

Regulation (EC) No 1946/2003 of the European Parliament and of the Council
of 15 July 2003 on transboundary movements of genetically modified organisms

CHAPTER I

OBJECTIVES, SCOPE AND DEFINITIONS

Article 1

Objectives

In accordance with the precautionary principle, and without prejudice to the provisions of Directive 2001/18/EC, the objectives of this Regulation are to establish a common system of notification and information for transboundary movements of genetically modified organisms (GMOs) and to ensure coherent implementation of the provisions of the Protocol on behalf of the Community in order to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 2

Scope

1 This Regulation shall apply to the transboundary movements of all GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health.

2 Pharmaceuticals for humans that are addressed by other relevant international agreements or organisations are excluded from the scope of this Regulation.

Article 3

Definitions

For the purpose of this Regulation, the following definitions shall apply:

- (1) 'organism' means organism as defined in Article 2(1) of Directive 2001/18/EC;
- (2) 'genetically modified organism', or 'GMO', means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex IB to Directive 2001/18/EC;
- (3) 'deliberate release' means deliberate release as defined in Article 2(3) of Directive 2001/18/EC;
- (4) 'placing on the market' means placing on the market as defined in Article 2(4) of Directive 2001/18/EC;
- (5) 'contained use' means:

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- (a) activities defined in Article 2(c) of Directive 90/219/EEC ⁽¹⁾;
 - (b) activities in which organisms other than micro-organisms are genetically modified or in which such GMOs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures, based on the same principles of containment as in Directive 90/219/EEC, are used appropriately to limit their contact with the general population and the environment;
- (6) ‘food’ means food as defined in Article 2 of Regulation (EC) No 178/2002 ⁽²⁾;
 - (7) ‘feed’ means feed as defined in Article 3(4) of Regulation (EC) No 178/2002;
 - (8) ‘notification’ means the submission of the information required from the exporter under this Regulation to the competent authority of a Party to the Protocol or to the competent authority of a non-Party;
 - (9) ‘the Biosafety Clearing-House’ or ‘the BCH’ means the Biosafety Clearing-House established under Article 20 of the Protocol;
 - (10) ‘export’ means:
 - (a) the permanent or temporary leaving of the customs territory of the Community of GMOs meeting the conditions of Article 23(2) of the Treaty;
 - (b) the re-export of GMOs not meeting the conditions referred to in (a) which are placed under a customs procedure other than transit procedure;
 - (11) ‘import’ means the placing under a customs procedure, other than transit procedure, of GMOs introduced into the customs territory of a Party or non-Party outside the Community from a Party within the Community;
 - (12) ‘exporter’ means any natural or legal person by whom or on whose behalf a notification is made, that is to say the person who, at the time when the notification is sent, holds the contract with the consignee in the third country and has the power to determine that the GMO is to be sent out of the customs territory of the Community. If no export contract has been concluded or if the holder of the contract does not act on its own behalf, the power to determine that the GMO is to be sent out of the customs territory of the Community shall be decisive;
 - (13) ‘importer’ means any natural or legal person, under the jurisdiction of the Party or non-Party of Import, who arranges for a GMO to be imported;
 - (14) ‘transboundary movement’ means the intentional or unintentional movement of a GMO between one Party or non-Party and another Party or non-Party, excluding intentional movements between Parties within the Community;
 - (15) ‘Party’ means any country or regional economic integration organisation being a Party to the Protocol;
 - (16) ‘non-Party’ means any country or regional economic integration organisation not being a Party to the Protocol;
 - (17) ‘the Protocol’ means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Convention);

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- (18) ‘biological diversity’ means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems;
- (19) ‘competent authority’ means a competent authority designated by a Party to the Protocol, or the relevant equivalent body of a non-Party, which is responsible for performing the administrative functions required by the Protocol, or equivalent functions in the case of a non-Party, and is authorised to act on its behalf with respect to those functions;
- (20) ‘focal point’ means the entity designated by a Party to be responsible on its behalf for liaising with the Secretariat;
- (21) ‘Secretariat’ means the Secretariat to the Protocol.

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- (1) Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (OJ L 117, 8.5.1990, p. 1). Directive as last amended by Decision 2001/204/EC (OJ L 73, 15.3.2001, p. 32).
- (2) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

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Changes and effects yet to be applied to :

