

## SCHEDULE 4

Regulation 10

### Insertion of Schedule 4 into the 2019 Regulations

After Schedule 3 to the 2019 Regulations (Amendments to Annex II to the EEA Agreement) insert—

## “SCHEDULE 4

Regulation 5

### Savings, transitional and consequential provision

#### **Provision relating to Regulation (EC) No 1272/2008**

1. In relation to Great Britain, a classification which, immediately before IP completion day, is set out in Table 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures is to be treated as if it were approved by the Secretary of State in accordance with Article 37A of Regulation (EC) No 1272/2008.

#### **Provision relating to Regulation (EU) No 528/2012**

2.—(1) After Article 95 of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, insert—

#### **“95A Transitional measures for simplified notification procedure**

1. Where, before IP completion day, a product was authorised in a country which was a Member State of the EU other than the United Kingdom in accordance with Article 26 of Regulation (EU) No 528/2012, and was placed on the market in the United Kingdom in accordance with Article 27 of Regulation (EU) No 528/2012—

- (a) it is to be treated as if it were authorised by the competent authority under Article 26 of this Regulation, and
- (b) the competent authority must grant an authorisation under Article 26 of this Regulation.

2. The authorisation must be cancelled and Article 52 of this Regulation will apply where—

- (a) the authorisation holder is not established in the United Kingdom within 12 months from IP completion day, or
- (b) the authorisation holder does not supply the competent authority with relevant scientific and authorisation data by whichever is the earlier of the following—
  - (i) the date of any application for renewal or the date of any application for amendment of the authorisation under Article 50 of this Regulation, or
  - (ii) within 60 days of any request made by the competent authority to the authorisation holder.

#### **95B Transitional measures for mutual recognition applications**

1. This Article applies where—

- (a) an application for mutual recognition of a national authorisation of a biocidal product was made before IP completion day in accordance with Articles 33, 34 or 39 of Regulation (EU) No 528/2012, and
- (b) a decision was not made before IP completion day.

**Draft Legislation:** This is a draft item of legislation. This draft has since been made as a UK Statutory Instrument: *The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 No. 1567*

2. Paragraphs 3, 4, 7 and 8 apply where the United Kingdom was the reference Member State, before exit day, for an application for mutual recognition under Article 34 of Regulation (EU) No 528/2012.

3. The application for mutual recognition is to be treated as having been made under Article 29 of this Regulation, and the time limits under Articles 29 and 30 are suspended until—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or
- (b) where the applicant relies on a letter of access, whichever is the later of the following—
  - (i) the applicant resubmits the application, or
  - (ii) the data owner resubmits the data.

4. On receipt of the resubmitted application and data to the competent authority, the time limits under Articles 29 and 30 of this Regulation apply, less any time which expired between the date of acceptance of the application and data under Article 34 of Regulation (EU) No 528/2012 and exit day.

5. Paragraphs 6, 7 and 8 apply where, before IP completion day, the United Kingdom was the Member State concerned in relation to an application for mutual recognition under Articles 33, 34 or 39 of Regulation (EU) No 528/2012.

6. The application is to be treated as having been made under Article 29 of this Regulation, and the time limits under Articles 29 and 30 apply from—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or
- (b) where the application relies on a letter of access, whichever is the later of the following—
  - (i) the applicant resubmits the application, or
  - (ii) the data owner resubmits the data.

7. Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9).

8. Anything done before IP completion day by the United Kingdom competent authority, where the United Kingdom was either the Member State concerned or the reference Member State, is taken as having been done by the competent authority under this Regulation.

9. The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

10. The resubmission of any application and data referred to in paragraph 6 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

#### **Article 95C Renewal of authorisations subject to mutual recognition under Regulation 492/2014**

1. This Article applies where—

- (a) an application for the renewal of a biocidal product authorisation subject to mutual recognition was made before IP completion day in accordance with Article 3 of Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014

supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for renewal of authorisations of biocidal products subject to mutual recognition, and

- (b) a decision on the renewal of the authorisation was not made before IP completion day.

2. Paragraph 3 applies where, before exit day, the United Kingdom was the reference Member State for an application for renewal.

