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 II

GENETICALLY MODIFIED FOOD

Section 1

Authorisation and supervision

Article 3

Scope

1 This Section shall apply to:

a GMOs for food use;

b food containing or consisting of GMOs;

c food produced from or containing ingredients produced from GMOs.

[[F1]2 Where necessary, the appropriate authority may prescribe measures designed to amend non-essential elements of this Regulation by supplementing it and determining whether a type of food falls within the scope of this Section.**]**

Textual Amendments

F1 Art. 3(2) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **7**; 2020 c. 1, Sch. 5 para. 1(1)

Article 4

Requirements

1 Food referred to in Article 3(1) must not:

a have adverse effects on human health, animal health or the environment;

b mislead the consumer;

c differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

2 No person shall place on the market a GMO for food use or food referred to in Article 3(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied.

3 No GMO for food use or food referred to in Article 3(1) shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of this Article.

4 The authorisation referred to in paragraph 2 may cover:

a a GMO and foods containing or consisting of that GMO as well as foods produced from or containing ingredients produced from that GMO; or

b food produced from a GMO as well as foods produced from or containing that food;

c an ingredient produced from a GMO as well as food containing that ingredient.

5 An authorisation as referred to in paragraph 2 shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation.

F2 6 . . . . . .

7 Authorisation under this Regulation shall be without prejudice to Directive 2002/53/EC, Directive 2002/55/EC and Directive 68/193/EEC.

Textual Amendments

F2 Art. 4(6) 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, **8**; 2020 c. 1, Sch. 5 para. 1(1)

Article 5

Application for authorisation

1 To obtain the authorisation referred to in Article 4(2), an application shall be submitted in accordance with the following provisions.

[F3 2 The application must be sent to the Food Safety Authority, who must—

a acknowledge receipt of the application, and confirm the date of its receipt, in writing to the applicant within 14 days of its receipt;

b make the summary of the dossier referred to in paragraph 3(1) available to the public.**]**

3 The application shall be accompanied by the following:

a the name and the address of the applicant;

b the designation of the food, and its specification, including the transformation event(s) used;

c where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter referred to as the Cartagena Protocol);

d where applicable, a detailed description of the method of production and manufacturing;

e a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the food complies with the criteria referred to in Article 4(1);

f either an analysis, supported by appropriate information and data, showing that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics and to the criteria specified in Article 13(2)(a), or a proposal for labelling the food in accordance with Article 13(2)(a) and (3);

g either a reasoned statement that the food does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with Article 13(2)(b);

h where appropriate, the conditions for placing on the market the food or foods produced from it, including specific conditions for use and handling;

i methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it;

j samples of the food and their control samples, and information as to the place where the reference material can be accessed;

k where appropriate, a proposal for post-market monitoring regarding use of the food for human consumption;

l a summary of the dossier in a standardised form.

4 In the case of an application relating to a GMO for food use, references to 'food' in paragraph 3 shall be interpreted as referring to food containing, consisting of or produced from the GMO in respect of which an application is made.

5 In the case of GMOs or food containing or consisting of GMOs, the application shall also be accompanied by:

a the complete technical dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC or, where the placing on the market of the GMO has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision;

b a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.

In such case, Articles 13 to 24 of Directive 2001/18/EC shall not apply.

6 Where the application concerns a substance, the use and placing on the market of which is subject, under other provisions of **[**[F4]retained EU**]** law, to its inclusion on a list of substances registered or authorised to the exclusion of others, this must be stated in the application and the status of the substance under the relevant legislation must be indicated.

[[F5]7 The appropriate authority, having first consulted the Food Safety Authority, may prescribe rules concerning the preparation and presentation of the application.**]**

8 **[**[F6]The Food Safety Authority must**]** publish detailed guidance to assist the applicant in the preparation and the presentation of the application.

Textual Amendments

F3 Art. 5(2) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **9(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F4 Words in Art. 5(6) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **9(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Art. 5(7) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **9(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Words in Art. 5(8) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **9(d)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 6

Opinion of the Authority

1 In giving its opinion, the Authority shall endeavour to respect 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 for in paragraph 2.

