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 VIII

NON-COMPLIANCE, SAFEGUARD CLAUSE

Article 25

Non-compliance by the responsible person

1 [F1]... Competent authorities shall require the responsible person to take all appropriate measures, including corrective actions bringing the cosmetic product into conformity, the withdrawal of the product from the market or its recall, within an expressly mentioned time limit, commensurate with the nature of the risk, where there is non-compliance with any of the following:

a the good manufacturing practice referred to in Article 8;

b the safety assessment referred to in Article 10;

c the requirements for the product information file referred to in Article 11;

d the provisions on sampling and analysis referred to in Article 12;

e the notification requirements referred to in Articles 13 and 16;

f the restrictions for substances referred to in Articles 14, 15 and 17;

g the animal testing requirements referred to in Article 18;

h the labelling requirements referred to in Article 19(1), (2), (5) and (6);

i the requirements related to product claims set out in Article 20;

j the access to information for the public referred to in Article 21;

k the communication of serious undesirable effects referred to in Article 23;

l the information requirements on substances referred to in Article 24.

[F2]2 . . . . . .

3 The responsible person shall ensure that the measures referred to in paragraph 1 are taken in respect of all the products concerned which are made available on the market [F3]....

[F4]4 . . . . . .

5 The competent authority shall take all appropriate measures to prohibit or restrict the making available on the market of the cosmetic product or to withdraw the product from the market or to recall it in the following cases:

a where an immediate action is necessary in the event of serious risk to human health; or

b where the responsible person does not take all appropriate measures within the time limit referred to in paragraph 1.

[F5]...

[[F6]6 In the event of serious risks to human health, a competent authority which has taken measures under paragraph 5 must inform all other competent authorities of the measures taken.**]**

[[F7]7 For the purposes of paragraph 6 the database provided for in regulation 33(A1) of the General Product Safety Regulations 2005 (S.I. 2005/1803) must be used.**]**

Textual Amendments

F1 Words in Art. 25(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. 23(a)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F2 Art. 25(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. 23(b)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in Art. 25(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. 23(c)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F4 Art. 25(4) 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. 23(d)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F5 Words in Art. 25(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. 23(e)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F6 Art. 25(6) 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. 23(f)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F7 Art. 25(7) 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. 23(g)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

Article 26

Non-compliance by distributors

Competent authorities shall require distributors to take all appropriate measures, including corrective actions bringing the cosmetic product into conformity, the withdrawal of the product from the market or its recall, within a given reasonable time limit, commensurate with the nature of the risk, where there is non-compliance with obligations laid down in Article 6.

Article 27

Safeguard clause

1 In the case of products meeting the requirements listed in Article 25(1), where **[**[F8]an enforcement authority**]** ascertains, or has reasonable grounds for concern, that a cosmetic product or products made available on the market present or could present a serious risk to human health, it shall take all appropriate provisional measures in order to ensure that the product or products concerned are withdrawn, recalled or their availability is otherwise restricted.

[[F9]2 An enforcement authority which is not the Secretary of State must obtain authorisation from the Secretary of State by requesting the authorisation in accordance with regulation 11 of the Enforcement Regulations prior to taking provisional measures under this Article.**]**

3 The **[**[F10]Secretary of State must**]** determine, as soon as possible, whether the provisional measures referred to in paragraph 1 are justified or not. For that purpose **[**[F11]the

Secretary of State must**]**, whenever possible, consult **[**F12any person the Secretary of State considers has an interest in the measure**]**.

[F134 Where the provisional measures are justified the Secretary of State must give authorisation to the enforcement authority to take those measures.**]**

F145 . . . . . .

Textual Amendments

F8 Words in Art. 27(1) 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. 24(a)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F9 Art. 27(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. 24(b)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F10 Words in Art. 27(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. 24(c)(i)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F11 Words in Art. 27(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. 24(c)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F12 Words in Art. 27(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. 24(c)(iii)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F13 Art. 27(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. 24(d)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F14 Art. 27(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. 24(e)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

Article 28

Good administrative practices

1 Any decision taken pursuant to Articles 25 and 27 shall state the exact grounds on which it is based. It shall be notified by the competent authority without delay to the responsible person, who shall at the same time be informed of the remedies available to **[**F15that responsible person**]** under the law F16... and of the time limits to which remedies are subject.

2 Except in the case where immediate action is necessary for reasons of serious risk to human health, the responsible person shall have the opportunity to put forward **[**F17their**]** viewpoint before any decision is taken.

3 Where applicable, the provisions mentioned in paragraphs 1 and 2 shall apply with regard to the distributor for any decisions taken pursuant to Articles 26 and 27.

Textual Amendments

F15 Words in Art. 28(1) 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. 25(a)(i)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F16 Words in Art. 28(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. 25(a)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F17 Word in Art. 28(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. 25(b)** (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 VIII.