

## SCHEDULE 2

### AMENDMENTS TO RETAINED DIRECT EU LEGISLATION

#### **Regulation (EU) No 528/2012**

**130.** For Article 89, substitute—

*“Article 89*

*Existing transitional measures*

1. The competent authority shall carry on with the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of [Directive 98/8/EC](#) with the aim of achieving it by 31 December 2024.

2. The Secretary of State may by regulations—

- (a) extend the date for the systematic examination of all existing active substances referred to in this Article;
- (b) specify matters in relation to the carrying out of the work programme and the related rights and obligations of the competent authority and the participants in the programme.

3. Where any of the Devolved Authorities makes proposals in relation to regulations under paragraph 2, the Secretary of State must have regard to such proposals in deciding whether to exercise functions under that paragraph.

4. Regulations made under paragraph 2 above are subject to the consent requirement.

5. In order to facilitate a smooth transition from [Directive 98/8/EC](#) to this Regulation, during the work programme the Secretary of State shall either issue decisions providing that an active substance is approved, and under which conditions, or, in cases where the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, issue decisions stating that an active substance is not approved. Decisions approving an active substance shall specify the date of approval. Article 9(2) shall apply.

6. A decision made under paragraph 5 is subject to the consent requirement.

7. By way of derogation from Articles 17(1), 19(1) and 20(1) of this Regulation, and without prejudice to paragraphs 1, 2 and 9 of this Article, the current system or practice of making available on the market or using a given biocidal product continues to apply for up to three years after the date of approval of the last of the active substances to be approved in that biocidal product. The competent authority may, in accordance with the current system or practice, authorise the making available on the market or use of a biocidal product containing only—

- (a) existing active substances which—
  - (i) have been evaluated under [Commission Regulation \(EC\) No 1062/2014](#) but which have not yet been approved of that product-type;
  - (ii) are being evaluated under that Regulation but have not yet been approved for that product-type; or
- (b) a combination of active substances referred to in point (a) and active substances approved in accordance with this Regulation.

**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 2019 No. 720*

**8.** By way of derogation from paragraph 7, in the case of a decision not to approve an active substance, the competent authority may continue to apply its current system or practice of making biocidal products available on the market for up to 12 months after the date of the decision not to approve an active substance in accordance with paragraph 5, and may continue to apply the current system or practice of using biocidal products for up to 18 months after that decision.

**9.** Following a decision to approve a particular active substance for a specific product-type, the competent authority shall ensure that authorisations for biocidal products of that product-type and containing that active substance are granted, modified or cancelled, as appropriate, in accordance with this Regulation within three years of the date of approval.

To that effect, those wishing to apply for the authorisation of biocidal products of that product-type containing no active substances other than existing active substances shall submit applications for authorisation no later than the date of approval of the active substance or substances. In the case of biocidal products containing more than one active substance, applications shall be submitted no later than the date of approval of the last active substance for that product-type.

**10.** Where no application for authorisation has been submitted in accordance with paragraph 9 above—

- (a) the biocidal product shall no longer be made available on the market with effect from 180 days after the date of approval of the active substance or substances; and
- (b) use of existing stocks of the biocidal product may continue for up to 365 days after the date of approval of the active substance or substances.

**11.** Where the competent authority decides to reject an application submitted in accordance with paragraph 9 for authorisation of a biocidal product already made available on the market, or decides not to grant an authorisation or to impose conditions for the authorisation making it necessary to change such a product, the following shall apply—

- (a) a biocidal product which has not been authorised or, where relevant, which does not comply with the conditions of the authorisation, shall no longer be made available on the market with effect from 180 days after the date of the decision of the competent authority; and
- (b) use of existing stocks of the biocidal product may continue for up to 365 days after the date of the decision of the competent authority.”