

SCHEDULE 2

AMENDMENTS TO RETAINED DIRECT EU LEGISLATION

Regulation (EU) No 528/2012

136.—(1) Article 95 is amended as follows.

(2) In paragraph 1—

(a) in the first subparagraph—

(i) for “As of 1 September 2013, the Agency” substitute “The competent authority”;

(ii) for “has been” substitute “is”;

(iii) for “a Member State” substitute “the competent authority”;

(iv) in the final sentence, for “Agency” substitute “competent authority”;

(b) in the second subparagraph—

(i) for “Union” substitute “United Kingdom”;

(ii) for “Agency” in both places it occurs substitute “competent authority”;

(iii) for “letter of access to a complete substance dossier” substitute “letter of access which provides the competent authority with access to a complete substance dossier”;

(iv) in the last sentence omit “evaluating”;

(c) in the third subparagraph—

(i) for “Agency” substitute “competent authority”;

(ii) for “fees payable under Article 80(1)” substitute “appropriate fees”;

(d) in the fourth subparagraph—

(i) for “fees payable under Article 80(1)” substitute “appropriate fees”;

(ii) for “Agency” substitute “competent authority”.

(3) In paragraph 4, after the words “Article 20(1)” insert “, where that letter of access gives the competent authority direct access to the information, and where the competent authority holds the relevant data”.

(4) In paragraph 6, for “Annex I” substitute “the Simplified Active Substance List”.

(5) In paragraph 7, for “Agency” in both places it occurs substitute “competent authority”.

(6) After paragraph 7, insert—

“**8.** The competent authority may refuse to accept a letter of access for the purposes of this Article if they do not hold the relevant data.”