Draft Regulations laid before Parliament under paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

D R A F T S T A T U T O R Y I N S T R U M E N T S

2022 No. XXXX

AGRICULTURE

FOOD

The Food and Feed (Miscellaneous Amendments) Regulations 2022

Made - - - -	**** 2022*
Coming into force - -	*31st December 2022*

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SCHEDULE 1 — Insertion of Schedule 5 to the Materials and Articles in Contact with Food (England) Regulations 2012

SCHEDULE 2 — Insertion of Schedule 6 to the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013

SCHEDULE 3 — Insertion of Schedules 3, 4 and 5 to the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**a**).

In accordance with paragraph 1(1) of Schedule 7 to that Act, a draft of these Regulations was laid before, and approved by a resolution of, each House of Parliament.

As required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the

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(**a**) 2018 c. 16. Section 8 was amended by section 27 of the European Union (Withdrawal Agreement) Act 2020 (c. 1); paragraph 21 of Schedule 7 was amended by paragraph 53 of Part 2 of Schedule 5 to that Act.

European Food Safety Authority and laying down procedures in matters of food safety(**a**), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

PART 1

Introductory

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Food and Feed (Miscellaneous Amendments) Regulations 2022 and come into force on 31st December 2022.

(2) This Part and Part 3 extend to England and Wales and Scotland.

(3) Part 2 extends to England and Wales but applies in relation to England only.

PART 2

Amendment of statutory instruments that apply in England

Amendment of the Materials and Articles in Contact with Food (England) Regulations 2012

2.—(1) The Materials and Articles in Contact with Food (England) Regulations 2012(**b**) are amended as follows.

(2) In regulation 2—

(a) in paragraph (1)—

(i) omit the definition of "Directive 84/500/EEC";

(ii) omit the definition of "Directive 2007/42/EC";

(b) in paragraph (3), in both places, omit "EU".

(3) In regulation 9—

(a) omit the "and" at the end of paragraph (a)(iii);

(b) omit paragraph (b).

(4) In regulation 11, omit paragraph (3).

(5) In regulation 12—

(a) in paragraph (1)—

(i) in both places, for "Annex II" substitute "Schedule 5";

(ii) for "that Annex" substitute "that Schedule";

(b) in paragraph (2), for "Annex II" substitute "Schedule 5".

(6) In regulation 30—

(a) in paragraph (2), for the words from "how the EU" to the end substitute "the operation of the relevant retained EU instruments";

(b) in paragraph (6)—

(i) in the defined term, before "EU instruments" insert "relevant retained";

(ii) omit the words from "Council Directive 78/142/EEC" to "Directive 2007/42/EC,".

(7) Schedule 1 has effect.

(**a**) EUR 2002/178, amended by S.I. 2019/641.
(**b**) S.I. 2012/2619, amended by S.I. 2019/704 and 2020/1410.

Amendment of the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013

3.—(1) The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013(**a**) are amended as follows.

(2) In regulation 2—

(a) in paragraph (1)—

(i) omit the definition of "Directive 2009/32";

(ii) in the definition of "the EU Regulations", before "EU" insert "retained";

(b) in paragraph (2) omit "EU";

(c) in paragraph (3) omit "EU";

(d) in paragraph (4) for "EU instruments are Directive 2009/32," substitute "instruments are".

(3) Omit regulation 9.

(4) In regulation 10(a), for "Annex I" substitute "Schedule 6".

(5) In regulation 11(a)—

(a) in sub-paragraph (i), for "Annex I" substitute "Schedule 6";

(b) in sub-paragraph (ii), for "that Annex" substitute "Schedule 6";

(c) in sub-paragraph (iii), insert "and" at the end;

(d) in sub-paragraph (iv), omit the "and" at the end;

(e) omit sub-paragraph (v).

(6) In regulation 14(1)(a), for "Annex I" substitute "Schedule 6".

(7) In regulation 16, before "EU Regulations" insert "retained".

(8) In regulation 19(2), before "EU Regulations" insert "retained".

(9) Omit regulation 22(2).

(10) Schedule 2 has effect.

Amendment of the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015

4.—(1) The Animal Feed (Composition, Marketing and Use) (England) Regulations 2015(**b**) are amended as follows.

(2) In regulation 2—

(a) in paragraph (1)—

(i) omit the definition of "Directive 82/475";

(ii) omit the definition of "Directive 2002/32";

(b) in paragraph (2), before "EU" insert "retained";

(c) in paragraph (3), in both places, omit "EU".

(3) In regulation 12(2), for "the Annex to Directive 82/475" substitute "Schedule 3".

(4) In Part 6 (immediately before regulation 14), for the heading to that Part substitute "Undesirable substances in products intended for animal feed".

(5) In regulation 14, omit paragraph (a).

(6) In regulation 15—

(a) in paragraph (1)—

(**a**) S.I. 2013/2210, amended by S.I. 2014/1855, 2019/860 and 2022/377 and 938.
(**b**) S.I. 2015/255, amended by S.I. 2019/654 and 2019/675 and 2020/1410.

(i) in sub-paragraph (a), for "Annex I" substitute "a table in Schedule 4";

(ii) in the words after sub-paragraph (b), for "Annex" substitute "table";

(b) in paragraph (2)—

(i) in sub-paragraph (a), for "Annex I" substitute "a table in Schedule 4";

(ii) in sub-paragraph (b), for "Annex" substitute "table";

(c) in paragraph (3)—

(i) for "Annex I" substitute "a table in Schedule 4";

(ii) for "Annex", in the second place it occurs, substitute "table";

(d) in paragraph (5)—

(i) for "Annex I" substitute "a table in Schedule 4";

(ii) for "Annex", in the second place it occurs, substitute "table";

(e) in paragraph (7)—

(i) omit the "and" at the end of sub-paragraph (c);

(ii) after sub-paragraph (d) insert—

"(e) peat;

(f) leonardite.";

(f) after paragraph (8) insert—

"(9) In order to reduce or eliminate sources of undesirable substances in products intended for animal feed, feed authorities must, in cooperation with feed business operators(**a**), carry out investigations to identify the sources of undesirable substances, in cases where the maximum levels are exceeded and in cases where increased levels of such substances are detected, taking into account background levels; for the purpose of ensuring a uniform approach in cases of increased levels, action thresholds to trigger investigations are set out in Schedule 5.

(10) Feed authorities must transmit to the Agency all relevant information and findings of the source and the measures taken to reduce the level of, or eliminate, undesirable substances.

(11) Where the Secretary of State has grounds to believe that a level fixed in Schedule 4 or 5, or an undesirable substance not listed in Schedule 4 or 5, presents a danger to animal or human health, or to the environment, the Secretary of State—

(a) may, pending amendment of Schedule 4 or 5—

(i) change an existing level;

(ii) introduce a level; or

(iii) prohibit the presence,

of the undesirable substance concerned in products intended for animal feed by issuing a direction; and

(b) must decide whether to make an amendment to Schedule 4 or 5 that corresponds with the direction issued under sub-paragraph (a).

(12) A direction issued under paragraph (11)(a)—

(a) must be in writing;

(b) may specify a period of time during which it has effect;

(c) may be revoked by the Secretary of State at any time, by way of a written notice;

(**a**) See Article 3(2)(a) of EUR 2009/767 for the meaning of "feed business operator".

(d) irrespective of any period of time specified under sub-paragraph (b), ceases to have effect upon the entry into force of any corresponding amendment of Schedule 4 or 5 made pursuant to paragraph (11)(b).

(13) A direction issued under paragraph (11)(a) and a revocation notice under paragraph (12)(c) must be published by the Secretary of State without delay.".

(7) After regulation 15 insert—

"**Regulations**

15A.—(1) The Secretary of State may, by regulations, make provision to—

(a) add, amend or remove an entry in Schedule 4 or 5;

(b) amend the acceptability criteria for detoxification processes in Regulation (EU) 2015/786(**a**).

(2) Any power to make regulations under this Part is exercisable by statutory instrument.

