

*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  
FOOD**

**The Genetically Modified Food and Feed  
(Amendment etc.) (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 Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 and come into force on exit day.

## PART 2

### Amendment of subordinate legislation

#### Amendment of the Genetically Modified Food (England) Regulations 2004

2. The Genetically Modified Food (England) Regulations 2004<sup>(2)</sup> are amended as follows.
3. In the Schedule, in Part 2—
  - (a) omit the entries in the Table which relate to Article 8.6 of Regulation (EC) No. 1829/2003;
  - (b) in the entry in the second column of the Table which corresponds to the entry in the first column of the Table relating to Article 9.3 of Regulation (EC) No. 1829/2003, for “Commission”, substitute “Food Safety Authority”.

## PART 3

### Amendment of retained direct EU legislation

#### Amendment of Regulation (EC) No. 1829/2003

4. Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed is amended as follows.
5. In Article 1—
  - (a) in point (a), omit “internal”;
  - (b) in point (b), omit “Community”.
6. In Article 2, at the end, insert—
  - “17. “Food Safety Authority” means—
    - (a) as regards England, Wales and Northern Ireland, the Food Standards Agency;
    - (b) as regards Scotland, Food Standards Scotland;
  18. “appropriate authority” means—
    - (a) in relation to England, the Secretary of State;
    - (b) in relation to Wales, the Welsh Ministers;
    - (c) in relation to Scotland, the Scottish Ministers;
    - (d) in relation to Northern Ireland, the Northern Ireland devolved authority;
  19. “prescribe” means prescribe by regulations;
  20. “third country” means a country or state other than the United Kingdom;
  21. “public analyst” has the meaning it bears in the Food Safety Act 1990<sup>(3)</sup> or, in the case of Northern Ireland, the Food Safety (Northern Ireland) Order 1991<sup>(4)</sup>;
  22. “Northern Ireland devolved authority” means the Department of Health;
  23. “reference laboratory” means the laboratory appointed by the appropriate authority in accordance with Article 32.”.

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(2) S.I. 2004/2335.

(3) 1990 c. 16.

(4) S.I. 1991/762. N.I. 7.

7. For Article 3(2), substitute “2. Where necessary, the appropriate authority may prescribe measures designed to amend non-essential elements of this Regulation by supplementing it and determining whether a type of food falls within the scope of this Section.”.

8. In Article 4, omit paragraph 6.

9. In Article 5—

(a) for paragraph 2, substitute—

“2. The application must be sent to the Food Safety Authority, who must—

- (a) acknowledge receipt of the application, and confirm the date of its receipt, in writing to the applicant within 14 days of its receipt;
- (b) make the summary of the dossier referred to in paragraph 3(1) available to the public.”;

(b) in paragraph 6, for “Community”, substitute “retained EU”;

(c) for paragraph 7, substitute—

“7. The appropriate authority, having first consulted the Food Safety Authority, may prescribe rules concerning the preparation and presentation of the application.”;

(d) in paragraph 8, for “Before the date of application of this Regulation, the Authority shall”, substitute “The Food Safety Authority must”.

10. In Article 6—

(a) in paragraph 2, omit “or a national competent authority through the Authority”;

(b) for paragraph 3, substitute—

“3. In order to prepare its opinion, the Food Safety Authority—

- (a) must verify that the particulars and documents submitted by the applicant are in accordance with Article 5 and examine whether the food complies with the criteria referred to in Article 4(1);
- (b) may ask a competent authority designated in accordance with Article 4 of [Directive 2001/18/EC](#) to carry out an environmental risk assessment; however, if the application concerns GMOs to be used as seeds or other plant-propagating material, the Food Safety Authority must ask a competent authority to carry out the environmental risk assessment;
- (c) may ask a public analyst to carry out a safety assessment of the food;
- (d) must forward to the reference laboratory referred to in Article 32 the particulars referred to in Article 5(3)(i) and (j). The reference laboratory must test and validate the method of detection and identification proposed by the applicant;
- (e) must, in verifying the application of Article 13(2)(a), examine the information and data submitted by the applicant to show that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics.”;

(c) in paragraph 4, for “national competent authority within the meaning of [Directive 2001/18/EC](#), designated by each Member State for this purpose”, substitute “competent authority designated in accordance with [Directive 2001/18/EC](#)”;

(d) in paragraph 5(f), omit “Community”;

(e) for paragraph 6, substitute—

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

(f) for paragraph 7, substitute—

“7. The Food Safety Authority must make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Food Safety Authority within 30 days from such publication.”.

11. For Article 7, substitute—

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

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

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

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

(b) the name of the authorisation holder;

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

4. The authorisation granted in accordance with the procedure referred to in this Regulation is valid for 10 years and is renewable in accordance with Article 11. The authorised food must be entered in the Register referred to in Article 28. Each entry in the Register must mention the date of authorisation and must include the particulars referred to in paragraph 3.

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

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

12. In Article 8, omit paragraphs 6 and 8.

13. In Article 9—

(a) in paragraph 1, for “Commission”, substitute “Food Safety Authority”;

(b) in paragraph 3, in both places in which it occurs, for “Commission”, substitute “Food Safety Authority”;

(c) for paragraph 4, substitute—

“4. The Food Safety Authority must make the information supplied by the applicant available to the appropriate authority without delay.”.

14. In Article 10, for subparagraphs 1 and 2, substitute—

“1. On its own initiative, the Food Safety Authority may, or following a request from the appropriate authority, must, issue an opinion on whether an authorisation for a product referred to in Article 3(1) still meets the conditions set by this Regulation. It shall immediately transmit this opinion to the appropriate authority and the authorisation-holder. The Food Safety Authority must make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Food Safety Authority within 30 days from such publication.

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

15. In Article 11—

- (a) in paragraph 1, for “Commission”, substitute “appropriate authority”;
- (b) for paragraph 5, substitute—

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

- (c) in paragraph 6, for “Authority”, substitute “Food Safety Authority”.