- Regulation words omitted by [S.I. 2019/90 reg. 5\(15\)](#)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Annex 1(c) words substituted in earlier amending provision [S.I. 2019/90, reg. 5\(16\)\(a\)](#) by [S.I. 2020/1421 Sch. para. 3\(12\)\(a\)](#)
- Annex 1(m) words substituted in earlier amending provision [S.I. 2019/90, reg. 5\(16\)\(b\)](#) by [S.I. 2020/1421 Sch. para. 3\(12\)\(b\)](#)
- Annex 3(b) words substituted in earlier amending provision [S.I. 2019/90, reg. 5\(17\)](#) by [S.I. 2020/1421 Sch. para. 3\(13\)](#)
- Art. 1 word omitted by [S.I. 2019/90 reg. 5\(2\)\(b\)](#)
- Art. 1 words omitted by [S.I. 2019/90 reg. 5\(2\)\(a\)](#)
- Art. 1 words omitted by [S.I. 2019/90 reg. 5\(2\)\(c\)](#)
- Annex 1(c) words substituted by [S.I. 2019/90 reg. 5\(16\)\(a\)](#)
- Annex 1(m) words omitted by [S.I. 2019/90 reg. 5\(16\)\(b\)\(ii\)](#)
- Annex 1(m) words substituted by [S.I. 2019/90 reg. 5\(16\)\(b\)\(i\)](#)
- Annex 3(b) words substituted by [S.I. 2019/90 reg. 5\(17\)](#)
- Art. 3(10)(a) substituted by [S.I. 2019/90, reg. 5\(3\)\(a\)](#) (as substituted) by [S.I. 2019/759 reg. 12\(2\)](#)
- Art. 3(10)(a) substituted in earlier amending provision [S.I. 2019/90, reg. 5\(3\)\(a\)](#) by [S.I. 2020/1421 Sch. para. 3\(2\)\(a\)](#)
- Art. 3(10)(a) words substituted by [S.I. 2019/90 reg. 5\(3\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Reg. 5(3)(a) substituted immediately before IP completion day by [S.I. 2019/759, regs. 1\(a\), 12\(2\)](#))
- Art. 3(11) words substituted by [S.I. 2019/90 reg. 5\(3\)\(b\)](#)
- Art. 3(11) words substituted in earlier amending provision [S.I. 2019/90, reg. 5\(3\)\(b\)](#) by [S.I. 2020/1421 Sch. para. 3\(2\)\(b\)](#)
- Art. 3(12) words substituted by [S.I. 2019/90 reg. 5\(3\)\(c\)](#)
- Art. 3(12) words substituted in earlier amending provision [S.I. 2019/90, reg. 5\(3\)\(c\)](#) by [S.I. 2020/1421 Sch. para. 3\(2\)\(c\)](#)
- Art. 3(14) words omitted by [S.I. 2019/90 reg. 5\(3\)\(d\)](#)
- Art. 3(15) substituted by [S.I. 2019/90, reg. 5\(3\)\(da\)](#) (as inserted) by [S.I. 2020/1421 Sch. para. 3\(2\)\(d\)](#)
- Art. 3(19) substituted by [S.I. 2019/90 reg. 5\(3\)\(e\)](#)
- Art. 3(19) words inserted in earlier amending provision [S.I. 2019/90, reg. 5\(3\)\(e\)](#) by [S.I. 2020/1421 Sch. para. 3\(2\)\(e\)](#)
- Art. 3(19A) inserted by [S.I. 2019/90, reg. 5\(3\)\(ea\)](#) (as inserted) by [S.I. 2020/1421 Sch. para. 3\(2\)\(f\)](#)
- Art. 3(20) substituted by [S.I. 2019/90 reg. 5\(3\)\(f\)](#)
- Art. 3(20) words inserted in earlier amending provision [S.I. 2019/90, reg. 5\(3\)\(f\)](#) by [S.I. 2020/1421 Sch. para. 3\(2\)\(g\)](#)
- Art. 3(20A) inserted by [S.I. 2019/90, reg. 5\(3\)\(fa\)](#) (as substituted) by [S.I. 2020/1421 Sch. para. 3\(2\)\(g\)](#)
- Art. 3(22)(23) inserted by [S.I. 2019/90 reg. 5\(3\)\(g\)](#)
- Art. 3(22) words substituted in earlier amending provision [S.I. 2019/90, reg. 5\(3\)\(g\)](#) by [S.I. 2020/1421 Sch. para. 3\(2\)\(h\)\(i\)](#)
- Art. 3(23) word inserted in earlier amending provision [S.I. 2019/90, reg. 5\(3\)\(g\)](#) by [S.I. 2020/1421 Sch. para. 3\(2\)\(h\)\(ii\)\(aa\)](#)

