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)

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission[(1)],

Having regard to the opinion of the European Economic and Social Committee[(2)],

Having regard to the opinion of the Committee of the Regions[(3)],

Acting in accordance with the procedure referred to in Article 251 of the Treaty[(4)],

Whereas:

(1) The free movement of safe and wholesome food and feed is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(2) A high level of protection of human life and health should be ensured in the pursuit of Community policies.

(3) In order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms (hereinafter referred to as genetically modified food and feed) should undergo a safety assessment through a Community procedure before being placed on the market within the Community.

(4) Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of genetically modified food and feed may hinder their free movement, creating conditions of unequal and unfair competition.

(5) An authorisation procedure involving Member States and the Commission has been established for genetically modified foods in Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients[(5)]. This procedure should be streamlined and made more transparent.

(6) Regulation (EC) No 258/97 also provides for a notification procedure for novel foods which are substantially equivalent to existing foods. Whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods,

it is not a safety assessment in itself. In order to ensure clarity, transparency and a harmonised framework for authorisation of genetically modified food, this notification procedure should be abandoned in respect of genetically modified foods.

(7) Feed consisting of or containing genetically modified organisms (GMOs) has so far been authorised, subject to the authorisation procedure provided by Council Directive 90/220/EEC of 23 April 1990[(6)] and 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[(7)]; no authorisation procedure exists for feed produced from GMOs; a single, efficient and transparent Community authorisation procedure for feed consisting of, containing or produced from GMOs should be established.

(8) The provisions of this Regulation should also apply to feed intended for animals which are not destined for food production.

(9) The new authorisation procedures for genetically modified food and feed should include the new principles introduced in Directive 2001/18/EC. They should also make use of the new framework for risk assessment in matters of food safety set up by 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[(8)]. Thus, genetically modified food and feed should only be authorised for placing on the Community market after a scientific evaluation of the highest possible standard, to be undertaken under the responsibility of the European Food Safety Authority (Authority), of any risks which they present for human and animal health and, as the case may be, for the environment. This scientific evaluation should be followed by a risk management decision by the Community, under a regulatory procedure ensuring close cooperation between the Commission and the Member States.

(10) Experience has shown that authorisation should not be granted for a single use, when a product is likely to be used both for food and feed purposes; therefore such products should only be authorised when fulfilling authorisation criteria for both food and feed.

(11) Under this Regulation, authorisation may be granted either to a GMO to be used as a source material for production of food or feed and products for food and/or feed use which contain, consist of or are produced from it, or to foods or feed produced from a GMO. Thus, where a GMO used in the production of food and/or feed has been authorised under this Regulation, foods and/or feed containing, consisting of or produced from that GMO will not need an authorisation under this Regulation, but will be subject to the requirements referred to in the authorisation granted in respect of the GMO. Furthermore, foods covered by an authorisation granted under this Regulation will be exempted from the requirements of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, except where they fall under one or more of the categories referred to in Article 1(2)(a) of Regulation (EC) No 258/97 in respect of a characteristic which has not been considered for the purpose of the authorisation granted under this Regulation.

(12) Council Directive 89/107/EEC of 21 December 1988 on the approximation of laws of the Member States concerning food additives authorised for use in foodstuffs intended

for human consumption[9] provides for authorisation of additives used in foodstuffs. In addition to this authorisation procedure, food additives containing, consisting of or produced from GMOs should fall also within the scope of this Regulation for the safety assessment of the genetic modification, while the final authorisation should be granted under the procedure referred to in Directive 89/107/EEC.

(13) Flavourings falling within the scope of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production[10] which contain, consist of or are produced from GMOs should also fall within the scope of this Regulation for the safety assessment of the genetic modification.

(14) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition[11] provides for an approval procedure for feed materials produced using different technologies that may pose risk to human or animal health and the environment. These feed materials containing, consisting of or produced from GMOs should fall instead within the scope of this Regulation.

(15) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[12], provides for an authorisation procedure for placing on the market additives used in feedingstuffs. In addition to this authorisation procedure, feed additives containing, consisting of or produced from GMOs should also fall within the scope of this Regulation.

(16) This Regulation should cover food and feed produced ‘from’ a GMO but not food and feed ‘with’ a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore, are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation.

(17) In accordance with Article 153 of the Treaty, the Community is to contribute to promoting the right of consumers to information. In addition to other types of information to the public provided for in this Regulation, the labelling of products enables the consumer to make an informed choice and facilitates fairness of transactions between seller and purchaser.

(18) Article 2 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[13] provides that labelling must not mislead the purchaser as to the characteristics of the foodstuff and among other things, in particular, as to its nature, identity, properties, composition, method of production and manufacturing.

(19) Additional requirements for the labelling of genetically modified foods are laid down in Regulation (EC) No 258/97, in Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication, on the labelling of certain foodstuffs produced from genetically modified organisms, of particulars other than those provided for in Directive 79/112/EEC[(14)] and in Commission Regulation (EC) No 50/2000 of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms[(15)].

(20) Harmonised labelling requirements should be laid down for genetically modified feed to provide final users, in particular livestock farmers, with accurate information on the composition and properties of feed, thereby enabling the user to make an informed choice.

(21) The labelling should include objective information to the effect that a food or feed consists of, contains or is produced from GMOs. Clear labelling, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product, meets the demands expressed in numerous surveys by a large majority of consumers, facilitates informed choice and precludes potential misleading of consumers as regards methods of manufacture or production.

(22) In addition, the labelling should give information about any characteristic or property which renders a food or feed different from its conventional counterpart with respect to composition, nutritional value or nutritional effects, intended use of the food or feed and health implications for certain sections of the population, as well as any characteristic or property which gives rise to ethical or religious concerns.

(23) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC[(16)] ensures that relevant information concerning any genetic modification is available at each stage of the placing on the market of GMOs and food and feed produced therefrom and should thereby facilitate accurate labelling.

