

*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.*

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DRAFT STATUTORY INSTRUMENTS

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**2019 No. 0000**

**EXITING THE EUROPEAN UNION  
AGRICULTURE**

**The Animal Feed (Amendment) (EU Exit) Regulations 2019**

*Made - - - - 2019*

*Coming into force in accordance with regulation 1*

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018<sup>(1)</sup>.

In accordance with paragraph 1(1) of Schedule 7 to that Act, a draft of this instrument has been laid before Parliament 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 European Food Safety Authority and laying down procedures in matters of food safety there has been open and transparent public consultation during the preparation of these Regulations.

**PART 1**

**Introduction**

**Citation and commencement**

1. These Regulations may be cited as the Animal Feed (Amendment) (EU Exit) Regulations 2019 and come into force on exit day.

**Interpretation**

2. In these Regulations—

“Regulation 1831/2003” means Regulation (EC) No. 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition;

“Regulation 183/2005” means Regulation (EC) No. 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene;

“Regulation 378/2005” means 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;

“Regulation 429/2008” means 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;

“Regulation 152/2009” means Commission Regulation (EC) No. 152/2009 laying down the methods of sampling and analysis for the official control of feed;

“Regulation 767/2009” means Regulation (EC) No. 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No. 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC;

“Regulation 892/2010” means Commission Regulation (EU) No. 892/2010 on the status of certain products with regard to feed additives within the scope of Regulation (EC) No. 1831/2003 of the European Parliament and of the Council;

“Regulation 619/2011” means 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;

“Regulation 68/2013” means Commission Regulation (EU) No. 68/2013 on the Catalogue of feed materials;

“Regulation 2015/786” means Commission Regulation (EU) 2015/786 defining acceptability criteria for detoxification processes applied to products intended for animal feed as provided for in Directive 2002/32/EC of the European Parliament and of the Council;

“Regulation 2017/625” means Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation).

## PART 2

### Amendment of subordinate legislation

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

3. The Animal Feed (Composition, Marketing and Use) (England) Regulations 2015(2) are amended as follows.

4. In regulation 7(2)—

- (a) in paragraph (2)(a), omit “(requirement that products in relation to which the Commission has adopted a measure under this Article must be withdrawn from the market)”;
- (b) in paragraph (2)(c), omit “(requirement that an authorisation holder inform the Commission of any new scientific or technical information about a product which might affect the evaluation of the safety of its use in feed, or of any prohibition or restriction on the feed in a third country)”.

5. In regulation 10(2)(d), for “Commission”, substitute “Food Safety Authority”.

6. In regulation 13(2)—

- (a) omit sub-paragraph (a);
- (b) in sub-paragraph (b), for “Commission”, substitute “appropriate authority”.

7. For Schedule 1, substitute the Schedule set out in the Schedule to these Regulations.

## PART 3

### Amendment of retained direct EU legislation

#### **Amendment of Regulation 1831/2003**

8. Regulation 1831/2003 is amended as follows.

9. In Article 1—

- (a) omit “Community”;
- (b) omit “internal”.

10. In Article 2—

(a) in paragraph 2—

- (i) at point (l), for “Community”, substitute “appropriate authority”;
- (ii) after point (n), insert—

“**(o)** “third country” means a country or state other than the United Kingdom;

**(p)** “prescribe” means prescribe by regulations;

**(q)** “appropriate authority” means—

- (i) in relation to England, the Secretary of State;
- (ii) in relation to Wales, the Welsh Ministers;

- (iii) in relation to Scotland, the Scottish Ministers;
  - (iv) in relation to Northern Ireland, the Northern Ireland devolved authority;
  - (r) “Food Safety Authority” means—
    - (i) as regards England, Wales and Northern Ireland, the Food Standards Agency;
    - (ii) as regards Scotland, Food Standards Scotland;
  - (s) “reference laboratory” means a laboratory prescribed by the appropriate authority under Regulation 2017/625;
  - (t) “Northern Ireland devolved authority” means the Department of Health.”;
- (b) omit paragraph 3.
- 11.** In Article 3—
- (a) at paragraph 2—
    - (i) for “Member States”, substitute “the appropriate authority”;
    - (ii) omit “at Community level”;
  - (b) at paragraph 3, omit “Community”;
  - (c) for paragraph 5, substitute—
 

“5. Where necessary, as a result of technological progress or scientific development, the appropriate authority may prescribe changes to the general conditions set out in Annex 4.”.
- 12.** In Article 4, omit paragraph 3.
- 13.** In Article 6, for paragraph 3, substitute—
- “3. Where necessary, as a result of technological progress or scientific development, the appropriate authority may prescribe additional feed additive categories and functional groups.”.
- 14.** For Article 7, substitute—

*“Application for authorisation*

- 1.** An application for an authorisation as provided for in Article 4 must be sent to the appropriate authority. The appropriate authority must without delay forward the application to the Food Safety Authority.
- 2.** The Food Safety Authority must—
  - (a) acknowledge receipt of the application, including the particulars and documents referred to in paragraph 3, in writing, to the applicant within 15 days of its receipt, stating the date of receipt;
  - (b) make any information supplied by the applicant available to the appropriate authority;
  - (c) make the summary of the dossier mentioned in paragraph 3(h) available to the public, subject to the confidentiality requirements laid down in Article 18(2).
- 3.** At the time of application, the applicant must send the following particulars and documents directly to the Food Safety Authority—

- (a) the applicant's name and address;
- (b) the identification of the feed additive, a proposal for its classification by category and functional group under Article 6, and its specifications, including, where applicable, purity criteria;
- (c) a description of the method of production, manufacturing and intended uses of the feed additive, of the method of analysis of the additive in feed according to its intended use and, where appropriate, of the method of analysis for the determination of the level of residues of the feed additive, or its metabolites, in food;
- (d) a copy of the studies which have been carried out and any other material which is available to demonstrate that the feed additive satisfies the criteria laid down in Article 5(2) and (3);
- (e) proposed conditions for placing the feed additive on the market, including labelling requirements and, where appropriate, specific conditions for use and handling (including known incompatibilities), use levels in complementary feedingstuffs and animal species and categories for which the feed additive is intended;
- (f) a written statement that three samples of the feed additive have been sent by the applicant directly to the reference laboratory referred to in Article 21, in accordance with the requirements set out in Annex 2;
- (g) for additives which, according to the proposal under point (b), do not belong to either category (a) or category (b) referred to in Article 6(1), and for additives falling within the scope of retained EU law relating to the marketing of products consisting of, containing or produced from GMOs, a proposal for post-market monitoring;
- (h) a summary containing the information provided under points (a) to (g);
- (i) for additives falling within the scope of retained EU law relating to the marketing of products consisting of, containing or produced from GMOs, details of any authorisation granted in accordance with the applicable legislation.

4. The appropriate authority, having first consulted the Food Safety Authority, may prescribe rules for the application and implementation of this Article, including rules concerning the preparation and the presentation of the application. Until such rules are prescribed, the application must be submitted in accordance with retained EU law.

5. After the Food Safety Authority has been consulted, specific guidelines for the authorisation of additives may be established, where necessary for each category of additive referred to in Article 6(1). These guidelines must take account of the possibility of extrapolating the results of the studies carried out on major species to minor species.

