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STATUTORY INSTRUMENTS

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**2002 No. 2443**

**Genetically Modified Organisms  
(Deliberate Release) Regulations 2002**

**PART I**

**GENERAL**

**Interpretation**

**2.** In these Regulations—

“the Act” means the Environmental Protection Act 1990;

“the Advisory Committee on Releases to the Environment” means the committee appointed by the Secretary of State under section 124 of the Act;

“antibiotic resistance markers” means genes employed in the modification of an organism to make that organism express resistance to a particular antibiotic or antibiotics;

“application for consent to release” shall include any notification made under the First Simplified Procedure (crop plants) Decision;

[<sup>F1</sup>“approved product” means a product—

(a) permitted to be marketed in England by—

- (i) a consent granted by the Secretary of State under section 111(1) of the Act, or
- (ii) an authorisation under the Food and Feed Regulation, or

(b) which, immediately before exit day, was permitted to be marketed by a consent granted in accordance with Article 15(3), 17(6) or 18(2) of the Deliberate Release Directive or Article 13(2) or (4) of the 1990 Directive (a “pre-exit approved product”);]

[<sup>F2</sup>“biological matter” means anything (other than an entity mentioned in the definition of organism) which consists of or includes—

- (a) tissue or cells (including gametes or propagules) or subcellular entities, of any kind, capable of replication or of transferring genetic material, or
- (b) genes or other genetic material, in any form, which are so capable,

and it is immaterial, in determining if something is or is not biological matter, whether it is the product of natural or artificial processes of reproduction or whether or not it has ever been part of a whole organism;]

<sup>F3</sup> ...

<sup>F4</sup> ...

[<sup>F5</sup>“the Deliberate Release Directive” means Council Directive [2001/18/EC](#) on the deliberate release into the environment of genetically modified organisms as it applied immediately before exit day;]

“the 1990 Directive” means Council Directive [1990/220/EEC](#)<sup>M1</sup> on the deliberate release into the environment of genetically modified organisms as amended by Commission Directive [1994/15/EC](#)<sup>M2</sup> and Commission Directive [1997/35/EC](#)<sup>M3</sup>;

“electronic communication” means the same as in the Electronic Communications Act 2000<sup>M4</sup>;

“environmental risk assessment” means the environmental risk assessment required to be contained in an application for consent to release or market genetically modified organisms by regulation 11(1)(c) and regulation 16(2)(c), respectively;

“the First Simplified Procedure (crop plants) Decision” means Commission Decision [94/730/EC](#)<sup>M5</sup>[<sup>F6</sup>as it applies immediately before exit day];

[<sup>F7</sup>“the Food and Feed Regulation” means Council Regulation (EC) No 1829/2003 on genetically modified food and feed;]

[<sup>F7</sup>“genetically modified feed” means—

- (a) feed containing, consisting of or produced from genetically modified organisms; or
- (b) genetically modified organisms for feed use;]

[<sup>F7</sup>“genetically modified food” means—

- (a) food containing or consisting of genetically modified organisms;
- (b) food produced from, or containing ingredients produced from, genetically modified organisms; or
- (c) genetically modified organisms for food use;]

“genetically modified organisms” means a genetically modified organism or a combination of genetically modified organisms;

“higher plant” means a plant belonging to the taxonomic group *Spermatophytae* (*Gymnospermae* or *Angiospermae*);

[<sup>F2</sup>“human admixed embryo” has the same meaning as it has in the Human Fertilisation and Embryology Act 1990 by virtue of section 4A(6) and (11) of that Act;]

[<sup>F2</sup>“human embryo” means an embryo within the meaning given in the provisions of the Human Fertilisation and Embryology Act 1990 (apart from section 4A) by virtue of section 1(1) and (6) of that Act; and]

“local authority” means a county council, a district council, a London borough council, the Common Council of the City of London in its capacity as a local authority, and the Council of the Isles of Scilly;

“monitoring plan” means the plan required by regulation 16(2)(g);

[<sup>F2</sup>“organism” means any acellular, unicellular or multicellular entity (in any form and whether or not it is the product of natural or artificial processes of reproduction), other than humans, human embryos or human admixed embryos; and, unless the context otherwise requires, the term also includes any article or substance consisting of or including biological matter;]

[<sup>F8</sup>“qualifying higher plant” means a higher plant which is a genetically modified organism but which has not been genetically modified other than to make modifications—

- (a) that could have occurred naturally, or
- (b) that could have been made using one or more of the techniques set out in regulation 5(2);]

“the register” means the public register kept by the Secretary of State under section 122 of the Act.

“the 1992 Regulations” means the Genetically Modified Organisms (Deliberate Release) Regulations 1992<sup>M6</sup>.

#### Textual Amendments

- F1** Words in reg. 2 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Words in reg. 2 inserted (1.10.2009) by The Human Fertilisation and Embryology (Consequential Amendments and Transitional and Saving Provisions) Order 2009 (S.I. 2009/1892), art. 1(1)(b), **Sch. 3 para. 5** (with Sch. 4)
- F3** Words in reg. 2 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Words in reg. 2 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in reg. 2 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(2)(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in reg. 2 inserted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(2)(e)**; 2020 c. 1, Sch. 5 para. 1(1)
- F7** Words in reg. 2 inserted (8.10.2004) by The Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations 2004 (S.I. 2004/2411), regs. 1, **2(2)(b)**
- F8** Words in reg. 2 inserted (11.4.2022) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 (S.I. 2022/347), regs. 1(1), **2(2)**

#### Marginal Citations

- M1** OJ No L117, 8.5.1990, p. 15.
- M2** OJ No L103, 22.4.1994, p. 20.
- M3** OJ No L169, 27.6.1997, p. 72.
- M4** 2000 c. 7.
- M5** OJ No L292, 12.11.1994, p. 31.
- M6** SI 1992/3280 as amended by the Genetically Modified Organisms (Deliberate Release) Regulations 1993 (SI 1993/152), the Genetically Modified Organisms (Deliberate Release) Regulations 1995 (SI 1995/304), the Genetically Modified Organisms (Deliberate Release and Risk Assessment) (Amendment) Regulations 1997 (SI 1997/1900) and the Genetically Modified Organisms (Contained Use) Regulations 2000 (SI 2000/2831).

**Changes to legislation:**

There are outstanding changes not yet made by the legislation.gov.uk editorial team to Genetically Modified Organisms (Deliberate Release) Regulations 2002. Any changes that have already been made by the team appear in the content and are referenced with annotations.

[View outstanding changes](#)

**Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:**

- Blanket amendment words substituted by [S.I. 2011/1043 art. 3-68-10](#)