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STATUTORY INSTRUMENTS

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**2014 No. 000**

**HEALTH AND SAFETY**

**The Genetically Modified Organisms (Contained Use)  
Regulations 2014**

*Made* - - - - - \*\*\*  
*Laid before Parliament* \*\*\*  
*Coming into force* - - - - - *1<sup>st</sup> October 2014*

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972(a) in relation to the control and regulation of genetically modified organisms(b).

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 and by sections 15(1), (2), (3)(b) and (5)(b), 52(2) and 82(3)(a) of, and paragraphs 1(1)(b) and (c), (2) and (3), 4, 5, 6, 11, 13(1), 15(1), 16, 17 and 20 of Schedule 3 to, the Health and Safety at Work etc. Act 1974(c) (“the 1974 Act”).

The Regulations give effect without modifications to proposals submitted to the Secretary of State by the Health and Safety Executive under section 11(3) of the 1974 Act.

Before submitting those proposals to the Secretary of State, the Health and Safety Executive consulted the bodies that appeared to be appropriate as required by section 50(3) of the 1974 Act.

**PART 1**

**Interpretation and General**

**Citation and commencement**

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

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- (a) 1972 c. 68. Section 2(2) was amended by section 27 of the Legislative and Regulatory Reform Act 2006 (c.51) and section 3 and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c.7).
  - (b) S.I. 1991/755.
  - (c) 1974 c 37. Section 15(1) was amended by the Employment Protection Act 1975 (c.71), Schedule 15, paragraphs 6 and S.I. 2002/794. Section 50(3) was amended by the Employment Protection Act 1975, Schedule 15 paragraph 16, S.I. 2008/960 and the Health Protection Agency Act 2004 (c.17), Schedule 3, paragraph 5(1) and (3) and by S.I. 2008/960, which also substituted section 11. In relation to Scotland, see also section 57(1) of the Scotland Act 1998 (c. 46), which provides that, despite the transfer to the Scottish Ministers of functions in relation to observing and implementing European Union law, any function of a Minister of the Crown in relation to any matter shall continue to be exercisable in relation to Scotland by that Minister, for the purposes specified in the in section 2(2) of the 1972 Act.

## Interpretation

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

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

“the 2000 Regulations” means the Genetically Modified Organisms (Contained Use) Regulations 2000(a);

“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—

(a) in relation to premises situated in, or contained use taking place in, England and Wales, the Secretary of State and the Executive, acting jointly; and

(b) in relation to premises situated in, or contained use taking place in, Scotland, the Scottish Ministers and the Executive, acting jointly,

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

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

“EEA State” means a State, other than the United Kingdom, which is a Contracting Party to the Agreement on the European Economic Area(b) signed at Oporto on 2nd May 1992, as adjusted by the Protocol signed at Brussels on 17th March 1993(c) and adopted as respects the United Kingdom by the European Economic Area Act 1993(d);

“emergency plan” means a plan required by virtue of regulation 21;

“emergency services” means the police, fire and ambulance services;

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

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

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

and “genetically modified” is to be construed accordingly;

“human admixed embryo” has the meaning given in the Human Fertilisation and Embryology Act 1990(e) by virtue of section 4A(6) and (11) of that Act;

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(a) 2000 No. 2831. The 2000 Regulations and all amending instruments are revoked by these Regulations.

(b) OJ L 1, 3.1.1994 p. 3.

(c) OJ L 1, 3.1.1994, p. 572 and as subsequently amended by EEA Council Decision No 1/95 of 10 March 1995, OJ L86, 20.4.1995 p 58; the Agreement on the participation of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic in the European Economic Area of 154 October 2003 OJ L 130, 29.4.2004 p 11; the Agreement on the participation of Bulgaria and Romania in the European Economic Area of 25 July 2007 OJ No I221, 25.8.2007 p 15 and the Agreement between the European Union, Iceland, Liechtenstein and Norway on an EEA Financial Mechanism for the period 2009 – 2014 (OJ L 291, 9.11.2010 p 4) *n.b. not sure if these are relevant to definition of EEA state - particularly the last one as they just change the definition of “EU” and EU presumably remains the contracting party for the purposes of the definition above.*

(d) 1993 c. 51 as amended by S.I. 2011/1043.

(e) 1990 c. 37. Sections 1(1) and (6) were substituted by section 1(2) (3) and (5) of the Human Fertilisation and Embryology Act 2008 (c.22) and section 4A was inserted by section 4(2) of that Act.

