DRAFT STATUTORY INSTRUMENTS

2022 No.

The Food and Feed (Miscellaneous Amendments) Regulations 2022

PART 3

Amendment of retained direct EU legislation

Amendment of Regulation (EC) No 1829/2003 on genetically modified food and feed

7.—(1) Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed(**1**) is amended as follows.

(2) In Article 8, after paragraph 5, insert—

"**6.** Where the notification and accompanying particulars referred to in paragraphs 1 and 2 are, or were, not supplied within the period specified or are, or were, found to be incorrect, or where an application is, or was, not submitted as required by paragraph 4 within the period specified, the appropriate authority may prescribe(**2**)—

(a) that the product concerned, and any products derived from it, be withdrawn from the market;

(b) a period of time within which existing stocks of the product concerned, and any products derived from it, may be used up.".

(3) In Article 20, after paragraph 5, insert—

"**6.** Where the notification and accompanying particulars referred to in paragraphs 1 and 2 are, or were, not supplied within the period specified or are, or were, found to be incorrect, or where an application is, or was, not submitted as required by paragraph 4 within the period specified, the appropriate authority may prescribe—

(a) that the product concerned, and any products derived from it, be withdrawn from the market;

(b) a period of time within which existing stocks of the product concerned, and any products derived from it, may be used up.".

Amendment of Regulation (EC) No 1831/2003 on additives for use in animal nutrition

8.—(1) Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition(**3**) is amended as follows.

(2) In Article 1—

(a) in paragraph 2(b), omit "as defined in Directive 2001/82/EC";

(**1**) EUR 2003/1829, amended by S.I. 2019/705.
(**2**) See Articles 2(19) and 35 of EUR 2003/1829 respectively for the meaning of "prescribed" and the procedure that applies to the making of Regulations.
(**3**) EUR 2003/1831, amended by S.I. 2019/654.

(b) after paragraph 2 insert—

"**3.** In this Article 'veterinary medicinal product' means:

(a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or

(b) any substance or combination of substances which may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

For the purposes of the definition of 'veterinary medicinal product', 'substance' means any matter, irrespective of origin, which may be:

(a) human, including human blood and human blood products;

(b) animal, including micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts and blood products;

(c) vegetable, including micro-organisms, plants, parts of plants, vegetable secretions and extracts; or

(d) chemical, including elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.".

(3) In Article 2(2)—

(a) for points (b) to (d) substitute—

"(b) 'feed materials' means products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from their industrial processing, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as a carrier of premixtures;

(c) 'compound feed' means a mixture of at least two feed materials, whether or not containing feed additives, for oral animal-feeding in the form of complete feed or complementary feed;

(d) 'complementary feed' means compound feed which has a high content of certain substances but which, by reason of its composition, is sufficient for a daily ration only if used in combination with other feed;";

(b) for point (g) substitute—

"(g) 'complete feed' means compound feed which, by reason of its composition, is sufficient for a daily ration;".

(4) In Article 3—

(a) in paragraph 2, for "Directive 87/153/EEC, Directive 83/228/EEC" substitute "Regulation (EC) No 767/2009(**4**)";

(b) in paragraph 4, for "Directive 95/69/EC" substitute "Regulation (EC) No 183/2005(**5**)".

(5) In Article 4(2), for "Articles 53 and 54" substitute "Article 53".

(6) In Article 7—

(a) in paragraph 3—

(i) in point (e), for "feedingstuffs" substitute "feed";

(**4**) EUR 2009/767, amended by S.I. 2019/654.
(**5**) EUR 2005/183, amended by S.I. 2019/654.

(ii) in point (f), for "have been sent by the applicant directly" substitute "will be made available, upon request,";

(b) in paragraph 4, omit the final sentence.

(7) In Article 8(4)(e), for the words from "Annex I" to the end substitute "Regulation (EC) No 470/2009(**6**)".

(8) Omit Article 13(6).

(9) In Article 16(1)—

(a) in the words before point (a), for "Great Britain" substitute "the British Islands";

(b) in point (d)—

(i) omit "Article 10 of";

(ii) omit "or, as applicable, to Article 5 of Directive 95/69/EC".