2 The Authority [F7]... may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit.

[[F8]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 5 and examine whether the food complies with the criteria referred to in Article 4(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 food;

d) must forward to the reference laboratory referred to in Article 32 the particulars referred to in Article 5(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 13(2)(a), examine the information and data submitted by the applicant to show that the characteristics of the food 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 food 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, the **[**[F9]competent authority designated in accordance with Directive 2001/18/EC**]** designated by each Member State for this purpose 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 food, the opinion shall also include the following particulars:

a the name and address of the applicant;

b the designation of the food, and its specification;

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

d the proposal for the labelling of the food and/or foods produced from it;

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 food containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas;

f the method, validated by the [F10]... 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 food and/or in foods produced from it; an indication of where appropriate reference material can be accessed;

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

[[F11]6 The Food Safety Authority must forward its opinion to the appropriate authority and the applicant, including a report describing its assessment of the food and stating the reasons for its opinion and the information on which this opinion is based.**]**

[[F12]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

F7 Words in Art. 6(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, **10(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F8 Art. 6(3) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **10(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F9 Words in Art. 6(4) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **10(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F10 Word in Art. 6(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, **10(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F11 Art. 6(6) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **10(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F12 Art. 6(7) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **10(f)**; 2020 c. 1, Sch. 5 para. 1(1)

[F13 Article 7

Authorisation

1 Within three months after receiving the opinion of the Food Safety Authority, the appropriate authority must determine, taking account of the opinion of the Food Safety Authority, any relevant provisions of retained EU law, and other legitimate factors relevant to the matter under consideration, the decision to be taken in respect of the application.

2 Where the decision is not in accordance with the opinion of the Food Safety Authority, the appropriate authority must provide an explanation for the differences.

3 For applications which are authorised, the terms of the authorisation must be prescribed by the appropriate authority and must include—

a) the particulars referred to in Article 6(5);

b) the name of the authorisation holder;

c) where appropriate, the unique identifier attributed to the GMO as referred to in the Regulation (EC) No 1830/2003.

4. The authorisation granted in accordance with the procedure referred to in this Regulation is valid for 10 years and is renewable in accordance with Article 11. The authorised

food must be entered in the Register referred to in Article 28. Each entry in the Register must mention the date of authorisation and must include the particulars referred to in paragraph 3.

5. The authorisation under this Section is without prejudice to other provisions of retained EU law governing the use and placing on the market of substances which may only be used if they are included in a list of substances registered or authorised to the exclusion of others.

6. References made in parts A and D of Directive 2001/18/EC to GMOs authorised under part C of that Directive shall be considered as applying equally to GMOs authorised under this Regulation.**]**

Textual Amendments

F13 Art. 7 substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **11**; 2020 c. 1, Sch. 5 para. 1(1)

Article 8

Status of existing products

1 By way of derogation from Article 4(2), products falling within the scope of this Section which have been lawfully placed on the market in the Community before the date of application of this Regulation may continue to be placed on the market, used and processed provided that the following conditions are met:

a in the case of products placed on the market under Directive 90/220/EEC before the entry into force of Regulation (EC) No 258/97 or in accordance with the provisions referred to in Regulation (EC) No 258/97, operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission of the date on which they were first placed on the market in the Community;

b in the case of products which have been lawfully placed on the market in the Community but are not covered by point (a), operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission that the products were placed on the market in the Community before the date of application of this Regulation.

2 The notification referred to in paragraph 1 shall be accompanied by the particulars mentioned in Article 5(3) and (5), as appropriate, which the Commission shall forward to the Authority and the Member States. The Authority shall forward to the Community reference laboratory the particulars referred to in Article 5(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant.

3 Within one year from the date of application of this Regulation and after verification that all the information required has been submitted and examined, the products concerned shall be entered in the Register. Each entry in the Register shall include the particulars referred to in Article 7(2) as appropriate and, in the case of the products referred to in paragraph 1(a), shall mention the date on which the products concerned were first placed on the market.

4 Within nine years from the date on which the products referred to in paragraph 1(a) were first placed on the market, but in no case earlier than three years after the date of application of this Regulation, operators responsible for placing them on the market shall submit an application in accordance with Article 11, which shall apply *mutatis mutandis*.

Within three years from the date of application of this Regulation, operators responsible for placing on the market products referred to in paragraph 1(b) shall submit an application in accordance with Article 11, which shall apply *mutatis mutandis*.