“human embryo” means an embryo within the meaning given in the Human Fertilisation and Embryology Act 1990 (apart from section 4A) by virtue of section 1(1) and (6) of that Act;

“joint competent authority” means the competent authority as regards England and Wales and the competent authority as regards Scotland, acting jointly;

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

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

“notifier” means a person who submits or has submitted a notification to the competent authority under regulation 9(2), 10(2), 11(2), 12(2) or 33(2) or a notification to the joint competent authority in accordance with regulation 9(5), 13(1) or 33(2);

“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;

“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” includes both single buildings and sites made up of more than one building;

“transboundary movement” has the meaning assigned to it by Article 3 of Regulation 1946/2003/EC(a) of the European Parliament and of the Council on transboundary movements of genetically modified organisms;

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

“working day” means any day other than a Saturday, a Sunday, Christmas Day or Good Friday, or a bank holiday within the meaning given by the Banking and Financial Dealings Act 1971.

(2) A reference in these Regulations to the competent authority is to be construed as a reference to the joint competent authority in relation to premises or contained use which are notified to the joint competent authority in accordance with regulation 9(5) or 13.

(3) In these Regulations—

(a) a reference to an appropriate containment level is a reference to the containment level assigned to that activity in accordance with paragraphs 3(i) and 4 of Part 2 of Schedule 3;

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

(4) The measures in—

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

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

## Application

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

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(a) OJ L 287 5.11.2003, p. 1.

- (2) These Regulations do not apply to any activity in which—
- (a) genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used, where such organisms are or are contained in—
    - (i) a product marketed in accordance with—
      - (aa) a consent granted by the Secretary of State, or, as regards Scotland, by the Scottish Ministers, or, as regards Wales, by the Welsh Ministers, under section 111(1) of the Environmental Protection Act 1990(a), or
      - (bb) a consent granted by the Northern Ireland Department of the Environment under article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991(b), or
      - (cc) 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 2001/18/EC(c) of the European Parliament and Council on the deliberate release into the environment of genetically modified organisms,

and, in each case, that activity is conducted in accordance with any conditions or limitations attached to that consent, or
    - (ii) a medicinal product for human or veterinary use marketed in accordance with Council Regulation (EEC) No 2309/93(d) or Regulation (EC) No 726/2004(e) 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, or
    - (iii) food or feed authorised in accordance with the provisions of Regulation 1829/2003/EC(f) of the European Parliament and of the Council on genetically modified food and feed, or
    - (iv) 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 1829/2003/EC;
  - (b) 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 Minister, as regards Wales, or
    - (ii) the consent of the Northern Ireland Department of the Environment is required under article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991.

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- (a) 1990 c. 43. The functions of the Secretary of State under section 111 are exercisable in relation to Scotland by the Scottish Ministers, by virtue of s 53 of the Scotland Act 1998 (c. 46). The functions of the Secretary of State so far as exercisable in relation to Wales, transferred to the Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006 which transferred functions conferred on National Assembly for Wales under s22 of the Government of Wales Act 1998 to the Welsh Ministers. The functions in s111 of c. 43 had been transferred to the Assembly under SI 1999/672. Section 111(6) was amended in relation to England by SI 2002/2443, in relation to Wales by SI 2002/3188 and in relation to Scotland by SSI 2002/541. Subsection (6A) was inserted by SI 1992/3280, and subsection (7) was amended by the Food Standards Act 1999 (c. 28) section18, Schedule 3, paragraph 17.
  - (b) 1991 No. 1714 (N.I.19).
  - (c) OJ L106, 17.04.2001, pp 1 – 37. under Article 4(4) Member States must designate a competent authority responsible for complying with the requirements of the Directive.
  - (d) OJ L 214, 24.8.1993, p. 1
  - (e) OJ L 136, 30.4.2004, p. 1 as amended by Regulation (EC) No 1901/2006 OJ L378 27.12.2006 p. 1, Regulation (EC) No 1394/2007 OJ L 324 10.12.2007 p. 121, Regulation (EC) No 219/2009 OJ L87 31.3.2009 p. 109, Regulation (EC) No 470/2009 OJ L 152, 16.6.2009, p. 11, and Regulation (EC) No 1235/2010 OJ L348 31.12.2010, p 1 which was corrected by Corrigendum OJ L 201, 27.7.2012 p 138.
  - (f) OJ L268 18.10.2003, pp. 1 – 23 as amended by Regulation (EC) No 1981/2006 OJ L368 23.12.2006 pp. 99 - 109 and Regulation (EC) No 298/2008 OJ L 97 9.4.2008 pp. 64 – 66.