(24) Despite the fact that some operators avoid using genetically modified food and feed, such material may be present in minute traces in conventional food and feed as a result of adventitious or technically unavoidable presence during seed production, cultivation, harvest, transport or processing. In such cases, this food or feed should not be subject to the labelling requirements of this Regulation. In order to achieve this objective, a threshold should be established for the adventitious or technically unavoidable presence of genetically modified material in foods or feed, both when the marketing of such material is authorised in the Community and when this presence is tolerated by virtue of this Regulation.

(25) It is appropriate to provide that, when the combined level of adventitious or technically unavoidable presence of genetically modified materials in a food or feed or in one of its components is higher than the set threshold, such presence should be indicated in

accordance with this Regulation and that detailed provisions should be adopted for its implementation. The possibility of establishing lower thresholds, in particular for foods and feed containing or consisting of GMOs or in order to take into account advances in science and technology, should be provided for.

(26) It is indispensable that operators strive to avoid any accidental presence of genetically modified material not authorised under Community legislation in food or feed. However, in order to ensure the practicability and feasibility of this Regulation, a specific threshold, with the possibility of establishing lower levels in particular for GMOs sold directly to the final consumer, should be established as a transitional measure for minute traces in food or feed of this genetically modified material, where the presence of such material is adventitious or technically unavoidable and provided that all specific conditions set in this Regulation are met. Directive 2001/18/EC should be amended accordingly. The application of this measure should be reviewed in the context of the general review of the implementation of this Regulation.

(27) In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of the genetically modified food or feed.

(28) Operators should avoid the unintended presence of GMOs in other products. The Commission should gather information and develop on this basis guidelines on the coexistence of genetically modified, conventional and organic crops. Moreover, the Commission is invited to bring forward, as soon as possible, any further necessary proposal.

(29) The traceability and labelling of GMOs at all stages of placing on the market, including the possibility of establishing thresholds, is ensured by Directive 2001/18/EC and Regulation (EC) No 1830/2003.

(30) It is necessary to establish harmonised procedures for risk assessment and authorisation that are efficient, time-limited and transparent, and criteria for evaluation of the potential risks arising from genetically modified foods and feed.

(31) In order to ensure a harmonised scientific assessment of genetically modified foods and feed, such assessments should be carried out by the Authority. However, as specific acts or omissions on the part of the Authority under this Regulation could produce direct legal effects on applicants, it is appropriate to provide for the possibility of an administrative review of such acts or omissions.

(32) It is recognised that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account.

(33) Where the application concerns products containing or consisting of a genetically modified organism, the applicant should have the choice of either supplying an authorisation for the deliberate release into the environment already obtained under part C of Directive 2001/18/EC, without prejudice to the conditions set by that authorisation, or of applying for the environmental risk assessment to be carried out at the same

time as the safety assessment under this Regulation. In the latter case, it is necessary for the evaluation of the environmental risk to comply with the requirements referred to in Directive 2001/18/EC and for the national competent authorities designated by Member States for this purpose to be consulted by the Authority. In addition, it is appropriate to give the Authority the possibility of asking one of these competent authorities to carry out the environmental risk assessment. It is also appropriate, in accordance with Article 12(4) of Directive 2001/18/EC, for the national competent authorities designated under the said Directive in all cases concerning GMOs and food and/or feed containing or consisting of a GMO to be consulted by the Authority before it finalises the environmental risk assessment.

(34) In the case of GMOs to be used as seeds or other plant-propagating materials falling within the scope of this Regulation, the Authority should be under an obligation to delegate the environmental risk assessment to a national competent authority. Nonetheless, authorisations under this Regulation should be without prejudice to the provisions of Directives 68/193/EEC[(17)], 2002/53/EC[(18)] and 2002/55/EC[(19)], which provide in particular for the rules and the criteria for the acceptance of varieties and their official acceptance for inclusion in common catalogues; nor should they affect the provisions of Directives 66/401/EEC[(20)], 66/402/EEC[(21)], 68/193/EEC, 92/33/EEC[(22)], 92/34/EEC[(23)], 2002/54/EC[(24)], 2002/55/EC, 2002/56/EC[(25)] or 2002/57/EC[(26)] which regulate in particular the certification and the marketing of seeds and other plant-propagating materials.

(35) It is necessary to introduce, where appropriate and on the basis of the conclusions of the risk assessment, post-market monitoring requirements for the use of genetically modified foods for human consumption and for the use of genetically modified feed for animal consumption. In the case of GMOs, a monitoring plan concerning environmental effects is compulsory under Directive 2001/18/EC.

(36) To facilitate controls on genetically modified food and feed, applicants for authorisation should propose appropriate methods for sampling, identification and detection, and deposit samples of the genetically modified food and feed with the Authority; methods of sampling and detection should be validated, where appropriate, by the Community reference laboratory.

(37) Technological progress and scientific developments should be taken into account when implementing this Regulation.

(38) Food and feed falling within the scope of this Regulation which have been lawfully placed on the Community market before the date of application of this Regulation should continue to be allowed on the market, subject to the transmission to the Commission by the operators of information concerning the risk assessment, methods for sampling, identification and detection as appropriate, including the transmission of samples of the food and feed and their control samples within six months after the date of application of this Regulation.

(39) A register of genetically modified food and feed authorised under this Regulation should be established, including product specific information, studies which demonstrate the safety of the product, including, where available, references to independent and peer-

reviewed studies, and to methods for sampling, identification and detection. Non-confidential data should be made available to the public.

(40) In order to stimulate research and development into GMOs for food and/or feed use, it is appropriate to protect the investment made by innovators in gathering the information and data supporting an application under this Regulation. This protection should however be limited in time in order to avoid the unnecessary repetition of studies and trials which would be against the public interest.

(41) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(27)].

(42) Provision should be made for consultation of the European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997, or any other appropriate body established by the Commission, with a view to obtaining advice on ethical issues regarding the placing on the market of genetically modified food or feed. Such consultations should be without prejudice to the competence of Member States as regards ethical issues.

(43) In order to provide a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, requirements arising from this Regulation should apply in a non-discriminatory manner to products originating in the Community and imported from third countries, in accordance with the general principles referred to in Regulation (EC) No 178/2002. The content of this Regulation takes account of the international trade commitments of the European Communities and of the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity as regards importer obligations and notification.

