

Commission Regulation (EC) No 65/2004 of 14 January 2004
establishing a system for the development and assignment
of unique identifiers for genetically modified organisms

CHAPTER III

**GMOs FOR WHICH CONSENT FOR THEIR PLACING ON THE MARKET HAS
BEEN GRANTED PRIOR TO THE ENTRY INTO FORCE OF THIS REGULATION**

Article 4

1 Unique identifiers shall be assigned to all GMOs in respect of which, prior to the entry into force of this Regulation, consent has been granted under Directive 90/220/EEC for their placing on the market.

2 Relevant consent holders or where appropriate the competent authority that has taken the final decision on the original application shall consult the OECD BioTrack product database, and the Biosafety clearing house, to determine whether or not a unique identifier has already been developed for that GMO in accordance with the formats set out in the Annex.

Article 5

1 Where, prior to the entry into force of this Regulation, consent has been granted for the placing on the market of a GMO and where a unique identifier has been developed for that GMO in accordance with the formats set out in the Annex, paragraphs 2, 3 and 4 shall apply.

2 Each consent holder, or where appropriate the competent authority that has taken the final decision on the original application, shall within 90 days following the date of entry into force of this Regulation, communicate the following, in writing, to the Commission:

- a the fact that the unique identifier has already been developed in accordance with the formats set out in the Annex;
- b the details of the unique identifier.

3 The unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission.

4 The Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house.

Article 6

1 Where, prior to the entry into force of this Regulation, consent has been granted for the placing on the market of a GMO but where a unique identifier has not been developed for that GMO in accordance with the formats set out in the Annex, paragraphs 2, 3, 4 and 5 shall apply.

2 Each consent holder or, where appropriate, the competent authority that has taken the final decision on the original application, shall develop a unique identifier for the GMO concerned in accordance with the formats set out in the Annex.

3 The consent holder shall, within 90 days following the date of entry into force of this Regulation, communicate the details of the unique identifier, in writing, to the competent

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 65/2004. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

authority granting consent, which in turn shall immediately transmit these details to the Commission.

4 The unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission.

5 The Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house.

Changes to legislation:

There are outstanding changes not yet made to Commission Regulation (EC) No 65/2004. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

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Changes and effects yet to be applied to :

- Regulation words omitted by [S.I. 2019/90 reg. 6\(6\)](#)

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

- Annex Section A para. 1(1) words omitted by [S.I. 2019/90 reg. 6\(7\)\(a\)](#)
- Annex Section B words substituted by [S.I. 2019/90 reg. 6\(7\)\(b\)](#)
- Art. 12 substituted for Art. 1 by [S.I. 2019/90 reg. 6\(2\)](#)
- Art. 1(d) omitted in earlier amending provision [S.I. 2019/90, reg. 8\(2\)](#) by [S.I. 2020/1421 Sch. para. 5\(2\)](#)
- Art. 1(1)(d) omitted in earlier amending provision [S.I. 2019/90, reg. 6\(2\)](#) by [S.I. 2020/1421 Sch. para. 4\(2\)\(a\)](#)
- Art. 2(2) words inserted by [S.I. 2019/90 reg. 6\(3\)](#)
- Art. 3(b) words substituted by [S.I. 2019/90 reg. 6\(4\)\(a\)](#)
- Art. 3(c) substituted by [S.I. 2019/90 reg. 6\(4\)\(b\)](#)
- Art. 4-6 omitted by [S.I. 2019/90 reg. 6\(5\)](#)