3. The application is to be treated as having been made under Article 31 of this Regulation and the time limits under Article 31 are suspended until—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or
- (b) where the applicant relies on a letter of access, whichever is the later of the following—
  - (i) the applicant resubmits the application, or
  - (ii) the data owner resubmits the data.

4. On receipt of the resubmitted application and data by the competent authority, the time limits under Articles 30 and 31 (where applicable) of this Regulation apply less any time which expired between the date of acceptance of the application and data under Articles 3 and 4 of Regulation (EU) No 492/2014 and exit day.

5. Paragraph 6 applies where, before IP completion day, the United Kingdom was the Member State concerned for an application for renewal.

6. The application is to be treated as having been made under Article 31 of this Regulation, and the time limits under Articles 30 and 31 apply from—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or
- (b) where the applicant relies on a letter of access, whichever is the later of the following—
  - (i) the applicant resubmits the application, or
  - (ii) the data owner resubmits the data.

7. Anything done before IP completion day by the United Kingdom, either as the Member State concerned or as the reference Member State, is taken as having been done by the competent authority under this Regulation.

8. The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

9. The resubmission of any application and data referred to in paragraph 6 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

10. Where the applicant or authorisation holder does not meet the requirements of this Article—

- (a) the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9), and
- (b) the authorisation must be cancelled by the competent authority and Article 52 applies.

#### **Article 95D Transitional measure for national authorisation applications**

1. This Article applies where—
  - (a) an application was made before IP completion day to the United Kingdom competent authority under Articles 29 or 31 of Regulation (EU) No 528/2012, and
  - (b) a decision was not made before IP completion day.
2. The application is to be treated as having been made under this Regulation and the time limits under Articles 29, 30 and 31 as appropriate apply from—
  - (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or
  - (b) where the applicant relies on a letter of access, whichever is the later of the following—
    - (i) the applicant resubmits the application, or
    - (ii) the data owner resubmits the data.
3. Where the applicant or authorisation holder does not meet the requirements of this Article, the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9).
4. Anything done before IP completion day by the United Kingdom competent authority as the receiving competent authority is taken as having been done by the competent authority under this Regulation.
5. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

#### **Article 95E Transitional measures simplified authorisation applications**

1. This Article applies where—
  - (a) an application was made to the United Kingdom competent authority before IP completion day under Articles 25 or 26 of Regulation (EU) No 528/2012, and
  - (b) a decision was not made before IP completion day.
2. Where the application was made to the United Kingdom competent authority as the receiving competent authority, the application is to be treated as having been made under this Regulation and the time limits under Article 26 apply from—
  - (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or
  - (b) where the applicant relies on a letter of access, whichever is the later of the following—
    - (i) the applicant resubmits the application, or
    - (ii) the data owner resubmits the data.
3. In a case where an application was made but the United Kingdom competent authority was not the receiving competent authority, the application is to be treated as having been made under this Regulation and the time limits under Article 26 apply from—
  - (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or
  - (b) where the applicant relies on a letter of access, whichever is the later of the following—

- (i) the applicant resubmits the application, or
- (ii) the data owner resubmits the data.

4. Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9).

5. Anything done before IP completion day by the United Kingdom competent authority as the receiving competent authority is taken as having been done by the competent authority under this Regulation.

6. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

7. The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

#### **Article 95F Transitional measures for applications for same biocidal product authorisations**

1. This Article applies where—

- (a) an application was made to the United Kingdom competent authority before IP completion day under Articles 3 or 4 of Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council, and
- (b) a decision was not made before IP completion day.

2. The application is to be treated as having been made under Articles 3 or 4 (as appropriate) of Regulation (EU) No 414/2013 and the time limits under those Articles are apply from—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or
- (b) where the applicant relies on a letter of access, whichever is the later of the following—
  - (i) the applicant resubmits the application, or
  - (ii) the data owner resubmits the data.

3. Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9).

4. For the purposes of this Article, data submitted by the applicant or the data owner must include relevant data for the reference product.

5. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

#### **Article 95G Transitional measures for Regulation (EU) No 528/2012 authorisations**

1. This Article applies to authorisations granted by the United Kingdom competent authority before IP completion day under Articles 19, 26, 30, 31, 33, 34, 36, 39 or 44 of Regulation (EU) No 528/2012.

2. The authorisation is to be treated as if it were authorised by the competent authority under the relevant Article of this Regulation.

3. The authorisation must be cancelled and Article 52 of this Regulation will apply where—

- (a) the authorisation holder is not established in the United Kingdom within 12 months after IP completion day, or
- (b) the authorisation holder does not supply the competent authority with relevant scientific and authorisation data by whichever is the earlier of the following—
  - (i) the date of any application for renewal or for amendment of the authorisation under Article 50 of this Regulation, or
  - (ii) within 60 days of any request made by the competent authority to the authorisation holder.

#### **Article 95H Transitional measures for ongoing applications for Union authorisations**

1. This Article applies where—

- (a) an application for Union authorisation was made before IP completion day in accordance with Articles 42, 43 or 45 of Regulation (EU) No 528/2012, and
- (b) a decision was not made before IP completion day.

2. Paragraph 3 applies where, before IP completion day, the United Kingdom competent authority was the evaluating competent authority for applications for Union authorisations made under Regulation (EU) No 528/2012.

3. The application is to be treated as being made under Articles 29 or 31 of this Regulation and the time limits under Articles 29, 30 or 31 are suspended until—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or
- (b) where the applicant relies on a letter of access, whichever is the later of the following—
  - (i) the applicant resubmits the application, or
  - (ii) the data owner resubmits the data.

4. On receipt of the resubmitted application and data to the competent authority, the time limits under Article 29, 30 or 31 of this Regulation apply less any time which expired between the date of acceptance of the application and data under Articles 43, 44, 45 or 46 of Regulation (EU) No 528/2012 and exit day.

5. Paragraph 6 applies to those ongoing Union authorisation applications made under Regulation (EU) No 528/2012 where the United Kingdom competent authority was not the evaluating competent authority.

6. The application is to be treated as having been made under Articles 29, 30 or 31 of this Regulation, and the time limits under those Articles apply from—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

- (i) the applicant resubmits the application, or
- (ii) the data owner resubmits the data.

7. Where the applicant or authorisation holder does not meet the requirements of this Article, the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9).

8. Anything done before IP completion day by the United Kingdom competent authority as the evaluating competent authority is taken as having been done by the competent authority under this Regulation.

9. The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

10. The resubmission of any application and data referred to in paragraph 6 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

#### **Article 95I Transitional measures for Article 95 List**

1. This Article applies to the list prepared pursuant to Article 95 of Regulation (EU) No 528/2012 (“the Article 95 pre-IP completion day List”) of active substances and persons having made submissions in relation to those active substances.

2. Subject to paragraph 3, from IP completion day the entries included in the Article 95 pre-IP completion day List are to be included in the list prepared pursuant to Article 95 of this Regulation (“the Article 95 List”).

3. An entry on the Article 95 List must be removed if either of the following conditions are not met within 2 years from IP completion day—

- (a) the person must be established in the United Kingdom;
- (b) the person must provide to the competent authority any of the following—
  - (i) a complete dossier for the relevant active substance;
  - (ii) a reference to a complete active substance dossier for which all data protection periods have expired and the competent authority is able to obtain all the data;
  - (iii) a letter of access to a complete active substance dossier, where that dossier has been submitted to the competent authority within 2 years of IP completion day.

4. Where an entry is removed from the Article 95 List for reasons beyond the control of the supplier of a biocidal product containing the relevant active substance, the competent authority may grant a period of grace for the making available on the market of that biocidal product, except in cases where the continued making available on the market of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

5. A period of grace in excess of 180 days may only be granted under paragraph 4 in exceptional circumstances.

6. Where a period of grace is granted in accordance with paragraph 4, and the supplier of a biocidal product does not comply with the second subparagraph of Article 95(1) during that period, the prohibition in Article 95(2) applies.