(44) Certain instruments of Community law should be repealed and others amended as a result of this Regulation.

(45) The implementation of this Regulation should be reviewed in the light of experience gained in the short term, and the impact of the application of this Regulation on human and animal health, consumer protection, consumer information and the functioning of the internal market should be monitored by the Commission,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

OBJECTIVE AND DEFINITIONS

Article 1

Objective

The objective of this Regulation, in accordance with the general principles laid down in Regulation (EC) No 178/2002, is to:

(a) provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the [F1]... market;

(b) lay down [F2]... procedures for the authorisation and supervision of genetically modified food and feed;

(c) lay down provisions for the labelling of genetically modified food and feed.

Textual Amendments

F1 Word in Art. 1(a) 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, **5(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Word in Art. 1(b) 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, **5(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 2

Definitions

For the purposes of this Regulation:

1. the definitions of ‘food’, ‘feed’, ‘final consumer’, ‘food business’ and ‘feed business’ given in Regulation (EC) No 178/2002 shall apply;

2. the definition of ‘traceability’, laid down in Regulation (EC) No 1830/2003;

3. ‘operator’ means the natural or legal person responsible for ensuring that the requirements of this Regulation are met within the food businesses or feed businesses under its control;

4. the definitions of ‘organism’, ‘deliberate release’ and ‘environmental risk assessment’ referred to in Directive 2001/18/EC shall apply;

5. ‘genetically modified organism’ or ‘GMO’ means a 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 I B to Directive 2001/18/EC;

6. ‘genetically modified food’ means food containing, consisting of or produced from GMOs;

7. ‘genetically modified feed’ means feed containing, consisting of or produced from GMOs;

8. ‘genetically modified organism for food use’ means a GMO that may be used as food or as a source material for the production of food;

9. ‘genetically modified organism for feed use’ means a GMO that may be used as feed or as a source material for the production of feed;

10. ‘produced from GMOs’ means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;

11. ‘control sample’ means the GMO or its genetic material (positive sample) and the parental organism or its genetic material that has been used for the purpose of the genetic modification (negative sample);

12. ‘conventional counterpart’ means a similar food or feed produced without the help of genetic modification and for which there is a well-established history of safe use;

13. ‘ingredient’ means ‘ingredient’ as referred to in Article 6(4) of Directive 2000/13/EC;

14. ‘placing on the market’ means the holding of food or feed for the purpose of sale, including offering for sale, or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves.

15. ‘pre-packaged food’ means any single item for presentation as such consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.

16. ‘mass caterer’ means ‘mass caterer’ as referred to in Article 1 of Directive 2000/13/EC. .

17. **[**[F3]"Food Safety Authority“” means—

    (a) as regards England and Wales, the Food Standards Agency;

    (b) as regards Scotland, Food Standards Scotland;

18 "appropriate authority“” means—

    (a) in relation to England, the Secretary of State;

    (b) in relation to Wales, the Welsh Ministers;

    (c) in relation to Scotland, the Scottish Ministers;

19. ‘prescribe’ means prescribe by regulations;

20 ‘third country’ means any country or territory other than the British Islands;

21. ‘public analyst’ has the meaning it bears in the Food Safety Act 1990;

23. ‘preference laboratory’ means the laboratory appointed by the appropriate authority in accordance with Article 32.**]**

Textual Amendments

F3 Art. 2(17)-(23) inserted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **6** (as amended by The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020 (S.I. 2020/1504), regs. 1(2), **17(2)**); 2020 c. 1, Sch. 5 para. 1(1)

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.

[[F4]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

F4 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.

F5 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

F5 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.

[F6 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 **[**[F7]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.

[[F8]7 The appropriate authority, having first consulted the Food Safety Authority, may prescribe rules concerning the preparation and presentation of the application.**]**

8 **[**[F9]The Food Safety Authority must**]** publish detailed guidance to assist the applicant in the preparation and the presentation of the application.

Textual Amendments

F6 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)

F7 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)

F8 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)

F9 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 [F10]... may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit.

[[F11]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 **[**[F12]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 [F13]... 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).

[[F14]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.**]**

[[F15]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

F10 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)

F11 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)

F12 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)

F13 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)

F14 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)

F15 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)

[[F16]*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

F16 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*.

[F17]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.

[F18]8 . . . . . .

Textual Amendments

F17 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)

F18 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 **[**[F19]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 **[**[F20]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 **[**[F20]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.

[[F21]4 The Food Safety Authority must make the information supplied by the applicant available to the appropriate authority without delay.**]**

Textual Amendments

F19 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)

F20 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)

F21 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

[F22 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

F22 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 **[**F23 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.

[F24 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 **[**F25 Food Safety Authority**]** shall publish detailed guidance to assist the applicant in the preparation and the presentation of its application.

Textual Amendments

F23 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)

F24 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)

F25 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)

Section 2

Labelling

Article 12

Scope

1 This Section shall apply to foods which are to be delivered as such to the final consumer or mass caterers in **[**F26 Great Britain**]** and which:

a contain or consist of GMOs; or

b are produced from or contain ingredients produced from GMOs.

2 This Section shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

3 In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material.

[F27 4 The appropriate authority may prescribe amendments to non-essential elements of this Regulation by supplementing it and establishing lower thresholds, in particular in respect of foods containing or consisting of GMOs, or taking account of advances in science and technology.**]**

Textual Amendments

F26 Words in Art. 12(1) substituted (31.12.2020) by S.I. 2019/705, reg. 16(a) (as substituted by The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020 (S.I. 2020/1504), regs. 1(2), **17(3)**)

F27 Art. 12(4) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **16(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 13

