

Overview of amendments to (EC) No 1223/2009

The purpose of this article is to give an overview of the amendments to Regulation (EC) No 1223/2009. When Regulation (EC) No 1223/2009 was published in 2009 some of the annexes were incomplete and contained a number of discrepancies compared with the annexes of Directive 76/768/EEC. Also since 2009 there have been a number of opinions from the Scientific Committee on Consumer Safety (SCCS) that have required changes to be made to the regulation. This article aims to summarise all the amendments to the regulation up to the end of 2014.

Regulation (EC) No 1223/2009

Cosmetics within Europe are regulated by Regulation (EC) No 1223/2009. Regulation (EC) No 1223/2009 came in to force on 11 January 2010 (twentieth day after its publication in the Official Journal of the European Union on 22 December 2009) and was fully implemented on 11 July 2013 when Directive 76/768/EEC was repealed. Regulation (EC) No 1223/2009 contains a number of annexes. Annex I is a description of what should be in the cosmetic product safety report, annex II is a list of substances prohibited in cosmetics, annex III is a list of substances which are restricted when used in cosmetic products, annex IV is a list of colorants permitted in cosmetics, annex V is a list of preservatives which are permitted in cosmetics, annex VI is a list of UV filters permitted in cosmetics, annex VII contains the symbols which can be used on packaging and containers, annex VIII is a list of validated alternative methods to animal testing, annex IX is a list of repealed directives and amendments and annex X is a correlation table of articles in Directive 76/768/EEC and Regulation (EC) No 1223/2009.

How is Regulation (EC) No 1223/2009 amended?

To amend Regulation (EC) No 1223/2009 the European Commission issues a commission regulation. The commission regulation gives the reasons why a change to Regulation (EC) No 1223/2009 is



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required, how the entries in the annexes will change, and when the changes will be implemented.

Commission Regulation (EU) No 344/2013

Commission Regulation (EU) No 344/2013 amended entries in annexes II, III, V and VI. It applies from 11 July 2013. The entries for 4-aminobenzoic acid and its esters, with the free amino group (annex II entry 167); verbena essential oils (annex II entry 450) and exudation of *Myroxylon pereirae* (Royle) Klotzsch (Peru balsam crude) when used as a fragrance ingredient (annex II entry 1136) have been amended. The European Commission has prohibited the use of 41 colours as hair dyes (annex II entries 1329-1338, 1340-1369, and 1372). Commission Regulation (EU) No 344/2013 also prohibits the use of hydroquinone with the exception of its use by professionals for artificial nail systems (annex II entry 1339); diethylene glycol except for trace levels as stated in annex II entry 1370 and phytonadione also known as vitamin K1 (annex II entry 1371).

Commission Regulation (EU) No 344/2013 amends the following entries in annex III: 8, 8a, 9 and 9a which are all hair dyes. The entry for diaminophenols (annex III entry 10) does not contain any information and is now blank. The entry for hydrogen peroxide and mixtures or compounds that release hydrogen peroxide has been amended (annex III entry 12). The entries for hydroquinone, 1-naphthol and its salts and resorcinol have all been amended (annex III entries 14, 16 and 22). The commission regulation amends the entries for 20 oral care ingredients (annex III entries 26-43, 47 and 56). The entries

for benzyl alcohol (annex III entry 45 and annex V entry 34) are amended. Entry 68 in annex III which was also for benzyl alcohol is now blank. The entries for hydroxycitronellal, isoeugenol, limonene and methyl 2-octynoate (annex III entries 72, 73, 88 and 89) have all been amended. Entries 103-197, 201-205 have been inserted in to annex III, these entries were missing when Regulation (EC) No 1223/2009 came in to force. The entries for 37 hair dye substances which can be used in oxidative or non oxidative hair dye products have been amended (annex III entries 215-239, 241-250, 252 and 254). The entries in annex III for o-aminophenol and its salts (entry 240), 2-chloro-6-ethylamino-4-nitrophenol (entry 251), Basic Blue 26 (CI 44045) (entry 253), Ponceau SX (CI 14700) (entry 255) and Basic Violet 14 (CI 42510) (entry 256) are now blank.

