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

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(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