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)

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[(3)] has been significantly amended on several occasions. Since further amendments are to be made, in this particular case it should be recast as one single text in the interests of clarity.

(2) A Regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for diverging transposition by Member States. Moreover, a Regulation ensures that legal requirements are implemented at the same time throughout the Community.

(3) This Regulation aims at simplifying procedures and streamlining terminology, thereby reducing administrative burden and ambiguities. Moreover, it strengthens certain elements of the regulatory framework for cosmetics, such as in-market control, with a view to ensuring a high level of protection of human health.

(4) This Regulation comprehensively harmonises the rules in the Community in order to achieve an internal market for cosmetic products while ensuring a high level of protection of human health.

(5) The environmental concerns that substances used in cosmetic products may raise are considered through the application of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a

European Chemicals Agency[4], which enables the assessment of environmental safety in a cross-sectoral manner.

(6) This Regulation relates only to cosmetic products and not to medicinal products, medical devices or biocidal products. The delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use.

(7) The assessment of whether a product is a cosmetic product has to be made on the basis of a case-by-case assessment, taking into account all characteristics of the product. Cosmetic products may include creams, emulsions, lotions, gels and oils for the skin, face masks, tinted bases (liquids, pastes, powders), make-up powders, after-bath powders, hygienic powders, toilet soaps, deodorant soaps, perfumes, toilet waters and eau de Cologne, bath and shower preparations (salts, foams, oils, gels), depilatories, deodorants and anti-perspirants, hair colorants, products for waving, straightening and fixing hair, hair-setting products, hair-cleansing products (lotions, powders, shampoos), hair-conditioning products (lotions, creams, oils), hairdressing products (lotions, lacquers, brilliantines), shaving products (creams, foams, lotions), make-up and products removing make-up, products intended for application to the lips, products for care of the teeth and the mouth, products for nail care and make-up, products for external intimate hygiene, sunbathing products, products for tanning without sun, skin-whitening products and anti-wrinkle products.

(8) The Commission should define the categories of cosmetic products which are relevant for the application of this Regulation.

(9) Cosmetic products should be safe under normal or reasonably foreseeable conditions of use. In particular, a risk-benefit reasoning should not justify a risk to human health.

(10) The presentation of a cosmetic product and in particular its form, odour, colour, appearance, packaging, labelling, volume or size should not endanger health and safety of consumers due to confusion with foodstuffs, in accordance with Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers[5].

(11) In order to establish clear responsibilities, each cosmetic product should be linked to a responsible person established within the Community.

(12) Ensuring traceability of a cosmetic product throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators.

(13) It is necessary to determine under which conditions a distributor is to be considered as the responsible person.

(14) All legal or natural persons in the wholesale trade as well as retailers selling directly to the consumer are covered by reference to the distributor. The obligations of the distributor should therefore be adapted to the respective role and part of the activity of each of these operators.

(15) The European cosmetics sector is one of the industrial activities affected by counterfeiting, which may increase risks to human health. Member States should pay particular attention to the implementation of horizontal Community legislation and measures regarding counterfeit products in the field of cosmetic products, for example Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights[(6)] and Directive 2004/48/EC of the European parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights[(7)]. In-market controls represent a powerful means of identifying products that do not comply with the requirements of this Regulation.

(16) To ensure their safety, cosmetic products placed on the market should be produced according to good manufacturing practice.

(17) For the purpose of effective market surveillance, a product information file should be made readily accessible, at one single address within the Community, to the competent authority of the Member State where the file is located.

(18) In order to be comparable and of high quality, the results of the non-clinical safety studies carried out for the purposes of assessing the safety of a cosmetic product should comply with the relevant Community legislation.

(19) It should be made clear which information is to be made available to the competent authorities. That information should include all the necessary particulars relating to identity, quality, safety for human health and the effects claimed for the cosmetic product. In particular, this product information should include a cosmetic product safety report documenting that a safety assessment has been conducted.

(20) To ensure the uniform application and control of the restrictions for substances, sampling and analysis should be carried out in a reproducible and standardised manner.

(21) The term ‘mixture’ as defined in this Regulation should have the same meaning as the term ‘preparation’ previously used in Community legislation.

(22) For reasons of effective market surveillance, the competent authorities should be notified of certain information about the cosmetic product placed on the market.

(23) In order to allow for rapid and appropriate medical treatment in the event of difficulties, the necessary information about the product formulation should be submitted to poison control centres and assimilated entities, where such centres have been established by Member States to that end.