Ethyl lauroyl arginate HCl has been added to the list of preservatives in annex V (annex V entry 58). In annex VI the entry for PABA (entry I) is now blank and the entry for diethylamino hydroxybenzoyl hexyl benzoate has been amended (entry 28).

Commission Regulation (EU) No 483/2013

Commission Regulation (EU) No 483/2013 inserts laureth-9 into annex III (annex III entry 257).

Commission Regulation (EU) No 655/2013

Commission Regulation (EU) No 655/2013 lays down common criteria for the justification of claims used in relation to cosmetic products. The common criteria are legal compliance, truthfulness, evidential support, honesty, fairness and informed decision making. The European Commission has published guidance for this regulation.¹

Commission Regulation (EU) No 658/2013

Commission No (EU) 658/2013 amends annex II and III. HC Red No 16 has been added to annex II (annex II entry 1373).

Twelve hair dyes have been added to annex III (annex III entries 198-200, 206-214), these were missing from annex III when Regulation (EC) No 1223/2009 came in to force. The entries for 8 hair dyes and one mixture of hair dyes have been amended: 1-naphthol, resorcinol, hydroxyethyl-2-nitro-p-toluidine, 4-nitro-o-phenylenediamine, HC Red No 10 + HC Red No 11, HC Red No 7, HC Yellow No 4, HC Yellow No 2, HC Orange No 1 (annex III entries 16, 22, 221, 240, 250, 251, 253, 255, 256). A further 7 hair dyes have been added to annex III: HC Red No 1, HC Yellow No 9, HC Yellow No 7, HC Yellow No 13, Basic Yellow 57, Disperse Black 9 and HC Blue No 14 (annex III entries 258-264).

Commission Regulation (EU) No 1197/2013

Commission Regulation (EU) No 1197/2013 amends annex III of Regulation (EC) No 1223/2009. p-Phenylenediamine and its salts are included in annex III for colouring eyelashes (annex III entry 8b). The entries for toluene-2,5-diamine and toluene-2,5-diamine sulfate (entry 9a), hydrogen peroxide (entry 12), resorcinol (entry 22), 6-methoxy-2-methylamino-3-aminopyridine HCl (entry 203), m-aminophenol and its salts (entry 217), 2-methyl-5-hydroxyethyl aminophenol (entry

229), 4-amino-2-hydroxytoluene (entry 241), 2,4-diaminophenoxyethanol HCl and 2,4-diaminophenoxyethanol sulfate (entry 242), 4-amino-m-cresol (entry 244), 2-amino-4-hydroxyethylaminoanisole and 2-amino-4-hydroxyethylaminoanisole sulfate (entry 245) have all been amended. The following hair dyes have been added to annex III (entries 265-285): Disperse Violet 1, HC Red No 3, Basic Red 76, Basic Red 51, 2-amino-5-ethylphenol HCl, Acid Red 92, Disperse Blue 377, p-aminophenol, 1-hydroxyethyl-4,5-diamino pyrazole sulfate, 4-formyl-1-methylquinolinium-p-toluene sulfonate, Basic Yellow 87, Basic Orange 31, 2,6-diamino-3-((pyridine-3-yl)azo)pyridine, Basic Violet 2, 2,3-diaminodihydropyrazolopyrazolone dimethosulfonate, picramic acid and sodium picramate, 2-nitro-5-glyceryl methylaniline, HC Blue 16, 5-amino-6-chloro-o-cresol and 5-amino-6-chloro-o-cresol HCl, 2,2'-methylenebis-4-aminophenol HCl, and 2,6-diaminopyridine.

