SCHEDULE 2

Amendment of Schedule 2 to the 2019 Regulations

Amendments relating to Regulation (EU) No 528/2012 ("the Biocides Regulation")

27. After paragraph 78 (amendment of Article 17 of the Biocides Regulation, insert—

"**78A.** After Article 17 insert—

"**Article 17A NI Product Market Access**

1. Subject to paragraphs 5-8, a biocidal product is to be treated as if it was authorised by the competent authority under Article 30 or, where relevant, Article 26, under the same terms and conditions as the product is authorised or permitted in Northern Ireland where—

(a) each of the following conditions are met—

(i) the biocidal product—

(aa) is a qualifying Northern Ireland good, and

(bb) has a Relevant NI Permission at that time;

(ii) the authorisation holder or the person with a Relevant NI Permission (as the case may be) is established in Northern Ireland;

(iii) all the active substances in the biocidal product are entered in—

(aa) the list prepared pursuant to Article 8A (the GB List), or

(bb) the list prepared pursuant to Article 24A (the Simplified Active Substance List);

(iv) the person referred to in point (a)(ii) notifies the competent authority no later than 90 days in advance of making the biocidal product available on the market by submitting in full to the competent authority the information that the person submitted in their application under Regulation (EU) No 528/2012 as it has effect in EU law to the evaluating competent authority, reference Member State(**1**) or Northern Ireland competent authority (as the case may be), for the Relevant NI Permission together with a copy of any relevant NI authorisation or permit;

(v) the competent authority takes no action pursuant to paragraph 2;

(b) if the person referred to in point (a)(ii) intends to make any changes to the product, that person notifies the competent authority no later than 90 days in advance of the date on which such changes will apply, with the information submitted to the reference Member State pursuant to Article 5 of Commission Implementing Regulation (EU) No 354/2013 as it has effect in EU law, or for administrative changes other than those referred to in the second subparagraph of Article 6(2) of that Regulation, that person notifies the competent authority within 12 months of making the change;

(c) if the person referred to in point (a)(ii) intends to renew the authorisation of the product in Northern Ireland, that person notifies the competent

(**1**) "reference Member State" has the meaning given by Article 33 of Regulation (EU) No 528/2012 as it has effect in EU law.

authority no later than 90 days in advance of the date of renewal by submitting in full the information that the person submitted to the reference Member State pursuant to Articles 31(1) or 45(1) of Regulation (EU) No 528/2012 as it has effect in EU law or, where relevant, Article 2 of Commission Delegated Regulation (EU) No 492/2014 as it has effect in EU law.

2. The competent authority may prohibit a biocidal product notified under paragraph 1 from being made available on the market in Great Britain where—

(a) such action can be justified on any of the following grounds—

(i) the protection of the environment,

(ii) public policy or security,

(iii) the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants,

(iv) the protection of national treasures possessing artistic, historic or archaeological value,

(v) the target organisms not being present in harmful quantities, or

(b) the competent authority considers that the biocidal product does not meet the criteria set out in Articles 19 or 25.

3. The competent authority may amend the terms and conditions under which a biocidal product may be made available on the market in Great Britain where—

(a) this can be justified on the grounds in paragraph 2(a), or

(b) the competent authority considers that the biocidal product does not meet the criteria set out in Articles 19 or 25.

4. Where the competent authority intends to take action under paragraphs 2 or 3, or identifies concerns as to whether the biocidal product meets the criteria in Articles 19 or 25, the competent authority—

(a) must inform the notifier, and

(b) may request additional information.

5. The period of 90 days referred to in paragraphs 1(a)(iv), (b) and (c) is suspended—

(a) where the competent authority takes action under paragraph 4(b), until the competent authority receives the additional information, and

(b) from the point when the competent authority receives the additional information, for a further period of 90 days to allow the competent authority to consider that additional information.

6. Where any information submitted to the competent authority under this Article includes one or more letters of access, the competent authority may reject the letter of access(**2**) where it does not hold the relevant data.

7. Where the additional information has not been submitted to the competent authority within 90 days of a request under paragraph 4(b), the notification made under paragraph 1 is to be treated as withdrawn.

8. Where the competent authority has amended the terms and conditions under which a biocidal product may be made available on the market under paragraph 3,

(**2**) "Letter of access" has the meaning given by Article 3(1)(t) of Regulation (EU) No 528/2012 as it has effect in EU law.

that product must not be made available and used in Great Britain other than under those amended terms and conditions.

9. Where a biocidal product has been treated as authorised due to meeting the requirements of paragraph 1 but ceases to satisfy those requirements—

(a) there is deemed to be a cancellation of the authorisation of that product by the competent authority, and

(b) the period of grace provided for in Article 52 applies.

10. For the purposes of this Article—

(a) "NI competent authority" means the competent authority appointed by regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013;

(b) "qualifying Northern Ireland good" has the meaning given by regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

(c) "Relevant NI Permission" means any of the following—

(i) a national authorisation granted by the NI competent authority under Article 30 of Regulation (EU) No 528/2012 as it has effect in EU law or under Article 5 of Regulation (EU) No 414/2013 as it has effect in EU law;

(ii) an authorisation granted by mutual recognition by the NI competent authority under Articles 33 or 34 of Regulation (EU) No 528/2012 as it has effect in EU law;

(iii) a Union authorisation granted by the Commission under Article 44 of Regulation (EU) No 528/2012 as it has effect in EU law or under Article 6 of Regulation (EU) No 414/2013 as it has effect in EU law;

(iv) an authorisation granted by the NI competent authority under the simplified procedure in accordance with Article 26 of Regulation (EU) No 528/2012 as it has effect in EU law or Article 6a of Regulation (EU) No 414/2013 as it has effect in EU law;

(v) a biocidal product permitted on the market by the NI competent authority under the Parallel Trade procedure in Article 53(1) of Regulation (EU) No 528/2012 as it has effect in EU law;

(vi) a critical use permit granted in Northern Ireland under Article 55(1) of Regulation (EU) No 528/2012 as it has effect in EU law;

(vii) a provisional authorisation under Article 55(2) of Regulation (EU) No 528/2012 as it has effect in EU law;

(viii) a cultural heritage authorisation granted under Article 55(3) of Regulation (EU) No 528/2012 as it has effect in EU law;

(ix) an essential use authorisation granted under regulation 12 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013.".".