

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 I

SCOPE, DEFINITIONS

Article 2

Definitions

- 1 For the purposes of this Regulation, the following definitions shall apply:
- a ‘cosmetic product’ means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;
 - b ‘substance’ means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
 - c ‘mixture’ means a mixture or solution composed of two or more substances;
 - d ‘manufacturer’ means any ^{F1}... person who manufactures a cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under [^{F2}their] name or trademark;
 - e ‘distributor’ means any ^{F3}... person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the ^{F4}... market;
 - f ‘end user’ means either a consumer or professional using the cosmetic product;
 - g ‘making available on the market’ means any supply of a cosmetic product for distribution, consumption or use on the [^{F5}market of Great Britain] in the course of a commercial activity, whether in return for payment or free of charge [^{F6}and related expressions are to be construed accordingly];
 - [^{F7}h placing on the market’ means the first making available of a cosmetic product on the market of Great Britain on or after IP completion day and related expressions are to be construed accordingly;]
 - [^{F8}i “importer” means a person who—
 - aa is established in the United Kingdom and places a cosmetic product from a country outside of the United Kingdom on the market; or
 - bb is established in Northern Ireland and places a cosmetic product on the market that has been supplied to them for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge, from an EEA state;]
 - [^{F9}j]
 - k ‘nanomaterial’ means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm;

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- l ‘preservatives’ means substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic product;
- m ‘colorants’ means substances which are exclusively or mainly intended to colour the cosmetic product, the body as a whole or certain parts thereof, by absorption or reflection of visible light; in addition, precursors of oxidative hair colorants shall be deemed colorants;
- n ‘UV-filters’ means substances which are exclusively or mainly intended to protect the skin against certain UV radiation by absorbing, reflecting or scattering UV radiation;
- o ‘undesirable effect’ means an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product;
- p ‘serious undesirable effect’ means an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death;
- q ‘withdrawal’ means any measure aimed at preventing the making available on the market of a cosmetic product in the supply chain;
- r ‘recall’ means any measure aimed at achieving the return of a cosmetic product that has already been made available to the end user;
- s ‘frame formulation’ means a formulation which lists the category or function of ingredients and their maximum concentration in the cosmetic product or gives relevant quantitative and qualitative information whenever a cosmetic product is not covered or only partially covered by such a formulation. ^{F10}...
- [^{F11}t ‘Regulation (EC) No 1272/2008’ means Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16th December 2008 on classifications, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) 1907/2006;
- u ‘EU Regulation (pre-exit)’ means Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (recast)^{F12}, as it has effect immediately before IP completion day;
- v ‘Enforcement Regulations’ means the Cosmetic Products Enforcement Regulations 2013;
- va ‘CMR’ means carcinogenic, mutagenic or toxic for reproduction;
- w ‘competent authority’ has the meaning given to it in regulation 4 of the Enforcement Regulations;
- x ‘enforcement authority’ has the meaning given to it in regulation 2(1) of the Enforcement Regulations;
- y ‘finished cosmetic product’ means the cosmetic product in its final formulation, as placed on the market and made available to the end user, or its prototype;
- ya ‘historic animal testing data’ means data from any animal testing that was carried out before the date on which such testing was prohibited in accordance with Article 18 of the EU Regulation (pre-exit);
- z ‘prototype’ means a first model or design that has not been produced in batches, and from which the finished cosmetic product is copied or finally developed;
- za “the transitory period” means the period of 90 days beginning on the day after the day on which IP completion day falls.]

2 For the purposes of point (a) of paragraph 1, a substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product.

[^{F13}3 —

- 1 Subject to subparagraphs (6) and (7), in this Regulation a “designated standard” means a technical specification which is—
 - a adopted by a recognised standardisation body [^{F14}or an international standardising body], for repeated or continuous application, with which compliance is not compulsory; and
 - b designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.
- 2 For the purposes of subparagraph (1), a “technical specification” means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following—
 - a the characteristics required of a cosmetic product, including—
 - i levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and
 - ii the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and
 - b production methods and processes relating to the product, where these have an effect on the characteristics of the product.
- 3 For the purposes of this regulation a “recognised standardisation body” means any one of the following organisations—
 - a the European Committee for Standardisation (CEN);
 - b the European Committee for Electrotechnical Standardisation (Cenelec);
 - c the European Telecommunications Standards Institute (ETSI);
 - d the British Standards Institution (BSI).
- [^{F15}3A In this paragraph “international standardising body” has the same meaning as it has for the purposes of the Agreement on Technical Barriers to Trade, part of Annex 1A to the agreement establishing the World Trade Organisation signed at Marrakesh on 15 April 1994 (as modified from time to time).]
- 4 When considering whether the manner of publication of a reference is appropriate in accordance with subparagraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.
- 5 Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with [^{F16}such] technical specifications adopted by the other recognised standardisation bodies [^{F17}or by international standardising bodies as the Secretary of State considers to be relevant].
- 6 The Secretary of State may remove from publication the reference to a standard which has been published in accordance with subparagraph (1)(b).
- 7 Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.]

Textual Amendments

- F1** Words in Art. 2(1)(d) 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. 3(a)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

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- F2** Word in Art. 2(1)(d) 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. 3(a)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)
- F3** Words in Art. 2(1)(e) 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. 3(b)(i)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)
- F4** Word in Art. 2(1)(e) 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. 3(b)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in Art. 2(1)(g) 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. 3(c)(i)** (as substituted by S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 23(2)(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F6** Words in Art. 2(1)(g) 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. 3(c)(ii)** (as substituted by S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 23(2)(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F7** Art. 2(1)(h) 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. 3(d)** (as amended by S.I. 2020/676, regs. 1(1), 3; S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(t)(i)**); and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 23(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F8** Art. 2(1)(i) 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. 3(e)** (as substituted by S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 23(2)(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F9** Art. 2(1)(j) 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. 3(f)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)
- F10** Words in Art. 2(1)(s) 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. 3(g)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)
- F11** Art. 2(1)(t)-(za) 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. 3(h)** (as amended by S.I. 2019/1246, regs. 1(3), **8(a)(i)(ii)**); S.I. 2020/676, regs. 1(1), 3; and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(t)(ii)(iii)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F12** OJ L 342, 22.12.2009, p.59.
- F13** Art. 2.3 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. 3(i)** (as amended by S.I. 2020/676, regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)
- F14** Words in Art. 2.3(1)(a) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 19(a)**; S.I. 2020/1662, reg. 2(ee)
- F15** Art. 2.3(3A) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 19(b)**; S.I. 2020/1662, reg. 2(ee)
- F16** Word in Art. 2.3(5) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 19(c)(i)**; S.I. 2020/1662, reg. 2(ee)
- F17** Words in Art. 2.3(5) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 19(c)(ii)**; S.I. 2020/1662, reg. 2(ee)

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