Commission Regulation (EU) No 358/2014

Commission Regulation (EU) No 358/2014 amends annex II and V of Regulation (EC) No 1223/2009. It removes isopropylparaben and its salts; isobutylparaben and its salts; phenylparaben; benzylparaben;

and pentylparaben from annex V and adds them to annex II. The entry in annex V for triclosan is also amended. The implementation of the amendments to the annexes of Regulation (EC) No 1223/2009 was deferred to allow industry time to make the necessary adjustments to formulations. From 30 October 2014 only cosmetic products which comply with this regulation shall be placed on the EU market. From 30 July 2015 only products which comply with this regulation shall be made available on the EU market. Companies have until the 30 July 2015 to sell through product that does not comply with this regulation but did comply with Regulation (EC) No 1223/2009 before it was amended by this commission regulation.

Commission Regulation (EU) No 866/2014

Cetrimonium chloride, stearammonium chloride and behentrimonium chloride are listed in annex V of Regulation (EC) No 1223/2009 under the description of alkyl (C12-22) trimethyl ammonium bromide and chloride and are permitted to be used as preservatives up to a maximum concentration of 0.1%. Commission Regulation (EU) No 866/2014 permits cetrimonium chloride, stearammonium



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chloride and behentrimonium chloride to be used at higher concentrations for rinse-off hair products, leave-on hair products and leave-on face products. The entry for alkyl (C12-22) trimethyl ammonium bromide and chloride in annex V has been amended and new entries for cetrimonium chloride, steartrimonium chloride and behentrimonium chloride added to annex III. Please note that the entry numbers for cetrimonium chloride, steartrimonium chloride and behentrimonium chloride are 286 and 287 and not 265 and 266 as stated in Commission Regulation (EU) No 866/2014.²

Commission Regulation (EU) No 866/2014 adds the mixture of citric acid and silver citrate to annex V and permits its use as a preservative up to a maximum concentration of 0.2% which corresponds to 0.0024% as silver. It is not to be used in oral products and eye products.

Commission Regulation (EU) No 866/2014 also adds tris-biphenyl triazine and tris-biphenyl triazine (nano) to annex VI. Tris-biphenyl triazine and tris-biphenyl triazine (nano) are permitted to be used as UV filters up to a maximum concentration of 10%. The nano material may be used providing that it is not used in sprays, the median primary particle size is greater than 80 nm, the purity is greater than 98% and it is uncoated.

Commission Regulation (EU) No 1003/2014

Commission Regulation (EU) No 1223/2009 permits the use of the mixture of methylchloroisothiazolinone and methylisothiazolinone with magnesium chloride and magnesium nitrate as a preservative at a maximum concentration of 0.0015% providing the mixture is in the ratio 3:1 of methylchloroisothiazolinone and methylisothiazolinone respectively. The SCCS concluded that the mixture of methylchloroisothiazolinone and methylisothiazolinone does not pose a risk to the health of the consumer when used as a preservative up to a maximum concentration of 0.0015% in rinse off products apart from its skin sensitising properties.³ Commission Regulation (EU) No 1003/2014 amends entry 39 of annex V of Regulation (EC) No 1223/2009 as follows: the reference to the stabilisers magnesium chloride and magnesium nitrate is deleted from the entry; and its use is restricted to rinse-off products. Methylisothiazolinone is also regulated in annex V (entry 57). Commission Regulation (EU) No 1003/2014 states that the use of the mixture of methylchloroisothiazolinone and methylisothiazolinone is incompatible with the use of methylisothiazolinone alone in the same product as it would alter the 3:1 ratio allowed for the mixture.

This is in line with the SCCS's opinion which states that methylisothiazolinone should not be used as an addition to a cosmetic product containing the mixture of methylchloroisothiazolinone and methylisothiazolinone.⁴ From 16 July 2015 only products which comply with this regulation may be placed on the market. From 16 April 2016 only products which comply with this regulation may be made available on the market.