Requirements

1 Without prejudice to the other requirements of **[**[F28]retained EU**]** law concerning the labelling of foodstuffs, foods falling within the scope of this Section shall be subject to the following specific labelling requirements:

a where the food consists of more than one ingredient, the words 'genetically modified' or 'produced from genetically modified (name of the ingredient)' shall appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC in parentheses immediately following the ingredient concerned;

b where the ingredient is designated by the name of a category, the words 'contains genetically modified (name of organism)' or 'contains (name of ingredient) produced from genetically modified (name of organism)' shall appear in the list of ingredients;

c where there is no list of ingredients, the words 'genetically modified' or 'produced from genetically modified (name of organism)' shall appear clearly on the labelling;

d the indications referred to in (a) and (b) may appear in a footnote to the list of ingredients. In this case they shall be printed in a font of at least the same size as the list of ingredients. Where there is no list of ingredients, they shall appear clearly on the labelling;

e where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10 cm^2, the information required under this paragraph must be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

2 In addition to the labelling requirements referred to in paragraph 1, the labelling shall also mention any characteristic or property, as specified in the authorisation, in the following cases:

a where a food is different from its conventional counterpart as regards the following characteristics or properties:

(i) composition;

(ii) nutritional value or nutritional effects;

(iii) intended use of the food;

(iv) implications for the health of certain sections of the population;

b where a food may give rise to ethical or religious concerns.

3 In addition to the labelling requirements referred to in paragraph 1 and as specified in the authorisation, the labelling of foods falling within the scope of this Section which do not have a conventional counterpart shall contain appropriate information about the nature and the characteristics of the foods concerned.

Textual Amendments

F28 Words in Art. 13(1) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **17**; 2020 c. 1, Sch. 5 para. 1(1)

[F29 Article 14

Implementing measures

The appropriate authority may prescribe the following measures designed to amend non-essential elements of this Regulation by supplementing it—

a the measures necessary for operators to satisfy the competent authorities as referred to in Article 12(3);

b the measures necessary for operators to comply with the labelling requirements set out in Article 13;

c measures concerning the information to be given by mass caterers providing food to the final consumer. In order to take account of the specific situation of mass caterers, such measures may provide for adaptation of the requirements set out in Article 13(1)(e); and

d measures to facilitate the uniform application of Article 13.**]**

Textual Amendments

F29 Art. 14 substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **18**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER III

GENETICALLY MODIFIED FEED

Section 1

Authorisation and supervision

Article 15

Scope

1 This Section shall apply to:

a GMOs for feed use;

b feed containing or consisting of GMOs;

c feed produced from GMOs.

[F30 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 feed falls within the scope of this Section.**]**

Textual Amendments

F30 Art. 15(2) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **19**; 2020 c. 1, Sch. 5 para. 1(1)

Article 16

Requirements

1 Feed referred to in Article 15(1) must not:

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

b mislead the user;

c harm or mislead the consumer by impairing the distinctive features of the animal products;

d differ from feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans.

2 No person shall place on the market, use or process a product referred to in Article 15(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 product referred to in Article 15(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 feed containing or consisting of that GMO as well as feed produced from that GMO; or

b feed produced from a GMO as well as feeds produced from or containing that feed.

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.

[F31]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

F31 Art. 16(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, **20**; 2020 c. 1, Sch. 5 para. 1(1)

Article 17

Application for authorisation

[[F32]1 To obtain the authorisation referred to in Article 16(2), an application must be submitted in accordance with the following provisions.

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 feed 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;

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

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 feed complies with the criteria referred to in Article 16(1), and, in particular for feed falling within the scope of Directive 82/471/EEC, the information required under Council Directive 83/228/EEC of 18 April 1983 on the fixing of guidelines for the assessment of certain products used in animal nutrition[(28)];

f either an analysis, supported by appropriate information and data, showing 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 and to the criteria specified in Article 25(2)(c), or a proposal for labelling the feed in accordance with Article 25(2)(c) and (3);

g either a reasoned statement that the feed does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with Article 25(2)(d);

h where appropriate, the conditions for placing the feed on the market, 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 feed and/or in the feed produced from it;

j samples of the feed 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 for the use of the feed for animal consumption;

l a summary of the dossier in a standardised form.

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

5 In the case of GMOs or feed 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 GMOs 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 **[**F33retained 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.

[F347 The appropriate authority, having first consulted the Food Safety Authority, may prescribe rules concerning the preparation and presentation of the application.**]**

8 **[**F35The Food Safety Authority must**]** publish detailed guidance to assist the applicant in the preparation and the presentation of the application.

Textual Amendments

F32 Art. 17(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, **21(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F33 Words in Art. 17(6) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **21(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F34 Art. 17(7) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **21(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F35 Words in Art. 17(8) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **21(d)**; 2020 c. 1, Sch. 5 para. 1(1)

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 F36... may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit.

[F373 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, **[**F38the 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 F39... 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).

[F406 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.**]**

[F417 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

F36 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)

F37 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)

F38 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)

F39 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)

F40 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)

F41 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)

[F42 Article 19

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 18(5);

b the name of the authorisation-holder;

c where appropriate, the unique identifier attributed to the GMO as referred to in 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 23. The authorised feed 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

F42 Art. 19 substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **23**; 2020 c. 1, Sch. 5 para. 1(1)

Article 20

Status of existing products

1 By way of derogation from Article 16(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 which have been authorised under Directives 90/220/EEC or 2001/18/EC, including use as feed, under Directive 82/471/EEC, which are produced from GMOs, or under Directive 70/524/EEC, which contain, consist of or are produced from GMOs, 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 which are not referred to in point (a), operators responsible for placing on the market in the Community 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 17(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 17(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 19(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 23, 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 23, which shall apply *mutatis mutandis*.

5 Products referred to in paragraph 1 and feed containing them or produced from them shall be subject to the provisions of this Regulation, in particular Articles 21, 22 and 34, which shall apply *mutatis mutandis*.

[F43]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 the Commission.

[F44]8 . . . . . .

Textual Amendments

F43 Art. 20(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, **24**; 2020 c. 1, Sch. 5 para. 1(1)

F44 Art. 20(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, **24**; 2020 c. 1, Sch. 5 para. 1(1)

Article 21

Supervision

1 After an authorisation has been issued in accordance with this Regulation, the authorisation-holder and the 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 17(3)(k) and/or monitoring as referred to in Article 17(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 **[**[F45]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 17(2). Articles 17, 18 and 19 shall apply *mutatis mutandis*.