(10) In Annex 2—

(a) before point 2 insert—

"**1A.** The reference laboratory may be assisted by scientific experts or official laboratories with the performance of the duties and tasks set out in this Annex.";

(b) in point 4, for "Articles 11 and 32 of Regulation (EC) No 882/2004 of the European Parliament and of the Council" substitute "Regulation (EU) 2017/625(**7**)";

(c) after point 5 insert—

"**6.** The reference laboratory shall:

(a) be responsible for the overall coordination of scientific experts or official laboratories; and

(b) ensure that the relevant data concerning the applications are made available to the scientific experts or official laboratories.";

(d) in point 7, for "Article 32 of Regulation (EC) No 882/2004" substitute "Regulation (EU) 2017/625".

(11) In Annex 4, in point 3, for "complete feedingstuffs" substitute "complete feed".

Amendment of Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin

9.—(1) Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin(**8**) is amended as follows.

(2) Omit Article 1(4).

(3) In Article 10—

(a) after paragraph 1 insert—

"**1A.** Amendments under paragraph 1 may, in particular, prescribe—

(a) the requirements on the identification marking of products of animal origin;

(b) the objectives of HACCP-based procedures;

(c) the requirements on the food chain information;

(**6**) EUR 2009/470, amended by S.I. 2019/676 and 865.
(**7**) EUR 2017/625, amended by S.I. 2020/1481.
(**8**) EUR 2004/853, amended by S.I. 2019/640.

(d) the specific hygiene requirements for the premises, including means of transport, where products of animal origin are produced, handled, processed, stored or distributed;

(e) the specific hygiene requirements for the operations involving the production, handling, processing, storage, transport or distribution of products of animal origin;

(f) the rules for the transport of meat while it is warm;

(g) the health standards or checks, where there is scientific evidence indicating that they are necessary to protect public health;

(h) the extension of Annex III, Section VII, Chapter IX (specific requirements for pectinidae, marine gastropods and echinoderms which are not filter feeders harvested outside classified production areas), to live bivalve molluscs other than pectinidae;

(i) the criteria for determining when epidemiological data indicate that a fishing ground does not present a health hazard with regard to the presence of parasites and, consequently, for determining when the competent authority may authorise food business operators not to freeze fishery products in accordance with Annex III, Section VIII, Chapter III, Part D (requirements concerning parasites);

(j) the additional health standards for live bivalve molluscs in cooperation with the relevant reference laboratory, including:

(i) limit values and analysis methods for other marine biotoxins;

(ii) virus testing procedures and virological standards; and

(iii) sampling plans and the methods and analytical tolerances to be applied to check compliance with the health standards.";

(b) in paragraph 2—

(i) for "exemptions" substitute "derogations";

(ii) after "Annexes 2 and 3" insert—

"taking into account the relevant risk factors and provided that such derogations do not affect the achievement of the following objectives of this Regulation:

(a) to facilitate the fulfilment, by small businesses, of the requirements laid down in the Annexes;

(b) to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food;

(c) to accommodate the needs of food businesses situated in regions that are subject to special geographic constraints;

(d) to facilitate the work of establishments producing raw material which is intended for the production of highly refined food products and which has undergone a treatment ensuring its safety".

(4) In Article 11, in the words before point 1, omit "to Annex 2 or 3".

Amendment of Commission Regulation (EC) No 378/2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the duties and tasks of the

Community Reference Laboratory concerning applications for authorisations of feed additives

10.—(1) Commission Regulation (EC) No 378/2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives(**9**) is amended as follows.

(2) In Article 3—

(a) in paragraph 1—

(i) in the first subparagraph, after "reference samples" insert "to the reference laboratory, upon request,";

(ii) in the second subparagraph—

(aa) in the words before point (a), after "In addition," insert "and upon request,";

(bb) in point (a), in the final indent, omit "in Annex I or III of Council Regulation (EEC) No 2377/90";

(b) in paragraph 3, in the second sentence of the second subparagraph—

(i) for "national reference laboratories of the consortium" substitute "scientific experts or official laboratories working on behalf of the reference laboratory";

(ii) for "of Articles 11, 32 and 33 of Regulation (EC) No 882/2004" substitute "to Regulation (EU) 2017/625".

(3) In Article 6—

(a) in paragraph 1, for "a consortium of national" substitute "scientific experts or official";

(b) for paragraph 2 substitute—

"**2.** For the purposes of paragraph 1, scientific experts or official laboratories must comply with the requirements set out in Annex I.";

(c) in paragraph 3—

(i) for "members of the consortium", in the first place it appears, substitute "scientific experts or official laboratories";

(ii) for "other members of the consortium" substitute "scientific experts or official laboratories";

(iii) in the final sentence, omit "to the members of the consortium".

