SCHEDULE 2

AMENDMENTS TO RETAINED DIRECT EU LEGISLATION

Regulation (EU) No 528/2012

64.—(1) Article 3 is amended as follows.

(2) In paragraph 1—

(a) in point (d), after the words "on 14 May 2000" insert ", in a country which was a Member State of the EU on that date,";

(b) in point (e), after the words "on 14 May 2000" insert "in a country which was a Member State of the EU on that date";

(c) in point (f), omit the first indent;

(d) in point (k), for "Union" substitute "United Kingdom";

(e) in point (m)—

(i) omit "of a Member State";

(ii) omit "in its territory or part thereof";

(f) for point (n), substitute—

"(n) 'Union authorisation' means the administrative act by which the Commission authorised the making available on the market and use of a biocidal product or a product family in the territory of the Union or part thereof before exit day;";

(g) in point (o), omit ", Union authorisation";

(h) in point (p)—

(i) for "within the Union" substitute "in the United Kingdom";

(ii) for "a particular Member State or in the Union" substitute "the United Kingdom";

(i) in point (t), for "competent authorities, the Agency, or the Commission" insert "the competent authority";

(j) omit point (x);

(k) after point (ae) insert—

"(af) 'the consent requirement' means the requirement for consent in accordance with Article 83B;

(ag) 'the UK List' means the list of approved substances established and maintained in accordance with Article 8A;

(ah) 'the Simplified Active Substance List' means the list of active substances which can be used in biocidal products that qualify for the simplified authorisation procedure, established and maintained in accordance with Article 24A.

(ai) 'appropriate fee' means the fee payable for the activity concerned in—

(i) regulations made under section 43 of the Health and Safety at Work etc. Act 1974(**1**) where the competent authority is appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013(**2**); or

(**1**) 1974 c. 37.
(**2**) S.I. 2013/1506.

(ii) regulations made under Article 40 of the Health and Safety at Work (Northern Ireland) Order 1978(**3**) where the competent authority is appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013(**4**).

(ah) 'Devolved Authority' means:

(i) the Scottish Ministers,

(ii) the Welsh Ministers, or

(iii) a Northern Ireland department."

(3) For paragraphs 3 and 4, substitute—

"**3.** The Secretary of State may issue a decision which is to be published, as to whether a substance is a nanomaterial, having regard in particular to Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial and whether a specific product or group of products is a biocidal product or a treated article or neither.

4. A decision issued under paragraph 3 above is subject to the consent requirement.

5. The Secretary of State may by regulations adapt the definition of nanomaterial set out in point (z) of paragraph 1 of this Article in view of technical and scientific progress, taking into account the Recommendation referred to in paragraph 3 above.

6. Regulations made under paragraph 5 above are subject to the consent requirement.

7. Where any of the Devolved Authorities makes proposals in relation to adaptations under paragraph 5 above, the Secretary of State must have regard to such proposals in deciding whether to exercise functions in that paragraph."

(**3**) S.I. 1978/1039 (N.I. 9).
(**4**) S.R. 2013 No. 206.