(3) A statutory instrument containing regulations is subject to annulment in pursuance of a resolution of either House of Parliament.

(4) Regulations made under this regulation may—

(a) contain consequential, incidental, supplementary, transitional or saving provision (including provision amending, repealing or revoking retained direct EU legislation);

(b) make different provision for different purposes.".

(8) Omit regulation 22(2).

(9) Schedule 3 has effect.

Amendment of the Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015

5.—(1) The Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015(**b**) are amended as follows.

(2) In regulation 4—

(a) in paragraph (1)(a), for "20(2), 21(1) and 22(2)(b)" substitute "19(3) and (7) and 21(1)";

(b) in paragraph (2)(a), for "2(e)" substitute "2(f)".

(3) In regulation 30(1)(b), for "Article 4.2 of Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed" substitute "regulation 15(9) of the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015".

(4) Omit regulation 41(2).

Amendment of the Animal Feed (Basic Safety Standards) (England) Regulations 2019

6.—(1) The Animal Feed (Basic Safety Standards) (England) Regulations 2019(**c**) are amended as follows.

(2) In regulation 2—

(a) in paragraph (1), omit the definition of "the Directive";

(b) in paragraph (3), in both places, for ", Regulation 767/2009 and in the Directive" substitute "and Regulation 767/2009".

(3) Omit regulation 9(2).

(**a**) EUR 2015/786, amended by S.I. 2019/654.
(**b**) S.I. 2015/454, amended by S.I. 2019/683 and 2019/1476 and 2020/1410.
(**c**) S.I. 2019/683.

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(**a**) 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(**b**)—

(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(**c**) is amended as follows.

(2) In Article 1—

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

(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;

(**a**) EUR 2003/1829, amended by S.I. 2019/705.
(**b**) 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.
(**c**) EUR 2003/1831, amended by S.I. 2019/654.

(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(**a**)";

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

(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";

(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(**c**)".

(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—

(**a**) EUR 2009/767, amended by S.I. 2019/654.
(**b**) EUR 2005/183, amended by S.I. 2019/654.
(**c**) EUR 2009/470, amended by S.I. 2019/676 and 865.

"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(**a**)";

(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(**b**) 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;

(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;

(**a**) EUR 2017/625, amended by S.I. 2020/1481.
(**b**) EUR 2004/853, amended by S.I. 2019/640.

(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(**a**) 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.";

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

(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".

(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(**a**), 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(**b**), for "2022" substitute "2025".

(**a**) EUDN 2007/305, amended by S.I. 2019/705.
(**b**) EUDN 2007/306, amended by S.I. 2019/705.

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(**a**), 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(**b**) is amended as follows.

(2) In Annex 1—

(a) after point 1.3 insert—

"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(**c**)";

(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(**d**)";

(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(**e**)";

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

(**a**) EUDN 2007/307, amended by S.I. 2019/705.
(**b**) EUR 2008/429, amended by S.I. 2019/654.
(**c**) EUR 2008/1272, amended by S.I. 2019/720.
(**d**) EUR 2006/1907, amended by S.I. 2019/758.
(**e**) EUR 2017/12, amended by S.I. 2019/676.

(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—

(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(**a**)";

(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(**b**), 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(**c**) 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;

(**a**) EUR 2012/872, amended by S.I. 2019/860.
(**b**) EUR 2008/1331, amended by S.I. 2019/860.
(**c**) EUR 2009/152, amended by S.I. 2019/654.

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

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

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

(3) In Annex 1—

(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(**c**) 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—

(**a**) S.S.I. 2010/373, amended by S.S.I. 2013/340, 2017/38, 2019/52 and 2020/467.
(**b**) 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).
(**c**) EUR 2009/450, amended by S.I. 2019/704.

(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.(**a**),";

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

(3) Omit Annex 1.

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(**b**), after "2012," insert "in the case of products falling within Decision 2007/304/EC(**c**) or Decision 2007/308/EC(**d**), 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.(**e**)—

(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(**f**) 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**) EUR 2011/1169, amended by S.I. 2019/529 and 2019/778 and 2020/1627.
(**b**) EUR 2011/619, amended by S.I. 2019/654.
(**c**) EUDN 2007/304.
(**d**) EUDN 2007/308.
(**e**) EUR 2015/2283, amended by S.I. 2019/702.
(**f**) Regulation (EC) No 258/97 was repealed by EUR 2015/2283 with effect from 1 January 2018.

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

(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(**b**) is updated to authorise the novel food in accordance with Article 12(1) of this Regulation.";

(c) omit paragraph 3.

Signatory text

Name
Parliamentary Under Secretary of State
Department of Health and Social Care

Address
Date

SCHEDULE 1

Regulation 2(7)

Insertion of Schedule 5 to the Materials and Articles in Contact with Food (England) Regulations 2012

After Schedule 4 to the Materials and Articles in Contact with Food (England) Regulations 2012 insert—

"SCHEDULE 5

Regulation 12(1)

LIST OF SUBSTANCES AUTHORISED IN THE MANUFACTURE OF REGENERATED CELLULOSE FILM

DESCRIPTION OF REGENERATED CELLULOSE FILM

Regenerated cellulose film is a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface. Regenerated cellulose film may be coated on one or both sides.

LIST OF SUBSTANCES AUTHORISED IN THE MANUFACTURE OF REGENERATED CELLULOSE FILM

Notes:

—The percentages in this Schedule, in the first and second parts, are expressed in weight/weight (w/w) and are calculated in relation to the quantity of anhydrous uncoated regenerated cellulose film.

—The usual technical denominations are given in square brackets.

—The substances used shall be of good technical quality as regards the purity criteria.

First Part: Uncoated regenerated cellulose film

(**a**) EUR 2017/2469, amended by S.I. 2019/702.
(**b**) EUR 2017/2470, amended by S.I. 2019/702.

Denominations	*Restrictions*
A. Regenerated cellulose	Not less than 72 % (w/w)
B. Additives	
1. Softeners	Not more than 27 % (w/w) in total
— Bis (2-hydroxyethyl) ether [= diethyleneglycol]	Only for films intended to be coated and then used for foodstuffs which are not moist, namely which do not contain water which is physically free at the surface. The total amount of bis(2-hydroxyethyl)ether and ethanediol present in foodstuffs that have been in contact with film of this type may not exceed 30 mg/kg of the foodstuff.
— Ethanediol [= monoethyleneglycol]	
— 1.3-butanediol	
— Glycerol	
— 1.2-propanediol [= 1.2 propyleneglycol]	
— Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 250 and 1200.
— 1.2-polypropylene oxide [= 1.2 polypropyleneglycol]	Average molecular weight not greater than 400 and free 1.3-propanediol content not greater than 1% (w/w) in substance.
— Sorbitol	
— Tetraethyleneglycol	
— Triethyleneglycol	
— Urea	
2. Other additives	Not more than 1% (w/w) in total.
First class	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm^2 of the uncoated film.
— Acetic acid and its NH_4, Ca, Mg, K and Na salts	
— Ascorbic acid and its NH_4, Ca, Mg, K and Na salts	
— Benzoic acid and sodium benzoate	
— Formic acid and its NH_4, Ca, Mg, K and Na salts	
— Linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also behenic and ricinoleic acids and the NH_4, Ca, Mg, K, Na, Al, Zn salts of these acids	
— Citric, d- and l-lactic, maleic, l-tartaric acids and their Na and K salts	
— Sorbic acid and its NH_4, Ca, Mg, K and Na salts	
— Amides of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also the amides of behenic and ricinoleic acids	
— Natural edible starches and flours	
— Edible starches and flours modified by chemical treatment	
— Amylose	
— Calcium and magnesium carbonates and	

