

SCHEDULE 2

AMENDMENTS TO RETAINED DIRECT EU LEGISLATION

Regulation (EU) No 528/2012

141.—(1) Annex III is amended as follows.

(2) In paragraph 2—

- (a) in the fourth subparagraph, for “Agency” substitute “competent authority”;
- (b) in the sixth subparagraph, for “available on the website of the Agency” substitute “to be made available online by the competent authority”;
- (c) in the seventh subparagraph, omit “that will evaluate the dossier”;
- (d) in the eighth subparagraph, omit “or Article 44(2)”.

(3) For paragraph 4, substitute

“**4.** Dossiers must be formatted, prepared and submitted in accordance with the data requirements and guidance as specified by the competent authority.”

(4) In paragraph 6, for “Commission or the Agency” substitute “competent authority”.

(5) In paragraph 8, omit “of the Member State”.