

## SCHEDULE 1

### Amendment of Titles 1 To 15

## PART 8

### Amendment of Title 8: Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles

#### Chapter 1 of Title 8

**53.**—(1) Article 67 is amended as follows.

(2) In paragraph 2—

(a) for “[Directive 76/768/EEC](#)” substitute “Regulation 1223/2009”;

(b) for “Directive”, in the second place it occurs, substitute “Regulation”.

(3) Omit paragraph 3.

#### Chapter 2 of Title 8

**54.**—(1) Article 68 is amended as follows.

(2) In paragraph 1—

(a) in the first sentence—

(i) omit “which needs to be addressed on a Community wide basis,”;

(ii) for “in accordance with the procedure referred to in Article 133(4) by adopting new restrictions or amending” substitute “by regulations made by the Secretary of State which provide for the adoption of new restrictions or the amendment of”;

(b) in the second sentence, for “Any such decision” substitute “In exercising the power to make regulations under this paragraph, the Secretary of State”.

(3) In paragraph 2, for the words from “and for which” to “Article 133(4).” substitute “the Secretary of State may propose restrictions. The function of proposing restrictions is subject to the consent requirement in Article 4A. The Secretary of State may, by regulations, amend Annex 17 to give effect to a proposed restriction.”.

(4) After paragraph 2 insert—

“**3.** Regulations under paragraph 2 of this Article are to be made by statutory instrument; and a statutory instrument containing regulations made under paragraph 2 of this Article is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under paragraph 2 of this Article is subject to the consent requirement in Article 4A.”.

**55.**—(1) Article 69 is amended as follows.

(2) In paragraph 1, for “the Commission”, substitute “an appropriate authority”;

(3) In paragraph 3—

(a) for “the Commission”, substitute “an appropriate authority”;

(b) omit “on a Community wide basis”.

(4) For paragraph 4 substitute—

“4. If the Agency considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, the Agency must prepare a dossier which conforms to the requirements and format of the relevant sections of Annex 15. If this dossier demonstrates that action is necessary, beyond any measures already in place, the Agency must initiate the restrictions process and must inform those who submitted a registration for that substance.

The Agency must refer to any dossier, chemical safety report or risk assessment submitted to it under this Regulation. The Agency must also refer to any relevant risk assessment submitted for other regulatory purposes. To this end other public bodies carrying out a similar task must provide information to the Agency on request.”.

(5) For paragraph 5 substitute—

“5. The Agency must maintain a list of substances for which a dossier conforming to the requirements of Annex 15 is planned or underway for the purposes of a proposed restriction.”.

(6) After paragraph 5, insert—

“5A. The Agency or an appropriate authority may propose the re-examination of an existing restriction listed in Annex 17.

If the Agency is proposing the re-examination, it must notify the appropriate authorities of the proposal. If an appropriate authority is proposing a re-examination, it must notify the Agency and the other appropriate authorities of the proposal. Where a re-examination is proposed (by the Agency or an appropriate authority), the Secretary of State must decide, on the basis of evidence presented by whoever proposed the re-examination, whether the re-examination should take place. That function of deciding whether the re-examination should take place is subject to the consent requirement in Article 4A. If the Secretary of State decides that the re-examination should take place, the Agency must carry out the re-examination.”.

**56.**—(1) Article 70 is amended as follows.

(2) In the heading, for “Committee for Risk Assessment” substitute “risk assessment”.

(3) In the Article—

(a) for “Committee for Risk Assessment” substitute “Agency”;

(b) for the words from “Member State” to “Commission” substitute “dossier”.

**57.**—(1) Article 71 is amended as follows.

(2) In the heading for “Committee for Socio-economic Analysis” substitute “socio-economic analysis”.

(3) In paragraphs 1 and 2, for “Committee for Socio-economic Analysis” substitute “Agency”.

(4) Omit paragraph 3.

**58.**—(1) Article 72 is amended as follows.

(2) In the heading, for “Commission” substitute “appropriate authorities”.

(3) In paragraph 1—

(a) in the first sentence—

(i) for “Commission”, substitute “appropriate authorities”;

- (ii) for “the opinions of the Committee for Risk Assessment and Socio-economic Analysis” substitute “its opinions on risk assessment and socio-economic analysis”;
- (b) in the last sentence—
  - (i) for “one or both of the Committees do” substitute “the Agency does”;
  - (ii) for “Commission” substitute “appropriate authorities”.
- (4) In paragraph 2, for “the opinions of the two Committees” substitute “its opinions”.
- (5) In paragraph 3, for “Commission and/or Member State on request” substitute “appropriate authorities that request them”.

**59.**—(1) Article 73 is amended as follows.

- (2) For the heading substitute “Restriction decisions”.
- (3) In paragraph 1—
  - (a) in the first subparagraph—
    - (i) for “Commission shall prepare”, substitute “Secretary of State must propose”;
    - (ii) for the words from “the opinion of the Committee for Socio-economic Analysis” to “whichever is the earlier” substitute “the Agency’s opinions”;
    - (iii) at the end, insert “The functions of deciding whether to propose a draft amendment, and of proposing a draft amendment, are subject to the consent requirement in Article 4A.”;
  - (b) in the second subparagraph, for “Commission” substitute “Secretary of State”.
- (4) For paragraph 2 substitute—

“**2.** The Secretary of State may, by regulations, amend Annex 17 to include the draft amendment.

Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations made under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this Article is subject to the consent requirement in Article 4A.”.