- Art. 3(23) words substituted in earlier amending provision S.I. 2019/90, reg. 5(3)(g) by [S.I. 2020/1421 Sch. para. 3\(2\)\(h\)\(ii\)\(bb\)](#)
- Art. 3(24) inserted in earlier amending provision S.I. 2019/90, reg. 5(3)(g) by [S.I. 2020/1421 Sch. para. 3\(2\)\(h\)\(iii\)](#)
- Art. 5(2) words substituted by [S.I. 2019/90 reg. 5\(4\)\(a\)](#)
- Art. 5(5) words substituted by [S.I. 2019/90 reg. 5\(4\)\(b\)](#)
- Art. 6 heading words substituted by [S.I. 2019/90 reg. 5\(5\)\(a\)](#)
- Art. 6 words substituted by [S.I. 2019/90 reg. 5\(5\)\(b\)](#)
- Art. 6 words substituted by [S.I. 2019/90 reg. 5\(5\)\(c\)\(i\)](#)
- Art. 6 words substituted by [S.I. 2019/90 reg. 5\(5\)\(c\)\(ii\)](#)
- Art. 9(1) words substituted by [S.I. 2019/90 reg. 5\(6\)\(a\)\(i\)\(aa\)](#)
- Art. 9(1) words substituted by [S.I. 2019/90 reg. 5\(6\)\(a\)\(i\)\(bb\)](#)
- Art. 9(1) words substituted by [S.I. 2019/90 reg. 5\(6\)\(a\)\(ii\)](#)
- Art. 9(3) words substituted by [S.I. 2019/90 reg. 5\(6\)\(b\)](#)
- Art. 9(4) words substituted by [S.I. 2019/90 reg. 5\(6\)\(c\)](#)
- Art. 10(3) words substituted by [S.I. 2019/90 reg. 5\(7\)](#)
- Art. 12(2) words substituted by [S.I. 2019/90 reg. 5\(8\)\(a\)](#)
- Art. 12(5) word omitted by [S.I. 2019/90 reg. 5\(8\)\(b\)](#)
- Art. 14(1) words substituted by [S.I. 2019/90 reg. 5\(9\)\(a\)](#)
- Art. 14(2) words substituted by [S.I. 2019/90 reg. 5\(9\)\(b\)\(i\)\(aa\)](#)
- Art. 14(2) words substituted by [S.I. 2019/90 reg. 5\(9\)\(b\)\(i\)\(bb\)](#)
- Art. 14(2)(a) words omitted by [S.I. 2019/90 reg. 5\(9\)\(bb\)\(ii\)](#)
- Art. 15(1) words omitted by [S.I. 2019/90 reg. 5\(10\)\(a\)\(i\)\(bb\)](#)
- Art. 15(1) words substituted by [S.I. 2019/90 reg. 5\(10\)\(a\)\(i\)\(aa\)](#)
- Art. 15(1)(c) words substituted by [S.I. 2019/90 reg. 5\(10\)\(a\)\(ii\)](#)
- Art. 15(1)(e) substituted by [S.I. 2019/90 reg. 5\(10\)\(a\)\(iii\)](#)
- Art. 15(1)(e) words omitted in earlier amending provision S.I. 2019/90, reg. 5(10)(a)(iii) by [S.I. 2020/1421 Sch. para. 3\(8\)\(b\)\(ii\)](#)
- Art. 15(1)(e) words substituted in earlier amending provision S.I. 2019/90, reg. 5(10)(a)(iii) by [S.I. 2020/1421 Sch. para. 3\(8\)\(b\)\(i\)](#)
- Art. 15(1)(f) words substituted by [S.I. 2019/90 reg. 5\(10\)\(a\)\(iv\)](#)
- Art. 15(1)(f) words substituted in earlier amending provision S.I. 2019/90, reg. 5(10)(a)(iv) by [S.I. 2020/1421 Sch. para. 3\(8\)\(c\)](#)
- Art. 15(1)(h) substituted by [S.I. 2019/90 reg. 5\(10\)\(a\)\(v\)](#)
- Art. 15(1)(h) words omitted in earlier amending provision S.I. 2019/90, reg. 5(10)(a)(v) by [S.I. 2020/1421 Sch. para. 3\(8\)\(d\)\(i\)](#)
- Art. 15(1)(i) words substituted in earlier amending provision S.I. 2019/90, reg. 5(10)(a)(v) by [S.I. 2020/1421 Sch. para. 3\(8\)\(d\)\(ii\)](#)
- Art. 15(2) omitted by [S.I. 2019/90 reg. 5\(10\)\(b\)](#)
- Art. 16(1) words substituted by [S.I. 2019/90 reg. 5\(11\)\(a\)](#)
- Art. 16(4) words substituted by [S.I. 2019/90 reg. 5\(11\)\(b\)](#)
- Art. 17 heading word substituted by [S.I. 2019/90 reg. 5\(12\)\(a\)](#)
- Art. 17(1) omitted by [S.I. 2019/90 reg. 5\(12\)\(b\)](#)
- Art. 17(2) omitted by [S.I. 2019/90 reg. 5\(12\)\(b\)](#)
- Art. 17(3) substituted by [S.I. 2019/90 reg. 5\(12\)\(c\)](#)
- Art. 18 omitted by [S.I. 2019/90 reg. 5\(13\)](#)
- Art. 19(1) omitted by [S.I. 2019/90 reg. 5\(14\)\(a\)](#)
- Art. 19(2) words substituted by [S.I. 2019/90 reg. 5\(14\)\(b\)\(i\)](#)
- Art. 19(2) words substituted by [S.I. 2019/90 reg. 5\(14\)\(b\)\(ii\)](#)