5 Products referred to in paragraph 1 and food containing them or produced from them shall be subject to the provisions of this Regulation, in particular Articles 9, 10 and 34, which shall apply *mutatis mutandis*.

[F14]6 . . . . . .

7 In the case of authorisations not issued to a specific holder, the operator who imports, produces or manufactures the products referred to in this Article shall submit the information or the application to Commission.

[F15]8 . . . . . .

Textual Amendments

F14 Art. 8(6) 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, **12**; 2020 c. 1, Sch. 5 para. 1(1)

F15 Art. 8(8) 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, **12**; 2020 c. 1, Sch. 5 para. 1(1)

Article 9

Supervision

1 After an authorisation has been issued in accordance with this Regulation, the authorisation-holder and parties concerned shall comply with any conditions or restrictions which have been imposed in the authorisation and shall in particular make sure that products not covered by the authorisation are not placed on the market as food or feed. Where post-market monitoring as referred to in Article 5(3)(k) and/or monitoring as referred to in Article 5(5)(b) has been imposed on the authorisation-holder, the authorisation-holder shall ensure that it is carried out and shall submit reports to the **[**[F16]Food Safety Authority**]** in accordance with the terms of the authorisation. The monitoring reports referred to shall be made accessible to the public after deletion of any information identified as confidential in accordance with Article 30.

2 If the authorisation-holder proposes to modify the terms of the authorisation, the authorisation-holder shall submit an application in accordance with Article 5(2). Articles 5, 6 and 7 shall apply *mutatis mutandis*.

3 The authorisation-holder shall forthwith inform the **[**[F17]Food Safety Authority**]** of any new scientific or technical information which might influence the evaluation of the safety in use of the food. In particular, the authorisation-holder shall forthwith inform the **[**[F17]Food Safety Authority**]** of any prohibition or restriction imposed by the competent authority of any third country in which the food is placed on the market.

[[F18]4 The Food Safety Authority must make the information supplied by the applicant available to the appropriate authority without delay.**]**

Textual Amendments

F16 Words in Art. 9(1) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **13(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F17 Words in Art. 9(3) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **13(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F18 Art. 9(4) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **13(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 10

Modification, suspension and revocation of authorisations

[[F19]1 On its own initiative, the Food Safety Authority may, or following a request from the appropriate authority, must, issue an opinion on whether an authorisation for a product referred to in Article 3(1) still meets the conditions set by this Regulation. It shall immediately transmit this opinion to the appropriate authority and the authorisation-holder. 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.

2 The appropriate authority must examine the opinion of the Food Safety Authority as soon as possible. Any appropriate measures must be taken in accordance with Article 34. If appropriate, the appropriate authority may prescribe modifications to, a suspension of, or revocation of, an authorisation.**]**

3 Articles 5(2), 6 and 7 shall apply *mutatis mutandis*.

Textual Amendments

F19 Art. 10(1)(2) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **14**; 2020 c. 1, Sch. 5 para. 1(1)

Article 11

Renewal of authorisations

1 Authorisations under this Regulation shall be renewable for 10-year periods, on application to the **[**[F20]appropriate authority**]** by the authorisation-holder at the latest one year before the expiry date of the authorisation.

2 The application shall be accompanied by the following:

a a copy of the authorisation for placing the food on the market;

b a report on the results of the monitoring, if so specified in the authorisation;

c any other new information which has become available with regard to the evaluation of the safety in use of the food and the risks of the food to the consumer or the environment;

d where appropriate, a proposal for amending or complementing the conditions of the original authorisation, *inter alia* the conditions concerning future monitoring.

3 Articles 5(2), 6 and 7 shall apply *mutatis mutandis*.

4 Where, for reasons beyond the control of the authorisation-holder, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until a decision is taken.

[[F21]5 The appropriate authority, having first consulted the Food Safety Authority, may make provision for the application of this Article, by prescribing provisions concerning the preparation and the presentation of the application.**]**

6 The **[**[F22]Food Safety Authority**]** shall publish detailed guidance to assist the applicant in the preparation and the presentation of its application.

Textual Amendments

F20 Words in Art. 11(1) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **15(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F21 Art. 11(5) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **15(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F22 Words in Art. 11(6) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **15(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Status:
Point in time view as at 31/12/2020.

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.