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 II

SAFETY, RESPONSIBILITY, FREE MOVEMENT

Article 3

Safety

A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular, of the following:

(a) presentation including conformity with **[**F1the Food Imitations (Safety) Regulations 1989**]**;

(b) labelling;

(c) instructions for use and disposal;

(d) any other indication or information provided by the responsible person defined in Article 4.

The provision of warnings shall not exempt persons defined in Articles 2 and 4 from compliance with the other requirements laid down in this Regulation.

Textual Amendments

F1 Words in Art. 3(a) 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. 4** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

*I*F2*Article 4*

Responsible person

1 A cosmetic product may not be placed on the market unless there is a responsible person established in the United Kingdom in respect of the cosmetic product.

2 Subject to paragraphs 6 and 7, a manufacturer of a cosmetic product is the responsible person in respect of that product where—

a the manufacturer is established in the United Kingdom; and

b the cosmetic product—

i is manufactured in the United Kingdom; and

ii after manufacture but prior to placing on the market is not exported and imported back into the United Kingdom.

3 Where paragraph 4 applies the manufacturer must ensure that—

a there is a person established in the United Kingdom designated by written mandate as the responsible person in respect of the cosmetic product; and

b that person has agreed in writing to be the responsible person in respect of that cosmetic product.

4 This paragraph applies where—

a a manufacturer of a cosmetic product is established in a country outside the United Kingdom; and

b the cosmetic product—

i is manufactured in the United Kingdom; and

ii after manufacture but prior to placing on the market is not exported and imported back into the United Kingdom.

5 Subject to paragraphs 6 and 7, any importer placing a cosmetic product on the market is the responsible person in respect of that cosmetic product.

6 An importer or a manufacturer established in the United Kingdom may by written mandate designate a person established in the United Kingdom as the responsible person.

7. Where the person designated by the importer or the manufacturer under paragraph 6 accepts the designation in writing, that person is the responsible person.

8. A distributor is the responsible person in respect of a cosmetic product where that distributor—

a places a product on the market under the distributor's name or trademark; or

b modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected.**]**

Textual Amendments

F2 Art. 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. 5** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

Article 5

Obligations of responsible persons

1 **[**F3Subject to Article 5A**]** responsible persons shall ensure compliance with Articles 3, 8, 10, 11, 12, 13, 14, 15, 16, 17, 18, Article 19(1),(2) and (5), as well as Articles 20, 21, 23 and 24.

2 Responsible persons who consider or have reason to believe that a cosmetic product which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate.

Furthermore, where the cosmetic product presents a risk to human health, responsible persons shall immediately inform the competent F4... authorities F5..., giving details, in particular, of the non-compliance and of the corrective measures taken.

3 Responsible persons shall cooperate with these authorities, at the request of the latter, on any action to eliminate the risks posed by cosmetic products which they have made available on the market. In particular, responsible persons shall, further to a reasoned request from a

competent [F6]... authority, provide it with all the information and documentation necessary to demonstrate the conformity of specific aspects of the product [F7]....

[[F8]4 The information and documentation referred to in paragraph 3 must be in English.**]**

Textual Amendments

F3 Words in Art. 5(1) inserted (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. 6(ia)** (as inserted by S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 23(3)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F4 Word in Art. 5(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. 6(a)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F5 Words in Art. 5(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. 6(b)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F6 Word in Art. 5(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. 6(a)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F7 Words in Art. 5(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. 6(c)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F8 Art. 5(4) inserted (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. 6(d)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

[[F9]*Article 5A*

Obligations of responsible persons established in Northern Ireland

1. Where paragraph 3 applies, a responsible person is to be treated as complying with Articles 3, 8, 10 to 12, 14 to 18, 19(1), (2) and (5) and 20 to 24.

2 Where paragraph 4 applies, a responsible person is to be treated as complying with Articles 8, 10 to 12, 14 to 18, 19(1), (2) and (5) and 20 to 24.