16. In Article 12—

- (a) in the opening words of paragraph 1, for “Community”, substitute “United Kingdom”;
- (b) for paragraph 4, substitute—

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

17. In Article 13, in paragraph 1, for “Community”, substitute “retained EU”.

18. For Article 14, substitute—

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

- (a) the measures necessary for operators to satisfy the competent authorities as referred to in Article 12(3);
- (b) the measures necessary for operators to comply with the labelling requirements set out in Article 13;
- (c) measures concerning the information to be given by mass caterers providing food to the final consumer. In order to take account of the specific situation of mass caterers, such measures may provide for adaptation of the requirements set out in Article 13(1)(e); and
- (d) measures to facilitate the uniform application of Article 13.”.

19. In Article 15, for paragraph 2, substitute—

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

20. Omit Article 16(6).

21. In Article 17—

- (a) for paragraphs 1 and 2, substitute—
    - “1. To obtain the authorisation referred to in Article 16(2), an application must be submitted in accordance with the following provisions.
    - 2. The application must be sent to the Food Safety Authority, who must—
      - (a) acknowledge receipt of the application, and confirm the date of its receipt, in writing to the applicant within 14 days of its receipt;
      - (b) make the summary of the dossier referred to in paragraph 3(1) available to the public.”;
  - (b) in paragraph 6, for “Community”, substitute “retained EU”;
  - (c) for paragraph 7, substitute—
    - “7. The appropriate authority, having first consulted the Food Safety Authority, may prescribe rules concerning the preparation and presentation of the application.”;
  - (d) in paragraph 8, for “Before the date of application of this Regulation, the Authority shall”, substitute “The Food Safety Authority must”.
22. In Article 18—
- (a) in paragraph 2, omit “or a national competent authority through the Authority”;
  - (b) for paragraph 3, substitute—
    - “3. In order to prepare its opinion, the Food Safety Authority—
      - (a) must verify that the particulars and documents submitted by the applicant are in accordance with Article 17 and examine whether the food complies with the criteria referred to in Article 16(1);
      - (b) may ask a competent authority designated in accordance with Article 4 of [Directive 2001/18/EC](#) to carry out an environmental risk assessment; however, if the application concerns GMOs to be used as seeds or other plant-propagating material, the Food Safety Authority must ask a competent authority to carry out the environmental risk assessment;
      - (c) may ask a public analyst to carry out a safety assessment of the feed;
      - (d) must forward to the reference laboratory the particulars referred to in Article 17(3)(i) and (j). The reference laboratory must test and validate the method of detection and identification proposed by the applicant;
      - (e) must, in verifying the application of Article 25(2)(c), examine the information and data submitted by the applicant to show that the characteristics of the feed are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics.”.
  - (c) in paragraph 4, for “the national competent authority within the meaning of [Directive 2001/18/EC](#), designated by each Member State for this purpose”, substitute “the competent authority designated in accordance with [Directive 2001/18/EC](#)”;
  - (d) in paragraph 5(f), omit “Community”;
  - (e) for paragraph 6, substitute—
    - “6. The Food Safety Authority must forward its opinion to the appropriate authority and the applicant, including a report describing its assessment of the feed and stating the reasons for its opinion and the information on which this opinion is based.”;
  - (f) for paragraph 7, substitute—

“7. The Food Safety Authority must make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Food Safety Authority within 30 days from such publication.”.

**23.** For Article 19, substitute —

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

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

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

- (a) the particulars referred to in Article 18(5);
- (b) the name of the authorisation-holder;
- (c) where appropriate, the unique identifier attributed to the GMO as referred to in Regulation (EC) No. 1830/2003.

4. The authorisation granted in accordance with the procedure referred to in this Regulation is valid for 10 years and is renewable in accordance with Article 23. The authorised feed must be entered in the Register referred to in Article 28. Each entry in the Register must mention the date of authorisation and must include the particulars referred to in paragraph 3.

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

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

**24.** In Article 20, omit paragraphs 6 and 8.

**25.** In Article 21—

- (a) in paragraph 1, for “Commission”, substitute “Food Safety Authority”;
- (b) in paragraph 3, in both places in which it occurs, for “Commission”, substitute “Food Safety Authority”;
- (c) for paragraph 4, substitute—

“4. The Food Safety Authority must make the information supplied by the applicant available to the appropriate authority without delay.”.

**26.** In Article 22, for subparagraphs 1 and 2, substitute—

“1. On its own initiative, the Food Safety Authority may, or following a request from the appropriate authority, must, issue an opinion on whether an authorisation for a product referred to in Article 15(1) still meets the conditions set by this Regulation. It shall immediately transmit this opinion to the appropriate authority and the authorisation-holder. The Food Safety Authority must make its opinion public, after deletion of any information

identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Food Safety Authority within 30 days from such publication.

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

27. In Article 23—

- (a) in paragraph 1, for “Commission”, substitute “appropriate authority”;
- (b) for paragraph 5, substitute—

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

28. For Article 24(4), substitute—

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

29. In Article 25(1), for “Community”, substitute “retained EU”.

30. For Article 26, substitute—

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

- (a) measures necessary for operators to satisfy the competent authorities as referred to in Article 24(3);
- (b) measures necessary for operators to comply with the labelling requirements set out in Article 25;
- (c) measures to facilitate the uniform application of Article 25.”.

31. For Article 27, substitute—

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

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

32. In Article 28(1)—

- (a) omit “Community” in both places in which it occurs (including the heading);
- (b) for “Commission”, substitute “appropriate authority”.

33. in Article 29, omit paragraphs 2 and 3.

34. In Article 30—

- (a) in paragraph 2, for “Commission”, substitute “Food Safety Authority”;
- (b) for paragraph 4, substitute—

“4. Notwithstanding paragraph 2, the Food Safety Authority must on request supply the appropriate authority with all information in its possession.”;



(c) for paragraph 6, substitute—

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

(d) for paragraph 7, substitute—

“7. If an applicant withdraws or has withdrawn an application, the Food Safety Authority and the appropriate authority must respect the confidentiality of commercial and industrial information, including research and development information, as well as any information in respect of which a claim of confidentiality is disputed.”

