Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 02/12/2008

The Committee on the Environment, Public Health and Food Safety adopted a report drafted by Dagmar **ROTH-BERENDT** (PES, D) and made several amendments to the proposal for a regulation of the European Parliament and of the Council on cosmetic products (recast). The committee was concerned to state that for every product that contains nanomaterials, a high level of consumer protection and the protection of human health is to be ensured. It wanted the Commission to adopt guidance on safety assessments and required Member States to perform adequate controls.

The main amendments are as follows:

Definitions: the committee 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, in accordance with the regulatory procedure with scrutiny, no later than 18 months after the entry into force of the Regulation. Members also inserted definitions for "subcontractor, distributor' 'vulnerable population groups' and 'counterfeit cosmetic product'.

Obligations of distributors, importers and retailers: the obligations of these persons are strengthened in a new Article. Where a distributor, importer or retailer has reason to believe that a product is a counterfeit cosmetic product, he shall not place the product on the market. If it is already on the market, it must be withdrawn and the competent authorities must be warned.

Safety assessment: particular consideration shall be given to particle size and more specifically to 'nanomaterials' as defined above. Members expanded and clarified the duties of the responsible person. This person must ensure 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. He must also ensure that an appropriate weight-of-evidence approach is used in the safety assessment for reviewing relevant data from several sources, including data from in-vitro, in-silico, existing GLP (Good Laboratory Practice) or non-GLP in-vivo and human studies. The Commission must **adopt appropriate guidelines** to enable enterprises, in particular small and medium-sized enterprises, to comply with the requirements laid down in Annex I, which collates the cosmetic product safety information and leads to cosmetic safety report.

Product information file: this must be kept accessible for a period of at least ten years after the last delivery of the cosmetic product. 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: information submitted to the Commission must include the presence of substances in the form of nanomaterials, regardless of their persistence and solubility.

CMR: Members tightened up the derogation for CMR substances: they must only apply to substances that are classified CMR in the future and must have been evaluated and found safe for use by the SCCP in specific cosmetic products in particular in view of the global exposure from other significant sources and

taking particular account of vulnerable population groups. 2 years after entry into force of the legislation, the procedures for the development and use of global exposure estimates for CMR substances must have been reviewed and appropriate guidelines developed with the aim of enabling a harmonised approach to the development and use of such overall exposure estimates in assessing the safe use of cosmetic products containing these substances.

Endocrine disruptors: a new clause states that when Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest 5 years after the 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 consumer protection and the protection of human health shall be ensured. 12 months before the date of application of the Regulation, the responsible person shall notify the Commission of all existing cosmetic products that contain nanomaterials. At the latest 6 months before the date of application of the Regulation, the Commission shall publish an **initial Status Report on all nanomaterials** already used in cosmetic products as well as on the exposure conditions linked to these cosmetic products. If the Commission has concerns, it will request the SCCP to give its opinion and urgently adopt a decision on the authorisation of the products of concern. Furthermore, 18 months before the date of application of the Regulation every new product that contains nanomaterials not included in the Status Report or placed on the market before the publication of the initial Status Report, or nanomaterials used in a new product category or under new exposure conditions, shall be notified to the Commission 6 months prior to the placing on the market. The Commission may request the SCCP to give its opinion. If the SCCP assessment concludes that the use of nanomaterials is unsafe, the Commission shall adopt a decision on the authorisation in accordance with the regulatory procedure.

The Commission must produce an **annual update of the Status Report**, which will give information on developments in the use of nanomaterials in cosmetic products within the Community, and will **review** the provisions of this Regulation concerning nanomaterials at least every 5 years.

Labelling: all ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be preceded by the word 'nano'.

Product claims: the Commission must **establish an action plan** regarding claims used in cosmetic products and fix priorities for determining common criteria for the use of a claim. After consultation of the SCCP it will 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, and produce a report 3 years after the date of application of the Regulation.

In-market control: Member States' obligations are increased. They are required by the committee to **perform controls of adequate scale** by assessing the documentation available and, where appropriate, by means of physical and laboratory tests, based on adequate samples, and report to the Commission.

Amendment to the Annexes: the Commission should consider risk to the environment as well as to human health. The committee inserted to a reference to the REACH legislation.