Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance)

CHAPTER III

GENETICALLY MODIFIED FEED

Section 1

Authorisation and supervision

Article 18

Opinion of the Authority

1 In giving its opinion, the Authority shall endeavour to comply with a time limit of six months as from the receipt of a valid application. Such time limit shall be extended whenever the Authority seeks supplementary information from the applicant as provided in paragraph 2.

2 The Authority [F1]... may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit.

[[F2]3 In order to prepare its opinion, the Food Safety Authority—

a) must verify that the particulars and documents submitted by the applicant are in accordance with Article 17 and examine whether the food complies with the criteria referred to in Article 16(1);

b) may ask a competent authority designated in accordance with Article 4 of Directive 2001/18/EC to carry out an environmental risk assessment; however, if the application concerns GMOs to be used as seeds or other plant-propagating material, the Food Safety Authority must ask a competent authority to carry out the environmental risk assessment;

c) may ask a public analyst to carry out a safety assessment of the feed;

d) must forward to the reference laboratory the particulars referred to in Article 17(3)(i) and (j). The reference laboratory must test and validate the method of detection and identification proposed by the applicant;

e) must, in verifying the application of Article 25(2)(c), examine the information and data submitted by the applicant to show that the characteristics of the feed are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics.**]**

4 In the case of GMOs or feed containing or consisting of GMOs, the environmental safety requirements referred to in Directive 2001/18/EC shall apply to the evaluation to ensure that all appropriate measures are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of GMOs. During evaluation of requests for the placing on the market of products consisting of or containing GMOs, **[**[F3]the competent authority designated in accordance with Directive 2001/18/EC**]** shall be consulted by the Authority. The competent authorities shall have three months after the date of receiving the request within which to make their opinion known.

5 In the event of an opinion in favour of authorising the feed, the opinion shall also include the following particulars:

a the name and address of the applicant;

b the designation of the feed, and its specification;

c where applicable, the information required under Annex II to the Cartagena Protocol;

d the proposal for the labelling of the feed;

e where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas;

f the method, validated by the [F4]... reference laboratory, for detection, including sampling, identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the feed and/or in feed produced from it; an indication of where appropriate reference material can be accessed;

g where appropriate, the monitoring plan as referred to in Article 17(5)(b).

[[F5]6 The Food Safety Authority must forward its opinion to the appropriate authority and the applicant, including a report describing its assessment of the feed and stating the reasons for its opinion and the information on which this opinion is based.**]**

[[F6]7 The Food Safety Authority must make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Food Safety Authority within 30 days from such publication.**]**

Textual Amendments

F1 Words in Art. 18(2) omitted (31.12.2020) by virtue of The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **22(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Art. 18(3) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **22(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in Art. 18(4) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **22(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F4 Word in Art. 18(5)(f) omitted (31.12.2020) by virtue of The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **22(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Art. 18(6) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **22(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Art. 18(7) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **22(f)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:
There are outstanding changes not yet made to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Regulation applied (with modifications) by S.I. 2023/959 reg. 4(a)Sch. 1

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

- Art. 5para. 3 Point (m) addition by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 5para. 3 Text replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 5para. 3 Point (l) replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 6para. 7 replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 10para. 1 replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 11para. 2 Text replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 17para. 3 Point (m) addition by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 17para. 3 Point (l) replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 17para. 3 Text replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 18para. 7 replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 22para. 1 replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 23para. 2 Text replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 29para. 2 replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 29para. 1 replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)

– Art. 35(4)(d) words substituted by S.I. 2019/1013 reg. 30 (This amendment not applied to legislation.gov.uk. S.I. 2019/1013 revoked immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 21(e))