6. Rules to allow for simplified provisions for the authorisation of additives which have been authorised for use in food may be prescribed by the appropriate authority.

7. Other implementing rules may be prescribed by the appropriate authority, which rules must, where appropriate, differentiate between requirements for feed additives in respect of food-producing animals and requirements in respect of other animals, in particular pets.

8. The Food Safety Authority must publish detailed guidance to assist the applicant in the preparation and the presentation of its application.”

15. In Article 8—

- (a) in each place in which it occurs (including the heading), for “Authority”, substitute “Food Safety Authority”;

(b) in paragraph 3(b), for “Community Reference Laboratory”, substitute “reference laboratory”;

(c) for paragraph 5, substitute—

“5. The Food Safety Authority must without delay forward its opinion to the appropriate authority including a report describing its assessment of the feed additive and stating the reasons for its conclusion.”.

16. In the heading to Article 9, omit “by the Community”.

17. For Article 9, substitute—

#### *“Authorisation*

1. Within three months of receipt of the opinion of the Food Safety Authority, the appropriate authority must determine whether to authorise the feed additive and the conditions upon which the feed additive is authorised. In making its determination, the appropriate authority must take into account the requirements of Article 5(2) and (3), retained EU law and other legitimate factors relevant to the matter under consideration and in particular benefits for animal health and welfare and for the consumer of animal products. The authorisation is to be in a form prescribed by the appropriate authority. Where the authorisation is not in accordance with the opinion of the Food Safety Authority, the appropriate authority must provide an explanation of the reasons for the differences. Where, in the opinion of the appropriate authority, the application raises exceptionally complex issues, the three-month deadline may be extended.

2. Rules for the implementation of this Article and in particular concerning an identification number for authorised additives may be prescribed by the appropriate authority.

3. The appropriate authority must without delay inform the applicant of the determination made in accordance with paragraph 1.

4. An authorisation must include the elements mentioned in Article 8(4)(b), (c), (d) and (e) and an identification number.

5. An authorisation for additives belonging to categories (d) and (e) referred to in Article 6(1) and also for additives consisting of, containing or produced from GMOs, must include the name of the holder of the authorisation, and, where appropriate, the unique identifier attributed to the GMO as referred to in Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

6. Where the levels of residues of an additive in food from animals fed with that additive might have a detrimental effect on human health, the authorisation must include MRLs for the active substance or for its metabolites in the relevant foodstuffs of animal origin. In this case the active substance must be considered for the purposes of Council Directive 96/23/EC as falling under Annex 1 to that Directive. Where an MRL for the substance concerned has already been established in retained EU law, that MRL must also apply to residues of the active substance or its metabolites originating from the use of the substance as a feed additive.

7. The authorisation is valid for 10 years and is renewable in accordance with Article 14. The authorised feed additive must be entered in the Register of Feed Additives referred to in Article 17 (the Register). Each entry in the Register must state the date of authorisation and must include the particulars referred to in paragraphs 4, 5 and 6.”.

**18.** In Article 10—

(a) for paragraph 5, substitute—

“5. Where the notification and accompanying particulars referred to in paragraph 1(a) are not supplied within the period specified or are found to be incorrect, or where an application is not submitted as required by paragraph 2 within the period specified, the appropriate authority may prescribe that—

(a) the additives concerned must be withdrawn from the market;

(b) that, for a limited period of time, existing stocks of the product may remain, or continue to be placed, on the market.”;

(b) in paragraph 6, in both places in which it occurs, for “Commission”, substitute “appropriate authority”.

**19.** Omit Article 11.

**20.** For Article 12, substitute—

*“Supervision*

1. After an additive has been authorised in accordance with this Regulation, any person using or placing on the market that substance, or a feedingstuff into which it has been incorporated, or any other interested party must comply with any conditions or restrictions which have been imposed on the placing on the market, use and handling of the additive or feedingstuffs containing it.

2. Where monitoring requirements, as referred to in Article 8(4)(c), have been imposed, the holder of the authorisation must ensure that monitoring is carried out and must submit reports to the appropriate authority in accordance with the authorisation. The holder of the authorisation must immediately communicate to the Food Safety Authority any new information that might influence the evaluation of the safety in use of the feed additive, in particular health sensitivities of specific categories of consumers. The holder of the authorisation must immediately inform the Food Safety Authority of any prohibition or restriction imposed by the competent authority of any third country in which the feed additive is placed on the market.”.

**21.** For Article 13, substitute—

*“Modification, suspension and revocation of authorisation*

1. On its own initiative or following a request from the appropriate authority, the Food Safety Authority must issue an opinion on whether an authorisation still meets the conditions set out by this Regulation. The Food Safety Authority must immediately transmit this opinion to the appropriate authority and, where applicable, to the holder of the authorisation. The opinion must be made public.

2. The appropriate authority must examine the opinion of the Food Safety Authority without delay. The appropriate authority must, in light of the opinion of the Food Safety Authority, determine whether to modify, suspend or revoke the authorisation.

3. If the holder of the authorisation proposes changing the terms of the authorisation by submitting an application to the appropriate authority, accompanied by the relevant data supporting the request for the change, the Food Safety Authority must transmit its opinion on the proposal to the appropriate authority. The appropriate authority must, in light of the opinion of the Food Safety Authority, determine whether to modify, suspend or revoke the authorisation.

4. The appropriate authority must, without delay—
    - (a) inform the applicant of any determination the appropriate authority makes under this Article;
    - (b) invite the Food Safety Authority to amend the Register where appropriate.
  5. Articles 7(1) and (2), 8 and 9 apply accordingly.
  6. The terms of any modification, suspension or revocation must be in a form prescribed by the appropriate authority.”.
22. For Article 14, substitute—

*“Renewal of authorisation*

1. Authorisations under this Regulation are renewable for 10 year periods. An application for renewal must be sent to the appropriate authority at the latest one year before the expiry date of the authorisation. In the case of authorisations not issued to a specific holder, any person who first places the additive on the market or any other interested party may submit the application to the appropriate authority and must be considered as the applicant. In the case of authorisations issued to a specific holder, the holder of the authorisation or the holder’s legal successor may submit the application to the appropriate authority and is deemed to be the applicant.
  2. At the time of application, the applicant must send the following particulars and documents directly to the Food Safety Authority—
    - (a) a copy of the authorisation for placing the feed additive on the market;
    - (b) a report on the results of the post-market monitoring, if such monitoring requirements are included in the authorisation;
    - (c) any other new information which has become available with regard to the evaluation of the safety in use of the feed additive and the risks of the feed additive to animals, humans or the environment;
    - (d) where appropriate, a proposal for amending or supplementing the conditions of the original authorisation, including, among other things, the conditions concerning future monitoring.
  3. Articles 7(1), (2), (4) ,(5), (6) and (7), 8 and 9 apply accordingly.
  4. Where, for reasons beyond the control of the applicant, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product is automatically extended until the appropriate authority makes a determination. Information on this extension of the authorisation must be made available to the public in the Register.”.
23. For Article 15, substitute—

*“Urgent authorisation*

In specific cases where urgent authorisation is needed to ensure the protection of animal welfare, the appropriate authority may provisionally authorise the use of an additive for a maximum period of five years. The authorisation is to be in a form prescribed by the appropriate authority.”.