chlorides	
— Esters of glycerol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and/or with adipic, citric, 12-hydroxystearic (oxystearin), ricinoleic acids	
— Esters of polyoxyethylene (8 to 14 oxyethylene groups) with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
— Esters of sorbitol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
— Mono-and/or di-esters of stearic acid with ethanediol and/or bis (2-hydroxyethyl) ether and/or triethylene glycol	
— Oxides and hydroxides of aluminium, calcium, magnesium and silicon and silicates and hydrated silicates of aluminium, calcium, magnesium and potassium	
— Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 1200 and 4000.
— Sodium propionate	
Second class	The total quantity of the substances may not exceed 1 mg/dm^2 of the uncoated film and the quantity of the substance or group of substances in each indent may not exceed 0.2 mg/dm^2 (or a lower limit where one is specified) of the uncoated film.
— Sodium alkyl (C_8-C_{18}) benzene sulphonate	
— Sodium isopropyl naphthalene sulphonate	
— Sodium alkyl (C_8-C_{18}) sulphate	
— Sodium alkyl (C_8-C_{18}) sulphonate	
— Sodium dioctylsulphosuccinate	
— Distearate of dihydroxyethyl diethylene triamine monoacetate	Not more than 0.05 mg/dm^2 of the uncoated film.
— Ammonium, magnesium and potassium lauryl sulphates	
— N,N′-distearoyl diaminoethane, N,N′-dipalmitoyl diaminoethane and N,N′-dioleoyl diaminoethane	
— 2-heptadecyl-4.4-bis(methylene-stearate) oxazoline	
— Polyethylene-aminostearamide ethylsulphate	Not more than 0.1 mg/dm^2 of the uncoated film.
Third class — Anchoring agent	The total quantity of substances may not exceed 1 mg/dm^2 of the uncoated film.
— Condensation product of melamine-formaldehyde unmodified, or which may be modified with one or more of the following	Free formaldehyde content not greater than 0.5 mg/dm^2 of the uncoated film. Free melamine content not greater than 0.3

products: butanol, diethylenetriamine, ethanol, triethylenetetramine, tetraethylenepentamine, tri-(2-hydroxyethyl) amine, 3.3′-diaminodipropylamine, 4.4′-diaminodibutylamine	mg/dm^2 of the uncoated film.
— Condensation product of melamine-urea-formaldehyde modified with tris-(2-hydroxyethyl)amine	Free formaldehyde content not greater than 0.5 mg/dm^2 of the uncoated film. Free melamine content not greater than 0.3 mg/dm^2 of the uncoated film.
— Cross-linked cationic polyalkyleneamines: (a) polyamide-epichlorhydrin resin based on diaminopropylmethylamine and epichlorhydrin; (b) polyamide-epichlorhydrin resin based on epichlorhydrin, adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine; (c) polyamide-epichlorhydrin resin based on adipic acid, diethylenetriamine and epichlorhydrin, or a mixture of epichlorhydrin and ammonia; (d) polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, dimethyl adipate and diethylenetriamine; (e) polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, adipamide and diaminopropylmethylamine	
— Polyethyleneamines and polyethyleneimines	Not more than 0.75 mg/dm^2 of the uncoated film.
— Condensation product of urea-formaldehyde unmodified, or which may be modified with one or more of the following products: aminomethylsulphonic acid, sulphanilic acid, butanol, diaminobutane, diaminodiethylamine, diaminodipropylamine, diaminopropane, diethylenetriamine, ethanol, guanidine, methanol, tetraethylenepentamine, triethylenetetramine, sodium sulphite	Free formaldehyde content not greater than 0.5 mg/dm^2 of the uncoated film.
Fourth class	The total quantity of substances may not exceed 0.01 mg/dm^2 of the uncoated film.
— Products resulting from the reaction of the amines of edible oils with polyethylene oxide	
— Monoethanolamine lauryl sulphate	

Second Part: Coated regenerated cellulose film

Denominations	***Restrictions***
A. Regenerated cellulose	See first part.
B. Additives	See first part.
C. Coating	
1. Polymers	The total quantity of substances may not

	exceed 50 mg/dm^2 of the coating on the side in contact with foodstuffs.
— Ethyl, hydroxyethyl, hydroxypropyl and methyl ethers of cellulose	
— Cellulose nitrate	Not more than 20 mg/dm^2 of the coating on the side in contact with foodstuffs; nitrogen content between 10.8 % (w/w) and 12.2 % (w/w) in the cellulose nitrate.
2. Resins	The total quantity of substances may not exceed 12.5 mg/dm^2 of the coating on the side in contact with foodstuffs and which is used solely for the preparation of regenerated cellulose films with cellulose nitrate based coatings.
— Casein	
— Colophony and/or its products of polymerization, hydrogenation, or disproportionation and their esters of methyl, ethyl or C_2 to C_6 polyvalent alcohols, or mixtures of these alcohols	
— Colophony and/or its products of polymerization, hydrogenation, or disproportionation condensed with acrylic, maleic, citric, fumaric and/or phthalic acids and/or 2.2 bis (4-hydroxyphenyl) propane formaldehyde and esterified with methyl ethyl or C_2 to C_6 polyvalent alcohols or mixtures of these alcohols	
— Esters derived from bis(2-hydroxyethyl) ether with addition products of betapinene and/or dipentene and/or diterpene and maleic anhydride	
— Edible gelatine	
— Castor oil and its products of dehydration or hydrogenation and its condensation products with polyglycerol, adipic, citric, maleic, phthalic and sebacic acids	
— Natural gum [= damar]	
— Poly-beta-pinene [= terpenic resins]	
— Urea-formaldehyde resins (see anchoring agents)	
3. Plasticisers	The total quantity of substances may not exceed 6 mg/dm^2 of the coating on the side in contact with foodstuffs.
— Acetyl tributyl citrate	
— Acetyl tri(2-ethylhexyl) citrate	
— Di-isobutyl adipate	
— Di-n-butyl adipate	
— Di-n-hexyl azelate	
— Dicyclohexyl phthalate	Not more than 4.0 mg/dm^2 of the coating on the side in contact with foodstuffs.
— 2-ethylhexyl diphenyl phosphate (synonym: phosphoric acid diphenyl 2 ethylhexyl ester)	The amount of 2-ethylhexyl diphenyl phosphate shall not exceed: (a) 2.4 mg/kg of the foodstuff in contact with this type of film; or

	(b) 0.4 mg/dm^2 in the coating on the side in contact with foodstuffs.
— Glycerol monoacetate [= monoacetin]	
— Glycerol diacetate [= diacetin]	
— Glycerol triacetate [= triacetin]	
— Di-butyl sebacate	
— Di-n-butyl tartrate	
— Di-isobutyl tartrate	
4. Other additives	The total quantity of substances may not exceed 6 mg/dm^2 in the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs.
4.1. Additives listed in the first part	Same restrictions as in the first part (however the quantities in mg/dm^2 refer to the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs).
4.2. Specific coating additives	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm^2 (or a lower limit where one is specified) of the coating on the side in contact with foodstuffs.
— 1-hexadecanol and 1-octadecanol	
— Esters of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and of ricinoleic acid with ethyl, butyl, amyl and oleyl linear alcohols	
— Montan waxes, comprising purified montanic (C_{26} to C_{32}) acids and/or their esters with ethanediol and/or 1.3 butanediol and/or their calcium and potassium salts	
— Carnauba wax	
— Beeswax	
— Esparto wax	
— Candelilla wax	
— Dimethylpolysiloxane	Not more than 1 mg/dm^2 of the coating on the side in contact with foodstuffs.
— Epoxidised soya-bean oil (oxirane content 6 to 8 %)	
— Refined paraffin and microcrystalline waxes	
— Pentaerythritol tetrastearate	
— Mono and bis(octadecyldiethyleneoxide)-phosphates	Not more than 0.2 mg/dm^2 of the coating on the side in contact with foodstuffs.
— Aliphatic acids (C_8 to C_{20}) esterified with mono- or di-(2-hydroxyethyl)amine	
— 2- and 3-tert.butyl-4-hydroxyanisole [= butylated hydroxyanisole — BHA]	Not more than 0.06 mg/dm^2 of the coating on the side in contact with foodstuffs.
— 2.6-di-tert.butyl-4-methylphenol [= butylated hydroxytoluene — BHT]	Not more than 0.06 mg/dm^2 of the coating on the side in contact with foodstuffs.
— Di-n-octyltin-bis(2-ethylhexyl) maleate	Not more than 0.06 mg/dm^2 of the coating on the side in contact with foodstuffs.