(24) In order to keep administrative burdens to a minimum, the notified information for competent authorities, poison control centres and assimilated entities should be submitted centrally for the Community by way of an electronic interface.

(25) In order to ensure a smooth transition to the new electronic interface, economic operators should be allowed to notify the information required in accordance with this Regulation before its date of application.

(26) The general principle of the responsibility of the manufacturer or importer for the safety of the product should be supported by restrictions of some substances in Annexes II and III. Moreover, substances which are intended to be used as colorants, preservatives and UV-filters should be listed in the Annexes IV, V and VI respectively in order to be allowed for these uses.

(27) To avoid ambiguities, it should be clarified that the list of allowed colorants contained in Annex IV includes only substances which colour through absorption and reflection and not substances which colour through photoluminescence, interference, or chemical reaction.

(28) To address safety concerns raised, Annex IV, which is currently restricted to skin colorants, should also include hair colorants once the risk assessment of these substances by the Scientific Committee for Consumer Safety (SCCS) set up by Commission Decision 2008/721/EC of 5 September 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment[8] has been finalised. To this end, the Commission should have the possibility to include hair colorants in the scope of that Annex by the comitology procedure.

(29) The use of nanomaterials in cosmetic products may increase with the further development of technology. In order to ensure a high level of consumer protection, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for nanomaterials at international level. The Community should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of nanomaterials in this Regulation should be adapted accordingly.

(30) At present, there is inadequate information on the risks associated with nanomaterials. In order to better assess their safety the SCCS should provide guidance in cooperation with relevant bodies on test methodologies which take into account specific characteristics of nanomaterials.

(31) The Commission should regularly review the provisions on nanomaterials in the light of scientific progress.

(32) Given the hazardous properties of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A, 1B and 2, pursuant to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures[9], their use in cosmetic products should be prohibited. However, as a hazardous property of a substance does not necessarily always entail a risk, there should be a possibility to allow the use of substances classified as CMR 2 substances where, in view of exposure and concentration, they have been found safe for use in cosmetic products by the SCCS and are regulated by the Commission in the Annexes to this Regulation. With regard to substances which are classified as CMR 1A or 1B substances, there should be a possibility, in the exceptional case that these substances comply with food safety requirements, inter alia as a result of their naturally occurring in food, and that no

suitable alternative substances exist, to use such substances in cosmetic products on the condition that such use has been found safe by the SCCS. Where such conditions are met, the Commission should amend the relevant Annexes to this Regulation within 15 months of classification of substances as CMR 1A or 1B substances under Regulation (EC) No 1272/2008. Such substances should be continuously reviewed by the SCCS.

(33) A safety assessment of substances, particularly those classified as CMR 1A or 1B substances, should consider the overall exposure to such substances stemming from all sources. At the same time, for those involved in producing safety assessments, it is essential that there be a harmonised approach to the development and use of such overall exposure estimates. In consequence, the Commission, in close cooperation with the SCCS, the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA) and other relevant stakeholders, should, as a matter of urgency, carry out a review and develop guidance regarding the production and use of overall exposure estimates for these substances.

(34) The assessment by the SCCS of the use of substances classified as CMR 1A and 1B in cosmetic products should also take into account the exposure to those substances of vulnerable population groups, such as children under three years of age, elderly people, pregnant and breast-feeding women and persons with compromised immune responses.

(35) The SCCS should give opinions where appropriate on the safety of use of nanomaterials in cosmetic products. These opinions should be based on full information being made available by the responsible person.

(36) Action by the Commission and Member States relating to the protection of human health should be based on the precautionary principle.

(37) In order to ensure product safety, prohibited substances should be acceptable at trace levels only if they are technologically inevitable with correct manufacturing processes and provided that the product is safe.

(38) The Protocol on protection and welfare of animals annexed to the Treaty provides that the Community and the Member States are to pay full regard to the welfare requirements of animals in the implementation of Community policies, in particular with regard to the internal market.

(39) Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[(10)] established common rules for the use of animals for experimental purposes within the Community and laid down the conditions under which such experiments must be carried out in the territory of the Member States. In particular, Article 7 of that Directive requires that animal experiments be replaced by alternative methods, where such methods exist and are scientifically satisfactory.

(40) The safety of cosmetic products and their ingredients may be ensured through the use of alternative methods which are not necessarily applicable to all uses of chemical ingredients. Therefore, the use of such methods by the whole cosmetic industry should

be promoted and their adoption at Community level ensured, where such methods offer an equivalent level of protection to consumers.