24. In Article 16—
- (a) in paragraph 1—
    - (i) for “Community”, substitute “United Kingdom”;



- (ii) for “at least the national language or languages of the Member State in which it is marketed,” substitute “English or in English and Welsh”;
  - (b) for paragraph 6, substitute—
    - “6. The appropriate authority may prescribe amendments to Annex 3 to take technological progress and scientific development into account.”.
- 25.** In Article 17—
- (a) in the heading, omit “Community”;
  - (b) for paragraph 1, substitute—
    - “1. The Food Safety Authority must establish and keep up to date a Register of Feed Additives.”.
- 26.** In Article 18—
- (a) in paragraph 2, for “Commission”, substitute “appropriate authority”;
  - (b) for paragraph 4, substitute—
    - “4. The Food Safety Authority must, on request, supply the appropriate authority with all information in its possession, including any identified as confidential pursuant to paragraph 2.”;
  - (c) omit paragraph 5;
  - (d) for paragraph 6, substitute—
    - “6. The appropriate authority and the Food Safety Authority must keep confidential all the information identified as confidential under paragraph 2 except where it is appropriate for such information to be made public in order to protect human health, animal health or the environment.”;
  - (e) in paragraph 7—
    - (i) for “Member States, the Commission and the Authority shall”, substitute “appropriate authority and the Food Safety Authority must”;
    - (ii) for “Commission”, substitute “appropriate authority”.
- 27.** Insert a new Article 18A—

*“Article 18A*

*Regulations and devolved powers*

- 1.** Any power to make regulations under this Regulation—
  - (a) so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;
  - (b) so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument;
  - (c) so far as exercisable by the Northern Ireland devolved authority is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979(3) (and not by statutory instrument).

2. For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010(4) (Scottish statutory instruments).
3. Any power to make regulations under this Regulation includes power—
- (a) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business); and
  - (b) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.
4. Any statutory instrument, Scottish statutory instrument or statutory rule containing regulations made under this Regulation is subject to annulment in pursuance of a resolution—
- (a) in the case of England, of either House of Parliament;
  - (b) in the case of Wales, of the National Assembly for Wales;
  - (c) in the case of Scotland, of the Scottish Parliament;
  - (d) in the case of Northern Ireland, being a negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954(5).
5. In this Regulation, any power—
- (a) of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
  - (b) of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
  - (c) of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only;
  - (d) of the Northern Ireland devolved authority to make regulations is limited to regulations which apply in relation to Northern Ireland only.”.
28. In Article 19—
- (a) in both places in which it occurs, for “Authority”, substitute “Food Safety Authority”;
  - (b) in each place in which it occurs, for “Commission”, substitute “appropriate authority”;
  - (c) in the first subparagraph, omit “a Member State or from”.
29. In Article 20—
- (a) in paragraph 3, for “Commission”, substitute “appropriate authority”;
  - (b) in paragraph 4, for “Authority”, substitute “Food Safety Authority”.
30. For Article 21, substitute—

*“Reference laboratory*

1. The duties and tasks of the reference laboratory are laid down in Annex 2.
2. Applicants for the authorisation of additives must contribute to supporting the cost of the duties and tasks of the reference laboratory.

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(4) 2010 asp 10.  
(5) 1954 c. 33.

3. The appropriate authority may prescribe rules for implementing Annex 2.
  4. The appropriate authority may prescribe amendments to Annex 2.”.
31. Omit Articles 22 and 24.
32. After Article 26, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.
33. In Annex 2—
- (a) in the heading, omit “Community”;
  - (b) omit point 1;
  - (c) in point 2, in the opening words—
    - (i) omit “For the duties and tasks set out in this Annex, the CRL may be assisted by a consortium of national reference laboratories.”;
    - (ii) for “CRL”, substitute “reference laboratory”;
  - (d) in point 2.2—
    - (i) for “Authority”, substitute “Food Safety Authority”;
    - (ii) for “and (5)”, substitute “, (6), and (7)”;
    - (iii) for “7(6)”, substitute “7(8)”;
  - (e) in point 2.3, for “Authority”, substitute “Food Safety Authority”;
  - (f) in point 3, for “CRL shall be”, substitute “reference laboratory is”;
  - (g) in point 4—
    - (i) for “CRL shall”, substitute “reference laboratory must”;
    - (ii) for “Commission”, substitute “appropriate authority”;
    - (iii) for “Member States”, substitute “there are reasonable grounds to”;
  - (h) in point 5—
    - (i) for “Commission”, substitute “appropriate authority”;
    - (ii) for “CRL”, substitute “reference laboratory”;
  - (i) omit point 6;
  - (j) in point 7—
    - (i) for “Community reference laboratories”, substitute “reference laboratory”;
    - (ii) for “CRL”, substitute “reference laboratory”;
    - (iii) omit “official control laboratories from Members States and”.

#### **Amendment of Regulation 183/2005**

34. Regulation 183/2005 is amended as follows.
35. Omit Article 2(3).
36. In Article 3—
- (a) in point (e), omit “of a Member State or of a third country”;
  - (b) after point (f), insert—
    - (g) “third country” means a country or state other than the United Kingdom;
    - (h) “appropriate authority” means—
      - (i) in relation to England, the Secretary of State;

- (ii) in relation to Wales, the Welsh Ministers;
  - (iii) in relation to Scotland, the Scottish Ministers;
  - (iv) in relation to Northern Ireland, the Northern Ireland devolved authority;
  - (i) “Food Safety Authority” means—
    - (i) as regards England, Wales and Northern Ireland, the Food Standards Agency;
    - (ii) as regards Scotland, Food Standards Scotland;
  - (j) “prescribe” means prescribe by regulations;
  - (k) “Northern Ireland devolved authority” means the Department of Health.”.
- 37.** For Article 4(1), substitute—
- “1. Feed business operators must ensure that all stages of production, processing and distribution under their control are carried out in accordance with relevant hygiene requirements laid down in retained EU law.”.
- 38.** For Article 5(3), substitute—
- “3. Feed business operators must:
- (a) comply with specific microbiological criteria;
  - (b) take measures or adopt procedures necessary to meet specific targets.
- The criteria and targets referred to in points (a) and (b) may be prescribed by the appropriate authority.”.
- 39.** In Article 6
- (a) in paragraph 4, omit “, developed in accordance with Article 20”;
  - (b) for paragraph 5, substitute—
- “5. Measures to facilitate the implementation of this Article, including for small businesses, may be prescribed by the appropriate authority.”.
- 40.** For Article 7(3), substitute—
- “3. Detailed arrangements for the implementation of this Article may be prescribed by the appropriate authority. Such arrangements may facilitate certain feed business operators’ implementation of HACCP principles developed in accordance with Chapter 3, with a view to complying with the requirements of Article 6(1).”.
- 41.** Omit Article 8.
- 42.** For Article 9(1), substitute—
- “1. Feed business operators must cooperate with the competent authorities as regards matters related to compliance with retained EU law.”.
- 43.** In Article 10—
- (a) omit paragraph (2);
  - (b) for paragraph 3, substitute—
- “(3) approval is required under measures prescribed by the appropriate authority, which measures must be designed to amend non-essential elements of this Regulation by supplementing it.”.
- 44.** Omit Article 12.