5. Solvents	The total quantity of substances may not exceed 0.6 mg/dm^2 of the coating on the side in contact with foodstuffs.
— Butyl acetate	
— Ethyl acetate	
— Isobutyl acetate	
— Isopropyl acetate	
— Propyl acetate	
— Acetone	
— 1-butanol	
— Ethanol	
— 2-butanol	
— 2-propanol	
— 1-propanol	
— Cyclohexane	
— Ethyleneglycol monobutyl ether	
— Ethyleneglycol monobutyl ether acetate	
— Methyl ethyl ketone	
— Methyl isobutyl ketone	
— Tetrahydrofuran	
— Toluene	Not more than 0.06 mg/dm^2 of the coating on the side in contact with foodstuffs.”.

SCHEDULE 2

Regulation 3(10)

Insertion of Schedule 6 to the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013

After Schedule 5 to the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 insert—

“SCHEDULE 6

Regulations 10, 11 and 14

EXTRACTION SOLVENTS WHICH MAY BE USED DURING THE PROCESSING OF RAW MATERIALS, OF FOODSTUFFS, OF FOOD COMPONENTS OR OF FOOD INGREDIENTS

Table 1: Extraction solvents to be used in compliance with good manufacturing practice for all uses

Name[1]
Propane
Butane
Ethyl acetate
Ethanol
Carbon dioxide
Acetone[2]
Nitrous oxide

[1] An extraction solvent is considered as being used in compliance with good manufacturing practice if its use results only in the presence of residues or derivatives in technically unavoidable quantities presenting no danger to human health.
[2] The use of Acetone in the refining of olive-pomace oil is forbidden.

Table 2: Extraction solvents for which conditions of use are specified

Name	***Conditions of use (summary description of extraction)***	***Maximum residue limits in the extracted foodstuff or food ingredient***
Hexane[1]	Production or fractionation of fats and oils and production of cocoa butter	1 mg/kg in the fat or oil or cocoa butter
	Preparation of defatted protein products and defatted flours	10 mg/kg in the food containing the defatted protein products and the defatted flours
		30 mg/kg in the defatted soya products as sold to the final consumer
	Preparation of defatted cereal germs	5 mg/kg in the defatted cereal germs
Methyl acetate	Decaffeination of, or removal of irritants and bitterings from coffee and tea	20 mg/kg in the coffee or tea
	Production of sugar from molasses	1 mg/kg in the sugar
Ethylmethylketone[2]	Fractionation of fats and oils	5 mg/kg in the fat or oil
	Decaffeination of, or removal of irritants and bitterings from coffee and tea	20 mg/kg in the coffee or tea
Dichloromethane	Decaffeination of, or removal of irritants and	2 mg/kg in the roasted coffee and 5 mg/kg in

	bitterings from coffee and tea	the tea
Methanol	For all uses	10 mg/kg
Propan-2-ol	For all uses	10 mg/kg
Dimethyl ether	Preparation of defatted animal protein products including gelatine[3]	0.009 mg/kg in the defatted animal protein products including gelatine
	Preparation of collagen[4] and collagen derivatives, except gelatine	3 mg/kg in the collagen and collagen derivatives, except gelatine

[1] Hexane means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C. The combined use of Hexane and Ethylmethylketone is forbidden.

[2] The level of n-Hexane in this solvent should not exceed 50 mg/kg. The combined use of Hexane and Ethylmethylketone is forbidden.

[3] 'Gelatine' means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals, in accordance with the relevant requirements of Regulation (EC) No 853/2004.

[4] 'Collagen' means the protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant requirements of Regulation (EC) No 853/2004.

Table 3: Extraction solvents for which conditions of use are specified

Name	***Maximum residue limits in the foodstuff due to the use of extraction solvents in the preparation of flavourings from natural flavouring materials***
Diethyl ether	2 mg/kg
Hexane (*)	1 mg/kg
Cyclohexane	1 mg/kg
Methyl acetate	1 mg/kg
Butan-1-ol	1 mg/kg
Butan-2-ol	1 mg/kg
Ethylmethylketone (*)	1 mg/kg
Dichloromethane	0.02 mg/kg
Propan-1-ol	1 mg/kg
1,1,1,2-tetrafluoroethane	0.02 mg/kg
Methanol	1.5 mg/kg
Propan-2-ol	1 mg/kg
* The combined use of Hexane and Ethylmethylketone is forbidden.".	

SCHEDULE 3

Regulation 4(9)

Insertion of Schedules 3, 4 and 5 to the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015

After Schedule 2 to the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 insert—

"SCHEDULE 3

Regulation 12(2)

Categories of feed materials which may be indicated in place of individual feed materials

Description of the category	***Definition***
1.Meat and animal derivatives	All the fleshy parts of slaughtered warm-blooded land animals, fresh or preserved by appropriate treatment, and all products and derivatives of the processing of the carcase or parts of the carcase of warm-blooded land animals
2.Milk and milk derivatives	All milk products, fresh or preserved by appropriate treatment, and derivatives from their processing
3.Eggs and egg derivatives	All egg products fresh or preserved by appropriate treatment and derivatives from their processing
4.Oils and fats	All animal and vegetable oils and fats
5.Yeasts	All yeasts, the cells of which have been killed and dried
6.Fish and fish derivatives	Fish or parts of fish, fresh or preserved by appropriate treatment, and derivatives from their processing
7.Cereals	All types of cereal, regardless of their presentation, or products made from the starchy endosperm
8.Vegetables	All types of vegetables and legumes, fresh or preserved by appropriate treatment
9.Derivatives of vegetable origin	Derivatives resulting from the treatment of vegetable products, in particular cereals, vegetables, legumes and oil seeds
10.Vegetable protein extracts	All products of vegetable origin in which the proteins have been concentrated by an adequate process to contain at least 50% crude protein, as related to the dry matter, and which may be restructured (textured)
11.Minerals	All inorganic substances suitable for animal feed
12.Various sugars	All types of sugar
13.Fruit	All types of fruit, fresh or preserved by appropriate treatment
14.Nuts	All kernels from shells
15.Seeds	All types of seeds as such or roughly crushed
16.Algae	Algae, fresh or preserved by appropriate treatment
17.Molluscs and crustaceans	All types of molluscs, crustaceans, shellfish, fresh or preserved by appropriate treatment, and their processing derivatives
18.Insects	All types of insects and their stages of development
19.Bakery products	All bread, cakes, biscuits and pasta

| products

SCHEDULE 4

Regulations 15 and 15A

Maximum levels of undesirable substances

Table 1: INORGANIC CONTAMINANTS AND NITROGENOUS COMPOUNDS

Undesirable substance	*Products intended for animal feed*	*Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %*
1. Arsenic[1]	Feed materials with the exception of:	2
	— meal made from grass, from dried lucerne and from dried clover, and dried sugar beet pulp and dried molasses sugar beet pulp;	4
	— palm kernel expeller;	4
	— peat; leonardite;	5
	— phosphates, calcareous marine algae;	10
	— calcium carbonate; calcium and magnesium carbonate[2]; calcareous marine shells;	15
	— magnesium oxide; magnesium carbonate;	20
	— fish, other aquatic animals and products derived from them;	25
	— seaweed meal and feed materials derived from seaweed.	40
	Iron particles used as tracer.	50
	Feed additives belonging to the functional group of compounds of trace elements with the exception of:	30
	— cupric sulphate pentahydrate; cupric carbonate; dicopper chloride trihydroxide; ferrous carbonate; dimanganese chloride trihydroxide	50
	— zinc oxide; manganous oxide; cupric oxide.	100
	Complementary feed with the exception of:	4
	— mineral feed;	12
	— complementary feed for pet animals containing fish, other aquatic animals and	10

	products derived from them and/or seaweed meal and feed materials derived from seaweed;	
	— long-term supply formulations of feed for particular nutritional purposes with a concentration of trace elements higher than 100 times the established maximum content in complete feed;	30
	Complete feed with the exception of:	2
	— complete feed for fish and fur animals;	10
	— complete feed for pet animals containing fish, other aquatic animals and products derived from them and/or seaweed meal and feed materials derived from seaweed.	10
2. Cadmium	Feed materials of vegetable origin	1
	Feed materials of animal origin	2
	Feed materials of mineral origin with the exception of:	2
	— phosphates.	10
	Feed additives belonging to the functional group of compounds of trace elements with the exception of:	10
	— cupric oxide, manganous oxide, zinc oxide and manganous sulphate monohydrate.	30
	Feed additives belonging to the functional groups of binders and anti-caking agents	2
	Premixtures[3]	15
	Complementary feed with the exception of:	0.5
	— mineral feed	
	– – containing < 7 % phosphorus[4]	5
	– – containing ≥ 7 % phosphorus[4]	0.75 per 1 % phosphorus[4], with a maximum of 7.5
	— complementary feed for pet animals	2