35. For Article 32, substitute—

*“Reference laboratory*

1. The appropriate authority may appoint a reference laboratory to perform the duties and tasks set out in the Annex.

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

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

4. The appropriate authority may prescribe—

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

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

36. Omit Articles 33 and 34.

37. For Article 35, substitute—

*“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(5) (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 under this Regulation shall be subject to annulment in pursuance of a resolution—

- (a) in the case of England, of either House of Parliament;
- (b) in the case of Wales, of 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(6).

**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.”.

**38.** For Article 36, substitute—

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

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

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

**39.** Omit Article 45.

**40.** After Article 49, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

**41.** In the Annex—

- (a) in the Title, omit “Community”;
- (b) omit paragraphs 1 and 2;
- (c) in paragraph 3—
  - (i) in the opening words, omit “Community”
  - (ii) omit points (a) and (b);
- (d) for paragraph 4, substitute—

“4. The reference laboratory must help to resolve disputes concerning the results of the duties and tasks outlined in this Annex.”.

#### **Amendment of Commission Regulation 641/2004**

42. Commission Regulation 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation is amended as follows.

43. In Article 2—

- (a) in paragraph 1, for “European Food Safety Authority (the Authority)”, substitute “Food Safety Authority”;
- (b) in paragraph 4, for “Commission”, substitute “appropriate authority”.

44. In Article 3—

- (a) in paragraph 1(a), omit “taking into account Council Decision 2002/811/EC”;
- (b) in paragraph 1(d), omit “in all official Community languages”.

45. After Article 20, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

46. In Annex 1—

- (a) in point 1.A, omit “Community”;
- (b) in point 1.B, for “have been compiled by the European Network of GMO Laboratories (ENGL)”, substitute “are set out”;
- (c) in point 1.C, omit “established under Regulation (EC) No 1829/2003 and assisted by ENGL,”;
- (d) in point 1.F, omit “, together with ENGL,”;
- (e) in point 1.G, omit “, assisted by ENGL,”;
- (f) in point 2.B, for “ENGL”, substitute “RL”;
- (g) in point 3.A—
  - (i) for “ENGL”, substitute “RL”;
  - (ii) omit “, together with ENGL,”;
- (h) in each place in which it occurs, for “CRL”, substitute “RL”.

#### **Amendment of Commission Implementing Regulation (EU) 503/2013**

47. Commission Implementing Regulation (EU) 503/2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No. 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No. 641/2004 and (EC) No. 1981/2006 is amended as follows.

48. For Article 3(6), substitute—

“6. When studies have been already submitted to the Food Safety Authority for the purposes of an application and, where relevant, to the extent that they may be used by the applicant in accordance with Article 31 of Regulation (EC) No. 1829/2003, a reference to such studies and the results of the Food Safety Authority’s assessment may, with the agreement of the Food Safety Authority, be made in the framework of another application.”.

- 49.** In Article 4(1)(b), for “Union”, substitute “United Kingdom”.
- 50.** In Article 5(3), for “EFSA”, substitute “Food Safety Authority”.
- 51.** In Article 6(2), in both places in which it occurs, for “EFSA”, substitute “Food Safety Authority”.
- 52.** For Article 12, substitute—
- 1.** The Food Safety Authority must monitor the application of this Regulation and the developments in scientific knowledge on replacement, reduction and refinement of animal use in scientific procedures.
- 2.** The Food Safety Authority may review the requirement to perform 90 day feeding studies in rodents with whole genetically modified food or feed (point 1.4.4.1 of Annex 2) on the basis of new scientific information.”.
- 53.** After Article 13, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.
- 54.** In Annex 1—
- (a) in Part 1—
- (i) in paragraph 2, for “European Food Safety Authority (EFSA)”, substitute “Food Safety Authority”;
- (ii) in paragraph 4(c), for “Union”, substitute “United Kingdom”;
- (iii) in paragraph 8, in both places in which it occurs, for “Union”, substitute “retained EU”;
- (b) in Part 2—
- (i) in paragraph 1.1(b), for “Union”, substitute “United Kingdom”;
- (ii) in paragraph 1.1(e)(v), for “Union”, substitute “United Kingdom”;
- (iii) in paragraph 1.1(e)(vi), for “Union”, substitute “United Kingdom”;
- (iv) in paragraph 7, for “EFSA”, substitute “Food Safety Authority”;
- (c) in Part 4, in both places in which it occurs, omit “in all official languages of the Union”;
- (d) in Part 5—
- (i) for “European Union Reference Laboratory (EURL)”, substitute “reference laboratory”;
- (ii) for “EURL”, substitute “reference laboratory”;
- (iii) for “EU Reference laboratory (EURL)”, substitute “reference laboratory”;
- (iv) omit “These instructions are published on the following webpage: <http://gmo-crl.jrc.ec.europa.eu/guidancedocs.htm>.”;
- (e) In Part 7—
- (i) in each place in which it occurs, for “EU”, substitute “United Kingdom”;
- (ii) in each place in which it occurs, for “Union”, substitute “United Kingdom”;
- (iii) omit paragraph 1.1(a);
- (iv) in paragraph 1.8(h), for “EU legislation”, substitute “retained EU law”.
- 55.** In Annex 2—
- (a) in Section 2—
- (i) in paragraph 1.1.2(b), for “Union”, substitute “United Kingdom”;