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

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

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

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

#### **Meaning of “work” and “at work” and modification of the 1974 Act**

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

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

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

- (i) an employer in those sections includes a reference to an educational establishment providing a course of study, and
- (ii) an employee in those sections includes a reference to a student of that educational establishment to the extent that the contained use is under the control of that educational establishment.

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

- (a) to a self-employed person 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 such an activity.

(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 must ensure that a suitable and sufficient assessment of the risks created to human health and the environment by the contained use is carried out.

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

#### **Risk assessment of contained use involving larger GMOs**

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

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

### **Review and recording of risk assessments**

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

- (a) there is reason to suspect that the assessment is no longer valid; or
- (b) there has been a significant change in the contained use to which the assessment relates.

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

- (a) keep a record of the assessment and any review of that 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.

(3) In this regulation, “assessment” means an assessment carried out for the purposes of regulation 5 or 6.

### **Advice from a genetic modification safety committee**

8.—(1) Subject to paragraph (2), a person responsible for contained use must obtain advice on the assessment carried out under regulation 5 or 6 from either—

- (a) a person, or
- (b) a genetic modification safety committee,

with expertise in risk assessment relating to contained use.

(2) Where the assessment indicates that the contained use will be assigned to class 2 or above the advice must be obtained from a genetic modification safety committee.

### **Notification of premises to be used for contained use**

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

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

- (a) submit a notification to the competent authority containing the information specified in Schedule 5; and
- (b) have received an acknowledgement of receipt of the notification from the Executive.

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

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

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

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

### **Notification of class 2 contained use involving micro-organisms**

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

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

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

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

- (a) 45 days have elapsed since the acknowledgement of receipt was received and the competent authority has not informed the notifier that the class 2 contained use must not be undertaken; or
  - (b) the competent authority has agreed in writing that the class 2 contained use may begin within a shorter period.
- (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 to the user undertaking that contained use.

(7) The competent authority must decide whether to provide a 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 involving micro-organisms**

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

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

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

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

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

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

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

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

### **Notification of contained use involving larger GMOs**

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

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

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

(4) A user must not undertake the contained use unless—

- (a) 45 days have elapsed since the acknowledgement of receipt was received and the competent authority has not informed the notifier that that the contained use must not be undertaken; or
- (b) the competent authority has agreed in writing that the contained use may begin within a shorter period.

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

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

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

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

- (a) one premises; or
- (b) more than one premises.

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

(4) In this regulation—

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

### **Changes of circumstances relating to notifications**

**14.**—(1) A person responsible for the contained use must immediately send to the competent authority full details in writing of—

- (a) any change in the information specified in paragraphs (a), (d) and (e) of Schedule 5 and provided by the notifier in accordance with regulation 9(2);
- (b) any new building—
  - (i) added to the premises previously notified by the notifier 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) above;
- (g) any use of additional premises in connection with a single contained use where a single notification for that contained use was submitted in accordance with regulation 13(3);
- (h) any change in the information specified in paragraphs (b) or (c) of Schedule 5 and provided by the notifier in accordance with regulation 9(2).
- (i) any change in the information specified in paragraphs (c) or (d) of Schedule 6 and provided by the 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 submitted under regulation 13(3), provide all the information required for notification of those premises under regulation 9(2),

the provision of such information will be treated as notification of those premises for the purposes of regulation 9(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 their 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,

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

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

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

**16.**—(1) If additional information is requested by the Executive under regulation 24(1), a user must not begin the contained use 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 under regulation 24(1), a user may not continue that 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 that contained use must comply with any such instructions.

(4) Subject to any such 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 their notification by giving written notice to the competent authority, provided that the contained use to which the notification relates has not commenced.

## **PART 3**

### **Conduct of Contained Use**

#### **Principles of occupational and environmental safety**

**18.**—(1) A user who undertakes a contained use involving micro-organisms must ensure that the exposure of humans and the environment to genetically modified micro-organisms is reduced to the lowest level that is reasonably practicable.

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

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

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

### **Containment and control measures for contained use involving micro-organisms**

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

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

- (a) the assessment, or any review of that 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 a contained use involving micro-organisms must review the containment measures applied to that contained use—

- (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 involving micro-organisms identified in the assessment is no longer appropriate, or
  - (iii) in the light of new scientific or technical knowledge, the assessment is no longer valid.

### **Containment and control measures for contained use involving larger GMOs**

**20.**—(1) A user who undertakes a contained use involving larger GMOs must apply the containment measures selected in accordance with the assessment made under regulation 6(1).

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

- (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 assessment is no longer valid.