(41) The safety of finished cosmetic products can already be ensured on the basis of knowledge of the safety of the ingredients that they contain. Provisions prohibiting animal testing of finished cosmetic products should therefore be laid down. The application, in particular by small and medium-sized enterprises, of both test methods and assessment procedures for relevant available data, including the use of read-across and weight-of-evidence approaches, which do not involve the use of animals for assessing the safety of finished cosmetic products could be facilitated by Commission guidelines.

(42) It will gradually become possible to ensure the safety of ingredients used in cosmetic products by using non-animal alternative methods validated at Community level, or approved as being scientifically validated, by the European Centre for the Validation of Alternative Methods (ECVAM) and with due regard to the development of validation within the Organisation for Economic Cooperation and Development (OECD). After consulting the SCCS as regards the applicability of the validated alternative methods to the field of cosmetic products, the Commission should immediately publish the validated or approved methods recognised as being applicable to such ingredients. In order to achieve the highest possible degree of animal protection, a deadline should be set for the introduction of a definitive prohibition.

(43) The Commission established timetables of deadlines up to 11 March 2009 for prohibiting the marketing of cosmetic products, the final formulation, ingredients or combinations of ingredients which have been tested on animals, and for prohibiting each test currently carried out using animals. In view, however, of tests concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, it is appropriate for the final deadline for prohibiting the marketing of cosmetic products for which those tests are used to be 11 March 2013. On the basis of annual reports, the Commission should be authorised to adapt the timetables within the abovementioned maximum time limit.

(44) Better coordination of resources at Community level will contribute to increasing the scientific knowledge indispensable for the development of alternative methods. It is essential, for this purpose, that the Community continue and increase its efforts and take the measures necessary for the promotion of research and the development of new non-animal alternative methods, in particular within its Framework Programmes for research.

(45) The recognition by third countries of alternative methods developed in the Community should be encouraged. In order to achieve this objective, the Commission and the Member States should take all appropriate steps to facilitate acceptance of such methods by the OECD. The Commission should also endeavour, within the framework of European Community cooperation agreements, to obtain recognition of the results of safety tests carried out in the Community using alternative methods so as to ensure that the export of cosmetic products for which such methods have been used is not hindered and to prevent or avoid third countries requiring the repetition of such tests using animals.

(46) Transparency is needed regarding the ingredients used in cosmetic products. Such transparency should be achieved by indication of the ingredients used in a cosmetic product on its packaging. Where for practical reasons it is impossible to indicate the ingredients on the packaging, such information should be enclosed so that the consumer has access to this information.

(47) A glossary of common ingredient names should be compiled by the Commission to ensure uniform labelling and to facilitate identification of cosmetics ingredients. This glossary should not be intended to constitute a limitative list of substances used in cosmetic products.

(48) In order to inform consumers, cosmetic products should bear precise and easily understandable indications concerning their durability for use. Given that consumers should be informed of the date until which the cosmetic product will continue to fulfil its initial function and remain safe, it is important to know the date of minimum durability, i.e. the date by which it is best to use the product. Where the minimum durability is more than 30 months, the consumer should be informed of the period of time after opening that the cosmetic product may be used without any harm to the consumer. However, this requirement should not apply where the concept of the durability after opening is not relevant, that is to say for single-use products, products not at risk of deterioration or products which do not open.

(49) A number of substances have been identified by the SCCS as likely to cause allergic reactions and it will be necessary to restrict their use and/or impose certain conditions concerning them. In order to ensure that consumers are adequately informed, the presence of these substances should be mentioned in the list of ingredients and consumers' attention should be drawn to the presence of these ingredients. This information should improve the diagnosis of contact allergies among consumers and should enable them to avoid the use of cosmetic products which they do not tolerate. For substances which are likely to cause allergy to a significant part of the population, other restrictive measures such as a ban or a restriction of concentration should be considered.

(50) In the safety assessment of a cosmetic product it should be possible to take into account results of risk assessments that have been carried out in other relevant areas. The use of such data should be duly substantiated and justified.

(51) The consumer should be protected from misleading claims concerning efficacy and other characteristics of cosmetic products. In particular Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market[(11)] is applicable. Furthermore, the Commission, in cooperation with Member States, should define common criteria in relation to specific claims for cosmetic products.

(52) It should be possible to claim on a cosmetic product that no animal testing was carried out in relation to its development. The Commission, in consultation with the Member States, has developed guidelines to ensure that common criteria are applied in the use of claims and that an aligned understanding of the claims is reached, and in particular that such claims do not mislead the consumer. In developing such guidelines, the

Commission has also taken into account the views of the many small and medium-sized enterprises which make up the majority of the 'non-animal testing' producers, relevant non-governmental organisations, and the need for consumers to be able to make practical distinctions between products on the basis of animal testing criteria.