45. For Article 17, substitute—

*“Exemption from on-site visits*

1. Competent authorities are exempted from the obligation to carry out on site visits, as provided for in Article 13, of feed businesses which act solely as traders, without holding the products on their premises.

2. Such feed businesses must submit to the competent authority a declaration, in a form decided upon by the competent authority, to the effect that the feeds placed on the market by them comply with the conditions of this Regulation.”.

46. In Article 19—

- (a) In each place in which it appears, for “Member States”, substitute “competent authorities”;
- (b) omit paragraph 6.

47. Omit Article 20.

48. In Article 21—

- (a) for paragraphs (1) and (2), substitute—
  - “1. When guides to good practice are developed, they must be developed and disseminated by feed business sectors:
    - (a) in consultation with representatives of parties whose interests may be substantially affected, such as competent authorities and user groups;
    - (b) having regard to relevant codes of practice of the Codex Alimentarius; and
    - (c) when they concern primary production of feed, having regard to the requirements set out in Annex 1.
  - 2. The Food Safety Authority must assess guides to ensure that:
    - (a) they have been developed in accordance with paragraph 1;
    - (b) their contents are practicable for the sectors to which they refer; and
    - (c) they are suitable as guides for compliance with Articles 4, 5 and 6, in the sectors and for the feeds concerned.”;
- (b) omit paragraphs 3 and 4.

49. Omit Article 22.

50. For Article 23, substitute—

*“Imports*

1. Feed business operators importing feed must ensure that importation takes place only in accordance with the following conditions—

- (a) the country of dispatch appears on a list of countries from which imports of feed are permitted;
- (b) the establishment of dispatch appears on a list of establishments from which imports of feed are permitted;
- (c) the feed was produced by the establishment of dispatch or by another establishment appearing on the list referred to in point (b) or in the United Kingdom; and
- (d) the feed satisfies—

- (i) the requirements laid down in this Regulation;
- (ii) those conditions recognised by the appropriate authority to be at least equivalent to those requirements;
- (iii) where a specific agreement between the United Kingdom and the exporting country exists, the requirements contained in that agreement.

2. A model import certificate may be prescribed by the appropriate authority.”.

51. In Article 25, for “Community”, substitute “United Kingdom”.

52. Omit Article 26.

53. For Article 27, substitute—

*“Amendments of Annexes 1, 2 and 3*

The appropriate authority may prescribe amendments of Annexes 1, 2 and 3 to take account of—

- (a) the development of codes of good practice;
- (b) the experience gained from the implementation of HACCP-based systems pursuant to Article 6;
- (c) technological developments;
- (d) scientific advice, particularly new risk assessments;
- (e) the setting of feed safety targets; and
- (f) the development of requirements relating to specific operations.”.

54. For Article 28, substitute—

*“Derogations from Annexes 1, 2 and 3*

Derogations from Annexes 1, 2 and 3 may be prescribed by the appropriate authority for particular reasons, provided that such derogations do not affect the achievement of the objectives of this Regulation.”.

55. Omit Articles 29, 30 and 31.

56. Insert a new Article 31A—

*“Article 31A*

*Regulations and devolved powers*

1. Any power to make regulations under this Regulation—
  - (a) so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;
  - (b) so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument;
  - (c) so far as exercisable by the Northern Ireland devolved authority is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979 (SI 1979/1573 (NI 12)) (and not by statutory instrument).

2. For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010<sup>(6)</sup> (Scottish statutory instruments).

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

- (a) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business); and
- (b) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.

4. Any statutory instrument, Scottish statutory instrument or statutory rule containing regulations made under this Regulation is subject to annulment in pursuance of a resolution—

- (a) in the case of England, of either House of Parliament;
- (b) in the case of Wales, of the National Assembly for Wales;
- (c) in the case of Scotland, of the Scottish Parliament;
- (d) in the case of Northern Ireland, being a negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954<sup>(7)</sup>.

5. In this Regulation, any power—

- (a) of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
- (b) of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
- (c) of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only;
- (d) of the Northern Ireland devolved authority to make regulations is limited to regulations which apply in relation to Northern Ireland only.”.

57. In the heading to Article 32, omit “European”.

58. For Article 32, substitute—

*“Consultation of the Food Safety Authority*

The appropriate authority must consult the Food Safety Authority on any matter, falling within the scope of this Regulation, that could have a significant impact on public health and, in particular, before proposing criteria or targets in accordance with Article 5(3).”.

59. After Article 34, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

60. In Annex 1—

- (a) in Part A, at point 3, for “Community and national legislative provisions”, substitute “retained EU law and any other enactment”;
- (b) in Part B—
  - (i) in point 1, omit “national and Community”;

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<sup>(6)</sup> 2010 asp 10.  
<sup>(7)</sup> 1954 c. 33.

- (ii) in point 2, for “Community and national legislation or in Community and national programmes”, substitute “retained EU law and any other enactment”.

**61.** In Annex 2—

- (a) in the part of the Annex headed “facilities and equipment”, for point 10, substitute—

“**10.** Establishments carrying out one or more of the following activities to place on the market products for use in feed are subject to approval by the appropriate authority in such a manner as the appropriate authority may prescribe—

- (a) processing of crude vegetable oil except those under the scope of Regulation (EC) No 852/2004;
- (b) oleochemical manufacturing of fatty acids;
- (c) manufacturing of biodiesel;
- (d) fat blending.”;

- (b) in the part of the Annex headed “dioxin monitoring for oils, fats and derived products”—

- (i) in point 2(c)(i), at the third indent, for “EU approved”, substitute “approved under retained EU law”;

- (ii) in point 7 —

- (aa) for the first paragraph, substitute—

“Where a feed business operator mandates a laboratory to perform an analysis, as referred to in point 1 the feed business operator must instruct the laboratory to communicate the results of that analysis to the competent authority in case the dioxin limits set out in points 1 and 2 of Section 5 of Annex 1 to Directive 2002/32/EC are exceeded.”;

- (bb) omit the second paragraph;

- (cc) in the third paragraph, omit “of the Member State where they are located”.

**62.** In Annex 5, in Chapter 2—

- (a) for point 2, substitute—

“**2.** the ISO code of the country where the feed business is located, if not the United Kingdom.”;

- (b) in point 3, omit “national”.

**Amendment of Regulation 378/2005**

**63.** Regulation 378/2005 is amended as follows.

**64.** For Article 1, substitute—

*“Subject matter and scope*

This Regulation lays down detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the duties and tasks of the reference laboratory.”.

**65.** In Article 3—

- (a) in each place it which it occurs, for “CRL”, substitute “reference laboratory”;
- (b) in subparagraph 1(a), in the third indent, for “Community legislation”, substitute “retained EU law”.

**66.** In Article 4—



- (a) in each place it which it occurs, for “CRL”, substitute “reference laboratory”;
- (b) for paragraph 3, substitute—

“3. The appropriate authority may, once a year, prescribe adaptations in the amount of the fee mentioned in paragraph 1. The adaptation shall take into account the experience gained during the operation of this Regulation and in particular the possibility of fixing different fees for different types of applications.”;

- (c) after paragraph 3, insert—

“4. In this Regulation, any rates, fees or charges denominated in euro (“EUR”) are to be read as converted into pounds sterling (“GBP”) using an exchange rate of GBP1 = EUR1.1413.