### **Emergency plans**

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

- (a) the health or safety of persons outside the premises in which the contained use is undertaken is liable to be seriously affected; or
- (b) there is a risk of serious damage to the environment from the contained use,

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

(2) Where an assessment carried out under regulation 6(1) shows that, as a result of any reasonably foreseeable accident, the health or safety of persons outside the premises in which the contained use is undertaken is liable to be seriously affected, a person responsible for the contained use must ensure that, before the contained use commences, a suitable plan is prepared with a view to securing the health and safety of those persons.

(3) Every emergency plan must—

- (a) include the measures to be taken in the event of an accident to which the plan relates; and
- (b) be reviewed and, where necessary, revised at suitably regular intervals.

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

- (a) inform the emergency services and any body or authority liable to be affected by an accident to which the plan relates of the contents of the plan and of any relevant revisions; and
- (b) make information about the plan and any such revisions publicly available.

### **Information relating to accidents**

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

- (a) the circumstances of the accident;
- (b) the identity and quantity of the genetically modified organisms concerned;
- (c) any information necessary to assess the effects of the accident on the health of the general population and, in the case of a genetically modified micro-organism, on the environment; and
- (d) any measures taken in response to the accident.

## **PART 4**

### **Duties and powers of the competent authority**

#### **Duties of the competent authority on receiving notifications**

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

- (a) conformity with the requirements of these Regulations;
- (b) the accuracy and completeness of the information provided;
- (c) the correctness of the assessment or summary of the assessment carried out under regulation 5(1) or 6(1);
- (d) the adequacy of the waste management and emergency response measures;
- (e) in the case of a notification submitted under regulation 10(2) or regulation 11(2) the correctness of the class assigned to the contained use involving micro-organisms; and
- (f) the inclusion of an emergency plan where the assessment carried out under regulation 5(1) or 6(1) indicates that such a plan is necessary.

#### **Requests for additional information**

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

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

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

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

(5) The period of time between the date when the Executive requests additional information and the date when the Executive receives all of that additional information will not be taken into account in calculating the period of days referred to in regulations 10(4), 10(7), 11(4), 11(5) or 12(4).

(6) Where—

(a) contained use has not commenced at the premises to which a notification made under regulation 9(2) relates, or a contained use notified under regulation 10(2), 11(2) or 12(2) has not commenced;

(b) the Executive requests additional information; and

(c) the notifier does not provide all that information within a period of six months of the date on which the Executive sent the request,

the competent authority may return the notification to that notifier.

### **Powers of competent authority in relation to activities which must be notified**

**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, to 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 that contained use must 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 must not grant an exemption unless, having regard to the circumstances of the case and in particular to—

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

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

it is satisfied about the matters referred to in paragraph (3).

(4) The matters about which the competent authority must be satisfied are—

(a) that the health and 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 on receipt of information about accidents**

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

(a) ensure that any necessary measures are taken;

- (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 must maintain a register of every notification submitted under regulations 9 to 12.

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

- (a) in relation to each notification submitted under regulation 9(2), 10(2), 11(2) or 12(2)—
  - (i) the name, address and telephone number and any fax number and any e-mail address of the notifier,
  - (ii) the date on which the Executive acknowledged receipt of the notification, and
  - (iii) where the competent authority receives details of a matter referred to in subparagraphs (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 relates;
- (c) in relation to each notification submitted under regulation 9(2)—
  - (i) the information specified in paragraphs (d) to (g), (h)(ii) and (h)(iii) of Schedule 5, and
  - (ii) if the competent authority has been informed of an accident under regulation 22 in relation to the premises to which the notification relates, confirmation that the requirements of regulation 22 have been complied with;
- (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), (l), (m)(i),(iii) and (iv) and (r) of Schedule 6, and
  - (ii) if appropriate, confirmation that consent for the contained use has been granted under regulation 11(4) or 11(5); and
- (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 register must not include any information which the competent authority would refuse to disclose under the Environmental Information Regulations 2004(a) or the Environmental Information (Scotland) Regulations 2004(b).

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

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(a) 2004 No. 3391.

(b) S.S.I. 2004 No. 520.

- (6) The competent authority may remove from the register—
- (a) information relating to a contained use ten years after being notified in accordance with regulation 14(1)(d) or (e) that the contained use has ceased; and
  - (b) information relating to premises ten years after being notified in accordance with regulation 14(1)(c) of a decision to cease to use such premises for the purposes of undertaking any contained use.

