

SCHEDULE 2

AMENDMENTS TO RETAINED DIRECT EU LEGISLATION

Regulation (EU) No 528/2012

137. After Article 95 insert—

“Article 95A

Transitional measures for simplified notification procedure

1. Where a product was authorised in a country which was a Member State of the EU other than the United Kingdom prior to exit day in accordance with Article 26 of Regulation (EU) No 528/2012 and 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 shall grant an authorisation under Article 26 of this Regulation.

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

- (a) the authorisation holder is not established in the United Kingdom within 12 months after exit day; or
- (b) the authorisation holder does not supply the competent authority with relevant scientific and authorisation data—
 - (i) by the date of any application for an amendment to 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

whichever is earlier.

Article 95B

Transitional measures for mutual recognition applications

1. This Article applies where an application for mutual recognition of a national authorisation of a biocidal product has been made before exit day in accordance with Article 33, 34 or 39 of this Regulation and where a decision on authorisation had not been made before exit day.

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 shall be treated as having been made under Article 29 of this Regulation and the time limits under Articles 29 and 30 shall be suspended until—

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

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- (b) where the applicant relies on a letter of access, whichever is the later of the date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

4. On receipt of the resubmitted application and data to the competent authority, the time limits under Articles 29 and 30 of this Regulation shall 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 the United Kingdom was, before exit day, 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 shall be treated as having been made under Article 29 of this Regulation and shall be subject to the time limits under Articles 29 and 30 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 date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 180 days from exit day.

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

8. Anything done before exit day by the United Kingdom, either as the Member State concerned or as the reference Member State is taken to have been done by the competent authority under this Regulation.

Article 95C

Renewal of authorisations subject to mutual recognition under Regulation 492/2014

1. This Article applies where an application for the renewal of a biocidal product authorisation subject to mutual recognition was made before exit day in accordance with Article 3 of Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition, where a decision on the renewal of the authorisation had not been made before exit day.

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

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

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- (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 date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

4. On receipt of the resubmitted application and data to the competent authority, the time limits under Articles 30 and 31 (where applicable) of this Regulation shall 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⁽¹⁾ and exit day.

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

6. The application shall be treated as having been made under Article 31 of this Regulation and shall be subject to the time limits under Articles 30 and 31 (where applicable) 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 date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 180 days from exit day.

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

Article 95D

Transitional measures for national authorisation applications

1. This Article shall apply to an application made, before exit day, under Article 29 or Article 31 of Regulation (EU) No 528/2012 and where a decision on authorisation or renewal has not been made before exit day.

2. The application shall be treated as having been made under this Regulation and the time limits under Articles 29, 30 and 31 as appropriate shall be 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 date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

(1) OJ L 139, 14.5.2014, p. 1–6

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in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

3. Where the applicant does not meet the requirements of this Article, the application shall be—

- (a) cancelled by the competent authority and Article 52 shall apply; or
- (b) rejected by the competent authority and Article 89(11) shall apply as if the application had been submitted in accordance with Article 89(9).

4. Anything done before exit day by the United Kingdom, as the receiving competent authority, is taken to have been done by the competent authority under this Regulation.

Article 95E

Transitional Measures Simplified Authorisation Applications

1. This Article shall apply to an application made before exit day under Article 25 or 26 of Regulation (EU) No 528/2012 and where a decision on authorisation has not been made before exit day.

2. Where the application was made to the United Kingdom as the receiving competent authority, the application shall be treated as having been made under this Regulation and the time limits under Article 26 shall be 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 date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

3. Where the application was made and the United Kingdom was not the receiving competent authority, the application shall be treated as having been made under this Regulation and the time limits under Article 26 shall be suspended until the date on which—

- (a) the applicant resubmits the application and any supporting data to the competent authority; or
- (b) where the applicant relies on a letter of access—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 180 days from exit day.

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

5. Anything done before exit day by the United Kingdom, as the receiving competent authority, is taken to have been done by the competent authority under this Regulation.

Article 95F

Transitional measures for applications for same biocidal product authorisations

1. This Article applies to an application under Article 3 or 4a 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⁽²⁾, and where a decision on authorisation has not been made before exit day.

2. The application shall be treated as having been made under Article 3 or 4a (as appropriate) of Regulation 414/2013 and the time limits under those Articles shall be suspended until—

- (a) the date on which the applicant either 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 date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

3. Where the applicant does not meet the requirements of this Article, the application shall be rejected by the competent authority and Article 89(11) shall apply 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 shall include relevant data on the reference product.