**5.** Any power to make regulations under this Article—

- (a) so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;
- (b) so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument;
- (c) so far as exercisable by the Northern Ireland devolved authority is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979 (SI 1979/1573 (NI 12)) (and not by statutory instrument).

**6.** For regulations made under this Article by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010<sup>(8)</sup> (Scottish statutory instruments).

**7.** Any power to make regulations under this Article includes power—

- (a) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business); and
- (b) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.

**8.** Any statutory instrument, Scottish statutory instrument or statutory rule containing regulations made under this Article is subject to annulment in pursuance of a resolution—

- (a) in the case of England, of either House of Parliament;
- (b) in the case of Wales, of the National Assembly for Wales;
- (c) in the case of Scotland, of the Scottish Parliament;
- (d) in the case of Northern Ireland, being a negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954<sup>(9)</sup>.

**9.** In this Article, any power—

- (a) of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
- (b) of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
- (c) of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only;

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<sup>(8)</sup> 2010 asp 10.

<sup>(9)</sup> 1954 c. 33.

(d) of the Northern Ireland devolved authority to make regulations is limited to regulations which apply in relation to Northern Ireland only.”.

**67.** In Article 5—

- (a) in each place in which it occurs (including the heading), for “CRL”, substitute “reference laboratory”;
- (b) in paragraph 1, in the opening words, for “European Food Safety Authority (the Authority)”, substitute “Food Safety Authority”;
- (c) in each place in which it occurs, for “Authority”, substitute “Food Safety Authority”;
- (d) in each place in which it occurs, for “Commission”, substitute “appropriate authority”.

**68.** In the heading to Chapter 2, omit “National”.

**69.** In Article 6—

- (a) in the heading, omit “National”;
- (b) for paragraph 1, substitute—
  - “1. The reference laboratory is to be assisted by a consortium of national laboratories for the duties and tasks set out in 2.2, 2.4 and 3 of Annex 2 to Regulation (EC) No. 1831/2003.”;
- (c) in paragraph 2, omit “The laboratories listed in Annex II are hereby appointed national reference laboratories to take part in the consortium.”;
- (d) in each place in which it occurs, for “CRL”, substitute “reference laboratory”;
- (e) omit paragraph 4.

**70.** Omit Articles 7 and 8.

**71.** For Article 9, substitute—

*“Duties and tasks of the laboratories participating in the consortium*

**1.** The laboratories participating in the consortium are responsible for assisting the reference laboratory in the preparation of evaluation reports by sending comments to the reference laboratory within 20 days of the reception of the initial report.

**2.** Each laboratory must communicate to the reference laboratory by 30 January each year an estimate of the number of applications for which the laboratory considers itself able to carry out the tasks for that year. The reference laboratory must make available annually to all the laboratories a compilation of the estimates provided.”.

**72.** In Article 10—

- (a) in each place in which it occurs, for “CRL”, substitute “reference laboratory”;
- (b) in both places in which it occurs, for “Authority” substitute “Food Safety Authority”;
- (c) in subparagraph 1, for “Commission”, substitute “appropriate authority”.

**73.** In Article 11—

- (a) in both places in which it occurs, for “CRL”, substitute “reference laboratory”;
- (b) for “Commission”, substitute “appropriate authority”.

**74.** In Article 12, in both places in which it occurs, for “CRL”, substitute “reference laboratory”.

**75.** After Article 14, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

- 76. In Annex 1, omit point (a).
- 77. Omit Annex 2.
- 78. In Annex 4—
  - (a) in each place in which it occurs, for “CRL”, substitute “reference laboratory”;
  - (b) in point 2, for “Rapporteur Laboratory for”, substitute “laboratory which performs”.

#### **Amendment of Regulation 429/2008**

79. Regulation 429/2008 is amended as follows.

80. In Article 2(2), for “Commission”, substitute “appropriate authority”.

81. After Article 5, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

82. In Annex 1—

- (a) in point 1—
  - (i) for “European Commission health and consumer protection Directorate-general”, substitute “The appropriate authority”;
  - (ii) for “The Applicant(s) and/or his/their Representative(s) in the Community (Article 4(3) of Regulation (EC) No 1831/ 2003), under the conditions required in Article 7(3)(a) of Regulation (EC) No 1831/2003 (name, address....)”, substitute “The Applicant (name, address...)”;
- (b) in point 1.3, for “Community Reference Laboratory (CRL)”, substitute “reference laboratory”;
- (c) in point 1.4—
  - (i) for “Authority”, substitute “Food Safety Authority”;
  - (ii) for “CRL”, substitute “reference laboratory”;
- (d) in point 1.5—
  - (i) in both places in which it occurs, for “Authority”, substitute “Food Safety Authority”;
  - (ii) for “Commission”, substitute “appropriate authority”;
  - (iii) in each place in which it occurs, for “CRL”, substitute “reference laboratory”;
  - (iv) at the end, in the wording which begins “Complete the parts” and ends “European Commission”, for “European Commission”, substitute “appropriate authority”;
- (e) in point 2(2), for “Commission, Authority and CRL”, substitute “appropriate authority, Food Safety Authority and reference laboratory”.

83. In Annex 2—

- (a) in the part of the Annex headed “General Aspects”,
  - (i) in the fifth paragraph (which begins with the words “The dossier”)—
    - (aa) omit “European”;
    - (bb) for “following the legislation in force in the Community”, substitute “under retained EU law”;
  - (ii) in the seventh paragraph (which begins with the words “Where in vivo”), for “Community”, substitute “United Kingdom”;
- (b) in Section 1, in point 1.1.2(f), for “Community Legislation”, substitute “retained EU law”;

- (c) in Section 2—
- (i) in point 2.1.3, in the sixth paragraph (which begins with the words “Without prejudice”), for “Authority”, substitute “Food Safety Authority”;
  - (ii) in point 2.1.4, in the third paragraph (which begins with the words “Specific requirements”), for “existing Community legislation”, substitute “retained EU law”;
  - (iii) in point 2.1.4.1, for “European Community”, substitute “United Kingdom”;
  - (iv) in point 2.1.4.2, in the second paragraph (which begins with the words “For feed additives”), for “European Community”, substitute “United Kingdom”;
  - (v) in point 2.2.1.2, in the second paragraph (which begins with the words “For micro-organisms”), for “European Union”, substitute “United Kingdom”;
  - (vi) in point 2.6—
    - (aa) in each place in which it occurs, for “CRL”, substitute “reference laboratory”;
    - (bb) in the fourth paragraph (which begins with the words “Analytical methods”), for “Commission”, substitute “appropriate authority”;
    - (cc) in both places in which it occurs, for “Authority”, substitute “Food Safety Authority”;
  - (vii) in point 2.6.1.1., in the first indent, for “Community rules (e.g. Community methods of analysis)” substitute “retained EU law”;
  - (viii) in point 2.6.1.3, omit the words from “For reasons of independence” to “evaluation of the application”;
  - (ix) in point 2.6.1.4—
    - (aa) for “CRL”, substitute “reference laboratory”;
    - (bb) for “Authority”, substitute “Food Safety Authority”;
  - (x) in point 2.6.1.5, for “CRL”, substitute “reference laboratory”;
  - (xi) in point 2.6.2.3—
    - (aa) omit the words from “For reasons of independence” to “evaluation of the application”;
    - (bb) in each place in which it occurs, for “CRL”, substitute “reference laboratory”;
  - (xii) in point 2.6.3—
    - (aa) for “Authority”, substitute “Food Safety Authority”;
    - (bb) for “Commission”, substitute “appropriate authority”;
  - (xiii) in point 2.6.2.4—
    - (aa) for “CRL”, substitute “reference laboratory”;
    - (bb) for “Authority”, substitute “Food Safety Authority”;
  - (xiv) in point 2.6.2.5, for “CRL”, substitute “reference laboratory”;
- (d) in Section 3—
- (i) in point 3.2.1, in the second paragraph (which begins with the words “Studies must be carried out”)—
    - (aa) for “European legislation in force”, substitute “retained EU law”;
    - (bb) for “European Community legislation”, substitute “retained EU law”;