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

### **Information not to be included in the register**

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

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

- (a) specifying information, or descriptions of information, to be excluded from the register; or
- (b) specifying descriptions of information to be referred to the Secretary of State for his or her determination.

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

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

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

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

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

## **PART 5**

### **Miscellaneous and General**

#### **Enforcement**

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

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

- (a) sections 16 to 26 (approved codes of practice and enforcement) and sections 33 to 42 (provisions as to offences) of the 1974 Act; and
- (b) the Health and Safety (Training for Employment) Regulations 1990(a).

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(a) 1990 No. 1380

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

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

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

## Appeals

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

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

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

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

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

(5) Where an appeal is brought under this regulation, none of the following is suspended pending the final determination of the appeal—

- (a) a decision of the competent authority referred to in paragraph (1)(a);
- (b) an instruction given under regulation 16(2);
- (c) the operation of regulations 16(1) or 24(1) or (5); or
- (d) a notice given under regulation 25.

(6) In this regulation,

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

“the appropriate person” means—

- (a) the Secretary of State, in the case of—
  - (i) an appeal under paragraph (1)(a) or (d) against a decision of, or a notice given by, the competent authority as regards England and Wales, or
  - (ii) an appeal under paragraph (1)(b) or (c) against a request or instruction relating to—

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(a) 1998 No. 494, there are various amendments to this S.I. but none is relevant to these Regulations.

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

### **Competent authority address**

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

### **Saving and transitional provisions**

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

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

(3) Where—

- (a) a user was undertaking contained use before the relevant date in accordance with the 2000 Regulations; and
- (b) under the new Regulations a change in one or more of the required containment measures in Schedule 8 increases the class of that contained use,

a person responsible for the contained use must submit a notification to the competent authority containing the information required in Schedule 6 that is applicable to the new class of contained use.

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

(5) The competent authority may exempt a notifier from some or all of the requirements of Schedule 6.

(6) Where a notification is submitted under paragraph (2) for a contained use that requires consent for class 3 or class 4 contained use, the competent authority must inform the notifier of its decision whether or not to grant consent within 90 days of receipt of the notification.

(7) The provisions of regulations 23 to 29 of these Regulations apply to a notification submitted under paragraph (2) as if it were a notification under regulations 9 to 12 of the 2000 Regulations.

(8) The contained use referred to in paragraph (2) may continue as long as:

- (a) the notification is submitted within the specified period;
- (b) the risk assessment shows no increase in the risks associated with the contained use;
- (c) the competent authority does not require the notifier or user to suspend or terminate the contained use under regulation 25 of these Regulations;
- (d) the competent authority has not refused consent for the contained use.

(9) In this regulation—

“relevant date” means the date on which these Regulations come into force;

“specified period” means the period of 90 days beginning with the relevant date.

### **Consequential Amendment**

**34.**—(1) The Health and Safety (Fees) Regulations 2012(**a**) are amended as follows—

(a) In regulation 13—

- (i) in the heading, for “2000” substitute “2014”,
- (ii) in paragraph (1), for “2000” substitute “2014”,
- (iii) omit paragraph (2) and substitute—

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

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

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

(c) In Schedule 10—

- (i) in the heading, for “2000” substitute “2014”,
- (ii) In column 1 of the table,
  - (aa) in paragraph (j), for “15(3)” substitute “16”; and
  - (bb) in paragraph (k) for 18(2) substitute “19(2)”.

### **Revocations**

**35.** The following are revoked—

- (a) the 2000 Regulations,
- (b) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002(**b**),
- (c) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005(**c**), and
- (d) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010(**d**).

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(a) 2012 No. 1652.

(b) 2002 No. 63.

(c) 2005 No. 2466.

(d) S.I. 2010/2840.

## SCHEDULE 1

Regulation 2(1)

### Classes of contained use

| <i>Class</i> | <i>Description</i>   |
|--------------|--|
| 1            | Activities of no or negligible risk, for which containment level 1 is appropriate to protect human health and the environment. |
| 2            | Activities of low risk, for which containment level 2 is appropriate to protect human health and the environment.              |
| 3            | Activities of moderate risk, for which containment level 3 is appropriate to protect human health and the environment.         |
| 4            | Activities of high risk, for which containment level 4 is appropriate to protect human health and the environment.             |

## SCHEDULE 2

Regulations 2(1) and 3(2)

### PART 1

#### Examples of techniques constituting genetic modification

1. Examples of the techniques which constitute genetic modification which are 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 genetically modified organisms made by techniques other than those listed in Part 3 or the use of recombinant nucleic acid molecules, namely—
  - (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) do 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 recombinant nucleic acid molecules or genetically modified organisms produced by one or more of the following techniques of genetic modification—

- (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 re-combination; 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 must not consist of any genetic elements other than those designed for vector structure, vector replication, vector maintenance or marker genes.