3 The authorisation-holder shall forthwith inform the **[**[F46] Food Safety Authority**]** of any new scientific or technical information which might influence the evaluation of the safety in use of the feed. In particular, the authorisation-holder shall forthwith inform the **[**[F46]Food Safety Authority**]** of any prohibition or restriction imposed by the competent Authority of any third country in which the feed is placed on the market.

[[F47]4 The Food Safety Authority must make the information supplied by the applicant available to the appropriate authority without delay.**]**

Textual Amendments

F45 Words in Art. 21(1) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **25(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F46 Words in Art. 21(3) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **25(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F47 Art. 21(4) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **25(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 22

Modification, suspension and revocation of authorisations

[[F48]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 15(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 shall 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 17(2), 18 and 19 shall apply *mutatis mutandis*.

Textual Amendments

F48 Art. 22(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, **26**; 2020 c. 1, Sch. 5 para. 1(1)

Article 23

Renewal of authorisations

1 Authorisations under this Regulation shall be renewable for 10-year periods, on application to the **[**F49appropriate 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 particulars and documents:

a a copy of the authorisation for placing the feed 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 feed and the risks of the feed to animals, humans 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 17(2), 18 and 19 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.

[F50 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 Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of its application.

Textual Amendments

F49 Words in Art. 23(1) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **27(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F50 Art. 23(5) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **27(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Section 2

Labelling

Article 24

Scope

1 This Section shall apply to feed referred to in Article 15(1).

2 This Section shall not apply to feed containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the feed and of each feed of which it is composed, provided that this presence is adventitious or technically unavoidable.

3 In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such materials.

[F51 4 The appropriate authority may prescribe amendments to non-essential elements of this Regulation by supplementing it and establishing lower thresholds, in particular in respect of feed containing or consisting of GMOs, or taking account of advances in science and technology.**]**

Textual Amendments

F51 Art. 24(4) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **28**; 2020 c. 1, Sch. 5 para. 1(1)

Article 25

Requirements

1 Without prejudice to the other requirements of **[**F52 retained EU**]** law concerning the labelling of feed, feed referred to in Article 15(1) shall be subject to the specific labelling requirements laid down below.

2 No person shall place a feed referred to in Article 15(1) on the market unless the particulars specified below are shown, in a clearly visible, legible and indelible manner, on an accompanying document or, where appropriate, on the packaging, on the container or on a label attached thereto.

Each feed of which a particular feed is composed shall be subject to the following rules:

a for the feeds referred to in Article 15(1) (a) and (b), the words ‘genetically modified (name of the organism)’ shall appear in parentheses immediately following the specific name of the feed.

Alternatively, these words may appear in a footnote to the list of feed. It shall be printed in a font of at least the same size as the list of feed;

b for the feed referred to in Article 15(1)(c), the words ‘produced from genetically modified (name of the organism)’ shall appear in parentheses immediately following the specific name of the feed.

Alternatively, these words may appear in a footnote to the list of feed. It shall be printed in a font of at least the same size as the list of feed;

c as specified in the authorisation, any characteristic of the feed referred to in Article 15(1) such as those indicated hereunder, which is different from its conventional counterpart:

(i) composition;

(ii) nutritional properties;

(iii) intended use;

(iv) implications for the health of certain species or categories of animals;

d as specified in the authorisation, any characteristic or property where a feed may give rise to ethical or religious concerns.

3 In addition to the requirements referred to in paragraph 2(a) and (b) and as specified in the authorisation, the labelling or accompanying documents of feed falling within the scope of this Section which does not have a conventional counterpart shall contain appropriate information about the nature and the characteristics of the feed concerned.

Textual Amendments

F52 Words in Art. 25(1) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **29**; 2020 c. 1, Sch. 5 para. 1(1)

I[F53 Article 26

Implementing measures

The appropriate authority may prescribe the following measures designed to amend non-essential elements of this Regulation by supplementing it—

a) measures necessary for operators to satisfy the competent authorities as referred to in Article 24(3);

b) measures necessary for operators to comply with the labelling requirements set out in Article 25;

c) measures to facilitate the uniform application of Article 25.**]**

Textual Amendments

F53 Art. 26 substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **30**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER IV

COMMON PROVISIONS

[F54 Article 27

Products likely to be used as both food and feed

1 Where a product is likely to be used as both food and feed, a single application under Articles 5 and 17 must be submitted and must give rise to a single opinion from the Food Safety Authority and a single decision of the appropriate authority.

2 The Food Safety Authority must consider whether the application for authorisation of a product should be submitted as a single application for authorisation as both food and feed and advise the appropriate authority accordingly.**]**

Textual Amendments

F54 Art. 27 substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **31**; 2020 c. 1, Sch. 5 para. 1(1)

Article 28

F55... Register

1 The **[**F56appropriate authority**]** shall establish and maintain a F57... register of genetically modified food and feed, hereinafter referred to as 'the Register'.

2 The Register shall be made available to the public.

Textual Amendments

F55 Word in Art. 28 heading 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, **32(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F56 Words in Art. 28(1) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **32(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F57 Word in Art. 28(1) 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, **32(a)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 29

Public access

1 The application for authorisation, supplementary information from the applicant, opinions from the competent authorities designated in accordance with Article 4 of Directive 2001/18/EC, monitoring reports and information from the authorisation holder, excluding confidential information, shall be made accessible to the public.

[F58]2 . . . . . .

[F59]3 . . . . . .

Textual Amendments

F58 Art. 29(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, **33**; 2020 c. 1, Sch. 5 para. 1(1)

F59 Art. 29(3) 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, **33**; 2020 c. 1, Sch. 5 para. 1(1)

Article 30

Confidentiality

1 The applicant may indicate which information submitted under this Regulation it wishes to be treated as confidential on the ground that its disclosure might significantly harm its competitive position. Verifiable justification must be given in such cases.

2 Without prejudice to paragraph 3, the **[**[F60]Food Safety Authority**]** shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant of its decision.