(53) In addition to the labelled information, consumers should be given the possibility to request certain product-related information from the responsible person in order to make informed product choices.

(54) Effective market surveillance is necessary in order to ensure that the provisions of this Regulation are respected. To this end, serious undesirable effects should be notified and competent authorities should have a possibility to request from the responsible person a list of cosmetic products containing substances which have raised serious doubts in terms of safety.

(55) This Regulation is without prejudice to the possibility for Member States to regulate, in compliance with Community law, the notification by health professionals or consumers of serious undesirable effects to the competent authorities of Member States.

(56) This Regulation is without prejudice to the possibility for Member States to regulate, in compliance with Community law, the establishment of economic operators in the area of cosmetic products.

(57) In case of non-compliance with this Regulation, a clear and efficient procedure for the withdrawal and recall of products may be necessary. This procedure should, where possible, build upon existing Community rules for unsafe goods.

(58) In order to address cosmetic products which, despite complying with the provisions of this Regulation, might endanger human health, a safeguard procedure should be introduced.

(59) The Commission should provide indications for the uniform interpretation and application of the concept of serious risks in order to facilitate the consistent implementation of this Regulation.

(60) In order to comply with principles of good administrative practices, any decision by a competent authority in the framework of market surveillance should be duly substantiated.

(61) In order to ensure effective in-market control, a high degree of administrative cooperation amongst the competent authorities is necessary. This concerns in particular mutual assistance in the verification of product information files located in another Member State.

(62) The Commission should be assisted by the SCCS, an independent risk assessment body.

(63) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(12)].

(64) In particular, power should be conferred on the Commission to adapt the Annexes to this Regulation to technical progress. Since those measures are of general scope and

are designed to amend non-essential elements of this Regulation they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(65) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of certain measures relating to CMRs, nanomaterials and potential risks to human health.

(66) Member States should lay down provisions on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

(67) Economic operators as well as Member States and the Commission need sufficient time to adapt to the changes introduced by this Regulation. Therefore it is appropriate to provide for a sufficient transitional period for that adaptation. However, in order to ensure a smooth transition, economic operators should be allowed to place on the market cosmetic products which comply with this Regulation before the expiry of that transitional period.

(68) In order to enhance the safety of cosmetic products and strengthen the market surveillance, cosmetic products placed on the market after the date of application of this Regulation should comply with its obligations regarding safety assessment, the product information file and notification, even if similar obligations have already been fulfilled under Directive 76/768/EEC.

(69) Directive 76/768/EEC should be repealed. However, in order to ensure appropriate medical treatment in the event of difficulties and to ensure market surveillance, the information received pursuant to Article 7(3) and Article 7a(4) of Directive 76/768/EEC concerning cosmetic products should be kept by the competent authorities for a certain period of time and the information kept by the responsible person should remain available for the same period of time.

(70) This Regulation should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Part B of Annex IX.

(71) Since the objective of this Regulation, namely the achievement of the internal market and a high level of protection of human health through the compliance of cosmetic products with the requirements laid down in this Regulation, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity, as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

(**1**) OJ C 27, 3.2.2009, p. 34.

(**2**) Opinion of the European Parliament of 24 March 2009 (not yet published in the Official Journal) and Council Decision of 20 November 2009.

(**3**) OJ L 262, 27.9.1976, p. 169.

(**4**) OJ L 396, 30.12.2006, p. 1.

(**5**) OJ L 192, 11.7.1987, p. 49.

(**6**) OJ L 196, 2.8.2003, p. 7.

(**7**) OJ L 157, 30.4.2004, p. 45.

(**8**) OJ L 241, 10.9.2008, p. 21.

(**9**) OJ L 353, 31.12.2008, p. 1.

(**10**) OJ L 358, 18.12.1986, p. 1.

(**11**) OJ L 149, 11.6.2005, p. 22.

(**12**) OJ L 184, 17.7.1999, p. 23.

Changes to legislation:
Regulation (EC) No 1223/2009 of the European Parliament and of the Council, Introductory Text is up to date with all changes known to be in force on or before 02 December 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

– Art. 2(1)(g) words substituted by S.I. 2019/696 Sch. 34 para. 3(c)(i) (This amendment not applied to legislation.gov.uk. Sch. 34 para. 3(c)(i) substituted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 23(2)(a))