for input air	required for input and extract air
System of work					
15	Access restricted to authorised personnel only	not required	required	required	required
16	Personnel must shower before	not required	not required	required where and to extent the	required

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
	leaving the controlled area			risk assessment shows it is required	
17	Personnel shall wear protective clothing	work clothing required	work clothing required	required	complete change required before exit and entry
18	Written procedures and records of staff training	not required	required where and to extent the risk assessment shows they are required	required	required
Waste					
19	Inactivation of GMMs in effluent from hand-washing sinks and showers or similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
20	Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge	required by validated means where and to extent the risk assessment shows it to be required	required by validated means	required by validated means	required by validated means

EXPLANATORY NOTE

(This note is not part of the Order)

1. These Regulations consolidate, revoke and replace the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001 (S.R. 2001 No.295) and its amending instruments (S.R. 2006 No.524, S.R. 2010 No.343). The Regulations implement Directive EC No 2009/41 (O.J. L 125 21.5.2009 p. 75) which lays down measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment. Section 2(2) of the European Communities Act 1972 is used to implement the aspects of the Directive which relate to protection of the environment. The Regulations also apply to the contained use of genetically modified organisms that are not micro-organisms, known as larger GMOs, but only in relation to risks to human health. Larger GMOs are not covered by the Directive.

2. Contained use includes any activity or other action (for example storage) involving a genetically modified organism within a controlled environment where there are physical barriers and/or other controls in place to ensure that any genetically modified organism is not released into the environment. Certain techniques are or are not regarded as genetic modification and the Regulations do not apply to genetically modified organisms in a number of circumstances, for example, where there is a consent for use under other legislation. Some of the regulations are disapplied to genetically modified organisms when they are being transported (regulation 3 and Schedule 2).

3. The Regulations impose duties on people who are undertaking or proposing to undertake contained use (users) and persons responsible for contained use. These are people who either have the authority to determine whether contained use can take place, or people with control over the planning or conduct of the contained use. The competent authority is the Department of the Environment and the Health and Safety Executive for Northern Ireland acting jointly.

4. The meaning of some terms within the Health and Safety at Work (Northern Ireland) Order 1978 is modified so that the Regulations apply to educational institutions as if they were workplaces and students as if they were employees of the educational institution. They also apply to any person who is not an employee undertaking contained use (except a student) as if they were self-employed within the meaning of that Order (regulation 4).

5. Before contained use involving micro-organisms can commence, a person responsible for the contained use must ensure that an assessment of the risks to human health and the environment has been carried out. The person carrying out the risk assessment must classify the contained use (from class 1 to class 4) depending on the seriousness of the risks posed, with 4 being the highest risk (regulation 5, Schedule 1 and Schedule 3). Contained use involving larger GMOs cannot commence until the person responsible has ensured that an assessment is carried out in relation to risks to human health (regulation 6 and Schedule 4) although there is no requirement to assign a class of use. There are specific requirements relating to the review, recording and keeping of risk assessments (regulation 7). A person responsible for contained use must obtain advice on the risk assessment either from an individual or a genetic modification safety committee with relevant expertise (regulation 8).

6. Before premises are used for the first time, for contained use, a person responsible for the first contained use must notify the competent authority and provide information specified by regulation 9 and Schedule 5. One notification can include more than one premises.

7. Before class 2 contained use can commence, a person responsible for the contained use must notify the competent authority of the contained use and provide information specified in Schedule 6 (regulation 10). A period of time must then elapse before contained use can begin. Class 3 or 4 contained use cannot commence unless the competent authority has given consent for the contained use. A person responsible must submit a notification for the contained use and provide the information specified in Schedule 6. Consent must be notified within a specified period that is

dependent on whether the notifier already has consent for class 3 or class 4 contained use (regulation 11).

8. Before contained use can commence involving a larger GMO (and the contained use will result in a more hazardous organism than its parent organism) a person responsible for that contained use must notify the competent authority of that contained use and provide the information specified in Schedule 6 (regulation 12).

9. In certain circumstances the competent authority may accept single notifications for a connected programme of work or contained use at more than one premises (regulation 13). There are various duties to notify the competent authority of changes of circumstances and changes that affect risks (regulations 14 and 15).

10. If the competent authority asks for further information about a notification, the contained use must not commence or continue, except to store or destroy the genetically modified organisms, until the competent authority has agreed in writing that it may (regulation 16). A notifier may withdraw their application as long as the contained use has not commenced (regulation 17).

11. Users are required to ensure that occupational and environmental safety principles are observed (Schedule 7) and that risks are kept to the lowest level reasonably practicable (regulation 18).

12. A user carrying out contained use involving genetically modified micro-organisms is required to apply the containment measures which are appropriate to that contained use in accordance with the risk assessment. The containment measures are classified into different containment levels which largely correspond with the class assigned to the contained use, with level 4 being the highest level of containment. The measures are set out in Schedule 8 (regulation 19). A user carrying out contained use involving a larger GMO must apply the containment measures applicable in accordance with the risk assessment for that contained use (regulation 20).

13. Where a risk assessment shows it is warranted, an emergency plan must be prepared before contained use can commence. In the case of genetically modified micro-organisms the plan must address risks to human health and the protection of the environment, in the case of larger GMOs the plan need only address human health, (regulation 21). If an accident occurs the person responsible for the contained use must notify the competent authority immediately and provide specified information (regulation 22).

14. The competent authority is placed under a duty to examine a notification submitted to it under regulations 9(2), 10(2), 11(2) and 12(2) (regulation 23) and the Executive may ask the notifier for additional information on behalf of the competent authority (regulation 24). The competent authority has power to impose time limits or conditions on contained use, to suspend or terminate contained use or require that the contained use is not commenced. The competent authority may also vary or revoke any consent previously granted under regulation 11 (regulation 25). The competent authority may grant an exemption from the requirements of the Regulations but only if it is satisfied that the health and safety of persons and the environment are not prejudiced by the granting of an exemption (regulation 26).

15. The competent authority is to maintain a register of all notifications and copies of the register are to be made available by the Executive for public inspection by appropriate means (regulation 28). Certain information may not be published if it would be a breach of confidentiality (regulation 29).

16. Provision is made for the enforcement of the Regulations under the Health and Safety at Work (Northern Ireland) Order 1978 (regulation 30).

17. There is a right of appeal for any person who is aggrieved by certain decisions or actions of the competent authority or the Executive (regulation 31).

18. Anything that must be submitted to the competent authority under the regulations must be submitted to the Executive at the address it publishes on its website for the purpose (regulation 32).

19. There are various transitional, saving and consequential provisions and a number of instruments are revoked (see paragraph 1 above) (regulations 33 to 35).

20. In Great Britain the corresponding Regulations are the Genetically Modified Organisms (Contained Use) Regulations 2014 (S.I. 2014/1663). The Great Britain Health and Safety Executive has prepared a regulatory impact assessment in relation to those Regulations. A copy of that assessment together with a Northern Ireland supplement prepared by the Health and Safety Executive for Northern Ireland can be accessed at http://www.hseni.gov.uk/ or may be obtained, on request, from the Executive, at 83 Ladas Drive, Belfast, BT6 9FR. A copy of the transposition note in relation to implementation of the Directive can also be obtained from the Health and Safety Executive for Northern Ireland at the above address. Copies of both documents are annexed to the Explanatory Memorandum which is available alongside these Regulations at www.legislation.gov.uk.

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