(4) In Article 9—

(a) in the heading, for "the laboratories participating in the consortium" substitute "scientific experts or official laboratories assisting the reference laboratory";

(b) in paragraph 1, for "The laboratories participating in the consortium" substitute "Scientific experts or official laboratories, who are assisting the reference laboratory,";

(c) in paragraph 2—

(i) for "Each laboratory" substitute "A scientific expert or official laboratory, who, or which, is assisting the reference laboratory,";

(ii) before "laboratory considers" insert "scientific expert or official";

(iii) in the final sentence, before "laboratories" insert "scientific experts or official".

(5) In Article 10(1), in the second subparagraph, for "the consortium" substitute "scientific experts or official laboratories".

(**9**) EUR 2005/378, amended by S.I. 2019/654.

(6) In Article 11, in both places, for "consortium" substitute "scientific experts or official laboratories".

(7) In Article 12(2), for "laboratories, including criteria for appointing rapporteur laboratories" substitute "scientific experts or official laboratories, including criteria for appointing scientific experts or official laboratories".

(8) Omit Article 13.

(9) In Annex 1—

(a) for the heading substitute "Requirements for participating scientific experts and official laboratories, as referred to in Article 6";

(b) in the words before point (b), for "Laboratories participating in the consortium" substitute "Scientific experts or official laboratories assisting the reference laboratory";

(c) in point (e), omit "with the other laboratories participating in the consortium".

(10) Omit Annex 3.

Amendment of Commission Decision 2007/305/EC on the withdrawal from the market of Ms1xRf1 (ACS-BNØØ4-7xACS-BNØØ1-4) hybrid oilseed rape and its derived products

11. In Article 2(1) of Commission Decision 2007/305/EC on the withdrawal from the market of Ms1xRf1 (ACS-BNØØ4-7xACS-BNØØ1-4) hybrid oilseed rape and its derived products(**10**), for "2022" substitute "2025".

Amendment of Commission Decision 2007/306/EC on the withdrawal from the market of Ms1xRf2 (ACS-BNØØ4-7xACS-BNØØ2-5) hybrid oilseed rape and its derived products

12. In Article 2(1) of Commission Decision 2007/306/EC on the withdrawal from the market of Ms1xRf2 (ACS-BNØØ4-7xACS-BNØØ2-5) hybrid oilseed rape and its derived products(**11**), for "2022" substitute "2025".

Amendment of Commission Decision 2007/307/EC on the withdrawal from the market of Topas 19/2 (ACS-BNØØ7-1) oilseed rape and its derived products

13. In Article 1(2) of Commission Decision 2007/307/EC on the withdrawal from the market of Topas 19/2 (ACS-BNØØ7-1) oilseed rape and its derived products(**12**), for "2022" substitute "2025".

Amendment of Commission Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives

14.—(1) Commission Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives(**13**) is amended as follows.

(2) In Annex 1—

(a) after point 1.3 insert—

(**10**) EUDN 2007/305, amended by S.I. 2019/705.
(**11**) EUDN 2007/306, amended by S.I. 2019/705.
(**12**) EUDN 2007/307, amended by S.I. 2019/705.
(**13**) EUR 2008/429, amended by S.I. 2019/654.

"Note: where applicable, in accordance with Regulation (EC) No 378/2005, reference samples, documentation and payment will be requested after submission of the feed additive application by the reference laboratory.";

(b) omit point 1.4;

(c) in point 1.5, omit the words from "three samples of" to "378/2005".

(3) In Annex 2—

(a) in the sixth unnumbered subparagraph, before "Directive 2004/10/EC" insert "Annex I to";

(b) in the eighth unnumbered subparagraph, for the words from "Council Directive 67/548/EEC" to "2004/73/EC" substitute "Regulation (EC) No 1272/2008(**14**)";

(c) in the tenth unnumbered subparagraph—

(i) before "Directive 2004/10/EC" insert "Annex I to";

(ii) for the words from "Article 11 of" to the end substitute "Articles 34 and 35 of Regulation (EU) 2017/625";

(d) in point 2.3.1, in the second subparagraph, for "Council Directive 90/219/EC applies. A" substitute "a";