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**Article 95J Transitional measure for active substance applications made to the United Kingdom competent authority before 30 March 2019 and subsequently reallocated**

1. This Article applies where—
  - (a) an application was made to the United Kingdom competent authority as evaluating competent authority before 30 March 2019 under Article 7 of Regulation (EU) No 528/2012,
  - (b) the competent authority had not completed its evaluation of the application before IP completion day due to the evaluation being reallocated at EU level, and
  - (c) a decision was not made before IP completion day.
2. An application referred to in paragraph 1 is to be treated as if it were made under Article 7 of this Regulation, and the time limits in Articles 7 and 8 are suspended until—
  - (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or
  - (b) where the application relies on a letter of access, whichever is the later of the following—
    - (i) the applicant resubmits the application, or
    - (ii) the data owner resubmits the data.
3. On receipt of the resubmitted application and data by the competent authority, the time limits under Articles 7 and 8 apply, less any time which expired between the date of acceptance of the application and data under Article 7 of Regulation (EU) No 528/2012 and—
  - (a) 30 March 2019 for active substances listed in the Annex to Commission Delegated Regulation (EU) 2019/227, or
  - (b) exit day for other substances.
4. Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority.
5. Anything done before exit day by the competent authority as the evaluating competent authority under Regulation (EU) No 528/2012 is taken as having been done by the competent authority under this Regulation.
6. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

**Article 95K Transitional measure for active substance applications made before IP completion day pursuant to Article 93 where the United Kingdom competent authority was not the evaluating competent authority**

1. This Article applies where—
  - (a) an application to approve an active substance was made before IP completion day under Article 7 of Regulation (EU) No 528/2012 and in compliance with point (a) of Article 93,
  - (b) the United Kingdom competent authority was not the evaluating competent authority, and
  - (c) a decision was not made before IP completion day.
2. An application referred to in paragraph 1 is to be treated as if it were made under Article 7 of this Regulation, and the time limits under Articles 7 and 8 apply from—



- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or
- (b) where the application relies on a letter of access, whichever is the later of the following—
  - (i) the applicant resubmits the application, or
  - (ii) the data owner resubmits the data.

3. Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority.

4. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

#### **Article 95L Transitional measures for renewal of an approval of an active substance**

1. This Article applies where—

- (a) an application for renewal of an approval of an active substance was made before IP completion day in accordance with Article 13 of Regulation (EU) No 528/2012, and
- (b) a decision was not made before IP completion day.

2. Where the United Kingdom competent authority was the evaluating competent authority before exit day, the application is to be treated as if it were made under Article 13 of this Regulation, and the time limits under Articles 13 and 14 are suspended until—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or
- (b) where the application relies on a letter of access, whichever is the later of the following—
  - (i) the applicant resubmits the application, or
  - (ii) the data owner resubmits the data.

3. On receipt of the resubmitted application and data by the competent authority, the time limits under Articles 13 and 14 of this Regulation apply less any time which expired between the date of acceptance of the application and data under Article 13 and 30 March 2019.

4. Where the United Kingdom competent authority was not the evaluating competent authority before exit day, the application is to be treated as if it were made under Article 13 of this Regulation and the time limits under Articles 13 and 14 apply from—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or
- (b) where the application relies on a letter of access, whichever is the later of the following—
  - (i) the applicant resubmits the application, or
  - (ii) the data owner resubmits the data.

5. Where the applicant does not meet the requirements of this Article, the approval must not be renewed by the competent authority and Article 52 applies to any biocidal product containing the active substance.

6. Anything done before IP completion day by the United Kingdom competent authority as the evaluating competent authority under Regulation (EU) No 528/2012 is taken as having been done by the competent authority under this Regulation.

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7. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

8. The resubmission of any application and data referred to in paragraph 4 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

#### **Article 95M Transitional measures for ongoing applications to change or amend authorisations**

1. This Article applies where—

- (a) an application was made before IP completion day to the United Kingdom competent authority under Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation EU (No) 528/2012 of the European Parliament and of the Council, and
- (b) a decision was not made before IP completion day.