- (ii) in paragraph 1.3.1, in the seventh subparagraph, omit “in the EFSA scientific opinion ‘Guidance on the selection of comparators for the risk assessment of genetically modified plants and derived food and feed’”;
- (iii) in paragraph 1.3.2.1, in the final subparagraph, for “in the EFSA opinion on ‘Statistical considerations for the safety evaluation of GMOs’”, substitute “from the Food Safety Authority”;
- (iv) in paragraph 1.3.2.2, in the final subparagraph, for “in the EFSA opinion on ‘Statistical considerations for the safety evaluation of GMOs’”, substitute “from the Food Safety Authority”;
- (v) in paragraph 1.4.2, for “analogous to that described in the ‘Guidance for submission for food additive evaluations by the EFSA Panel on Food Additives and Nutrient Sources added to Food’ of 16 August 2012” substitute “in accordance with food additives guidance available from the Food Safety Authority”;
- (vi) in paragraph 1.4.4.1, in the final subparagraph, for “for performing this study is provided in the EFSA Guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed.”, substitute “on conducting repeated dose 90-day oral toxicity study in rodents on whole food and feed is available from the Food Safety Authority”;
- (vii) in paragraph 1.5, in the final subparagraph, for “in the EFSA scientific opinion on the assessment of the allergenicity of GM plants and micro-organisms and derived food and feed adopted on 30 June 2010.”, substitute “from the Food Safety Authority.”;
- (viii) in paragraph 1.6.4, in the final subparagraph, for “in the Report of the EFSA GMO Panel Working Group on Animal Feeding Trials.”, substitute “from the Food Safety Authority.”;
- (ix) in paragraph 2—
  - (aa) in the first subparagraph, omit “in the EU”;
  - (bb) in the second subparagraph, for “EU population”, substitute “population of the United Kingdom and the EU”.

**56.** In Annex 3—

- (a) in paragraph 1, at subparagraph 3—
  - (i) for “EU Reference Laboratory (EURL)”, substitute “reference laboratory”;
  - (ii) omit “, assisted by the European Network of GMO Laboratories”;
- (b) in each place in which it occurs, for “EURL”, substitute “reference laboratory”;
- (c) in paragraph 3.1, in point C, in subparagraph 4, omit “, and the ENGL”.

**Amendment of Commission Decision 2006/197/EC**

**57.** Commission Decision 2006/197/EC authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 58.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 59.** For the heading to Article 5, substitute “Register”.
- 60.** In Article 5, omit “Community”.
- 61.** In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2007/305/EC**

62. 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 is amended as follows.

63. In Article 1—

- (a) in the first paragraph for “Union” substitute “United Kingdom”;
- (b) omit the second paragraph.

64. In Article 3, omit “Community”.

#### **Amendment of Commission Decision 2007/306/EC**

65. 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 is amended as follows.

66. In Article 1—

- (a) in the first paragraph, for “Union” substitute “United Kingdom”;
- (b) omit the second paragraph.

67. In Article 3, omit “Community”.

#### **Amendment of Commission Decision 2007/307/EC**

68. Commission Decision 2007/307/EC on the withdrawal from the market of Topas 19/2 (ACS-BNØØ7-1) oilseed rape and its derived products is amended as follows.

69. In Article 1(1)—

- (a) in the first subparagraph, for “Union” substitute “United Kingdom”;
- (b) omit the second subparagraph.

70. In Article 2 omit “Community”.

#### **Amendment of Commission Decision 2007/692/EC**

71. Commission Decision 2007/692/EC authorising the placing on the market of food and feed produced from genetically modified sugar beet H7-1 (KM-ØØØH71-4) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

72. For the heading to Article 4, substitute “Register”.

73. In Article 4, omit “Community”.

74. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2007/701/EC**

75. Commission Decision 2007/701/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603xMON810 (MON-ØØ6Ø3-6xMON-ØØ81Ø-6) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

76. In Article 4(2), for “Commission” substitute “Food Safety Authority”.

77. For the heading to Article 5, substitute “Register”.

78. In Article 5, omit “Community”.

79. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2007/702/EC**

80. Commission Decision 2007/702/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

81. In Article 4(2), for “Commission” substitute “Food Safety Authority”.

82. For the heading to Article 5, substitute “Register”.

83. In Article 5, omit “Community”.

84. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2007/703/EC**

85. Commission Decision 2007/703/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507xNK603 (DAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

86. In Article 4(2), for “Commission” substitute “Food Safety Authority”.

87. For the heading to Article 5, substitute “Register”.

88. In Article 5, omit “Community”.

89. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2008/280/EC**

90. Commission Decision 2008/280/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21 (MON-ØØØ21-9) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

91. In Article 4(2), for “Commission” substitute “Food Safety Authority”.

92. For the heading to Article 5, substitute “Register”.

93. In Article 5, omit “Community”.

94. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2008/730/EC**

95. Commission Decision 2008/730/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

96. In Article 4(2), for “Commission” substitute “Food Safety Authority”.

97. For the heading to Article 5, substitute “Register”.

98. In Article 5, omit “Community”.

99. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2008/837/EC**

100. Commission Decision 2008/837/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified LLCotton25 (ACS-GHØØ1-3) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and the Council is amended as follows.

101. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
102. For the heading to Article 5, substitute “Register”.
103. In Article 5, omit “Community”.
104. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2008/933/EC**

105. Commission Decision 2008/933/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON89788 (MON-89788-1) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

106. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
107. For the heading to Article 5, substitute “Register”.
108. In Article 5, omit “Community”.
109. In the Annex, in the “NB”, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2009/184/EC**

110. Commission Decision 2009/184/EC authorising the placing on the market of products containing or produced from genetically modified oilseed rape T45 (ACS-BNØØ8-2) resulting from the commercialisation of this oilseed rape in third countries until 2005 pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

111. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
112. In Article 5(1), for “European Union” substitute “United Kingdom”.
113. In Article 5(3), for “Commission” substitute “Food Safety Authority”.
114. For the heading to Article 6, substitute “Register”.
115. In Article 6, omit “Community”.
116. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2009/813/EC**

117. Commission Decision 2009/813/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034 (MON-89Ø34-3) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

118. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
119. For the heading to Article 5, substitute “Register”.
120. In Article 5, omit “Community”.
121. In the Annex, in the “NB”, in the final sentence, omit “Community”.



