

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 [F1IP completion 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

Changes to legislation: *There are currently no known outstanding effects for the The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, Paragraph 16. (See end of Document for details)*

- (b) paragraphs 2 and 3 are to be treated as being satisfied in respect of the cosmetic product where—
 - (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 [F1IP completion 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 [F1IP completion 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.

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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).”

F1 Words in Sch. 34 para. 16 substituted (31.12.2020 immediately before IP completion day) by [The Product Safety and Metrology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/852\)](#), regs. 2(2), 4(2), **Sch. 1 para. 1(t)(v)**

Commencement Information

II Sch. 34 para. 16 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), **Sch. 5 para. 1(1)**), see [reg. 1](#)

Changes to legislation:

There are currently no known outstanding effects for the The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, Paragraph 16.