

SCHEDULE 34

Amendment of Regulation (EC) No 1223/2009 and related amendments

Amendment of Article 11

11. In Article 11 (product information file)—

- (a) in point (e) for “his” substitute “their”;
- (b) for paragraph 3 substitute—

“**3.** The responsible person must make the product information file readily accessible to a competent authority in an electronic or other format at the address notified in accordance with Article 13 as the address at which the product information file is kept.”;

- (c) for paragraph 4 substitute—

“**4.** The information contained in the product information file must be in English”.