#### **Amendment of Commission Decision 2009/814/EC**

122. Commission Decision 2009/814/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 (MON-88Ø17-3) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council authorising the placing on the market of products containing, consisting of, or produced from genetically modified LLCotton25 (ACS-GHØØ1-3) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and the Council is amended as follows.

- 123. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 124. For the heading to Article 5, substitute “Register”.
- 125. In Article 5, omit “Community”.
- 126. In the Annex, in the “NB”, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2009/866/EC**

127. Commission Decision 2009/866/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR604 (SYN-IR6Ø4-5) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 128. In Article 4(2) for “Commission” substitute “Food Safety Authority”.
- 129. For the heading to Article 5 substitute “Register”.
- 130. In Article 5 omit “Community”.
- 131. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2010/419/EU**

132. Commission Decision 2010/419/EU renewing the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified maize Bt11 (SYN-BTØ11-1), authorising foods and food ingredients containing or consisting of field maize Bt11 (SYN-BTØ11-1) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council and repealing Decision 2004/657/EC is amended as follows.

- 133. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 134. For the heading to Article 5, substitute “Register”.
- 135. In Article 5, omit “Community”.
- 136. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2010/429/EU**

137. Commission Decision 2010/429/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 x MON 810 (MON-88Ø17-3 x MON-ØØ81Ø-6) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 138. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 139. For the heading to Article 5, substitute “Register”.
- 140. In Article 5, omit “Community”.
- 141. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2011/354/EU**

142. Commission Decision 2011/354/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB614 (BCS-GHØØ2-5) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 143. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 144. For the heading to Article 5, substitute “Register”.
- 145. In Article 5, omit “Community”.
- 146. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2011/366/EU**

147. Commission Decision 2011/366/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034 × MON 88017 (MON-89Ø34-3xMON-88Ø17-3) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 148. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 149. For the heading to Article 5, substitute “Register”.
- 150. In Article 5, omit “Community”.
- 151. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Decision 2011/891/EU**

152. Commission Decision 2011/891/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236x3006-210-23 (DAS-24236-5xDAS-21Ø23-5) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 153. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 154. For the heading to Article 5, substitute “Register”.
- 155. In Article 5, omit “Community”.
- 156. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision 2012/81/EU**

157. Commission Implementing Decision 2012/81/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A5547-127 (ACS-GMØØ6-4) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 158. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 159. For the heading to Article 5, substitute “Register”.
- 160. In Article 5, omit “Community”.
- 161. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision 2012/82/EU**

162. Commission Implementing Decision 2012/82/EU as regards the renewal of the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified soybean 40-3-2 (MON-Ø4Ø32-6) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

163. In Article 4(2), for “Commission” substitute “Food Safety Authority”.

164. For the heading to Article 5, substitute “Register”.

165. In Article 5, omit “Community”.

166. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision 2012/83/EU**

167. Commission Implementing Decision 2012/83/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87701 (MON-877Ø1-2) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

168. In Article 4(2), for “Commission” substitute “Food Safety Authority”.

169. For the heading to Article 5, substitute “Register”.

170. In Article 5, omit “EU”.

171. In the Annex, in the Note, in the final sentence, omit “EU”.

#### **Amendment of Commission Implementing Decision 2012/84/EU**

172. Commission Implementing Decision 2012/84/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 356043 (DP-356Ø43-5) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

173. In Article 4(2), for “Commission” substitute “Food Safety Authority”.

174. For the heading to Article 5, substitute “Register”.

175. In Article 5, omit “EU”.

176. In the Annex, in the Note, in the final sentence, omit “EU”.

#### **Amendment of Commission Implementing Decision 2012/347/EU**

177. Commission Implementing Decision 2012/347/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87701 × MON 89788 (MON-877Ø1-2 × MON-89788-1) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

178. In Article 4(2), for “Commission” substitute “Food Safety Authority”.

179. For the heading to Article 5, substitute “Register”.

180. In Article 5, omit “EU”.

181. In the Annex, in the Note, in the final sentence, omit “EU”.

#### **Amendment of Commission Implementing Decision 2012/651/EU**

**182.** Commission Implementing Decision 2012/651/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR162 (SYN-IR162-4) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

**183.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.

**184.** For the heading to Article 5, substitute “Register”.

**185.** In Article 5, omit “EU”.

**186.** In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision 2013/327/EU**

**187.** Commission Implementing Decision 2013/327/EU authorising the placing on the market of food containing or consisting of genetically modified oilseed rape Ms8, Rf3 and Ms8 × Rf3, or food and feed produced from those genetically modified organisms pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

**188.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.

**189.** For the heading to Article 5, substitute “Register”.

**190.** In Article 5, omit “Community”.

**191.** In the Annex—

(a) in point (f), omit “Community”;

(b) in point (h), omit “Community”.

#### **Amendment of Commission Implementing Decision 2013/648/EU**

**192.** Commission Implementing Decision 2013/649/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 × 1507 × NK603 (MON-89034-3 × DAS-01507-1 × MON-00603-6) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

**193.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.

**194.** For the heading to Article 5, substitute “Register”.

**195.** In Article 5, omit “EU”.

**196.** In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision 2013/649/EU**

**197.** Commission Implementing Decision 2013/649/EU authorising the placing on the market of pollen produced from maize MON 810 (MON-00810-6) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

**198.** For the heading to Article 4, substitute “Register”.

**199.** In Article 4, omit “Community”.

**200.** In the Annex, in the Note, in the final sentence, omit “Community”.

### **Amendment of Commission Implementing Decision 2013/650/EU**

**201.** Commission Implementing Decision 2013/650/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified (GM) maize MON 89034 × 1507 × MON88017 × 59122 (MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7), four related GM maizes combining three different single GM events (MON89034 × 1507 × MON88017 (MON-89034-3 × DAS-01507-1 × MON-88017-3), MON89034 × 1507 × 59122 (MON-89034-3 × DAS-01507-1 × DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89034-3 × MON-88017-3 × DAS-59122-7), 1507 × MON 88017 × 59122 (DAS-01507-1 × MON-88017-3 × DAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034 × 1507 (MON-89034-3 × DAS-01507-1), MON89034 × 59122 (MON-89034-3 × DAS-59122-7), 1507 × MON88017 (DAS-01507-1 × MON-88017-3), MON 88017 × 59122 (MON-88017-3 × DAS-59122-7)) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 202.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 203.** For the heading to Article 5, substitute “Register”.
- 204.** In Article 5, omit “EU”.
- 205.** In the Annex, in the Note, in the final sentence, omit “Community”.