3 Information relating to the following shall not be considered confidential:

a name and composition of the GMO, food or feed referred to in Articles 3(1) and 15(1) and, where appropriate, indication of the substrate and the micro-organism;

b general description of the GMO and the name and address of the authorisation-holder;

c physico-chemical and biological characteristics of the GMO, food or feed referred to in Articles 3(1) and 15(1);

d effects of the GMO, food or feed referred to in Articles 3(1) and 15(1) on human and animal health and on the environment;

e effects of the GMO, food or feed referred to in Articles 3(1) and 15(1) on the characteristics of animal products and its nutritional properties;

f methods for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed referred to in Articles 3(1) and 15(1);

g information on waste treatment and emergency response.

[[F61]4 Notwithstanding paragraph 2, the Food Safety Authority must on request supply the appropriate authority with all information in its possession.**]**

5 The use of the detection methods and the reproduction of the reference materials, provided under Article 5(3) and 17(3) for the purpose of applying this Regulation to the GMOs, food or feed to which an application refers, shall not be restricted by the exercise of intellectual property rights or otherwise.

[[F62]6 The appropriate authority and the Food Safety Authority must take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.**]**

[[F63]7 If an applicant withdraws or has withdrawn an application, the Food Safety Authority and the appropriate authority must respect the confidentiality of commercial and industrial

information, including research and development information, as well as any information in respect of which a claim of confidentiality is disputed.**]**

Textual Amendments

F60 Words in Art. 30(2) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **34(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F61 Art. 30(4) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **34(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F62 Art. 30(6) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **34(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F63 Art. 30(7) substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **34(d)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 31

Data protection

The scientific data and other information in the application dossier required under Article 5(3) and (5) and Article 17(3) and (5) may not be used for the benefit of another applicant for a period of 10 years from the date of authorisation, unless the other applicant has agreed with the authorisation-holder that such data and information may be used.

On the expiry of this 10-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the Authority for the benefit of another applicant if the applicant can demonstrate that the food or feed for which it is seeking authorisation is essentially similar to a food or feed already authorised under this Regulation.

[F64*Article 32*

Reference laboratory

1. The appropriate authority may designate in accordance with Article 100 of Regulation (EU) 2017/625 a reference laboratory to perform the duties and tasks set out in the Annex.

2. Applicants for authorisation of genetically modified food and feed shall contribute to supporting the costs of the duties and tasks of the reference laboratory.

3. The contributions from applicants shall not exceed the costs incurred in carrying out the validation of detection methods.

3. The appropriate authority may prescribe—

a) measures for implementing this Article and the Annex; and

b) measures designed to amend non-essential elements of this Regulation and adapting the Annex.**]**

Textual Amendments

F64 Art. 32 substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **35** (as amended by The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020 (S.I. 2020/1504), regs. 1(2), **17(4)**); 2020 c. 1, Sch. 5 para. 1(1)

F65 Article 33

Consultation with the European Group on Ethics in Science and New Technologies

. . . . . .

Textual Amendments

F65 Art. 33 omitted (31.12.2020) by virtue of S.I. 2019/705, reg. 36 (as substituted by The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020 (S.I. 2020/1504), regs. 1(2), **17(5)**)

Article 34

Emergency measures

Where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment, or where, in the light of an opinion of the **[**F66Food Safety**]** Authority issued under Article 10 or Article 22, the need to suspend or modify urgently an authorisation arises, measures shall be taken under the procedures provided for in Articles 53 F67... of Regulation (EC) No 178/2002.

Textual Amendments

F66 Words in Art. 34 inserted (31.12.2020) by S.I. 2019/705, reg. 36(a) (as inserted by The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020 (S.I. 2020/1504), regs. 1(2), **17(6)**)

F67 Words in Art. 34 omitted (31.12.2020) by virtue of S.I. 2019/705, reg. 36(b) (as inserted by The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020 (S.I. 2020/1504), regs. 1(2), **17(6)**)

I F68 Article 35

Committee procedure

1 Any power to make regulations under this Regulation—

a so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;

b so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument;

2 For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (Scottish statutory instruments).

3 Any power to make regulations under this Regulation includes power—

4 Any statutory instrument or Scottish statutory instrument containing regulations under this Regulation shall be subject to annulment in pursuance of a resolution—

a in the case of England, of either House of Parliament;

b in the case of Wales, of Senedd Cymru;

c in the case of Scotland, of the Scottish Parliament;

5 In this Regulation, any power—

a of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;

b of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;

c of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only;**]**

Textual Amendments

F68 Art. 35 substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **37** (as amended by The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020 (S.I. 2020/1504), regs. 1(2), **17(7)**); 2020 c. 1, Sch. 5 para. 1(1)

I[F69] Article 36

Administrative review

1 Any decision taken under, or failure to exercise, the powers vested in the Food Safety Authority by this Regulation may be reviewed by the appropriate authority on its own initiative or in response to a request from any person directly and individually concerned.

2 To this effect a request shall be submitted to the appropriate authority within two months from the day on which the party concerned became aware of the act or omission in question.

3 The appropriate authority must take a decision within two months requiring, if appropriate, the Food Safety Authority to withdraw its decision or to remedy its failure to act.**]**

Textual Amendments

F69 Art. 36 substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **38**; 2020 c. 1, Sch. 5 para. 1(1)

Article 37

Repeals

The following Regulations shall be repealed with effect from the date of application of this Regulation:

— Regulation (EC) No 1139/98,

— Regulation (EC) No 49/2000,

— Regulation (EC) No 50/2000.

Article 38

Amendments to Regulation (EC) No 258/97

Regulation (EC) No 258/97 is hereby amended with effect from the date of application of this Regulation as follows:

1. The following provisions shall be deleted:
   — Article 1(2)(a) and (b),
   — Article 3(2), second subparagraph, and (3),
   — Article 8(1)(d),
   — Article 9.

2. In Article 3, the first sentence of paragraph 4 shall be replaced by the following:

4. By way of derogation from paragraph 2, the procedure referred to in Article 5 shall apply to foods or food ingredients referred to in Article 1(2)(d) and (e) which, on the basis of the scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies referred to in Article 4(3), are substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.

