



STATUTORY INSTRUMENTS.

S.I. No. 278 of 2021



GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE)
(AMENDMENT) REGULATIONS 2021

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I, EAMON RYAN, Minister for the Environment, Climate and Communications, in exercise of the powers conferred on me by sections 6 and 111 of the Environmental Protection Agency Act 1992 (No. 7 of 1992) (as adapted by the Communications, Climate Action and Environment (Alteration of Name of Department and Title of Minister) Order 2020 (S.I. No. 373 of 2020)), and for the purpose of giving effect to Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019¹, hereby make the following regulations:

1. These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations 2021.

2. In these Regulations “Principal Regulations” means the Genetically Modified Organisms (Deliberate Release) Regulations 2003 (S.I. No. 500 of 2003).

3. Article 3 of the Principal Regulations is amended by the substitution, in sub-article (1) of the following definition for the definition of “the Directive”:

“ ‘the Directive’ means Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC² as amended by –

- (a) Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003³,
- (b) Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003⁴,
- (c) Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008⁵,
- (d) Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015⁶,
- (e) Commission Directive (EU) 2018/350 of 8 March 2018⁷,

¹ OJ No. L.231, 6.9.2019, p. 1

² OJ No. L.106, 17.4.2001, p.1

³ OJ No. L.268, 18.10.2003, p.1

⁴ OJ No. L.268, 18.10.2003, p.24

⁵ OJ No. L.81, 20.3.2008, p.45

⁶ OJ No. L.68, 13.3.2015, p.1

⁷ OJ No. L.67, 9.3.2018, p.30

- (f) Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019⁸,
- (g) Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019⁹,
- (h) Regulation (EU) 2020/1043 of the European Parliament and of the Council of 15 July 2020¹⁰.”.

4. The Principal Regulations are amended by the substitution of the following article for Article 10:

“10. (1) A notifier who submits a notification of or otherwise provides information in pursuance of these Regulations may request the Agency to treat all or any items of the information set out in sub-article (4) as confidential and the Agency shall consider that request.

(2) A request made under sub-article (1) shall be accompanied by verifiable justification in accordance with sub-article (3).

(3) When considering a request made by a notifier under sub-article (1) the Agency may treat the items of information set out in sub-article (4) as confidential information where the notifier provides verifiable justification by way of demonstrating to the Agency that the disclosure of such information would potentially harm its interests to a significant degree.

(4) The items of information referred to in sub-articles (1) and (3) are as follows:

- (a) the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;
- (b) commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
- (c) commercial information revealing sourcing, market shares or business strategy of the applicant;
- (d) DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event;
- (e) breeding patterns and strategies.

(5) The Agency shall, after consultation with the notifier, decide which information is to be treated as confidential information and shall inform the notifier of its decision.

⁸ OJ No. L.198, 25.7.2019, p.241

⁹ OJ No. L.231, 6.9.2019, p.1

¹⁰ OJ No. L.231, 17.7.2020, p.12

(6) The Agency shall take the necessary measures to ensure that information notified or exchanged under this article which the Agency has decided to treat as confidential information under sub-article (5) is not made public.

(7) Notwithstanding sub-articles (3) and (6), where urgent action is essential to protect human health, animal health or the environment, such as in the case of an emergency, the Agency may disclose the information referred to in sub-article (4).”.



GIVEN under my Official Seal,
2 June 2021.

EAMON RYAN
Minister for the Environment, Climate and
Communications.

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