Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 24/03/2009 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 633 votes to 29, with 11 abstentions, a legislative resolution amending, under the first reading of the codecision procedure, the proposal for a regulation of the European Parliament and of the Council on cosmetic products (recast).

The amendments were the result of a compromise negotiated with the Council. The main amendments were as follows:

Definitions: Parliament defined 'nanomaterial' as an insoluble or bio-persistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm. It also stated that, in view of the various definitions of nanomaterials published by different bodies and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adapt this definition to technical and scientific progress and with definitions subsequently agreed at international level, in accordance with the regulatory procedure with scrutiny. Members also inserted definitions for "substance", "mixture", "end user", distributor and "frame formulation".

Responsible person: Parliament stipulated in the text that only cosmetic products for which a legal or natural person is designated within the Community as responsible person shall be placed on the market.

New provisions in the text set out the obligations of the responsible person, the obligations of the distributors and identification within the supply chain. A new recital notes that Ensuring traceability of a 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..

Safety assessment: Members expanded and clarified the duties of the responsible person. This person must ensure that the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation is taken into account in the safety assessment. This also shall also apply to cosmetic products that have been notified under Directive 76/768/EEC. He must also ensure that an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources. The Commission, in close cooperation with all stakeholders, shall adopt appropriate guidelines to enable enterprises, in particular small and medium-sized enterprises, to comply with the requirements laid down in the text.

Product information file: this must be kept during a period of 10 years following the date when the last batch of the cosmetic product was placed on the market. Should the development and/or manufacturing activities be subcontracted, responsibilities relating to preservation of the product information file may be shared, by written contract, between the person responsible for placing the product on the market and the subcontractors.

Notification: Parliament made substantial amendments to the provisions regarding information to be submitted to the Commission.

Restrictions for certain substances: these substances are listed as follows: prohibited Substances; restricted substances; colorants; preservatives; and UV-filters. Use of these substances, other than those listed in the text, is prohibited.

Substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR): Members tightened up the derogation for CMR substances. The use of such products under category 1A and 1B under part 3 of Regulation (EC) 1272/2008 is prohibited unless certain conditions are met. These include the conditions that the application is made for a particular use of the product category with a known exposure; and they have been evaluated and found safe for use by the SCCS in cosmetic products in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, as well as under particular consideration of vulnerable population groups. 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 SCCS, the ECHA, the EFSA and other relevant stakeholders, drawing as appropriate on relevant best practice.

A new clause states that when Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest five years after this Regulation has entered into force, the Commission shall review the Regulation with regard to substances with endocrine-disrupting properties..

Nanomaterials: a new Article is inserted stating that for every product that contains nanomaterials, a high level of protection of human health shall be ensured. The Article details the information that must be notified to the Commission in addition to the notification requirements already existing under the text, and sets out the procedure that the Commission must follow if it has safety concerns. The Commission will request the SCCS to give its opinion on the safety of these nanomaterials for the relevant categories of cosmetic products and the reasonably foreseeable exposure conditions, and it will make this information public. 48 months after the date of entry into force of this Regulation. It will make available a catalogue of all nanomaterials used in cosmetic products, including those used as colorants, UV-filters and preservatives in a separate section, placed on the market, 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 submit an annual status report, which will give information on developments in the use of nanomaterials in cosmetic products within the Community, including those used as colorants, UV-filters and preservatives in a separate section.

Traces of prohibited substances: The non intended presence of small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be allowed provided that such presence is in conformity with the provisions on safety.

Labelling: Parliament stipulates 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: Parliament tightened up the provisions on labelling, stating that labelling and advertising of cosmetic products must not be used to imply that these products have characteristics or functions which they do not have. The Commission must establish an action plan

regarding claims used and fix priorities for determining common criteria justifying the use of a claim. After consultation of the SCCS or other relevant authorities, the Commission shall adopt a list of common criteria for claims which may be used in respect of cosmetic products, in accordance with the regulatory procedure with scrutiny, taking into account provisions of Directive 2005/29/EC. After 3 years, it will submit a report regarding the use of claims on the basis of the common criteria. 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' obligations are increased. They are required to perform appropriate checks of products and 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. Market surveillance authorities should be entrusted with the necessary powers, resources and knowledge in order to properly perform their tasks.

Communication of serious undesirable effects: the competent authority is required to transmit information as stated whether information in undesirable effects are reported by the responsible person, the distributor, the end user or health professionals.

Lastly, Parliament made a series of amendments to provisions on non compliance by the responsible person and the distributor. The regulation will apply 42 month after entry into force except for certain parts on CMR substances and nanomaterials, which will apply from an earlier stage.