

Regulation (EC) No 1223/2009 of the European Parliament and of the Council  
of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance)

CHAPTER IV

**RESTRICTIONS FOR CERTAIN SUBSTANCES**

*[<sup>F1</sup>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 IP 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
  - b paragraphs 2 and 3 are to be treated as being satisfied in respect of the cosmetic product where—

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1223/2009 of the European Parliament and of the Council, Article 16. (See end of Document for details)*

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- 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 IP 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 IP 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.
- 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—

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- 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).]

**Textual Amendments**

- F1** Art. 16 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 34 para. 16** (as amended by S.I. 2020/676, regs. 1(1), 3 and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(t)(v)**); 2020 c. 1, **Sch. 5 para. 1(1)**

**Changes to legislation:**

There are currently no known outstanding effects for the Regulation (EC) No 1223/2009 of the European Parliament and of the Council, Article 16.