- (ii) in point 3.2.2, in the final subparagraph, in both places in which it occurs, for “European legislation”, substitute “retained EU law”;
  - (iii) in point 3.2.3.3, in the final paragraph (which begins with the words “In certain situations”), for “Community”, substitute “United Kingdom”;
  - (iv) in point 3.2.3.4, in the first paragraph, for “Community”, substitute “United Kingdom”;
  - (e) in Section 4—
    - (i) in the first paragraph (which begins with the words “Studies shall demonstrate”), for “EU”, substitute “United Kingdom”;
    - (ii) in point 4.4, in the second paragraph (which begins with the words “Efficacy trials”), for “European Union”, substitute “the United Kingdom”;
    - (iii) in point 5, in the second paragraph (which begins with the words “The design”), for “Commission and the Authority”, substitute “appropriate authority and the Food Safety Authority”;
- 84.** In Annex 3—
- (a) in point 8.3, in the second paragraph (which begins with the words “For those additives”), for “European Union”, substitute “United Kingdom”;
  - (b) in point 10.1, in the first paragraph (which begins with the words “The whole of”), omit “Community”.

#### **Amendment of Regulation 152/2009**

**85.** Regulation 152/2009 is amended as follows.

**86.** In Article 1, insert after the final paragraph, “In this Regulation, “reference laboratory” means a reference laboratory prescribed by the appropriate authority under Regulation 2017/625.”.

**87.** After Article 7, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

**88.** In Annex 1—

- (a) in point 1, in the fourth paragraph—
  - (i) for “EU requirements”, substitute “retained EU law”;
  - (ii) for “the EU requirements”, substitute “retained EU law”;
- (b) in point 3, in the fourth indent, for “Member States’ rules as regards the right of the feed business operator”, substitute “the right of the feed business operator to challenge the method of sampling.”;
- (c) in point 8.2.1, in the fourth paragraph—
  - (i) for “EU requirements”, substitute “retained EU law”;
  - (ii) for “the EU requirements”, substitute “retained EU Law”;
- (d) in point 8.2.2, in the second paragraph—
  - (i) for “EU requirements”, substitute “retained EU law”;
  - (ii) for “the EU requirements”, substitute “retained EU Law”;
- (e) in point 8.3—
  - (i) for “EU requirements”, substitute “retained EU law”;
  - (ii) for “the EU requirements”, substitute “retained EU Law”;

- (f) in point 8.4.1—
    - (i) for “EU requirements”, substitute “retained EU law”;
    - (ii) for “the EU requirements”, substitute “retained EU Law”;
  - (g) in point 8.4.2.2—
    - (i) for “EU requirements”, substitute “retained EU law”;
    - (ii) for “the EU requirements”, substitute “retained EU Law”.
- 89.** In Annex 5, in Part B—
- (a) in Chapter 1—
    - (i) in point 2.1, for “the national rules shall apply”, substitute “enactments other than EU-derived domestic legislation apply”;
    - (ii) in point 2.2, for “the national rules shall apply”, substitute “enactments other than EU-derived domestic legislation apply”;
  - (b) in Chapter 2, in point 7.1.4, for “the Union legislation”, substitute “retained EU law”.
- 90.** In Annex 6—
- (a) in point 1, at the fifth paragraph—
    - (i) omit “EU”;
    - (ii) omit “(EURL-AP)”;
  - (b) in point 2.1.3.5, in the first paragraph, for “EURL-AP”, substitute “reference laboratory”;
  - (c) in point 2.1.4.1, in the third paragraph, for “EURL-AP”, substitute “reference laboratory”.
  - (d) in point 2.2.2.1.2.1, for “EURL-AP”, substitute “reference laboratory”;
  - (e) in point 2.2.4, in the first paragraph, for “EURL-AP”, substitute “reference laboratory”;
  - (f) in point 2.2.5, in the first paragraph, for “EURL-AP”, substitute “reference laboratory”;
  - (g) in point 2.2.6, in the fourth paragraph, for “EURL-AP”, substitute “reference laboratory”.
- 91.** In Annex 7, in point 4, in the first paragraph, omit “Community”.

#### **Amendment of Regulation 767/2009**

- 92.** Regulation 767/2009 is amended as follows.
- 93.** In Article 1, omit “internal”.
- 94.** In Article 2—
- (a) in paragraph 1, for “Community”, substitute “United Kingdom”;
  - (b) in paragraph 2, omit “Community”.
- 95.** In Article 3—
- (a) in paragraphs 2(c) and (f), for “Community”, substitute “[United Kingdom]”;
  - (b) in paragraph 2, after paragraph (u), insert—
    - “(v) “prescribe” means prescribe by regulations;
    - (w) “appropriate authority” means—
      - (i) in relation to England, the Secretary of State;
      - (ii) in relation to Wales, the Welsh Ministers;
      - (iii) in relation to Scotland, the Scottish Ministers;
      - (iv) in relation to Northern Ireland, the Northern Ireland devolved authority;

- (x) “Food Safety Authority” means—
  - (i) as regards England, Wales and Northern Ireland, the Food Standards Agency;
  - (ii) as regards Scotland, Food Standards Scotland;
- (y) “Northern Ireland devolved authority” means the Department of Health.”.

**96.** In Article 4(2)(b), omit “Community”.

**97.** In Article 6, for paragraph 2, substitute—

“2. The appropriate authority may prescribe the list of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited taking into account in particular scientific evidence, technological developments, information available through or derived from the Rapid Alert System for Food and Feed (RASFF) or similar intelligence sharing systems or results of official controls pursuant to Regulation (EC) No 882/2004.”.

**98.** For Article 7, substitute—

*“Characteristics of types of feed*

The appropriate authority may, where necessary, prescribe whether a certain product constitutes feed for the purposes of this Regulation.”.

**99.** For Article 10, substitute—

*“List of intended uses of feed intended for particular nutritional purposes*

The appropriate authority may prescribe how the list of intended uses set out in [Directive 2008/38/EC](#) may be updated, to include—

- (a) how an intended use is to be assessed;
- (b) how the conditions of use should be determined;
- (c) the procedure by which—
  - (i) an application for adding a new use may be made;
  - (ii) an amendment to a use or one or more of its conditions may be authorised; and
  - (iii) a use may be removed.”.