	— long-term supply formulations of feed for particular nutritional purposes with a concentration of trace elements higher than 100 times the established maximum content in complete feed;	15
	Complete feed with the exception of:	0.5
	— complete feed for cattle (except calves), sheep (except lambs), goats (except kids) and fish;	1
	— complete feed for pet animals.	2
3. Fluorine[5]	Feed materials with the exception of:	150
	— feed materials of animal origin except marine crustaceans such as marine krill; calcareous marine shells;	500
	— marine crustaceans such as marine krill;	3 000
	— phosphates;	2 000
	— calcium carbonate; calcium and magnesium carbonate[2]	350
	— magnesium oxide;	600
	— calcareous marine algae.	1 250
	Vermiculite (E 561).	3 000
	Complementary feed:	
	— containing ≤ 4 % phosphorus[4];	500
	— containing > 4 % phosphorus[4].	125 per 1 % phosphorus[4]
	Complete feed with the exception of:	150
	— complete feed for pigs;	100
	— complete feed for poultry (except chicks) and fish;	350
	— complete feed for chicks;	250
	— complete feed for cattle, sheep and goats	
	– – in lactation;	30
	– – other.	50
4. Lead[6]	Feed materials with the exception of:	10
	— forage[7];	30
	— phosphates, calcareous marine algae and calcareous marine shells;	15
	— calcium carbonate;	20

	calcium and magnesium carbonate[2]; — yeasts.	5
	Feed additives belonging to the functional group of compounds of trace elements with the exception of: — zinc oxide; — manganous oxide, ferrous carbonate, cupric carbonate, copper (I) oxide.	100 400 200
	Feed additives belonging to the functional groups of binders and anti-caking agents with the exception of: — clinoptilolite of volcanic origin; natrolite-phonolite.	30 60
	Premixtures[3]	200
	Complementary feed with the exception of: — mineral feed; — long-term supply formulations of feed for particular nutritional purposes with a concentration of trace elements higher than 100 times the established maximum content in complete feed.	10 15 60
	Complete feed.	5
5. Mercury[8]	Feed materials with the exception of: — fish, other aquatic animals and products derived from them intended for the production of compound feed for food producing animals; — fish, other aquatic animals and products derived from them intended for the production of compound feed for dogs, cats, ornamental fish and fur animals; — fish, other aquatic animals and products derived from them as canned wet feed material for direct feeding of dogs and cats; — calcium carbonate; calcium and magnesium carbonate[2].	0.1 0.5 1.0[9] 0.3 0.3

	Compound feed	0.1
	with the exception of:	
	— mineral feed;	0.2
	— compound feed for fish;	0.2
	— compound feed for dogs, cats, ornamental fish and fur animals.	0.3
6. Nitrite[10]	Feed materials	15
	with the exception of:	
	— fishmeal;	30
	— silage;	—
	— products and by-products from sugar beet and sugarcane and from starch and alcoholic drink production.	—
	Complete feed	15
	with the exception of:	
	— complete feed for dogs and cats with a moisture content exceeding 20 %.	—
7. Melamine[11]	Feed	2.5
	with the exception of:	
	— canned pet food	2.5[12]
	— the following feed additives:	
	— guanidino acetic acid (GAA);	20
	— urea;	—
	— biuret.	—

[1] The maximum levels refer to total arsenic.

[2] Calcium and magnesium carbonate refers to the natural mixture of calcium carbonate and magnesium carbonate as described in Commission Regulation (EU) No 68/2013 on the Catalogue of feed materials.

[3] The maximum level established for premixtures takes into account the additives with the highest level of lead and cadmium and not the sensitivity of the different animal species to lead and cadmium. As provided in Article 16 of Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition, in order to protect animal and public health, it is the responsibility of the producer of premixtures to ensure that, in addition to compliance with the maximum levels for premixtures, the instructions for use of the premixture are in accordance with the maximum levels for complementary and complete feed.

[4] The % of phosphorus is relative to a feed with a moisture content of 12 %.

[5] Maximum levels refer to an analytical determination of fluorine, whereby extraction is performed with hydrochloric acid 1 N for 20 minutes at ambient temperature. Equivalent extraction procedures can be applied for which it can be demonstrated that the used extraction procedure has an equal extraction efficiency.

[6] For the determination of lead in kaolinitic clay and in feed containing kaolinitic clay, the maximum level refers to an analytical determination of lead, whereby extraction is performed in nitric acid (5 % w/w) for 30 minutes at boiling temperature. Equivalent extraction procedures can be applied for which it can be demonstrated that the used extraction procedure has an equal extraction efficiency.

[7] Forage includes products intended for animal feed such as hay, silage, fresh grass, etc.

[8] The maximum levels refer to total mercury.

[9] The maximum level is applicable on wet weight basis.

[10] The maximum levels are expressed as sodium nitrite.

(11) The maximum level refers to melamine only. The inclusion of the structurally related compounds cyanuric acid, ammeline and ammelide in the maximum level will be considered at a later stage.
(12) The maximum level is applicable to canned pet food as sold.

Table 2: MYCOTOXINS

Undesirable substance	*Products intended for animal feed*	*Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %*
1. Aflatoxin B1	Feed materials	0.02
	Complementary and complete feed with the exception of:	0.01
	— compound feed for dairy cattle and calves, dairy sheep and lambs, dairy goats and kids, piglets and young poultry animals,	0.005
	— compound feed for cattle (except dairy cattle and calves), sheep (except dairy sheep and lambs), goats (except dairy goats and kids), pigs (except piglets) and poultry (except young animals).	0.02
2. Rye ergot (Claviceps purpurea)	Feed materials and compound feed containing unground cereals.	1 000

Table 3: INHERENT PLANT TOXINS

Undesirable substance	*Products intended for animal feed*	*Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %*
1. Free gossypol	Feed materials with the exception of:	20
	— cottonseed,	6 000
	— cottonseed cakes and cottonseed meal.	1 200
	Complete feed with the exception of:	20
	— complete feed for cattle (except calves),	500
	— complete feed for sheep (except lambs) and goats (except kids),	300
	— complete feed for poultry (except laying hens) and calves,	100
	— complete feed for rabbits, lambs, kids and pigs (except piglets).	60

2. Hydrocyanic acid	Feed materials with the exception of: — linseed, — linseed cakes, — manioc products and almond cakes. Complete feed with the exception of: — complete feed for young chickens (< 6 weeks).	50 250 350 100 50 10
3. Theobromine	Complete feed with the exception of: — complete feed for pigs, — complete feed for dogs, rabbits, horses and fur animals.	300 200 50
4. vinyl thiooxazolidone (5-vinyloxazolidine-2-thione)	Complete feed for poultry with the exception of: — complete feed for laying hens.	1 000 500
5. Volatile mustard oil[1]	Feed materials with the exception of: — Camelina seed and products derived from it[2], products derived from mustard seed[2], rape seed and products derived from them. Complete feed with the exception of: — complete feed for cattle (except calves), sheep (except lambs) and goats (except kids); — complete feed for pigs (except piglets) and poultry.	100 4 000 150 1 000 500

[1] The maximum levels are expressed as allyl isothiocyanate.