3. This paragraph applies where—

a the responsible person—

i is established in Northern Ireland;

ii is a responsible person for the purposes of EU Regulation (Northern Ireland);

iii has complied with the obligations of a responsible person under Article 5 of EU Regulation (Northern Ireland); and

iv when submitting information under Article 13 the responsible person at the same time gives notice to the Secretary of State confirming the matters in points (i) to (iii); and

b the cosmetic product is qualifying Northern Ireland goods.

4. This paragraph applies where—

a the responsible person is a person—

i to which Article 2(i)(bb) applies; and

ii who gives notice to the Secretary of State when submitting information under Article 13 that a responsible person for the purposes of EU Regulation (Northern Ireland) has complied with the obligations of a responsible person under Article 5 of EU Regulation (Northern Ireland); and

b the cosmetic product is qualifying Northern Ireland goods.

5. In this Article—

"EU Regulation (Northern Ireland)" means Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30th December 2008 on cosmetic products (recast), as it has effect by virtue of the Protocol on Ireland/Northern Ireland in the withdrawal agreement.

"qualifying Northern Ireland goods" has the meaning given to it in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018.**]**

Textual Amendments

F9 Art. 5A inserted (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. 6** (as inserted by S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 23(4)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 6

Obligations of distributors

1 In the context of their activities, when making a cosmetic product available on the market, distributors shall act with due care in relation to applicable requirements.

2 Before making a cosmetic product available on the market distributors shall verify that:

— the labelling information provided for in Article 19(1)(a), (e) and (g) and Article 19(3) and (4) is present,

— the language requirements provided for in Article 19(5) are fulfilled,

— the date of minimum durability specified, where applicable under Article 19(1), has not passed.

3 Where distributors consider or have reason to believe that:

— a cosmetic product is not in conformity with the requirements laid down in this Regulation, they shall not make the product available on the market until it has been brought into conformity with the applicable requirements,

— a cosmetic product which they have made available on the market is not in conformity with this Regulation, they shall make sure that the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate, are taken.

Furthermore, where the cosmetic product presents a risk to human health, distributors shall immediately inform the responsible person and the competent **F10**... authorities **F11**..., giving details, in particular, of the non-compliance and of the corrective measures taken.

4 Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in this Regulation.

5 Distributors shall cooperate with competent authorities, at the request of the latter, on any action to eliminate the risks posed by products which they have made available on the market. In particular, distributors shall, further to a reasoned request from a competent F12... authority, provide it with all the information and documentation necessary to demonstrate the conformity of the product with the requirements listed under paragraph 2 F13....

[F14 6 The information and documentation referred to in paragraph 5 must be in English.**]**

Textual Amendments

F10 Word in Art. 6(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. 7(a)(i)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F11 Words in Art. 6(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. 7(a)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F12 Word in Art. 6(5) 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. 7(b)(i)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F13 Words in Art. 6(5) 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. 7(b)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F14 Art. 6(6) inserted (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. 7(c)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

Article 7

Identification within the supply chain

At the request of a competent authority:

— responsible persons shall identify the distributors to whom they supply the cosmetic product,

— the distributor shall identify the distributor or the responsible person from whom, and the distributors to whom, the cosmetic product was supplied.

This obligation shall apply for a period of three years following the date on which the batch of the cosmetic product was made available to the distributor.

Article 8

Good manufacturing practice

1 The manufacture of cosmetic products shall comply with good manufacturing practice with a view to ensuring the objectives of Article 1.

2 Compliance with good manufacturing practice shall be presumed where the manufacture is in accordance with the relevant **[**F15 designated**]** standards F16....

Textual Amendments

F15 Word in Art. 8(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. 8(a)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F16 Words in Art. 8(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. 8(b)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F17 Article 9

Free movement

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Textual Amendments

F17 Art. 9 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. 9** (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, CHAPTER II.