**100.** In Article 11, for paragraph 1(c), substitute—

- “(c) as to the compliance of the labelling with the Catalogue of Feed Materials and the Codes referred to in Articles 24 and 25.”.

**101.** In Article 13—

(a) for paragraph 1(b), substitute—

- “(b) the person responsible for the labelling provides, at the request of the competent authority, scientific substantiation of the claim, either by reference to publicly available scientific evidence or through documented company research. The scientific substantiation must be available at the time the feed is placed on the market. Purchasers must have the right to bring to the attention of the competent authority their doubts in respect of the truthfulness of the claim. Where the conclusion is reached that the claim is not sufficiently substantiated, the labelling in respect of such claim must be considered misleading for the purposes of Article 11. Where the competent authority has doubts regarding the scientific

substantiation of the claim concerned, it may submit the issue to the appropriate authority.”;

(b) omit paragraph 4.

**102.** For Article 14, substitute—

*“Presentation of labelling particulars*

**1.** The mandatory labelling particulars must be given in their entirety in a prominent place on the packaging, the container, on a label attached to it or on the accompanying document provided for in Article 11(2), in a conspicuous, clearly legible and indelible manner, in English or in English and Welsh.

**2.** The mandatory labelling particulars must be easily identifiable and must not be obscured by any other information. They must be displayed in a colour, font and size that does not obscure or emphasise any part of the information, unless such variation is to draw attention to precautionary statements.”.

**103.** In Article 16, for paragraph 1(b), substitute—

“(b) the compulsory declaration corresponding to the respective category as set out in the list in Annex 5; the compulsory declaration may be replaced by the particulars laid down in the Catalogue of Feed Materials referred to in Article 24 for each feed material in the respective category.”.

**104.** In Article 17, omit paragraph 4.

**105.** For Article 20, substitute—

*“Additional mandatory labelling requirements for non-compliant feed*

**1.** In addition to the requirements laid down in Articles 15, 16, 17 and 18, feed which does not comply with the requirements set out in Annex 8, such as contaminated materials, must bear the labelling particulars laid down in that Annex.

**2.** The appropriate authority may prescribe amendments to Annex 8 in order to bring it into line with the development of standards.”.

**106.** In Article 21, for paragraph 8, substitute—

“**8.** The appropriate authority may derogate from the provisions of this Regulation in respect of of feed intended for animals kept for scientific or experimental purposes on condition that such purpose is clearly indicated on the label.”.

**107.** In Article 22, omit paragraph 2.

**108.** In the heading to Chapter 5, omit “Community” in both places in which it appears.

**109.** In the heading to Article 24, omit “Community”.

**110.** For Article 24, substitute—

*“Catalogue of feed materials*

**1.** A Catalogue of Feed Materials (the Catalogue) must be maintained by the appropriate authority. The Catalogue must include for each feed material listed at least the following particulars—

(a) the name;



- (b) the identification number;
- (c) a description of the feed material including information on the manufacturing process, if appropriate;
- (d) particulars replacing the compulsory declaration for the purpose of Article 16(1) (b); and
- (e) a glossary with the definition of the different processes and technical expressions mentioned.

2. Use of the Catalogue by the feed business operators is voluntary. However, the name of a feed material listed in the Catalogue may be used only on condition that all relevant provisions of the Catalogue are complied with.

3. The person who, for the first time, places on the market a feed material that is not listed in the Catalogue must immediately notify its use to the representatives of feed businesses in the United Kingdom.

4. The appropriate authority may prescribe amendments to the Catalogue.”.

111. In the heading to Article 25, omit “Community”.

112. For Article 25, substitute—

*“Codes of good labelling practice*

1. The Food Safety Authority is to develop Codes of good labelling practice (the Codes), one for pet food and one for compound feed for food producing animals, which may include a section concerning compound feed for fur animals.

2. The Codes must aim to improve the appropriateness of the labelling. They must, in particular, include provisions on the presentation of labelling particulars provided for in Article 14, on the voluntary labelling provided for in Article 22 and on the use of claims provided for in Article 13.

3. Use of the Codes by the feed business operators is voluntary. However, use of any of the Codes may be indicated on the labelling only on condition that all relevant provisions of such Code are complied with.”.

113. Omit Article 26.

114. For Article 27, substitute—

*“Implementing measures*

The appropriate authority may prescribe amendments to the Annexes in order to adapt them in light of scientific and technological developments.”.

115. Omit Article 28.

116. Insert a new Article 28A—

*“Article 28A*

*Regulations and devolved powers*

1. Any power to make regulations under this Regulation—

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

- (b) so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument;
  - (c) so far as exercisable by the Northern Ireland devolved authority is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979<sup>(10)</sup> (and not by statutory instrument).
2. For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010<sup>(11)</sup> (Scottish statutory instruments).
3. Any power to make regulations under this Regulation includes power—
- (a) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business);
  - (b) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.
4. Any statutory instrument, Scottish statutory instrument or statutory rule containing regulations under this Regulation is subject to annulment in pursuance of a resolution—
- (a) in the case of England, of either House of Parliament;
  - (b) in the case of Wales, of the National Assembly for Wales;
  - (c) in the case of Scotland, of the Scottish Parliament;
  - (d) in the case of Northern Ireland, being a negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954<sup>(12)</sup>.
5. In this Regulation, any power—
- (a) of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
  - (b) of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
  - (c) of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only;
  - (d) of the Northern Ireland devolved authority to make regulations is limited to regulations which apply in relation to Northern Ireland only.”.

117. Omit Article 31.

118. After Article 33, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

119. In Annex 2, omit point 3.

120. In Annex 4, in Part A, at point (1), omit “at Union level”.

121. In Annex 8, in the heading, for “Community”, substitute “retained EU”.

### **Amendment of Regulation 892/2010**

122. Regulation 892/2010 is amended as follows.

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<sup>(10)</sup> S.I. 1979/1573, N.I. 12.

<sup>(11)</sup> 2010 asp 10.

<sup>(12)</sup> 1954 c. 33.

**123.** After Article 4, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

#### **Amendment of Regulation 619/2011**

**124.** Regulation 619/2011 is amended as follows.

**125.** In Article 1(1), insert a new subparagraph (4)—

“(4) “reference laboratory” means a laboratory prescribed by the appropriate authority under Regulation 2017/625.”.

**126.** In Article 2—

- (a) for “EFSA”, substitute “Food Safety Authority”;
- (b) in both places in which it occurs, for “European Union Reference Laboratory”, substitute “reference laboratory”.

**127.** In Article 3, in paragraph 1, for “Member States”, substitute “the competent authority”.

**128.** For Article 6, substitute—

#### *“Measures in case of detection of GM material referred to in Article 2*

**1.** Where results of analytical tests indicate the presence of GM material referred to in Article 2 are at or above the MRPL as defined in accordance with the rules of interpretation set out in Annex 2, Part B, the feed must be considered as non-compliant with Regulation (EC) No 1829/2003.

**2.** Where results of analytical tests indicate the presence of GM material referred to in Article 2 is below the MRPL as defined in accordance with the rules of interpretation set out in Annex 2, Part B, competent authorities must record this information and notify the Food Safety Authority and the appropriate authority by 30 June of each year. Recurrent findings over a period of time of 3 months must be notified without delay.”.

