

SCHEDULE 34

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

Substitution of Article 16

16. For Article 16 (nanomaterials) substitute—

“Article 16

Nanomaterials

- 1.** The provisions of this Article do not apply to nanomaterials used as colourants, UV-filters or preservatives that are regulated under Article 14.
- 2.** A cosmetic product containing nanomaterials must be notified in accordance with paragraph 3.
- 3.** To meet the requirements of paragraph 2, the information set out in paragraph 4 must be submitted by electronic means—
 - (a) to the Secretary of State;
 - (b) by the responsible person; and
 - (c) at least six months prior to the cosmetic product being placed on the market.
- 4.** The information referred to in paragraph 3 must contain—
 - (a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes 2 to 6 to this Regulation;
 - (b) the specification of the nanomaterial including size of particles and chemical properties;
 - (c) an estimate of the quantity of nanomaterials contained in cosmetic products intended to be placed on the market per year;
 - (d) except where paragraph 13 applies, the toxicological profile of the nanomaterial;
 - (e) the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products;
 - (f) the reasonably foreseeable exposure conditions.
- 5.** Paragraph 6 applies in relation to a cosmetic product containing nanomaterials where prior to exit day—
 - (a) the cosmetic product has been supplied on the market of the United Kingdom or the market of any EEA state for distribution, consumption or use in the course of a commercial activity (whether in return for payment or free of charge); and
 - (b) a responsible person designated under Article 4 of the EU Regulation (pre-exit) has complied with Article 16 of that Regulation in relation to that product.
- 6.** Where this paragraph applies—
 - (a) if the cosmetic product containing nanomaterials is placed on the market at any time before the expiry of the transitory period, subject to subparagraph (b) paragraphs 2 and 3 are to have effect as if they required the information specified in paragraph 4 before the end of the transitory period; and
 - (b) paragraphs 2 and 3 are to be treated as being satisfied in respect of the cosmetic product where—

Status: This is the original version (as it was originally made).

- (i) before the end of the transitory period, the responsible person for the cosmetic product submits to the Secretary of State by electronic means the information set out in paragraph 4; and
 - (ii) when submitting that information, the responsible person at the same time gives notice confirming the matters set out in paragraph 5 in relation to the cosmetic product;
 - (c) if at any time a request is made to the responsible person by a competent authority in accordance with paragraphs 9 and 10, the responsible person must comply with the request within the period specified in the request.
7. Paragraph 8 applies in relation to a cosmetic product containing nanomaterials where—
- (a) prior to exit day a responsible person designated under Article 4 of the EU Regulation (pre-exit) has complied with the requirements of Article 16 of that Regulation in relation to that product; and
 - (b) the period between the day on which exit day falls and the day on which the person designated under Article 4 of the EU Regulation (pre-exit) complied with Article 16 of that Regulation is less than six months.
8. Where this paragraph applies—
- (a) paragraphs 2 and 3 are to be treated as being satisfied where—
 - (i) a period of 7 months has elapsed between the day on which the responsible person designated under Article 4 of the EU Regulation (pre-exit) complied with Article 16 of that Regulation and the day on which the responsible person places the cosmetic product on the market;
 - (ii) before the expiry of the transitory period, the responsible person for that cosmetic product submits to the Secretary of State the information set out in paragraph 4; and
 - (iii) when submitting that information, the responsible person at the same time gives notice confirming the matters set out in paragraph 7; and
 - (b) if at any time a request is made to the responsible person by a competent authority in accordance with paragraphs 9 and 10, the responsible person must comply with the request within the period specified in the request.
9. Where a competent authority has concerns regarding the safety of a nanomaterial, the competent authority may request that a responsible person submits the following information to the competent authority—
- (a) which nanomaterials are used in a cosmetic product; and
 - (b) the reasonably foreseeable exposure conditions.
10. When a competent authority makes a request under paragraph 9, the competent authority must specify a period—
- (a) within which the responsible person must respond; and
 - (b) which is reasonable and commensurate with the nature of the concerns held by the competent authority.
11. Where paragraph 12 applies, the information set out in paragraph 4 may be provided by the person designated in accordance with that paragraph on behalf of the responsible person.
12. This paragraph applies where—

- (a) the responsible person designates another person by written mandate to meet the notification requirements under this Article in respect of a cosmetic product on that responsible person's behalf ("the designated person");
- (b) the designated person accepts the designation in writing; and
- (c) the responsible person informs the Secretary of State of the name and address of that designated person.

13. The Secretary of State may provide a reference for the toxicological profile and that reference may be provided in the place of the information referred to in paragraph 4(d)".