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## STATUTORY INSTRUMENTS

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# 2014 No. 1663

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

### PART 1

#### Interpretation and General

##### Citation and commencement

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

##### Interpretation

2.—(1) In these Regulations—

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

“the 2000 Regulations” means the Genetically Modified Organisms (Contained Use) Regulations 2000<sup>MI</sup>;

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

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

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

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

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

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

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

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

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

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

- (a) genetic modification occurs at least through the use of the techniques listed in Part 1 of Schedule 2; and
- (b) the techniques set out in Part 2 of Schedule 2 are not considered to result in genetic modification,

and “genetically modified” is to be construed accordingly;

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

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

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

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

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

- (a) “human admixed embryo” has the same meaning as in the Human Fertilisation and Embryology Act 1990 <sup>M2</sup> by virtue of section 4A(6) and (11) of that Act; and
- (b) “human embryo” has the same meaning as “embryo” in the Human Fertilisation and Embryology Act 1990 (apart from section 4A) by virtue of section 1(1) and (6) of that Act;

“person responsible for contained use” or “person responsible for the contained use” means—

- (a) a person who has the authority to determine whether a particular contained use takes place; or
  - (b) a person who has control of the planning or conduct (or both) of that contained use,
- and there may be more than one person responsible for the same contained use;

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

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

- (a) genetically modified micro-organisms, an assessment carried out as required by regulation 5(1); or
- (b) larger GMOs, an assessment carried out as required by regulation 6(1);

“transboundary movement” has the meaning assigned to it by Article 3 of Regulation (EC) No 1946/2003 of the European Parliament and the Council on transboundary movements of genetically modified organisms <sup>M3</sup>;

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

“working day” means any day other than a Saturday, a Sunday, Christmas Day or Good Friday, or a bank holiday specified in Schedule 1 to the Banking and Financial Dealings Act 1971 <sup>M4</sup>.

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

(3) In these Regulations—

- (a) a reference to an appropriate containment level is a reference to the containment level assigned to a contained use involving micro-organisms in accordance with paragraphs 3(i) and 4 of Part 2 of Schedule 3;
- (b) any reference to a contained use in a numbered class is a reference to a contained use involving micro-organisms which has been classified as belonging to the class of that number in accordance with paragraph 3(j) and (k) of Part 2 of Schedule 3.
- (4) The measures in—
  - (a) Part 2 of Schedule 8 are to be applied in accordance with Part 1 of that Schedule; and
  - (b) Tables 1a, 1b and 1c in Part 2 of Schedule 8 are to be applied in accordance with the notes set out at the end of the table in question.

#### Marginal Citations

- M1** [S.I. 2000/2831](#). The 2000 Regulations and all its amending instruments are revoked by these Regulations (see [regulation 35](#)).
- M2** [1990 c. 37](#). Sections 1(1) and (6) were substituted by section 1(2) and (5) of the [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#) and section 4A was inserted by section 4(2) of that Act.
- M3** OJ No L 287, 5.11.2003, p1.
- M4** [1971 c. 80](#). Schedule 1 was amended by section 1 of the St Andrew's Day Bank Holiday (Scotland) Act 2007 (2007 asp.2).

#### Application

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

- (2) These Regulations do not apply to any activity in which—
    - (a) genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used, where such organisms are, or are contained in, a product marketed in accordance with—
      - (i) the consent of any of the following granted under section 111(1) of the Environmental Protection Act 1990 <sup>M5</sup>—
        - (aa) the Secretary of State;
        - (bb) the Scottish Ministers, as regards Scotland;
        - (cc) the Welsh Ministers, as regards Wales;
      - (ii) a consent granted by the Northern Ireland Department of the Environment under article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991 <sup>M6</sup>,
      - <sup>F1</sup>(iii) . . . . .
- and, in each case, that activity is conducted in accordance with any conditions or limitations attached to that consent;
- (b) genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used, where such organisms are, or are contained in—
    - <sup>F2</sup>(i) a medicinal product for veterinary use marketed in accordance with the Veterinary Medicines Regulations 2013; <sup>F3</sup>or

- (ii) food or feed authorised in accordance with the provisions of Regulation (EC) No 1829/2003 of the European Parliament and the Council on genetically modified food and feed<sup>M7F4</sup> ...
- <sup>F5</sup>(iii) ..... [<sup>F6</sup>; or
- (iv) a medicinal product for human use marketed in accordance with the Human Medicines Regulations 2012;]
- (c) genetically modified organisms are released or marketed in cases or circumstances in which—
- (i) the consent of any of the following is required under section 111(1) of the Environmental Protection Act 1990—
- (aa) the Secretary of State;
- (bb) the Scottish Ministers, as regards Scotland;
- (cc) the Welsh Ministers, as regards Wales; or
- (ii) the consent of the Northern Ireland Department of the Environment is required under article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991.
- (3) Regulations 7, 9 to 17, 18(2) and (4), 19, 20, and 23 to 25 do not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.
- (4) Regulation 5 applies to the transport of genetically modified organisms by road, rail, inland waterway, sea or air, except that, in making the assessment required by regulation 5(1), the person undertaking that assessment is not required to include the steps set out in paragraph 3(i) to (k) of Part 2 of Schedule 3.
- (5) These Regulations do not extend to Northern Ireland.
- (6) In this regulation, “product” means a product consisting of, or containing, a genetically modified organism or a combination of genetically modified organisms.

#### Textual Amendments

- F1** Reg. 3(2)(a)(iii) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 40(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Reg. 3(2)(b)(i) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 40(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** Word in reg. 3(2)(b)(i) inserted (31.12.2020) by The Health and Safety (Amendment) (EU Exit) Regulations 2018 (S.I. 2018/1370), regs. 1(1), **9(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Words in reg. 3(2)(b)(ii) omitted (31.12.2020) by virtue of The Health and Safety (Amendment) (EU Exit) Regulations 2018 (S.I. 2018/1370), regs. 1(1), **9(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Reg. 3(2)(b)(iii) omitted (31.12.2020) by virtue of The Health and Safety (Amendment) (EU Exit) Regulations 2018 (S.I. 2018/1370), regs. 1(1), **9(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Reg. 3(2)(b)(iv) and word inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 12**; 2020 c. 1, Sch. 5 para. 1(1)

#### Marginal Citations

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

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

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

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

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

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

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

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

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

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

- (a) to a self-employed person [<sup>F7</sup>who conducts an undertaking of a prescribed description] were a reference to any person (except a student) undertaking contained use who is not an employer or an employee; and
- (b) to [<sup>F8</sup>the undertaking] includes a reference to that contained use.

(4) In this regulation—

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

“student” means any person studying at an educational establishment.

### Textual Amendments

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

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

**Changes to legislation:**

There are currently no known outstanding effects for the The Genetically Modified Organisms (Contained Use) Regulations 2014, PART 1.