Article 39

Amendment to Directive 82/471/EEC

The following paragraph shall be added to Article 1 of Directive 82/471/EEC with effect from the date of application of this Regulation:

3. This Directive does not apply to products which act as direct or indirect protein sources that fall within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[29].

Article 40

Amendments to Directive 2002/53/EC

Directive 2002/53/EC is hereby amended with effect from the date of application of this Regulation as follows:

1. Article 4(5) shall be replaced by the following:

5. Further, when material derived from a plant variety is intended to be used in food falling within the scope of Article 3, or in feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[30], the variety shall be accepted only if it has been approved in accordance with that Regulation.

2. Article 7(5) shall be replaced by the following:

5. Member States shall ensure that a variety intended to be used in food or feed as defined in Articles 2 and 3 of 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[31] is accepted only if it has been authorised under the relevant legislation.

Article 41

Amendments to Directive 2002/55/EC

Directive 2002/55/EC is hereby amended with effect from the date of application of this Regulation as follows:

1. Article 4(3) shall be replaced by the following:

3. Further, when material derived from a plant variety is intended to be used in food falling within the scope of Article 3, or in feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[32], the variety shall be accepted only if it has been approved in accordance with that Regulation.

2. Article 7(5) shall be replaced by the following:

5. Member States shall ensure that a variety intended to be used in food or feed as defined in Articles 2 and 3 of 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[33] is accepted only if it has been authorised under the relevant legislation.

Article 42

Amendment to Directive 68/193/EEC

Article 5ba(3) of Directive 68/193/EEC shall be replaced by the following wording with effect from the date of application of this Regulation:

3.

a) Where products derived from vine-propagating material are intended to be used as or in food falling within the scope of Article 3 or as or in a feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[34], the vine

variety concerned shall be accepted only if it has been authorised pursuant to the said Regulation.

b) Member States shall ensure that a vine variety, from the propagating material of which products were derived intended for use in food and feed pursuant to Articles 2 and 3 of 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[35] shall be accepted only if it has been authorised pursuant to the relevant legislation.

Article 43

Amendments to Directive 2001/18/EC

Directive 2001/18/EC is hereby amended with effect from the date of entry into force of this Regulation, as follows:

1. The following Article shall be inserted:

Article 12a

Transitional measures for adventitious or technically unavoidable presence of genetically modified organisms having benefited from a favourable risk evaluation

1 Placing on the market of traces of a GMO or combination of GMOs in products intended for direct use as food or feed or for processing shall be exempted from Articles 13 to 21 provided that they meet the conditions referred to in Article 47 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[36].

2 This Article shall be applicable for a period of three years after the date of application of Regulation (EC) No 1829/2003.

2. The following Article shall be inserted:

Article 26a

Measures to avoid the unintended presence of GMOs

1 Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.

2 The Commission shall gather and coordinate information based on studies at Community and national level, observe the developments regarding coexistence in the Member States and, on the basis of the information and observations, develop guidelines on the coexistence of genetically modified, conventional and organic crops.

Article 44

Information to be provided in accordance with the Cartagena Protocol

1 Any authorisation, renewal, modification, suspension or revocation of authorisation of a GMO, food or feed referred to in Articles 3(1)(a) or (b) or 15(1)(a) or (b) shall be notified by the **[**F70Food Safety Authority**]** to the Parties to the Cartagena Protocol through the biosafety clearing house in accordance with Article 11(1) or Article 12(1) of the Cartagena Protocol, as the case may be.

The **[**F70Food Safety Authority**]** shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the biosafety clearing house.

2 The **[**F70Food Safety Authority**]** shall also process requests for additional information made by any Party in accordance with Article 11(3) of the Cartagena Protocol and shall provide copies of the laws, regulations and guidelines in accordance with Article 11(5) of that Protocol.

Textual Amendments

F70 Words in Art. 44 substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), **reg. 38A** (as inserted by S.I. 2020/1504, regs. 1(2), **17(8)**)

F71Article 45

Penalties

. . . . . .

Textual Amendments

F71 Art. 45 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, **39**; 2020 c. 1, Sch. 5 para. 1(1)

Article 46

Transitional measures for requests, labelling and notifications

1 Requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be transformed into applications under Chapter II, Section 1 of this Regulation where the initial assessment report provided for under Article 6(3) of Regulation (EC) No 258/97 has not yet been forwarded to the Commission, as well as in all cases where an additional assessment report is required in accordance with Article 6(3) or (4) of Regulation (EC) No 258/97. Other requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be processed under the provisions of Regulation (EC) No 258/97, notwithstanding Article 38 of this Regulation.

2 The labelling requirements referred to in this Regulation shall not apply to products, the manufacturing process of which has commenced before the date of application of this

Regulation, provided that these products are labelled in accordance with the legislation applicable to them before the date of application of this Regulation.

3 Notifications concerning products including their use as feed submitted under Article 13 of Directive 2001/18/EC before the date of application of this Regulation shall be transformed into applications under Chapter III, Section 1 of this Regulation where the assessment report provided for in Article 14 of Directive 2001/18/EC has not yet been sent to the Commission.

4 Requests submitted for products referred to in Article 15(1)(c) of this Regulation under Article 7 of Directive 82/471/EEC before the date of application of this Regulation shall be transformed into applications under Chapter III, Section 1 of this Regulation.

5 Requests submitted for products referred to in Article 15(1) of this Regulation under Article 4 of Directive 70/524/EEC before the date of application of this Regulation shall be supplemented by applications under Chapter III, Section 1 of this Regulation.

Article 47

Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation

1 The presence in food or feed of material which contains, consists of or is produced from GMOs in a proportion no higher than 0,5 % shall not be considered to be in breach of Article 4(2) or Article 16(2), provided that:

a this presence is adventitious or technically unavoidable;

b the genetically modified material has benefited from a favourable opinion from the Community Scientific Committee(s) or the Authority before the date of application of this Regulation;

c the application for its authorisation has not been rejected in accordance with the relevant Community legislation; and

d detection methods are publicly available.

