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 **[**F2the 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 **[**F3must comply with the Good Laboratory Practice Regulations 1999**]**, or with F4... international standards recognised as being equivalent by the **[**F5Secretary 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)

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)

Article 11

Product information file

1 When a cosmetic product is placed on the market, the responsible person shall keep a product information file for it. The product information file shall be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.

2 The product information file shall contain the following information and data which shall be updated as necessary:

a a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;

b the cosmetic product safety report referred to in Article 10(1);

c a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8;

d where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product;

e data on any animal testing performed by the manufacturer, **[**[F6]their**]** agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.

[[F7]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.**]**

[[F8]4 The information contained in the product information file must be in English.**]**

Textual Amendments

F6 Word in Art. 11(2)(e) 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. 11(a)** (as amended by S.I. 2020/676, regs. 1(1), **3**); 2020 c. 1, **Sch. 5 para. 1(1)**

F7 Art. 11(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. 11(b)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F8 Art. 11(4) 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. 11(c)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

Article 12

Sampling and analysis

1 Sampling and analysis of cosmetic products shall be performed in a reliable and reproducible manner.

2 F9... Reliability and reproducibility shall be presumed if the method used is in accordance with the relevant **[**F10designated**]** standards F11....

Textual Amendments

F9 Words in Art. 12(2) 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. 12(a)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F10 Word in Art. 12(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. 12(b)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F11 Words in Art. 12(2) 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. 12(c)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

*I*F12*Article 13*

Notification

1 Before placing a cosmetic product on the market, the responsible person must submit by electronic means the following information to the Secretary of State—

a the category of cosmetic product and its name or names, enabling its specific identification;

b the name of the responsible person;

c the address at which the product information file in respect of the cosmetic product is kept;

d the contact details of a natural person to contact in the case of urgency;

e where applicable, the following information—

i presence of substances in the form of nanomaterials;

ii the identification including the chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes 2 to 6 to this Regulation; and

iii the reasonably foreseeable exposure conditions;

f the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as CMR substances of category 1A or 1B under Regulation (EC) No 1272/2008;

g the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

2 When a cosmetic product is placed on the market, the responsible person must notify to the Secretary of State the original labelling and, where reasonably legible, a photograph of the corresponding packaging

3 Paragraph 4 applies in relation to a cosmetic product 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 13 of that Regulation in relation to that product.

4 Where this paragraph applies—

a if the cosmetic product is placed on the market at any time before the expiry of the transitory period, subject to subparagraph (b), paragraphs 1 and 2 are to have effect as if they required the information specified in those paragraphs before the end of the transitory period;

b paragraph 1 is to be treated as being satisfied in respect of the cosmetic product and paragraph 2 does not apply in respect of that product where—

i before the expiry 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 points (a) to (d) and (g) of paragraph 1; and

ii when submitting that information, the responsible person at the same time gives notice confirming the matters set out in paragraph 3 in relation to the cosmetic product;

c if at any time a request is made to the responsible person by the Secretary of State in accordance with paragraphs 5 and 6, the responsible person must comply with the request within the period specified in the request.

5 Where the Secretary of State considers it necessary for the purposes of reducing a risk to human health, the Secretary of State may request that a responsible person submits the information referred to in paragraph 1(e) to (f) in relation to a cosmetic product to which paragraph 4 applies.

6 When making a request under paragraph 5 the Secretary of State must specify a period—

a within which the responsible person must respond; and

b which is reasonable and commensurate with the nature of the risk presented by the product.

7 The Secretary of State must make the following information available in relation to a cosmetic product to all other competent authorities—

a the information referred to in paragraph 1(a) to (f); and

b the information referred to in paragraph 2.

8 Competent authorities may only use the information referred to in paragraph 7 for the purposes of market surveillance, market analysis, evaluation and consumer information in the context of Articles 25 to 27.

9. The Secretary of State must without delay make the following information available to poison centres or similar bodies established in the United Kingdom—

a the information referred to in paragraph 1; and

b the information referred to in paragraph 2.

10. Those poison centres and similar bodies may only use that information for the purposes of medical treatment.

11. Where any information provided under this Article in relation to a cosmetic product changes, the responsible person must provide an update by electronic means to the Secretary of State without delay.**]**

Textual Amendments

F12 Art. 13 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. 13** (as amended by S.I. 2019/1246, regs. 1(3), **8(b)**; S.I. 2020/676, regs. 1(1), **3**; and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(t)(iv)**); 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, CHAPTER III.