### **Amendment of Commission Implementing Decision (EU) 2015/683**

**206.** Commission Implementing Decision (EU) 2015/683 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87460 (MON 87460-4) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 207.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 208.** For the heading to Article 5, substitute “Register”.
- 209.** In Article 5, omit “EU”.
- 210.** In the Annex—
  - (a) in point (f), omit “EU”;
  - (b) in point (h), omit “EU”.

### **Amendment of Commission Implementing Decision (EU) 2015/684**

**211.** Commission Implementing Decision (EU) 2015/684 authorising the placing on the market of genetically modified maize NK603 (MON-00603-6) and renewing the existing maize NK603 (MON-00603-6) products, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council is amended as follows.

- 212.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 213.** For the heading to Article 5, substitute “Register”.
- 214.** In Article 5, omit “EU”.
- 215.** In the Annex—
  - (a) in point (f), omit “EU”;
  - (b) in point (h), omit “EU”.

#### **Amendment of Commission Implementing Decision (EU) 2015/685**

216. Commission Implementing Decision (EU) 2015/685 authorising the placing on the market of genetically modified cotton MON 15985 (MON-15985-7) products pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 217. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 218. For the heading to Article 5, substitute “Register”.
- 219. In Article 5, omit “Community”.
- 220. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/686**

221. Commission Implementing Decision (EU) 2015/686 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87769 (MON-87769-7) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 222. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 223. In Article 5(2), for “Commission” substitute “Food Safety Authority”.
- 224. For the heading to Article 6, substitute “Register”.
- 225. In Article 6, omit “Community”.
- 226. In the Annex—
  - (a) in point (g)(1)(i), for “European Union” substitute “United Kingdom”;
  - (b) in point (g)(1)(ii), for “Member State” substitute “the United Kingdom”;
  - (c) in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/687**

227. Commission Implementing Decision (EU) 2015/687 authorising the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rape MON 88302 (MON-88302-9) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 228. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 229. For the heading to Article 5, substitute “Register”.
- 230. In Article 5, omit “Community”.
- 231. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/688**

232. Commission Implementing Decision (EU) 2015/688 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton MON 88913 (MON-88913-8) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 233. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 234. For the heading to Article 5, substitute “Register”.
- 235. In Article 5, omit “Community”.

236. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/689**

237. Commission Implementing Decision (EU) 2015/689 renewing the authorisation for existing genetically modified cotton MON 531 (MON-ØØ531-6) products pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

238. For the heading to Article 4, substitute “Register”.

239. In Article 4, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/690**

240. Commission Implementing Decision (EU) 2015/690 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB614xLLCotton25 (BCS-GHØØ2-5xACS-GHØØ1-3) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

241. In Article 4(2), for “Commission” substitute “Food Safety Authority”.

242. For the heading to Article 5, substitute “Register”.

243. In Article 5, omit “Community”.

244. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/691**

245. Commission Implementing Decision (EU) 2015/691 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean BPS-CV127-9 (BPS-CV127-9) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

246. In Article 4(2), for “Commission” substitute “Food Safety Authority”.

247. For the heading to Article 5, substitute “Register”.

248. In Article 5, omit “Community”.

249. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/693**

250. Commission Implementing Decision (EU) 2015/693 renewing the authorisation for existing genetically modified cotton MON 1445 (MON-Ø1445-2) products pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

251. For the heading to Article 4, substitute “Register”.

252. In Article 4, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/695**

253. Commission Implementing Decision (EU) 2015/695 renewing the authorisation for existing genetically modified cotton MON 531 x MON 1445 (MON-ØØ531-6 x MON-Ø1445-2) products and authorising the placing on the market of cottonseed oil produced from genetically modified cotton MON 531 x MON 1445 (MON-ØØ531-6 x MON-Ø1445-2) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

254. For the heading to Article 4, substitute “Register”.

255. In Article 4, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/696**

256. Commission Implementing Decision (EU) 2015/696 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON87705 (MON-87705-6) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

257. In Article 4(2), for “Commission” substitute “Food Safety Authority”.

258. In Article 5(2), for “Commission” substitute “Food Safety Authority”.

259. For the heading to Article 6, substitute “Register”.

260. In Article 6, omit “Community”.

261. In the Annex—

- (a) in point (g)(1)(i), for “European Union” substitute “United Kingdom”;
- (b) in point (g)(1)(ii), for “Member State” substitute “the United Kingdom”;
- (c) in the final sentence, in the Note, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/697**

262. Commission Implementing Decision (EU) 2015/697 authorising the placing on the market of genetically modified maize T25 (ACS-ZMØØ3-2) and renewing the existing maize T25 (ACS-ZMØØ3-2) products, pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

263. In Article 4(2), for “Commission” substitute “Food Safety Authority”.

264. For the heading to Article 5, substitute “Register”.

265. In Article 5, omit “Community”.

266. In the Annex—

- (a) in point (f), omit “EU”;
- (b) in point (h), omit “EU”.