[2] Upon request of the competent authorities, the responsible operator must perform an analysis to demonstrate that the content of total glucosinolates is lower than 30 mmol/kg. The method of analysis of reference is EN-ISO 9167:2019 (Rapeseed and rapeseed meals — Determination of glucosinolates content — Method using high-performance liquid chromatography); published by the International Organization for Standardization in May 2019, edition 1. Available from the ISO website https://www.iso.org/home.html.

Table 4: ORGANOCHLORINE COMPOUNDS (EXCEPT DIOXINS AND PCBs)

Undesirable substance	*Products intended for animal feed*	*Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %*
1. Aldrin[1]	Feed materials and compound feed	0.01[2]
	with the exception of:	
	— fats and oils,	0.1[2]
	— compound feed for fish.	0.02[2]
2. Dieldrin[1]	Feed materials and compound feed	0.01[2]
	with the exception of:	
	— fats and oils,	0.1[2]
	— compound feed for fish.	0.02[2]
3. Camphechlor (toxaphene) – sum of indicator congeners CHB 26, 50 and 62[3]	Fish, other aquatic animals and products derived from them	0.02
	with the exception of:	
	— fish oil.	0.2
	Complete feed for fish.	0.05
4. Chlordane (sum of cis- and trans-isomers and of oxychlordane, expressed as chlordane)	Feed materials and compound feed	0.02
	with the exception of:	
	— fats and oils.	0.05
5. DDT (sum of DDT-, DDD- (or TDE-) and DDE-isomers, expressed as DDT)	Feed materials and compound feed	0.05
	with the exception of:	
	— fats and oils.	0.5
6. Endosulfan (sum of alpha- and beta-isomers and of endosulfansulphate expressed as endosulfan)	Feed materials and compound feed	0.1
	with the exception of:	
	— cotton seed and products derived from its processing, except crude cotton seed oil	0.3
	— soybean and products derived from its processing, except crude soybean oil	0.5
	— crude vegetable oil	1.0
	— complete feed for fish except for *Salmonids*	0.005
	— complete feed for *Salmonids*	0.05
7. Endrin (sum of endrin and of delta-ketoi-endrin, expressed as endrin)	Feed materials and compound feed	0.01
	with the exception of:	
	— fats and oils.	0.05
8. Heptachlor (sum of	Feed materials and	0.01

heptachlor and of heptachlorepoxide, expressed as heptachlor)	compound feed	
	with the exception of:	
	— fats and oils.	0.2
9. Hexachlorobenzene (HCB)	Feed materials and compound feed	0.01
	with the exception of:	
	— fats and oils.	0.2
10. Hexachlorocyclo-hexane (HCH)		
— alpha-isomers	Feed materials and compound feed	0.02
	with the exception of:	
	— fats and oils.	0.2
— beta-isomers	Feed materials	0.01
	with the exception of:	
	— fats and oils.	0.1
	Compound feed	0.01
	with the exception of:	
	— compound feed for dairy cattle.	0.005
— gamma-isomers	Feed materials and compound feed	0.2
	with the exception of:	
	— fats and oils.	2.0

(1) Singly or combined expressed as dieldrin.

(2) Maximum level for aldrin and dieldrin, singly or combined, expressed as dieldrin.

(3) Numbering system according to Parlar, prefixed by either CHB or 'Parlar':

CHB 26: 2-endo,3-exo,5-endo,6-exo,8,8,10,10-octochlorobornane,

CHB 50: 2-endo,3-exo,5-endo,6-exo,8,8,9,10,10-nonachlorobornane,

CHB 62: 2,2,5,5,8,9,9,10,10-nonachlorobornane.

Table 5 (Part 1): DIOXINS AND PCBs

Undesirable substance	**Products intended for animal feed**	**Maximum content in ng WHO-PCDD/F-TEQ/kg (ppt) (1) relative to a feed with a moisture content of 12 %**
1. Dioxins (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005)(2))	Feed materials of plant origin	0.75
	with the exception of:	
	— vegetable oils and their by-products.	0.75

	Feed materials of mineral origin	0.75
	Feed materials of animal origin:	
	— Animal fat, including milk fat and egg fat,	1.50
	— Other land animal products including milk and milk products and eggs and egg products.	0.75
	— Fish oil,	5.0
	— Fish, other aquatic animals, and products derived from them with the exception of fish oil, hydrolysed fish protein containing more than 20 % fat[3] and crustacea meal,	1.25
	— Hydrolysed fish protein containing more than 20 % fat; crustacea meal.	1.75
	Feed additives belonging to the functional groups of binders and anti-caking agents[4]	0.75
	Feed additives belonging to the functional group of compounds of trace elements.	1.0
	Premixtures	1.0
	Compound feed	0.75
	with the exception of:	
	— compound feed for pet animals and fish,	1.75
	— compound feed for fur animals.	—
Undesirable substance	Products intended for animal feed	Maximum content in ng WHO-PCDD/F-PCB-TEQ/kg (ppt)[1] relative to a feed with a moisture content of 12 %
2. Sum of dioxins and dioxin-like PCBs (sum of polychlorinated dibenzo-para-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors), 2005[2])	Feed materials of plant origin	1.25
	with the exception of:	
	— vegetable oils and their	1.5

	by-products	
	Feed materials of mineral origin	1.0
	Feed materials of animal origin:	
	— Animal fat, including milk fat and egg fat	2.0
	— Other land animal products including milk and milk products and eggs and egg products	1.25
	— Fish oil	20.0
	— Fish, other aquatic animals, and products derived from them with the exception of fish oil and fish protein, hydrolysed, containing more than 20 % fat[3]	4.0
	— Fish protein, hydrolysed, containing more than 20 % fat	9.0
	Feed additives belonging to the functional groups of binders and anti-caking agents[4]	1.5
	Feed additives belonging to the functional group of compounds of trace elements	1.5
	Premixtures	1.5
	Compound feed with the exception of:	1.5
	— compound feed for pet animals and fish	5.5
	— compound feed for fur animals	—
Undesirable substance	Products intended for animal feed	Maximum content in µg/kg (ppb) relative to a feed with a moisture content of 12 %[1]
3. Non-dioxin-like PCBs (sum of PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180 (ICES – 6)[1])	Feed materials of plant origin	10
	Feed materials of mineral origin	10
	Feed materials of animal origin:	
	— Animal fat, including milk fat and egg fat	10
	— Other land animal products including milk and milk products and eggs and egg products	10
	— Fish oil	175

— Fish, other aquatic animals and products derived from them with the exception of fish oil and fish protein, hydrolysed, containing more than 20 % fat[5]	30
— Fish protein, hydrolysed, containing more than 20 % fat	50
Feed additives belonging to the functional groups of binders and anti-caking agents[4]	10
Feed additives belonging to the functional group of compounds of trace elements	10
Premixtures	10
Compound feed with the exception of:	10
— compound feed for pet animals and fish	40
— compound feed for fur animals	—

[1] Upper-bound concentrations; upper-bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification.

[2] Table 5 (Part 2): Table of TEF (toxic equivalency factors) for dioxins, furans and dioxin-like PCBs: WHO-TEFs for human risk assessment based on the conclusions of the World Health Organisation (WHO) – International Programme on Chemical Safety (IPCS) expert meeting which was held in Geneva in June 2005 (Martin van den Berg et al., The 2005 World Health Organisation Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological Sciences 93(2), 223–241 (2006)).

[3] Fresh fish and other aquatic animals directly delivered and used without intermediate processing for the production of feed for fur animals are not subject to the maximum levels, while maximum levels of 3.5 ng WHO-PCDD/F-TEQ/kg product and 6.5 ng WHO-PCDD/F-PCB-TEQ/kg product are applicable to fresh fish and 20.0 ng WHO-PCDD/F-PCB-TEQ/kg product is applicable to fish liver used for the direct feeding of pet animals, zoo and circus animals or used as feed material for the production of pet food. The products or processed animal proteins produced from these animals (fur animals, pet animals, zoo and circus animals) cannot enter the food chain and cannot be fed to farmed animals which are kept, fattened or bred for the production of food.