## SCHEDULE 3

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

### PART 1

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

1. The following matters must 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), and
  - (v) the resulting genetically modified micro-organism;
- (b) the characteristics of the activity;
- (c) the severity of the potentially harmful effects;
- (d) the likelihood of the potentially harmful effects being realised; and
- (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 must 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 recipient's existing properties;
  - (c) recognition that, in general, only contained uses which show the following characteristics are 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 2000/54/EU of the European Parliament and of the Council<sup>(a)</sup> on the protection of workers from risks related to exposure to biological agents at work, 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, and
    - (iii) any contained uses of micro-organisms which cannot be adequately controlled by standard laboratory procedures, and which present 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) above;
  - (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 (f) above;

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(a) OJ L262, 17.10.2000 p. 21-45.

- (i) assignment of the contained use involving micro-organisms to the appropriate containment level, in accordance with paragraph 4;
- (j) classification of that activity in the class of the same number as that of the appropriate containment level; and
- (k) review and reconsideration of that classification in the light of the completed assessment.

4. To assign a contained use involving micro-organisms to the appropriate containment level for the purposes of paragraph 3(i), the person carrying out the assessment for the purposes of regulation 5 must—

- (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 subparagraph (a) above; and
- (c) then assign the contained use in question 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(i).

## SCHEDULE 4

Regulation 6(2)

### PART 1

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

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

- (a) the identification of 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, and
  - (v) the resulting genetically modified organism;
- (b) the characteristics of the contained use;
- (c) the severity of the potentially harmful effects; and
- (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 must include—
- (a) identification of the 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) above; and
  - (f) review and reconsideration of the containment and other protective measures in the light of the steps required by sub-paragraphs (a) to (e) above.

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

### Information required for a notification under regulation 9(2)

A notification required for the purposes of regulation 9(2) must 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 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 the principal address of premises notified under regulation 9(6);
- (f) the nature of the work to be undertaken;
- (g) the class of any contained use involving micro-organisms; and
- (h) where the first activity to be carried out in those premises is a class 1 contained use—
  - (i) a summary of the assessment of that activity made for the purposes of regulation 5(1),
  - (ii) any advice received in relation to that assessment from a person or genetic modification safety committee in accordance with regulation 8,
  - (iii) information on waste management, and
  - (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; or
- (i) where the first activity to be carried out in those premises involves genetic modification of larger GMOs and that activity is not notifiable under regulation 12(2)—
  - (i) a copy of the assessment made for the purposes of regulation 6(1), 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 plan and of any relevant revisions.

## SCHEDULE 6 Regulations 10(2), 11(2), 12(2), 14(1) and 26

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

A notification required for the purposes of regulations 10(2), 11(2) or 12(2) must contain the information below 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 assessment carried out under regulation 5(1);
- (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 assessment carried out under regulation 6(1);
- (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 plan and of any relevant revisions.
- (iii) for regulation 11(2) this should also include—

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

# SCHEDULE 8

Regulations 2(3) and 19(1)

## Containment measures

### 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; and

"risk assessment" means the assessment carried out in accordance with regulation 5.

**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 relevant measure in Table 1a.

**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

**Table 1a: Containment measures for contained use involving micro-organisms in laboratories**

|   | <i>Containment Measures</i>   | <i>Containment Levels</i> |                    |                              |   |
|---|---|---------------------------|--------------------|------------------------------|---|
|   |   | <i>1</i>                  | <i>2</i>           | <i>3</i>                     | <i>4</i>                                    |
| 1 | Laboratory suite: isolation ( <b>note 1</b> )   | not required              | not required       | required                     | required                                    |
| 2 | Laboratory: sealable for fumigation   | not required              | not required       | required                     | required                                    |
|   | <b>Equipment</b>  |                           |                    |                              |   |
| 3 | Surfaces impervious to water, resistant to acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean | required for bench        | required for bench | required for bench and floor | required for bench, floor ceiling and walls |

|    |  |                                       |   |   |  |
|----|--|---------------------------------------|---|---|--|
| 4  | Entry to lab via airlock<br>(note 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 (note 3)   |
| 7  | Microbiological 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 (note 4)   | double ended autoclave required in laboratory  |
|    | <b>System of work</b>  |                                       |   |   |  |
| 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 dissemination                       | 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   |
| 13 | Protective clothing  | suitable protective clothing required | suitable protective clothing required                                 | suitable protective clothing required; footwear required where and to extent the risk assessment                    | complete change of clothing and footwear required before entry and exit                                    |

|    |  |  |  |   |   |
|----|--|--|--|---|---|
|    |  |  |  | shows it is required  |   |
| 14 | Gloves   | not required   | required where and to the 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  |
|    | <b>Waste</b>   |  |  |   |   |
| 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 the 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 |
|    | <b>Other measures</b>  |  |  |   |   |
| 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 be seen          | 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  |
| 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  |

