Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 30/11/2009 - Final act

PURPOSE: to recast EU legislation on cosmetic products.

LEGISLATIVE ACT: Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (recast).

CONTENT: This Regulation establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health. To recall, Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products has been significantly amended on several occasions. Since further amendments are to be made, in this particular case it has been recast as one single text in the interests of clarity.

European companies are market leaders in cosmetics. 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. It simplifies the rules and procedures for the marketing and safety of cosmetics.

Consumers will benefit through the uniform application of rules, the enhanced coordination of market surveillance activities as well as the increased responsibilities placed on economic operators with a view to ensuring a higher level of consumer protection, notably with the introduction of a product information file.

Another advantage for consumers and businesses alike will be the free movement of cosmetic products resulting from the harmonisation of procedures and technical requirements.

Cosmetic products include make-up products, soaps, bath and shower preparations (salts, foams, oils and gels), perfumes, depilatories, deodorants, hair products (lotions, powders, shampoos, creams and lacquers), creams and emulsions for the skin, face masks, tinted bases, shaving products, lip-sticks and tooth-paste.

The main elements of the regulation are the following:

Safety: a cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use. In particular, a risk-benefit reasoning should not justify a risk to human health.

Responsible person: only cosmetic products for which a legal or natural person is designated within the Community as ‘responsible person’ shall be placed on the market. The text contains new provisions concerning the obligations of responsible persons, obligations of distributors and the identification within the supply chain. The distributor shall be the responsible person where he places a cosmetic product on the market under his name or trademark or modifies a product already placed on the market in sucha way that compliance with the applicable requirements may be affected.

Safety assessment: the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up. The responsible person shall ensure that: (a) the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment; (b) an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources; (c) the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market.

Product information file: when a cosmetic product is placed on the market, the responsible person shall keep a product information file for it. The product information file shall be kept for a period of 10 years following the date on which the last batch of the cosmetic product was placed on the market. The responsible person shall make the product information file readily accessible in electronic or other format at his address indicated on the label to the competent authority of the Member State in which the file is kept.

Sampling and analysis: sampling and analysis of cosmetic products shall be performed in a reliable and reproducible manner.

Notification: prior to placing the cosmetic product on the market the responsible person shall submit, by electronic means, the following information to the Commission: (a) the category of cosmetic product and its name or names, enabling its specific identification; (b) the name and address of the responsible person where the product information file is made readily accessible; (c) the country of origin in the case of import; (d) the Member State in which the cosmetic product is to be placed on the market; (e) the contact details of a physical person to contact in the case of necessity; (f) the presence of substances in the form of nanomaterials; (g) the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as carcinogenic, mutagenicor toxic for reproduction (CMR), of category 1A or 1B, (h) the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

Restrictions for substances listed in the Annexes: cosmetic products shall not contain any of the following: (a) prohibited substances listed in Annex II; (b) restricted substances which are not used in accordance with the restrictions laid down in Annex III; (c) colorants; (d) preservatives; (e) UV-filters.

Substances classified as CMR substances: the use in cosmetic products of substances classified as CMR substances, of category 2 and category 1A and 1B, under Part 3 of Annex VI to Regulation (EC) No 1272 /2008 shall be prohibited. However, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products.

By 11 January 2012, the Commission shall ensure that appropriate guidance is developed with the aim of enabling a harmonised approach to the development and use of overall exposure estimates in assessing the safe use of CMR substances. This guidance shall be developed in consultation with the Scientific Committee for Consumer Safety (SCCS), the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA) and other relevant stakeholders, drawing, as appropriate, on relevant best practice.

When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties.

Nanomaterials: for every cosmetic product that contains nanomaterials, a high level of protection of human health shall be ensured. Moreover, the text lays down the minimum information to be notified to the Commission. In the event that the Commission has concerns regarding the safety of a nanomaterial,

the Commission shall, without delay, request the SCCS to give its opinion on the safety of such nanomaterial for use in the relevant categories of cosmetic products and on the reasonably foreseeable exposure conditions. The Commission shall make this information public. By 11 January 2014, the Commission shall make available a catalogue of all nanomaterials used in cosmetic products placed on the market, including those used as colorants, UV-filters and preservatives in a separate section, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions. This catalogue shall be regularly updated thereafter and be made publicly available. The Commission shall regularly review the provisions of this Regulation concerning nanomaterials in the light of scientific progress. The first review shall be undertaken by 11 July 2018.

Animal testing:the regulation sets out provisions as regards the prohibition of animal testing. The Commission shall study possible technical difficulties in complying with the ban in relation to tests, in particular those concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration.

Every year the Commission shall present a report to the European Parliament and the Council on: (i) progress made in the development, validation and legal acceptance of alternative methods; (ii) progress made by the Commission in its efforts to obtain acceptance by the OECD of alternative methods validated at Community level and recognition by third countries of the results of the safety tests carried out in the Community using alternative methods, in particular within the framework of cooperation agreements between the Community and these countries; (iii) the manner in which the specific needs of small and medium-sized enterprises have been taken into account.

Labelling: cosmetic products shall be made available on the market only where the container and packaging of cosmetic products bear the following information in indelible, easily legible and visible lettering.

Date of minimum durability shall be clearly expressed and shall consist of either the month and year or the day, month and year, in that order. If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability. Indication of the date of minimum durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product is safe and can be used without any harm to the consumer.

The text states that the country of origin shall be specified for imported cosmetic products. All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word ‘nano’ in brackets.

Product claims: in the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have. The Commission shall, in cooperation with Member States, establish an action plan regarding claims used and fix priorities for determining common criteria justifying the use of a claim. By 11 July 2016, the Commission shall submit to the European Parliament and the Council a report regarding the use of claims on the basis of the common criteria adopted under the second subparagraph. If the report concludes that claims used in respect of cosmetic products are not in conformity with the common criteria, the Commission shall take appropriate measures to ensure compliance in cooperation with the Member States.

In-market control: Member States shall monitor compliance with this Regulation via in-market controls of the cosmetic products made available on the market. They shall perform appropriate checks of cosmetic products and checks on the economic operators on an adequate scale, through the product information file and, where appropriate, physical and laboratory checks on the basis of adequate samples. They shall also: (i) monitor compliance with the principles of good manufacturing practices; (ii) entrust to market

surveillance authorities the necessary powers, resources and knowledge in order for those authorities to properly perform their tasks; (iii) periodically review and assess the functioning of their surveillance activities.

Communication of serious undesirable effects: in the event of serious undesirable effects, the responsible person and distributors shall without delay notify the following to the competent authority of the Member State where the serious undesirable effect occurred: (i) all serious undesirable effects which are known to him or which may reasonably be expected to be known to him; (ii) the name of the cosmetic product concerned, enabling its specific identification; (iii) the corrective measures taken by him, if any.

Where the responsible person, distributors and end users report serious undesirable effects to the competent authority of the Member State where the effect occurred, that competent authority shall immediately transmit the information to the competent authorities of the other Member States.

Safeguard clause: in the case of products meeting the requirements listed in the regulation, where a competent 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.

ENTRY INTO FORCE: 11/01/2010.

APPLICATION: from 11/07/2013, with the exception of provisions concerning the CMR substances which shall apply from 01/01/2010 and provisions concerning nanomaterials which shall apply from 11/01 /2013.