**129.** For Article 7, substitute—

#### *“List of GM material referred to in Article 2*

The Food Safety Authority must publish the list of GM material complying with the conditions set out in Article 2 on its website. The list must include information as to the place where the certified reference material can be accessed as required by Article 17(3)(j) of Regulation (EC) No 1829/2003 and, if applicable, information on the measures taken by the appropriate authority and Food Safety Authority.”.

**130.** For Article 8, substitute—

#### *“Review*

The Food Safety Authority must monitor the application of this Regulation and its impact on feed, livestock and other operators, and, if necessary, advise the appropriate authority as regards amendments which might be made to this Regulation.”.

**131.** After Article 9, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

**132.** In Annex 2, Part B—

- (a) in point 1—

- (i) omit “European Union”;
- (ii) omit “European”;
- (b) in point 2, for “EU-RL” substitute “reference laboratory”.

#### **Amendment of Regulation 68/2013**

**133.** Regulation 68/2013 is amended as follows.

**134.** After Article 4, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

**135.** In the Annex, in Part A—

- (a) in point (2), for “the relevant legislation of the Union” substitute “retained EU Law”;
- (b) in point (3), for “the EU food law”, substitute “retained EU law”.

#### **Amendment of Regulation 2015/786**

**136.** Regulation 2015/786 is amended as follows.

**137.** In Article 1, insert the following new paragraph—

“**3.** The following definitions apply for the purposes of this Regulation—

- (a) “appropriate authority” means—
  - (i) in relation to England, the Secretary of State;
  - (ii) in relation to Wales, the Welsh Ministers;
  - (iii) in relation to Scotland, the Scottish Ministers;
  - (iv) in relation to Northern Ireland, the Northern Ireland devolved authority;
- (b) “Food Safety Authority” means—
  - (i) as regards England, Wales and Northern Ireland, the Food Standards Agency;
  - (ii) as regards Scotland, Food Standards Scotland;
- (c) “Northern Ireland devolved authority” means the Department of Health.”.

**138.** In Article 2, for the second indent, substitute—

“— the Food Safety Authority has performed, on request of the appropriate authority, a scientific assessment of the detoxification process, and concluded that the detoxification process complies with the acceptability criteria, as set out in Articles 3, 4 and 5.”.

**139.** In Article 3—

- (a) in the opening words of paragraph 1, for “EFSA”, substitute “the Food Safety Authority”;
- (b) in paragraph 2, for “Commission”, substitute “appropriate authority”.

**140.** In Article 4—

- (a) in the opening words of paragraph 1, for “EFSA”, substitute “the Food Safety Authority”;
- (b) in paragraph 2, for “Commission”, substitute “appropriate authority”.

**141.** In Article 5—

- (a) in the opening words of paragraph 1, for “EFSA”, substitute “the Food Safety Authority”;
- (b) in paragraph 2, for “Commission”, substitute “appropriate authority”.

**142.** In Article 6(3), omit “The Commission shall display the national links to those lists on the Commission’s website, for information purposes.”.

**143.** In Article 7—

- (a) in each place in which it occurs, for “EFSA”, substitute “the Food Safety Authority”;
- (b) for “Commission”, substitute “appropriate authority”.

**144.** After Article 9, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

**145.** In the Annex, in each place in which it occurs, for “Commission”, substitute “appropriate authority”.

Signed by the authority of the Secretary of State for Health and Social Care.

Date

*Name*  
Parliamentary Under-Secretary of State,  
Department of Health and Social Care

## SCHEDULE

Regulation 7

Schedule to be substituted for Schedule 1 to the Animal Feed  
(Composition, Marketing and Use) (England) Regulations 2015

## “Schedule 1

## Specified Provisions of Regulation 767/2009

**Table 1**

| <i>Specified provision</i>  | <i>Subject matter</i>  |
|---|--|
| Article 4(1) and (2), as read with Article 4(3) and Annex 1   | General safety and other requirements to be met when feed is placed on the market or used.   |
| Article 5(1)  | Extension of requirements in relation to feed for food-producing animals in other legislation to apply to feed for non food-producing animals. |
| Article 5(2), as read with Article 12(1), (2) and (3)   | Obligation on person responsible for labelling to make information available to competent authority.   |
| Article 6(1), as read with Annex 3  | Prohibition or restriction on the marketing or use of certain materials for animal nutritional purposes  |
| Article 8   | Controls on the levels of additives in feeds.  |
| Article 9   | Controls on the marketing of feeds for particular nutritional purposes.  |
| Article 11, as read with Article 12(1), (2) and (3), Annexes 2 and 4 and the Catalogue of feed materials              | Rules and principles governing the labelling and presentation of feed.   |
| Article 12(4) and (5)   | Designation of the person responsible for labelling and the obligations and responsibilities of that person.                                   |
| Article 13(1), as read with Article 12(1), (2) and (3)  | General conditions on making a claim about the characteristics or functions of a feed on the labelling or presentation of it.                  |
| Article 13(2) and (3), as read with Article 12(1), (2) and (3)  | Special conditions applying to claims concerning optimisation of the nutrition and support or protection of the physiological conditions.      |
| Article 14(1) and (2), as read with Article 12(1), (2) and (3)  | Requirements for the presentation of the mandatory labelling particulars.  |
| Article 15, as read with Articles 12(1), (2) and (3) and 21 and with Annex 6 and 7                                    | General mandatory labelling requirements for feed materials and compound feeds.  |
| Article 16, as read with Article 12(1), (2) and (3) and 21 and with Annex 2 and 5 and the Catalogue of feed materials | Specific labelling requirements for feed materials   |

| <i>Specified provision</i>  | <i>Subject matter</i>  |
|---|--|
| Article 17(1) and (2) as read with Articles 12(1), (2) and (3) and 21 and with Annex 2, 6 & 7 | Specific labelling requirements for compound feeds.  |
| Article 18, as read with Article 12(1), (2) and (3)   | Additional labelling requirements for feed for particular nutritional purposes (dietetic feeds).   |
| Article 19, as read with Article 12(1), (2) and (3)   | Additional labelling requirements for pet food.  |
| Article 20(1) as read with Article 12(1), (2) and (3) and with Annex 8                        | Additional requirements for labelling of non-compliant feed, such as that containing contaminated materials.   |
| Article 23  | Requirements relating to the packaging and sealing of feed materials and compound feeds for placing on the market.   |
| Article 24(2)   | Requirement that if the name of a feed material listed in the Catalogue of feed materials is used, all relevant provisions of the Catalogue must be complied with. |
| Article 24(3)   | Obligation on a person who first places on the market a feed material not listed in the Catalogue of feed materials to notify its use.”                            |

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 (c.16) 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. In particular, the Regulations address the deficiency specified in section 8(2)(b) of that Act, namely the conferral of functions by retained EU law on, or in relation to, EU entities which no longer have functions in that respect under EU law in relation to the United Kingdom.

These Regulations make amendments to legislation relating to the safety of animal feed. Part 2 amends subordinate legislation in England. Part 3 amends retained direct EU law for the whole of the United Kingdom.

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