[4] The maximum level is also applicable to the feed additives belonging to the functional groups of substances for the control of radionuclide contamination and substances for reduction of the contamination of feed by mycotoxins which also belong to the functional groups of binders and anti-caking agents.

[5] Fresh fish and other aquatic animals directly delivered and used without intermediate processing for the production of feed for fur animals are not subject to the maximum levels, while maximum levels of 75 μg/kg product are applicable to fresh fish and 200 μg/kg product are applicable to fish liver used for the direct feeding of pet animals, zoo and circus animals or used as feed material for the production of pet food. The products or processed animal proteins produced from these animals (fur animals, pet animals, zoo and circus animals) cannot enter the food chain and cannot be fed to farmed animals which are kept, fattened or bred for the production of food.

Table 5 (Part 2): Table of TEF (toxic equivalency factors) for dioxins, furans and dioxin-like PCBs

Congener	*TEF value*
Dibenzo-para-dioxins ('PCDDs') and Dibenzo-para-furans (PCDFs)	
2,3,7,8-TCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.0003
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.03
2,3,4,7,8-PeCDF	0.3
1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
2,3,4,6,7,8-HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01
OCDF	0.0003
'Dioxin-like' PCBs: Non-ortho PCBs + Mono-ortho PCBs	
Non-ortho PCBs	
PCB 77	0.0001
PCB 81	0.0003
PCB 126	0.1
PCB 169	0.03
Mono-ortho PCBs	
PCB 105	0.00003
PCB 114	0.00003
PCB 118	0.00003
PCB 123	0.00003
PCB 156	0.00003
PCB 157	0.00003
PCB 167	0.00003
PCB 189	0.00003
Abbreviations used: 'T' = tetra; 'Pe' = penta; 'Hx' = hexa; 'Hp' = hepta; 'O' = octa; 'CDD' = chlorodibenzodioxin; 'CDF' = chlorodibenzofuran; 'CB' = chlorobiphenyl.	

Table 6: HARMFUL BOTANICAL IMPURITIES

Undesirable substance	*Products intended for animal feed*	*Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %*
1. Weed seeds and unground and uncrushed fruits containing alkaloids,	Feed materials and compound feed	3 000

glucosides or other toxic substances separately or in combination including		
— Datura sp.		1 000
2. Crotalaria spp.	Feed materials and compound feed	100
3. Seeds and husks from Ricinus communis L., Croton tiglium L. and Abrus precatorius L. as well as their processed derivatives[(1)], separately or in combination	Feed materials and compound feed	10[(2)]
4. Unhusked beech mast — Fagus sylvatica L.	Feed materials and compound feed	Seeds and fruit as well as their processed derivatives may only be present in feed in trace amounts not quantitatively determinable
5. Purghera — Jatropha curcas L.	Feed materials and compound feed	Seeds and fruit as well as their processed derivatives may only be present in feed in trace amounts not quantitatively determinable
6. Seeds from Ambrosia spp.	Feed materials[(3)]	50
	with the exception of:	
	– Millet (grains of Panicum miliaceum L.) and sorghum (grains of Sorghum bicolor (L) Moench s.l.) not directly fed to animals[(3)]	200
	Compound feed containing unground grains and seeds	50
7. Seeds from — Indian mustard — Brassica juncea (L.) Czern. and Coss. ssp. integrifolia (West.) Thell. — Sareptian mustard — Brassica juncea (L.) Czern. and Coss. ssp. juncea — Chinese mustard — Brassica juncea (L.) Czern. and Coss. ssp. juncea var. lutea Batalin — Black mustard — Brassica nigra (L.) Koch — Ethiopian mustard — Brassica carinata A. Braun	Feed materials and compound feed	Seeds may only be present in feed in trace amounts not quantitatively determinable

(1) Insofar as determinable by analytical microscopy.

(2) Includes also seed husk fragments.

(3) Where unequivocal evidence is provided that the grains and seeds are intended for milling or crushing, there is no need to perform a cleaning of the grains and seeds containing non-compliant levels of seeds of Ambrosia spp. before milling or crushing on the condition that:

— the consignment is transported as a whole to the milling or crushing plant, and the milling or crushing plant is informed in advance of the presence of high levels of Ambrosia spp. seeds in order to take additional prevention measures to avoid dissemination into the environment,

—solid evidence is provided that prevention measures are taken to avoid dissemination of Ambrosia spp. seeds into the environment during transport to the crushing or milling plant, and

—the competent authority agrees to the transport, after having ensured that the abovementioned conditions are fulfilled.

In case these conditions are not fulfilled, the consignment must be cleared before any transport into the country and the screenings must be appropriately destroyed.

Table 7: AUTHORISED FEED ADDITIVES IN NON-TARGET FEED FOLLOWING UNAVOIDABLE CARRY-OVER

Coccidiostat	***Products intended for animal feed***[1]	***Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %***
1. Decoquinate	Feed materials	0.4
	Compound feed for	
	— laying birds and chickens reared for laying (> 16 weeks);	0.4
	— other animal species	1.2
	Premixtures for use in feed in which the use of decoquinate is not authorised.	[2]
2. Diclazuril	Feed materials	0.01
	Compound feed for	
	— laying birds and chickens reared for laying (> 16 weeks),	0.01
	— rabbits for fattening and breeding for the period before slaughter in which the use of diclazuril is prohibited (withdrawal feed),	0.01
	— other animal species other than chickens reared for laying (< 16 weeks), chickens for fattening, guinea fowl and turkeys for fattening.	0.03
	Premixtures for use in feed in which the use of diclazuril is not authorised.	[2]
3. Halofuginone hydrobromide	Feed materials	0.03
	Compound feed for	
	— laying birds, chickens reared for laying and turkeys (> 12 weeks),	0.03
	— chickens for fattening and turkeys (< 12 weeks) for the period before slaughter	0.03

	in which the use of halofuginone hydrobromide is prohibited (withdrawal feed),	
	— other animal species.	0.09
	Premixtures for use in feed in which the use of halofuginone hydrobromide is not authorised.	(2)
4. Lasalocid A sodium	Feed materials	1.25
	Compound feed for	
	— dogs, calves, rabbits, equine species, dairy animals, laying birds, turkeys (> 16 weeks) and chickens reared for laying (> 16 weeks),	1.25
	— chickens for fattening, chickens reared for laying (< 16 weeks) and turkeys (< 16 weeks) for the period before slaughter in which the use of lasalocid A sodium is prohibited (withdrawal feed),	1.25
	— pheasants, guinea fowl, quails and partridges (except laying birds) for the period before slaughter in which the use of lasalocid A sodium is prohibited (withdrawal feed),	1.25
	— other animal species.	3.75
	Premixtures for use in feed in which the use of lasalocid A sodium is not authorised.	(2)
5. Maduramicin ammonium alpha	Feed materials	0.05
	Compound feed for	
	— equine species, rabbits, turkeys (> 16 weeks), laying birds and chickens reared for laying (> 16 weeks),	0.05
	— chickens for fattening and turkeys (< 16 weeks) for the period before slaughter in which the use of maduramicin ammonium alpha is prohibited (withdrawal feed),	0.05
	— other animal species.	0.15
	Premixtures for use in feed in which the use of maduramicin ammonium alpha is not authorised.	(2)
6. Monensin sodium	Feed materials	1.25