(e) in point 2.5.2.1—

(i) omit "material";

(ii) for the words from "Commission Directive" to "88/379/EEC" substitute "Regulation (EC) No 1907/2006(**15**)";

(f) in point 2.6—

(i) in the third unnumbered subparagraph—

(aa) for the words from "Council Regulation (EEC)" to "animal origin" substitute "Regulation (EC) No 470/2009";

(bb) for the words from "to European Medicines Agency" to the end substitute "in accordance with Commission Implementing Regulation (EU) 2017/12(**16**)";

(ii) in the fifth unnumbered subparagraph, for "prior to the evaluation of the technical dossier" substitute ", upon request";

(g) in point 2.6.1.1, for "Article 11 of Regulation (EC) No 882/2004" substitute "Regulation (EU) 2017/625.";

(h) in point 2.6.1.2, for "Regulation (EC) No 882/2004" substitute "Regulation (EU) 2017/625";

(i) in point 2.6.1.4, for "Regulation (EC) No 882/2004" substitute "Regulation (EU) 2017/625";

(j) in point 2.6.2.1, for "Article 11 of Regulation (EC) No 882/2004" substitute "Regulation (EU) 2017/625";

(k) in point 2.6.2.2, for "Regulation (EC) No 882/2004" substitute "Regulation (EU) 2017/625";

(l) in point 2.6.3—

(**14**) EUR 2008/1272, amended by S.I. 2019/720.
(**15**) EUR 2006/1907, amended by S.I. 2019/758.
(**16**) EUR 2017/12, amended by S.I. 2019/676.

(i) in the third unnumbered subparagraph, before "Directive 2004/10/EC" insert "Annex I to";

(ii) in the fourth unnumbered subparagraph, for "Article 11 of Regulation (EC) No 882/2004" substitute "Regulation (EU) 2017/625";

(m) in point 3.4, in the second unnumbered subparagraph, for "Directive 67/548/EEC" substitute "Regulation (EC) No 1272/2008".

(4) In Annex 3—

(a) in point 2.2.3.1, in subparagraph 2, for the words from "of the Commission Regulation (EC) No 1565/2000" to "European Parliament and of the Council" substitute "Regulation (EU) No 872/2012(**17**)";

(b) in point 3.3.1.1, in subparagraph 1—

(i) omit "authorised by Directive 82/471/EEC";

(ii) for "Directive 70/524/EEC" substitute "Article 10 of Regulation (EC) No 1831/2003".

Amendment of Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings

15. In Article 7(4) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings(**18**), for "Community" substitute "domestic".

Amendment of Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed

16.—(1) Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed(**19**) is amended as follows.

(2) In Article 1—

(a) in the first paragraph, for "Directive 2002/32/EC of the European Parliament and of the Council" substitute "the CMU Regulations";

(b) for the third paragraph substitute—

"In this Regulation—

'CMU Regulations' means—

(a) in relation to England, the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015;

(b) in relation to Scotland, the Animal Feed (Scotland) Regulations 2010(**20**); and

(c) in relation to Wales, the Animal Feed (Composition, Marketing and Use) (Wales) Regulations 2016(**21**).

'reference laboratory' means a reference laboratory prescribed by the appropriate authority under Regulation (EU) 2017/625.".

(3) In Annex 1—

(**17**) EUR 2012/872, amended by S.I. 2019/860.
(**18**) EUR 2008/1331, amended by S.I. 2019/860.
(**19**) EUR 2009/152, amended by S.I. 2019/654.
(**20**) S.S.I. 2010/373, amended by S.S.I. 2013/340, 2017/38, 2019/52 and 2020/467.
(**21**) S.I. 2016/386 (W.120), amended by S.I. 2018/806 (W.162), 2019/1046 (W.185), 2020/1381 (W.307) and 2021/371 (W.114).

(a) in point 7, in the table, in the third footnote, omit the words from "in accordance with" to the end;

(b) in point 9.4, in the final indent, for "footnote (**) in chapter 6 and footnote (*) in chapter 7" substitute "footnote (b) to the table in point 6 of this Annex and footnote (a) to the table in point 7 of this Annex".

(4) In Annex 2, in Part C, in point 6, for "Directive 2002/32/EC" substitute "the CMU Regulations".

(5) In Annex 3, in Part L, in point 1, for "Council Directive 96/25/EC" substitute "Regulation (EC) No 767/2009".