Article 95G

Transitional measures for Regulation (EU) No 528/2012 authorisations

1. This Article applies to authorisations granted before exit 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 shall be cancelled and Article 52 of this Regulation shall apply where—

- (a) the authorisation holder is not established in the United Kingdom within 365 days after exit day; or
- (b) the authorisation holder does not supply the competent authority with relevant scientific and authorisation data—
 - (i) by the date of any application for renewal or the date of any application for amendment to the authorisation under Article 50; or
 - (ii) within 60 days of any request made by the competent authority to the authorisation holder

whichever is earlier.

(2) OJ L 125, 7.5.2013, p.4-6.

Article 95H

Transitional measures for ongoing applications for Union authorisations

1. This Article applies to an application for Union authorisation made in accordance with Article 42, 43 or 45 and evaluated under either Article 44 or Article 46 of Regulation (EU) No 528/2012, and where a decision on authorisation has not been made before exit day.

2. Paragraph 3 applies where, prior to exit day, the United Kingdom was the evaluating competent authority for applications for Union authorisation made under Regulation (EU) No 528/2012.

3. The application shall be taken as being made under Article 29 or 31 of this Regulation and the time limits under Article 29, 30 or 31 shall be 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 date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

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 shall apply less any time which expired between the date of acceptance of the application and data under Article 43, 44, 45 or 46 of Regulation (EU) No 528/2012 and exit day.

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

6. The application shall be treated as having been made under Article 29, 30 or 31 of this Regulation and shall be subject to the time limits under those Articles 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 date on which:
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided the date is within 180 days from exit day.

7. Where the applicant or authorisation holder does not meet the requirements of this Article, the application shall be—

- (a) cancelled by the competent authority and Article 52 shall apply; or
- (b) rejected by the competent authority and Article 89(11) shall apply as if the application had been submitted in accordance with Article 89(9).

8. Anything done before exit day by the United Kingdom, as the evaluating competent authority, is taken to have been done by the competent authority under this Regulation.

Article 95I

Transitional measures 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-exit day List”).

2. The entries included on the Article 95 pre-exit day List shall be included in the list prepared pursuant to Article 95 of this regulation (“the Article 95 List”) subject to paragraph 3 below.

3. An entry on the Article 95 List shall be removed if the following conditions are not met within 2 years from exit day—

- (a) the person is established in the United Kingdom; and
- (b) the person provides to the competent authority—
 - (i) a complete substance dossier for the relevant substance;
 - (ii) a reference to a complete 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 the complete substance dossier and the data owner has submitted the data to the competent authority and the competent authority holds the data after exit 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.

A period of grace in excess of 180 days may only be granted in exceptional circumstances.

5. Where a period of grace is granted and the supplier of a biocidal product does not comply with Article 95 (2) in that period the prohibition in Article 95 (2) shall apply.

Article 95J

Transitional measures active substance applications

1. This Article applies to applications made before exit day under Article 7 of Regulation (EU) No 528/2012.

2. Where the United Kingdom was the evaluating competent authority and has not concluded its evaluation of an application before exit day, the application is to be treated as if it were made under Article 7 of this Regulation and the time limits under Articles 7 and 8 shall be 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 date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

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3. On receipt of the resubmitted application and data to the competent authority, the time limits under Articles 7 and 8 shall 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 exit day.

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

5. Anything done before exit day by the United Kingdom as the evaluating competent authority under Regulation (EU) No 528/2012 is to be taken to have been done by the competent authority under this Regulation.

Article 95K

Transitional measures application for renewal of an approval of an active substance

1. This Article shall apply where an application for renewal of an approval of an active substance was made in accordance with Article 13 of Regulation (EU) No 528/2012.

2. Where the United Kingdom was the evaluating competent authority and has not concluded its evaluation of an application 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 shall be 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 date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

3. On receipt of the resubmitted application and data by the competent authority, the time limits under Articles 13 and 14 of this Regulation shall apply less any time which expired between the date of acceptance of the application and data under Article 13 Regulation (EU) No 528/2012 and exit day.

4. Where the United Kingdom was not the evaluating competent authority and the evaluation of the application has not been concluded 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 shall be 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 date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 180 days from exit day.

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

6. Anything done before exit day by the United Kingdom as the evaluating competent authority under Regulation (EU) No 528/2012 is to be taken to have been done by the competent authority under this Regulation.

Article 95L

Transitional measures for ongoing applications to change or amend authorisations

1. This Article applies to an application 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.

2. The application shall be treated as having been made under Regulation 354/2013 and the time limits under that Regulation shall be suspended until—

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

in accordance with Article 71 of this Regulation, provided this date is within 180 days from exit day.

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

4. For the purposes of this Article, data submitted by the applicant or the data owner shall include relevant data on the reference product.”