

SCHEDULE 2

AMENDMENTS TO RETAINED DIRECT EU LEGISLATION

Regulation (EU) No 528/2012

68.—(1) Article 8 is amended as follows.

(2) In the first subparagraph of paragraph 1—

- (a) omit “evaluating”;
- (b) for “send” substitute “produce”;
- (c) for “the conclusions of its evaluation to the Agency” substitute “evaluation conclusions”.

(3) For the second subparagraph of paragraph 1 substitute—

“The competent authority shall give the applicant the opportunity to provide written comments on the assessment report and on the conclusions of the evaluation within 30 days. The competent authority shall take due account of those comments.”

(4) In paragraph 2—

- (a) omit “evaluating” in both places it occurs;
- (b) omit “, and shall inform the Agency accordingly”.

(5) After paragraph 2, insert—

“**2A.** The competent authority may request from the applicant available information on, and take into account, evaluations undertaken by third countries in order to complete its evaluation. The weight given to those third country evaluations shall take into account the equivalence of the evaluation process.”

(6) In paragraph 3, omit “evaluating”.

(7) For paragraph 4 substitute—

“**4.** Within 270 days of producing its assessment reports and evaluation conclusions the competent authority shall prepare and submit an opinion on the approval of the active substance to the Secretary of State and the Devolved Authorities.”