## NOTES

1. In the table above, "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 involving micro-organisms 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 for contained use involving micro-organisms in plant growth facilities (to be read with table 1a as indicated in paragraph 3)**

|   | <i>Containment Measures</i>   | <i>Containment Levels</i>   |   |   |   | <i>Additional/ modification</i> |
|---|---|---|---|---|---|---------------------------------|
|   |   | <i>1</i>  | <i>2</i>  | <i>3</i>  | <i>4</i>                                |                                 |
|   | <b>Building</b>   |   |   |   |   |                                 |
| 1 | Permanent structure ( <b>note</b> )   | required where and to extent the risk assessment shows it is required | required  | required  | required                                | Modification                    |
|   | <b>Equipment</b>  |   |   |   |   |                                 |
| 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                      |
|   | <b>System of work</b>   |   |   |   |   |                                 |
| 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 dissemination                              | required so as to prevent dissemination                               | required so as to prevent dissemination | Additional                      |
| 6 | Procedures for transfer of living material between the plant growth                                       | required so as to minimise dissemination                              | required so as to minimise dissemination                              | required so as to prevent dissemination                               | required so as to prevent dissemination | Additional                      |

|  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|
|  | facilities, protective structure and laboratory must control dissemination of GMMs |  |  |  |  |  |
|--|--|--|--|--|--|--|

**NOTE**

A permanent structure refers to a fixed structure with walls, a roof and a floor. Where the permanent structure is a greenhouse, that structure must 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 for contained use involving micro-organisms in animal units (to be read with table 1a as indicated in paragraph 3)**

|   | <i>Containment Measures</i>  | <i>Containment Levels</i>   |   |                              |                                       | <i>Additional/ modification</i> |
|---|--|---|---|------------------------------|---------------------------------------|---------------------------------|
|   |  | <i>1</i>  | <i>2</i>  | <i>3</i>                     | <i>4</i>                              |                                 |
|   | <b>Facilities</b>  |   |   |                              |                                       |                                 |
| 1 | Isolation of animal unit ( <b>note 1</b> )   | required where and to extent the risk assessment shows it is required | required  | required                     | required                              | Modification                    |
| 2 | Animal facilities ( <b>note 2</b> ) separated by lockable doors  | required where and to extent the risk assessment shows it is required | required  | required                     | required                              | Additional                      |
| 3 | Animal facilities (cages, etc.) designed to facilitate decontamination (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 ( <b>note 3</b> )   | not required  | required where and to extent the risk assessment shows it is required | required                     | required                              | Additional                      |
| 7 | Appropriate barriers at the room exit, and at  | required  | required  | required                     | required                              | Additional                      |

|   |  |   |   |   |   |              |
|---|--|---|---|---|---|--------------|
|   | drains or ventilation duct work  |   |   |   |   |              |
| 8 | 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   |
| 9 | Animals kept in isolators  | not required  | required where and to extent the risk assessment shows it is required | required  | required  | Modification |

## NOTES

1. In the table above, "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. In the table above and in note 1 above, "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. In the table above, "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 for contained use involving micro-organisms in premises other than those referred to in tables 1a, 1b and 1c**

|   | <i>Containment Measures</i>   | <i>Containment Levels</i>   |   |                                   |                                   |
|---|---|---|---|-----------------------------------|-----------------------------------|
|   |   | <i>1</i>  | <i>2</i>  | <i>3</i>                          | <i>4</i>                          |
|   | <b>General</b>  |   |   |                                   |                                   |
| 1 | Viable micro-organisms must 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  | required where and to extent the risk assessment shows it is          | required so as to minimise release                                    | required so as to prevent release | required so as to prevent release |

|    |   |  |  |  |   |
|----|---|--|--|--|---|
|    | system or transfer of material to another closed system   | required   |  |  |   |
| 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 must 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 contain spillage of the entire contents of the closed system                      | 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  |
| 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  |
|    | <b>Equipment</b>  |  |  |  |   |
| 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 adequately ventilate 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, optional for input air                         | required for input and extract air                |
|    | <b>System of work</b>   |  |  |  |   |
| 15 | Access restricted to authorised personnel only  | not required   | required   | required   | required  |