	Compound feed for	
	— equine species, dogs, small ruminants (sheep and goat), ducks, bovine, dairy cattle, laying birds, chickens reared for laying (> 16 weeks) and turkeys (> 16 weeks),	1.25
	— chickens for fattening, chickens reared for laying (< 16 weeks) and turkeys (< 16 weeks) for the period before slaughter in which the use of monensin sodium is prohibited (withdrawal feed),	1.25
	— other animal species.	3.75
	Premixtures for use in feed in which the use of monensin sodium is not authorised.	(2)
7. Narasin	Feed materials	0.7
	Compound feed for	
	— turkeys, rabbits, equine species, laying birds and chickens reared for laying (> 16 weeks),	0.7
	— other animal species.	2.1
	Premixtures for use in feed in which the use of narasin is not authorised.	(2)
8. Nicarbazin	Feed materials	1.25
	Compound feed for	
	— equine species, laying birds and chickens reared for laying (> 16 weeks),	1.25
	— other animal species.	3.75
	Premixtures for use in feed in which the use of nicarbazin (alone or in combination with narasin) is not authorised.	(2)
9. Robenidine hydrochloride	Feed materials	0.7
	Compound feed for	
	— laying birds and chickens reared for laying (> 16 weeks),	0.7
	— chickens for fattening, rabbits for fattening and breeding and turkeys for the period before slaughter in which the use of robenidine hydrochloride is prohibited (withdrawal feed),	0.7
	— other animal species.	2.1
	Premixtures for use in feed	(2)

	in which the use of robenidine hydrochloride is not authorised.	
10. Salinomycin sodium	Feed materials	0.7
	Compound feed for	
	— equine species, turkeys, laying birds and chickens reared for laying (> 12 weeks),	0.7
	— chickens for fattening, chickens reared for laying (< 12 weeks) and rabbits for fattening for the period before slaughter in which the use of salinomycin sodium is prohibited (withdrawal feed),	0.7
	— other animal species.	2.1
	Premixtures for use in feed in which the use of salinomycin sodium is not authorised	(2)
11. Semduramicin sodium	Feed materials	0.25
	Compound feed for	
	— laying birds and chickens reared for laying (> 16 weeks),	0.25
	— chickens for fattening for the period before slaughter in which the use of semduramicin sodium is prohibited (withdrawal feed),	0.25
	— other animal species.	0.75
	Premixtures for use in feed in which the use of semduramicin sodium is not authorised.	(2)

(1) Without prejudice to the authorised levels pursuant to Regulation (EC) No 1831/2003.

(2) The maximum level of the substance in the premixture is the concentration which shall not result in a level of the substance higher than 50 % of the maximum levels established in the feed when the instructions for use of the premixture are followed.

SCHEDULE 5

Regulations 15 and 15A

Action thresholds triggering investigations: dioxins and PCBs

Table 1: DIOXINS AND PCBs

Undesirable substances	*Products intended for animal feed*	*Action threshold in ng WHO-PCDD/F TEQ/kg (ppt)(2) relative to a feedingstuff with a moisture content of 12 %*	*Comments and additional information (e.g. nature of investigations to be performed)*

1. Dioxins (sum of polychlorinated dibenzo-para-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005)[1])	Feed materials of plant origin	0.5	[3]
	with the exception of:		
	— vegetable oils and their by-products.	0.5	[3]
	Feed materials of mineral origin	0.5	[3]
	Feed materials of animal origin:		
	— Animal fat, including milk fat and egg fat,	0.75	[3]
	— Other land animal products including milk and milk products and eggs and egg products,	0.5	[3]
	— Fish oil,	4.0	[4]
	— Fish, other aquatic animals and products derived from them, with the exception of fish oil, hydrolysed fish protein containing more than 20 % fat and crustacea meal,	0.75	[4]
	— Hydrolysed fish protein containing more than 20 % fat; crustacea meal.	1.25	[4]
	Feed additives belonging to the functional groups of binders and anti-caking agents	0.5	[3]
	Feed additives belonging to the functional group of compounds of trace elements	0.5	[3]

	Premixtures	0.5	(3)
	Compound feed with the exception of:	0.5	(3)
	— compound feed for pet animals and fish,	1.25	(4)
	— compound feed for fur animals.	—	
2. Dioxin-like PCBs (sum of polychlorinated biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005)(1))	Feed materials of plant origin	0.35	(3)
	with the exception of:		
	— vegetable oils and their by-products	0.5	(3)
	Feed materials of mineral origin	0.35	(3)
	Feed materials of animal origin:		
	— Animal fat, including milk fat and egg fat	0.75	(3)
	— Other land animal products including milk and milk products and eggs and egg products	0.35	(3)
	— Fish oil	11.0	(4)
	— Fish, other aquatic animals and products derived from them, with the exception of fish oil and fish protein, hydrolysed, containing more than 20 % fat(3)	2.0	(4)
	— Fish protein, hydrolysed, containing more than 20 % fat	5.0	(4)
	Feed additives belonging to the functional groups of binders and anti-	0.5	(3)

caking agents		
Feed additives belonging to the functional group of compounds of trace elements	0.35	(3)
Premixtures	0.35	(3)
Compound feed with the exception of:	0.5	(3)
— compound feed for pet animals and fish	2.5	(4)
— compound feed for fur animals	—	

(1) Table 2: Table of TEF (toxic equivalency factors) for dioxins, furans and dioxin-like PCBs: WHO-TEFs for human risk assessment based on the conclusions of the World Health Organisation (WHO) – International Programme on Chemical Safety (IPCS) expert meeting which was held in Geneva in June 2005 (Martin van den Berg et al., The 2005 World Health Organisation Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological Sciences 93(2), 223–241 (2006)).

(2) Upper-bound concentrations; upper-bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification.

(3) Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination.

(4) In many cases it might not be necessary to perform an investigation into the source of contamination as the background level in some areas is close to or above the action level. However, in cases where the action level is exceeded, all information, such as sampling period, geographical origin, fish species etc., shall be recorded with a view to future measures to manage the presence of dioxins and dioxin-like compounds in these materials for animal nutrition.

Table 2: Table of TEF (toxic equivalency factors) for dioxins, furans and dioxin-like PCBs

Congener	***TEF value***
Dibenzo-para-dioxins ('PCDDs') and Dibenzo-para-furans (PCDFs)	
2,3,7,8-TCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.0003
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.03
2,3,4,7,8-PeCDF	0.3
1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
2,3,4,6,7,8-HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01

OCDF	0.0003
'Dioxin-like' PCBs: Non-ortho PCBs + Mono-ortho PCBs	
Non-ortho PCBs	
PCB 77	0.0001
PCB 81	0.0003
PCB 126	0.1
PCB 169	0.03
Mono-ortho PCBs	
PCB 105	0.00003
PCB 114	0.00003
PCB 118	0.00003
PCB 123	0.00003
PCB 156	0.00003
PCB 157	0.00003
PCB 167	0.00003
PCB 189	0.00003

Abbreviations used: 'T' = tetra; 'Pe' = penta; 'Hx' = hexa; 'Hp' = hepta; 'O' = octa; 'CDD' = chlorodibenzodioxin; 'CDF' = chlorodibenzofuran; 'CB' = chlorobiphenyl.".

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers in the European Union (Withdrawal) Act 2018 (c. 16) (in particular under section 8(1) and (2)(a), (b), (c), (d), (f) and (g)) in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union.

Part 2 contains amendments to various statutory instruments relating to food and feed that apply in England only. In particular, the amendments remove cross-references to various EU Directives and insert various tables from the Annexes to those Directives, as they had effect immediately before IP completion day, as new Schedules to the instruments concerned, as follows—

(a) Annexes 1 and 2 from Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (OJ L 172, 30.6.2007, p. 71–82) are inserted as Schedule 5 to the Materials and Articles in Contact with Food (England) Regulations 2012 (S.I. 2012/2619);

(b) Annex 1 from Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3–11) is inserted as Schedule 6 to the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 (S.I. 2013/2210); and

(c) the Annex to Commission Directive 82/475/EEC laying down the categories of feed materials which may be used for the purposes of labelling compound feedingstuffs for pet animals (OJ L 213, 21.7.1982, p. 27–28) is inserted as Schedule 3 to the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 (S.I. 2015/255) and Annexes 1 and 2 from Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10–22) are inserted as Schedules 4 and 5 to those Regulations.

Part 3 contains amendments to retained direct EU legislation relating to food and feed.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sectors is foreseen.

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