#### **Amendment of Commission Implementing Decision (EU) 2015/698**

267. Commission Implementing Decision (EU) 2015/698 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 (DP-3Ø5423-1) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

268. In Article 4(2), for “Commission” substitute “Food Safety Authority”.

269. In Article 5(2), for “Commission” substitute “Food Safety Authority”.

270. For the heading to Article 6, substitute “Register”.

271. In Article 6, omit “Community”.

272. In the Annex—

- (a) in point (g)(1)(i), for “European Union” substitute “United Kingdom”;



- (b) in point (g)(1)(ii), for “Member State” substitute “the United Kingdom”;
- (c) in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/699**

**273.** Commission Implementing Decision (EU) 2015/699 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton T304-40 (BCS-GH004-7) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 274.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 275.** For the heading to Article 5, substitute “Register”.
- 276.** In Article 5, omit “Community”.
- 277.** In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/700**

**278.** Commission Implementing Decision (EU) 2015/700 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON87708 (MON-87708-9) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 279.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 280.** For the heading to Article 5, substitute “Register”.
- 281.** In Article 5, omit “Community”.
- 282.** In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/701**

**283.** Commission Implementing Decision (EU) 2015/701 authorising the placing on the market of food containing or consisting of genetically modified oilseed rape GT73, or food and feed produced from that genetically modified organism pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 284.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 285.** For the heading to Article 5, substitute “Register”.
- 286.** In Article 5, omit “Community”.
- 287.** In the Annex—
  - (a) in point (f), omit “Community”;
  - (b) in point (h), omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/2279**

**288.** Commission Implementing Decision (EU) 2015/2279 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603 × T25 (MON-00603-6 × ACS-ZM003-2) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 289.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.

**290.** For the heading to Article 5, substitute “Register”.

**291.** In Article 5, omit “Community”.

**292.** In the Annex—

(a) in point (f), omit “Community”;

(b) in point (h), omit “Community”;

(c) in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2015/2281**

**293.** Commission Implementing Decision (EU) 2015/2281 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 (MON-87427-7) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

**294.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.

**295.** For the heading to Article 5, substitute “Register”.

**296.** In Article 5, omit “Community”.

**297.** In the Annex—

(a) in point (f), omit “Community”;

(b) in point (h), omit “Community”;

(c) in the note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2016/1215**

**298.** Commission Implementing Decision (EU) 2016/1215 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 (MST-FGØ72-2) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

**299.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.

**300.** For the heading to Article 5, substitute “Register”.

**301.** In Article 5, omit “Community”.

**302.** In the Annex—

(a) in point (f), omit “Community”;

(b) in point (h), omit “Community”;

(c) in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2016/1216**

**303.** Commission Implementing Decision (EU) 2016/1216 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87708 × MON 89788 (MON-877Ø8-9 × MON-89788-1) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

**304.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.

**305.** For the heading to Article 5, substitute “Register”.

**306.** In Article 5, omit “Community”.

**307.** In the Annex—

- (a) in point (f), omit “Community”;
- (b) in point (h), omit “Community”;
- (c) in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2016/1217**

**308.** Commission Implementing Decision (EU) 2016/1217 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87705 × MON 89788 (MON-87705-6 × MON-89788-1) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

**309.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.

**310.** In Article 5(2), for “Commission” substitute “Food Safety Authority”.

**311.** For the heading to Article 6, substitute “Register”.

**312.** In Article 6, omit “Community”.

**313.** In the Annex—

- (a) in point (f), omit “Community”;
- (b) in point (g)(1)(i), for “European Union” substitute “United Kingdom”;
- (c) in point (g)(1)(ii), for “Member State” substitute “the United Kingdom”;
- (d) in point (h), omit “Community”;
- (e) in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2016/1685**

**314.** Commission Implementing Decision (EU) 2016/185 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21, and genetically modified maize combining two or three of the events Bt11, MIR162, MIR604 and GA21, and repealing Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU is amended as follows.

**315.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.

**316.** In Article 5(2), for “Commission” substitute “Food Safety Authority”.

**317.** For the heading to Article 6, substitute “Register”.

**318.** In Article 6, omit “Community”.

**319.** In the Annex—

- (a) in point (f), omit “Community”;
- (b) in point (g)(1), for “Commission” substitute “Food Safety Authority”;
- (c) in point (h), omit “Community”;
- (d) in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2017/1208**

**320.** Commission Implementing Decision (EU) 2017/1208 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB119 (BCS-

GHØØ5-8) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed is amended as follows.

- 321. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 322. For the heading to Article 5, substitute “Register”.
- 323. In Article 5, omit “Community”.
- 324. In the Annex—
  - (a) in point (f), omit “Community”;
  - (b) in point (h), omit “Community”;
  - (c) in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2017/1209**

325. Commission Implementing Decision (EU) 2017/1209 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21, and genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21 pursuant to Regulation (EC) No. 1829/2003 of the European parliament and of the Council on genetically modified food and feed is amended as follows.

- 326. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 327. In Article 5(2), for “Commission” substitute “Food Safety Authority”.
- 328. For the heading to Article 6, substitute “Register”.
- 329. In Article 6, omit “Community”.
- 330. In the Annex—
  - (a) in point (f), omit “Community”;
  - (b) in point (g)(1), for “Commission” substitute “Food Safety Authority”;
  - (c) in point (h), omit “Community”;
  - (d) in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2017/1211**

331. Commission Implementing Decision (EU) 2017/1211 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 (DAS-24236-5 × DAS-21Ø23-5 × MON-88913-8) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

- 332. In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 333. For the heading to Article 5, substitute “Register”.
- 334. In Article 5, omit “Community”.
- 335. In the Annex, in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2017/1212**

336. Commission Implementing Decision (EU) 2017/1212 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize DAS-40278-9,

pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and the Council is amended as follows.

**337.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.

**338.** For the heading to Article 5, substitute “Register”.

**339.** In Article 5, omit “Community”.

**340.** In the Annex—

(a) in point (f), omit “Community”;

(b) in point (g), omit “Community”;

(c) in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2017/2448**

**341.** Commission Implementing Decision (EU) 2017/2448 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 × 40-3-2 (DP-3Ø5423-1 × MON-Ø4Ø32-6) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed is amended as follows.