Methylisothiazolinone


The SCCS published an opinion in December 2013 that the use of methylisothiazolinone at a concentration of 0.01% (100 ppm) is not safe for consumers.⁴ They concluded for leave-on products including wet wipes that there was no safe concentration for methylisothiazolinone. For rinse-off products they concluded that a concentration of 0.0015% (15 ppm) is safe for the consumer from the view of contact allergy. This opinion was based on the data related to the mixture of methylchloroisothiazolinone and methylisothiazolinone.³ It has been brought to the attention of the European Commission that using methylisothiazolinone at a concentration of 0.0015% (15 ppm) is insufficient for the preservation of many cosmetic products. The European Commission has asked the SCCS to consider whether methylisothiazolinone is safe for consumers when used as a preservative in rinse-off products up to a maximum concentration of 100 ppm from the view of induction of contact allergy; and in leave-on hair products up to a maximum concentration of 100 ppm from the view of contact allergy.⁵

Commission Regulation (EU) No 1004/2014

This is the commission regulation which changes the maximum permitted concentration of propylparaben and butylparaben in cosmetics. The Scientific Committee on Consumer Safety (SCCS) concluded that to achieve a margin of safety of 100 the sum of their individual concentrations must not exceed 0.19% (as esters).⁶ Based on these findings and to maintain consistency in Regulation (EC) No 1223/2009 the European Commission has converted 0.19% as esters to its equivalent of 0.14% as acid. Please note that this equates to 0.18% for propylparaben and 0.19% for butylparaben which is slightly different from the SCCS opinion. Entry 12 of annex V of Regulation (EC) No 1223/2009 permits 4-hydroxybenzoic acid, methylparaben, potassium ethylparaben, potassium paraben, sodium methylparaben, sodium ethylparaben, ethylparaben, sodium paraben, potassium methylparaben and calcium paraben to be used at a maximum

concentration of 0.4% (as acid) for single esters and 0.8% (as acid) for mixtures of esters. Entry 12a is inserted into annex V and permits the use of butylparaben, propylparaben, sodium propylparaben, sodium butylparaben, potassium butylparaben and potassium propylparaben to be used at a maximum concentration of "0.14% (as acid) for the sum of the individual concentrations" and "0.8% (as acid) for mixtures of substances mentioned in entry 12 and 12a, where the sum of the individual concentrations of butylparaben and propylparaben and their salts does not exceed 0.14%".⁷ Entry 12a also prohibits the use of propylparaben and butylparaben and their sodium and potassium salts in leave-on products designed for the nappy area of children under three years of age. For leave-on products designed for children under three years of age the phrase "Do not use on the nappy area" must appear in the wording of the conditions of use and warnings. The European Commission has deferred implementation of this regulation to allow industry to make the appropriate changes to their formulations. From 16 April 2015 only products which comply with this regulation can be placed on the European Union market. From 16 October 2015 only cosmetic products which comply with this regulation shall be made available on the European Union market.

Conclusion

This article gives an overview to the changes that have been made to Regulation (EC) No 1223/2009. For the exact wording of the amendments to regulation 1223/2009 it is recommended that the implementing commission regulation is referred to. 

References

- 1 Guidelines to Commission Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products.
- 2 Corrigendum to Commission Regulation (EU) No 866/2014 of 8 August 2014 amending Annexes III, V, and VI to Regulation (EC) No 1223/2009 of the European Parliament and the Council on cosmetic products.
- 3 Scientific Committee on Consumer Safety SCCS/1238/09.
- 4 Scientific Committee on Consumer Safety SCCS/1521/13.
- 5 Request for a scientific opinion on Methylisothiazolinone (MI) (P94) – in rinse-off and leave-on hair products, 5 January 2015.
- 6 Scientific Committee on Consumer Safety SCCS/1348/10 Revision 22 March 2011.
- 7 Commission Regulation (EU) No 1004/2014 of 18 September 2014 amending Annex V of Regulation (EC) No 1223/2009 of the European Parliament and to the Council on cosmetic products.