

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 III

SAFETY ASSESSMENT, PRODUCT INFORMATION FILE, NOTIFICATION

Article 10

Safety assessment

1 In order to demonstrate that a cosmetic product complies with Article 3, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I.

The responsible person shall ensure that:

- a the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment;
- b an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources;
- c the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market.

^{F1} ...

2 The cosmetic product safety assessment, as set out in Part B of Annex I shall be carried out by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognised as equivalent by [^{F2}the Secretary of State].

3 Non-clinical safety studies referred to in the safety assessment according to paragraph 1 and carried out after 30 June 1988 for the purpose of assessing the safety of a cosmetic product [^{F3}must comply with the Good Laboratory Practice Regulations 1999], or with ^{F4}... international standards recognised as being equivalent by the [^{F5}Secretary of State].

Textual Amendments

- F1** Words in Art. 10(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 34 para. 10(a) (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)
- F2** Words in Art. 10(2) 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. 10(b) (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)
- F3** Words in Art. 10(3) 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. 10(c)(i) (as amended by S.I. 2020/676, regs. 1(1), 3); 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 10. (See end of Document for details)

- F4** Word in Art. 10(3) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 34 para. 10(c)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in Art. 10(3) 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. 10(c)(iii)** (as amended by S.I. 2020/676, regs. 1(1), 3); 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 10.