(6) In Annex 5, in Part B—

(a) in Chapter 1—

(i) in point 1, for "Directive 2002/32/EC" substitute "the CMU Regulations";

(ii) in point 2.1, in both places, for "Directive 2002/32/EC" substitute "the CMU Regulations";

(iii) in point 2.2, in each place, for "Directive 2002/32/EC" substitute "the CMU Regulations";

(iv) in point 3, in the heading, for "Annex II to Directive 2002/32/EC" substitute "the CMU Regulations";

(b) in Chapter 2—

(i) in point 4.1, for "Regulation (EC) No 882/2004" substitute "Regulation (EU) 2017/625";

(ii) in point 8.1.5, for "Directive 2002/32/EC" substitute "the CMU Regulations";

(iii) in point 8.3.3, for "Directive 2002/32/EC" substitute "the CMU Regulations";

(c) in Chapter 3—

(i) in point 8, for "Regulation (EC) No 882/2004" substitute "Regulation (EU) 2017/625";

(ii) in point 10.5, for "Directive 2002/32/EC" substitute "the CMU Regulations".

Amendment of Commission Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food

17.—(1) Commission Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food(**22**) is amended as follows.

(2) In Article 11—

(a) in paragraph 1, for the words from "edible:" to the end substitute "edible, with the words 'DO NOT EAT'";

(b) in paragraph 3—

(i) for "Article 6(4)(a) of Directive 2000/13/EC of the European Parliament and of the Council" substitute "Article 2 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, etc.(**23**),";

(ii) for "that Directive" substitute "that Regulation".

(3) Omit Annex 1.

(**22**) EUR 2009/450, amended by S.I. 2019/704.
(**23**) EUR 2011/1169, amended by S.I. 2019/529 and 2019/778 and 2020/1627.

Amendment of Regulation (EC) No 767/2009 on the placing on the market and use of feed, etc.

18.—(1) Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed, etc. is amended as follows.

(2) In Article 16.1(a), for "24(5)" substitute "24(2)".

(3) In Annex 2, after point 2 insert—

"**3.** In the designation of feed for pets, the expression 'pet food' shall be allowed.".

Amendment of Commission Regulation (EU) No 619/2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired

19. In Article 2(b) of Commission Regulation (EU) No 619/2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired(**24**), after "2012," insert "in the case of products falling within Decision 2007/304/EC(**25**) or Decision 2007/308/EC(**26**), or after 30 December 2025, in the case of products falling within Decision 2007/305/EC, Decision 2007/306/EC or Decision 2007/307/EC,".

Amendment of Regulation (EU) 2015/2283 on novel foods, etc.

20. In Article 35 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, etc.(**27**)—

(a) omit paragraph 1;

(b) for paragraph 2 substitute—

"**2.** A novel food, which is the subject of an application for authorisation submitted in accordance with Article 10, and which is received by the appropriate authority on or before 31 December 2023, may remain on the market in Great Britain until the application concludes, if—

(a) it did not fall within scope of Regulation (EC) No 258/97(**28**) before that Regulation was repealed;

(b) it was lawfully placed on the market in the European Union or the United Kingdom before 1 January 2018; and

(c) it was the subject of an application for authorisation or notification of a traditional food from a third country received by the European Commission on or before 1 January 2019.

2A. For the purpose of paragraph 2, an application concludes when—

(a) the appropriate authority informs the applicant, in accordance with Article 6(5) of Commission Implementing Regulation (EU) 2017/2469(**29**), that the application is not considered valid;

(**24**) EUR 2011/619, amended by S.I. 2019/654.
(**25**) EUDN 2007/304.
(**26**) EUDN 2007/308.
(**27**) EUR 2015/2283, amended by S.I. 2019/702.
(**28**) Regulation (EC) No 258/97 was repealed by EUR 2015/2283 with effect from 1 January 2018.
(**29**) EUR 2017/2469, amended by S.I. 2019/702.

(b) the appropriate authority terminates the procedure in accordance with Article 10(6);

(c) the applicant withdraws the application; or

(d) the list established in Commission Implementing Regulation (EU) 2017/2470(**30**) is updated to authorise the novel food in accordance with Article 12(1) of this Regulation.";

(c) omit paragraph 3.

(**30**) EUR 2017/2470, amended by S.I. 2019/702.