**342.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.

**343.** In Article 5(2), for “Commission”, substitute “Food Safety Authority”.

**344.** For the heading to Article 6, substitute “Register”.

**345.** In Article 6, omit “Community”.

**346.** In the Annex—

(a) in point (f), omit “Community”;

(b) in point (g)(1)(i), for “European Union” substitute “United Kingdom”;

(c) in point (g)(1)(ii), for “Member State” substitute “the United Kingdom”;

(d) in point (h), omit “Community”;

(e) in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2017/2449**

**347.** Commission Implementing Decision (EU) 2017/2449 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-68416-4, pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed is amended as follows.

**348.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.

**349.** For the heading to Article 6, substitute “Register”.

**350.** In Article 6, omit “Community”.

**351.** In the Annex—

(a) in point (f), omit “Community”;

(b) in point (h), omit “Community”;

(c) in the Note, in the final sentence, omit “Community”.

### **Amendment of Commission Implementing Decision (EU) 2017/2450**

**352.** Commission Implementing Decision (EU) 2017/2450 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-44406-6, pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed is amended as follows.

**353.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.

**354.** For the heading to Article 6, substitute “Register”.

**355.** In Article 6, omit “Community”.

**356.** In the Annex—

(a) in point (f), omit “Community”;

(b) in point (h), omit “Community”;

(c) in the Note, in the final sentence, omit “Community”.

### **Amendment of Commission Implementing Decision (EU) 2017/2451**

**357.** Commission Implementing Decision (EU) 2017/2451 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 × A5547-127, pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed is amended as follows.

**358.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.

**359.** For the heading to Article 6, substitute “Register”.

**360.** In Article 6, omit “Community”.

**361.** In the Annex—

(a) in point (f), omit “Community”;

(b) in point (h), omit “Community”;

(c) in the Note, in the final sentence, omit “Community”.

### **Amendment of Commission Implementing Decision (EU) 2017/2452**

**362.** Commission Implementing Decision (EU) 2017/2452 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

**363.** In Article 5(2), for “Commission” substitute “Food Safety Authority”.

**364.** For the heading to Article 6, substitute “Register”.

**365.** In Article 6, omit “Community”.

**366.** In the Annex—

(a) in point (f), omit “Community”;

(b) in point (h), omit “Community”;

(c) in the Note, in the final sentence, omit “Community”.

### **Amendment of Commission Implementing Decision (EU) 2017/2453**

**367.** Commission Implementing Decision (EU) 2017/2453 of 21 December 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rapes MON 88302 × Ms8 × Rf3 (MON-88302-9 × ACSBN005-8 × ACS-BN003-6), MON 88302 × Ms8 (MON-88302-9 × ACSBN005-8) and MON 88302 × Rf3 (MON-88302-9 × ACS-BN003-6) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed is amended as follows.

**368.** In Article 5(2), for “Commission” substitute “Food Safety Authority”.

**369.** For the heading to Article 6, substitute “Register”.

**370.** In Article 6, omit “Community”.

**371.** In the Annex—

(a) in point (f), omit “Community”;

(b) in point (h), omit “Community”;

(c) in the Note, in the final sentence, omit “Community”.

### **Amendment of Commission Implementing Decision (EU) 2018/1109**

**372.** Commission Implementing Decision (EU) 2018/1109 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council is amended as follows.

**373.** In Article 5(2), for “Commission” substitute “Food Safety Authority”.

**374.** For the heading to Article 6, substitute “Register”.

**375.** In Article 6, omit “Community”.

### **Amendment of Commission Implementing Decision (EU) 2018/1110**

**376.** Commission Implementing Decision (EU) 2018/1110 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 × MON 810 × NK603, and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603, and repealing Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU is amended as follows.

**377.** In Article 5(2), for “Commission” substitute “Food Safety Authority”.

**378.** For the heading to Article 6, substitute “Register”.

**379.** In Article 6, omit “Community”;

**380.** In the Annex—

(a) in point (f), omit “Community”;

(b) in point (h), omit “Community”;

(c) in the Note, in the final sentence, omit “Community”.

### **Amendment of Commission Implementing Decision (EU) 2018/1111**

**381.** Commission Implementing Decision (EU) 2018/1111 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × NK603 (MON-87427-7 × MON-89034-3 × MON-00603-6) and genetically

modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealing [Decision 2010/420/EU](#) is amended as follows.

- 382.** In Article 4(2), for “Commission” substitute “Food Safety Authority”.
- 383.** For the heading to Article 6, substitute “Register”.
- 384.** In Article 6, omit “Community”.
- 385.** In the Annex—
  - (a) in point (f), omit “Community”;
  - (b) in point (h), omit “Community”;
  - (c) in the Note, in the final sentence, omit “Community”.

#### **Amendment of Commission Implementing Decision (EU) 2018/1112**

**386.** Commission Implementing Decision (EU) 2018/1112 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21 (MON-ØØØ21-9) pursuant to Regulation [\(EC\) No. 1829/2003](#) of the European Parliament and of the Council is amended as follows.

- 387.** In Article 5(2), for “Commission” substitute “Food Safety Authority”.
- 388.** For the heading to Article 6, substitute “Register”.
- 389.** In Article 6, omit “Community”.

## PART 4

### Revocation of retained direct EU legislation

#### **Revocation of [Commission Regulation \(EC\) No. 1981/2006](#)**

**390.** [Commission Regulation \(EC\) No. 1981/2006](#) on detailed rules for the implementation of Article 32 of Regulation [\(EC\) No. 1829/2003](#) of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms is revoked.

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

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



## 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 genetically modified food and animal feed. Part 2 amends subordinate legislation in England. Part 3 amends retained direct EU legislation for the whole of the United Kingdom. Part 4 revokes retained direct EU legislation 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.