

*Draft Regulations laid before Parliament under paragraph 13(4) of Schedule 8 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.*

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DRAFT STATUTORY INSTRUMENTS

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**2022 No. 0000**

**ENVIRONMENTAL PROTECTION, ENGLAND**

**The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022**

*Made* - - - - **\*\*\***  
*Coming into force* - - **\*\*\***

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 108, 111 and 122 of the Environmental Protection Act 1990(1).

In accordance with section 126(5) of that Act, the Secretary of State has consulted the Food Standards Agency.

In accordance with paragraph 13(4) of Schedule 8 to the European Union (Withdrawal) Act 2018(2), a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

**Citation, commencement, extent and application**

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 and come into force 21 days after the day on which they are made.

(2) These Regulations extend to England and Wales and apply to England only.

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

2.—(1) The Genetically Modified Organisms (Deliberate Release) Regulations 2002(3) are amended as follows.

(2) In regulation 2 (interpretation), after the entry for “organism” insert—

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(1) 1990 c. 43. Sections 108 and 111 were amended by paragraph 17 of Schedule 3 to the Food Standards Act 1999 (c. 28) and by paragraph 4 of the Schedule to the Food (Scotland) Act 2015 (asp 1). Section 111 was also amended by S.I. 1992/3280, 2002/2443. Section 126 was substituted by paragraph 18 of Schedule 3 to the Food Standards Act 1999 and amended by paragraph 4 of the Schedule to the Food (Scotland) Act 2015.

(2) 2018 c. 16. Paragraph 13(4) of Schedule 8 was amended by paragraph 54(8)(a) of Schedule 5 to the European Union (Withdrawal Agreement) Act 2020 (c. 1).

(3) S.I. 2002/2443, amended by S.I. 2009/1892; there are other amending instruments but none are relevant.

““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);”.

(3) In regulation 9, for the heading substitute—

*“Exemption for approved products”.*

(4) After regulation 9 insert—

**“Exemption for release of qualifying higher plants**

**9A.** The cases and circumstances prescribed for the purposes of sections 108(7) and 111(7) of the Act in which persons are exempt from the requirements of section 108(1)(a) of the Act (to carry out a risk assessment) and of section 111(1)(a) of the Act (to obtain consent) respectively, insofar as those requirements relate to releasing qualifying higher plants (which includes the import or acquisition of such plants for the purpose of release), are all cases and circumstances in which a person intends to release a qualifying higher plant, other than those in relation to the marketing of such qualifying higher plants.

**Notification requirement for release of qualifying higher plants**

**9B.—(1)** The cases and circumstances prescribed for the purposes of section 108(1)(b) of the Act in which persons intending to release a genetically modified organism must give notice to the Secretary of State of that intention and such information as may be prescribed are all cases and circumstances in which a person intends to release a qualifying higher plant, other than those in relation to the marketing of such qualifying higher plants.

(2) A person to whom paragraph (1) applies must give that notice to the Secretary of State at least 20 days before the day on which the qualifying higher plant is released.

(3) A person to whom paragraph (1) applies must give the information set out in Schedule 3A to the Secretary of State in respect of their plans concerning the release of the qualifying higher plant (“the project”) at the same time as giving notice in accordance with this regulation.”.

(5) In regulation 34 (information to be included in the register)—

- (a) in paragraph (1), for “(2)” substitute “(1A)”;
- (b) after paragraph (1) insert—

“(1A) In relation to a notice given under section 108(1)(b) of the Act, the content of that notice and the information given under regulation 9B(3), except information falling within paragraphs 3 to 5 of Schedule 3A.”.

(6) In regulation 35 (keeping the register), at the beginning insert—

“(A1) The information prescribed in regulation 34(1A) must be placed on the register within twelve days of receipt by the Secretary of State of the notice.”.

(7) After Schedule 3 insert—

“SCHEDULE 3A

Regulation 9B

Information to be provided to the Secretary of State alongside  
a notice of intention to release a qualifying higher plant

1. The title of the project under which the qualifying higher plant is to be released.
2. The aim of the project (including any matters being investigated as part of the project).
3. The name, address, telephone number and email address of the person with overall responsibility for the project.
4. The name, qualifications and experience of every person responsible for planning and carrying out the project.
5. The name, qualifications and experience of every person responsible for the supervision, monitoring and safety of the release of the qualifying higher plant.
6. The full name of the qualifying higher plant to be released under the project, including—
  - (a) family name;
  - (b) genus;
  - (c) species;
  - (d) subspecies.
7. The expected date on which the project will start.
8. The expected duration of the project.”.

Date

*Name*  
Parliamentary Under Secretary of State  
Department for Environment, Food and Rural  
Affairs

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443) (“the 2002 Regulations”). They apply in England only.

Regulation 2(2) defines the concept of a “qualifying higher plant” for the purposes of the 2002 Regulations.

Regulation 2(4) inserts new regulation 9A into the 2002 Regulations, which provides for an exemption in respect of qualifying higher plants from the requirements of sections 108(1)(a) and 111(1)(a) of the Environmental Protection Act 1990 (c. 43) (“the Act”) where they are being released into the environment in cases and circumstances which do not relate to marketing those qualifying higher plants.

Regulation 2(4) further inserts new regulation 9B into the 2002 Regulations, which provides for a notification requirement under section 108(1)(b) of the Act in respect of the intended release into the environment of qualifying higher plants, except in cases and circumstances which relate to the marketing of those qualifying higher plants. Schedule 3A to the 2002 Regulations, inserted by regulation 2(7), sets out the information which must be provided alongside such a notice.

Regulation 2(5) and (6) amends regulations 34 and 35 of the 2002 Regulations requiring the Secretary of State to publish information relating to a notice given under regulation 9B on the public register under the Act within twelve days of receipt of the notice.

A regulatory triage assessment of the effect that this instrument will have on the costs of business, the voluntary sector and the public sector is available from the Genetic Resources and GM Team, Department for Environment, Food and Rural Affairs, 2 Marsham Street, London, SW1P 4DF and is published with the Explanatory Memorandum alongside these Regulations on [www.legislation.gov.uk](http://www.legislation.gov.uk).