2. An application referred to in paragraph 1 is to be treated as having been made under Regulation (EU) No 354/2013 and the time limits under that Regulation apply from—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or
- (b) where the application relies on a letter of access, whichever is the later of the following—
  - (i) the applicant resubmits the application, or
  - (ii) the data owner resubmits the data.

3. Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority.

4. For the purposes of this Article, data submitted by the applicant or the data owner for changes to authorisations issued under Commission Implementing Regulation (EU) No 414/2013 must include relevant data on the reference product.

5. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

#### **Article 95N Interpretation of Articles 95A to 95M**

1. For the purposes of Articles 95A to 95M, the following definitions apply—

“evaluating competent authority” has the meaning given in Article 7 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day;

“Member State concerned” has the meaning given in Articles 33 and 34 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day;

“receiving competent authority” has the meaning given in Article 17 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day;

“reference Member State” has the meaning given in Articles 33 and 34 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day.”.

### **Provision relating to critical use permits**

3.—(1) This paragraph applies where—

- (a) before IP completion day, the United Kingdom competent authority granted a permit under the first subparagraph of Article 55(1) of Regulation (EU) No 528/2012 for a period not exceeding 180 days, and
- (b) on receipt of a reasoned request from the United Kingdom competent authority, the Commission granted an extension of that permit under the third subparagraph of Article 55(1) of Regulation (EU) No 528/2012 until IP completion day.

(2) The extension referred to in paragraph (1)(b) is to be taken as having been granted for a period of 550 days from the date when the Commission granted the extension referred to.

### **Provision relating to the Simplified Active Substance List**

4.—(1) Any chemical which is included in Annex I to Regulation (EU) No 528/2012 immediately before IP completion day, is on IP completion day—

- (a) if from categories 1 to 5 of Annex I, to be included in category A of the Simplified Active Substance List;
- (b) if from category 6 of Annex I, to be included in category B of the Simplified Active Substance List;
- (c) if from category 7 of Annex I, to be included in category C of the Simplified Active Substance List.

(2) In Regulation (EU) No 528/2012, in Article 95(6), for “categories 1 to 5 and category 7” substitute “categories A and C”.

(3) In Regulation 1062/2014—

- (a) in Article 3(1), for “category 1, 2, 3, 4, 5 or 6” substitute “categories A or B”;
- (b) in Article 6(1)(c), for “category 1, 2, 3, 4 or 5” substitute “category A”;
- (c) in Article 7(2), for “category 1, 2, 3, 4, 5 or 6” substitute “categories A or B”.

### **Provision relating to Regulation (EU) No 649/2012**

5.—(1) A chemical which, immediately before IP completion day, is listed in Annex I or Annex V to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals is to be treated as having been included in the GB PIC list and assigned to one or more of five groups of chemicals in the GB PIC list by the Secretary of State on IP completion day in accordance with Article 7 of Regulation (EU) No 649/2012.

(2) In paragraph (1), “GB PIC list” means the list established and maintained in accordance with Articles 7 and 23 of Regulation (EU) No 649/2012 as amended by Schedule 2.

(3) This paragraph applies to the following—

- (a) any export notification made by an exporter under Article 8 of Regulation (EU) No 649/2012, and
- (b) any explicit consent received by an exporter through the exporter’s designated national authority under Article 14(6) of that Regulation.

(4) Any export notification or explicit consent to which paragraph (3) applies, which continues to be effective on or after IP completion day by virtue of Part 3 of Schedule 8 to the European Union (Withdrawal) Act 2018, is to be treated as if it were made or obtained under Regulation (EU) No 649/2012 on or after IP completion day.

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(5) Any export notification or explicit consent to which paragraph (3) applies, which was processed by the Designated National Authority for Great Britain during the months leading up to IP completion day in accordance with the rules which are provided for in these Regulations, is to be treated as if it were made or obtained under Regulation (EU) No 649/2012 on or after IP completion day.

#### **EU implementing Regulations**

6. Where, as a result of these Regulations, any provision of retained direct EU legislation imposes an obligation on the Secretary of State to make regulations, that obligation is to be treated as having been met in a case where, before IP completion day, the European Commission adopted a delegated act under that provision.”