2 In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of such materials.

[[F72]3 Measures designed to amend non-essential elements of this Regulation by supplementing it and lowering the thresholds referred to in paragraph 1, in particular for GMOs sold directly to the final consumer, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 35(3).**]**

4 Detailed rules for implementing this Article shall be adopted in accordance with the procedure referred to in Article 35(2).

5 This Article shall remain applicable for a period of three years after the date of application of this Regulation.

Textual Amendments

F72 Substituted by Regulation (EC) No 298/2008 of the European Parliament and of the Council of 11 March 2008 amending Regulation (EC) No 1829/2003 on genetically modified food and feed, as regards the implementing powers conferred on the Commission.

Article 48

Review

1 No later than 7 November 2005 and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation and in particular of Article 47, accompanied, where appropriate, by any suitable proposal. The report and any proposal shall be made accessible to the public.

2 Without prejudice to the powers of national authorities, the Commission shall monitor the application of this Regulation and its impact on human and animal health, consumer protection, consumer information and the functioning of the internal market and, if necessary, will bring forward proposals at the earliest possible date.

Article 49

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from six months after the date of publication of this Regulation.

F73 …

Textual Amendments

F73 Words in Signature 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, **40**; 2020 c. 1, Sch. 5 para. 1(1)

ANNEX

DUTIES AND TASKS OF THE [F74]... REFERENCE LABORATORY

Textual Amendments

F74 Word in Annex title 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, **41(a)**; 2020 c. 1, Sch. 5 para. 1(1)

[F75]1. .....

Textual Amendments

F75 Annex para. 1 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, **41(b)**; 2020 c. 1, Sch. 5 para. 1(1)

[F76]2. .....

Textual Amendments

F76 Annex para. 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, **41(b)**; 2020 c. 1, Sch. 5 para. 1(1)

[[F77]3. The [F78]... reference laboratory shall be responsible, in particular, for:

(a) [F79]...

(b) [F80]...

(c) evaluating the data provided by the applicant for authorisation for placing the food or feed on the market, for the purpose of testing and validation of the method for sampling and detection;

(d) testing and validating the method for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed;

(e) submitting full evaluation reports to the Authority.**]**

Textual Amendments

F79 Annex para. 3(a) 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, **41(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F80 Annex para. 3(b) 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, **41(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F77 Substituted by Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance).

F78 Word in Annex para. 3 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, **41(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

[[F81]4. The reference laboratory must help to resolve disputes concerning the results of the duties and tasks outlined in this Annex.**]**

Textual Amendments

F81 Annex para. 4 substituted (31.12.2020) by The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705), regs. 1, **41(d)**; 2020 c. 1, Sch. 5 para. 1(1)

(**1**) OJ C 304 E, 30.10.2001, p. 221.

(**2**) OJ C 221, 17.9.2002, p. 114.

(**3**) OJ C 278, 14.11.2002, p. 31.

(**4**) Opinion of the European Parliament of 3 July 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 (OJ C 113 E, 13.5.2003, p. 31), Decision of the European Parliament of 2 July 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.

(**5**) OJ L 43, 14.2.1997, p. 1.

(**6**) OJ L 117, 8.5.1990, p. 15. Directive repealed by Directive 2001/18/EC.

(**7**) OJ L 106, 17.4.2001, p. 1. Directive as last amended by Council Decision 2002/811/EC (OJ L 280, 18.10.2002, p. 27).

(**8**) OJ L 31, 1.2.2002, p. 1.

(**9**) OJ L 40, 11.2.1989, p. 27. Directive as amended by Directive 94/34/EC of the European Parliament and of the Council (OJ L 237, 10.9.1994, p. 1).

(**10**) OJ L 184, 15.7.1988, p. 61. Directive as amended by Commission Directive 91/71/EEC (OJ L 42, 15.2.1991, p. 25).

(**11**) OJ L 213, 21.7.1982, p. 8. Directive as last amended by Directive 1999/20/EC (OJ L 80, 25.3.1999, p. 20).

(**12**) OJ L 270, 14.12.1970, p. 1. Directive as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).

(**13**) OJ L 109, 6.5.2000, p. 29. Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p. 19).

(**14**) OJ L 159, 3.6.1998, p. 4. Regulation as amended by Commission Regulation (EC) No 49/2000 (OJ L 6, 11.1.2000, p. 13).

(**15**) OJ L 6, 11.1.2000, p. 15.

(**16**) See page 24 of this Official Journal.

(**17**) OJ L 93, 17.4.1968, p. 15. Directive as last amended by Directive 2002/11/EC (OJ L 53, 23.2.2002, p. 20).

(**18**) OJ L 193, 20.7.2002, p. 1.

(**19**) OJ L 193, 20.7.2002, p. 33.

(**20**) OJ 125, 11.7.1966, p. 2298/66. Directive as last amended by Directive 2001/64/EC (OJ L 234, 1.9.2001, p. 60).

(**21**) OJ 125, 11.7.1966, p. 2309/66. Directive as last amended by Directive 2001/64/EC.

(**22**) OJ L 157, 10.6.1992, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

(**23**) OJ L 157, 10.6.1992, p. 10. Directive as last amended by Regulation (EC) No 806/2003.

(**24**) OJ L 193, 20.7.2002, p. 12.

(**25**) OJ L 193, 20.7.2002, p. 60. Directive amended by Commission Decision 2003/66/EC (OJ L 25, 30.1.2003, p. 42).

(**26**) OJ L 193, 20.7.2002, p. 74. Directive amended by Commission Directive 2003/45/EC (OJ L 138, 5.6.2003, p. 40).

(**27**) OJ L 184, 17.7.1999, p. 23.

(**28**) OJ L 126, 13.5.1983, p. 23.

(**29**) OJ L 268, 18.10.2003, p. 1.

(**30**) OJ L 268, 18.10.2003, p. 1.

(**31**) OJ L 31, 1.2.2002, p. 1.

(**32**) OJ L 268, 18.10.2003, p. 1.

(**33**) OJ L 31, 1.2.2002, p. 1.

(**34**) OJ L 268, 18.10.2003, p. 1.

(**35**) OJ L 31, 1.2.2002, p. 1.

(**36**) OJ L 268, 18.10.2003, p. 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.