|    |  |   |  |   |  |
|----|--|---|--|---|--|
| 17 | Personnel must shower before leaving the controlled area   | not required  | not required   | required where and to extent the risk assessment shows it is required | required                                       |
| 18 | Personnel must wear protective clothing  | work clothing required  | work clothing required   | required  | complete change required before exit and entry |
| 19 | Written procedures and records of staff training   | not required  | required where and to the extent the risk assessment shows it to be required | required  | required                                       |
|    | <b>Waste</b>   |   |  |   |  |
| 20 | 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                                       |
| 21 | Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge | required by validated means where and to the 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 Regulations)*

1. These Regulations implement Directive 2009/41/EC (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. 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. The Regulations revoke and replace the Genetically Modified Organisms (Contained Use) Regulations 2000 (S.I. 2831/2000), and its amending instruments (S.I.2002/63, S.I. 2005/2466, S.I. 2010/2840).

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 including where there is a licence 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 extend to England, Scotland and Wales but not to Northern Ireland. The competent authority in relation to contained use in England and Wales is the Secretary of State and the Health and Safety Executive (HSE) acting jointly. The competent authority in relation to contained use in Scotland is the Scottish Ministers and the Executive acting jointly. The joint

competent authority is the two competent authorities acting jointly (regulation 2). 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.

3. The meaning of some terms within the Health and Safety at Work etc Act 1974 are modified so that the Regulations apply to educational institutions as if they were workplaces and students as if they were employees of that university. 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 Act (regulation 4).

4. Before contained use can commence a person responsible for that contained use must ensure that an assessment of the risks created by the contained use to human health and the environment has been carried out. The person carrying out the risk assessment must assign a class (from 1 to 4 with 4 being the highest risk) to the contained use depending on the seriousness of the risks posed (regulation 5, Schedule 1 and Schedule 3). Similarly, 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 (where the risk is assessed at class 2 or above) a genetic modification safety committee with relevant expertise (regulation 8).

5. Premises cannot be used for contained use unless they have been notified to the competent authority together with information specified (regulation 9 and Schedule 5) by a person responsible for the first contained use. One notification can include more than one premises. Where a notification contains premises situated in both Scotland and in England, or in both Scotland and in Wales the notification must be made to the joint competent authority.

6. Before class 2 contained use can commence, a person responsible for contained use must notify the competent authority of that contained use and provide information specified in Schedule 6 (regulation 10). A period of time must then elapse before contained use can begin, the period is dependent on whether contained use of that class or higher has taken place on those premises before.

7. Class 3 or 4 contained use cannot commence unless the competent authority has given consent for that contained use. A person responsible must submit a notification for that 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 contained use in that class (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. A notification for contained use where the premises notification had to be made to the joint competent authority must also be made to the joint competent authority. In certain circumstances the competent authority or joint competent authorities may accept single notifications for 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 cannot begin or continue until the competent authority has agreed in writing except to store or destroy the genetically modified organisms (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 activity 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 activity (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 consider risks to human health and the protection of the environment, in the case of larger GMOs the plan only considers 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 impose time limits or conditions on contained use, to suspend, terminate or not commence contained use and to vary or revoke any consent previously granted under regulation 11 (regulation 25).
15. The competent authority must take certain steps if notified of an accident (regulation 26). 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 such an exemption (regulation 26).
16. The competent authority is to maintain a register of all notifications and copies of the register are to be made available for public inspection by the Executive by such means as are appropriate including by publication on its website. (regulation 28) Certain information may not be published if it would be contrary to the interests of national security (regulation 29).
17. Provision is made for the enforcement of the Regulations under the Health and Safety at Work etc Act 1974 (regulation 30).
18. There is a right of appeal for any person who is aggrieved by certain decisions of the competent authority, a request for information or an instruction given to him by the Executive (regulation 31).
19. Anything that must be submitted to the competent authority under the regulations must be submitted to the Executive at the address they publish for the purpose, this could be an email or other form of electronic submission (regulation 32).
20. There are various transitional, saving and consequential provisions and various instruments are revoked (see paragraph 1 above) (regulations 33 to 35).
21. A copy of the impact assessment prepared in respect of these Regulations can be obtained from the Health and Safety Executive, Economic Adviser’s Unit, Rose Court, 2, Southwark Bridge, London SE1 9HS. A copy has been placed in the Library of each House of Parliament.