

Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 05/02/2008 - Legislative proposal

PURPOSE: to recast EU legislation on cosmetic products.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

CONTENT: the simplification of EU cosmetic legislation was included in the Commission's annual Policy Strategy for 2007. The purpose of this proposal, therefore, is threefold:

1. To remove legal uncertainties and inconsistencies in cosmetic legislation.
2. To avoid divergences in national transpositions.
3. To ensure that cosmetic products placed on the EU market are safe.

The Cosmetics Directive has been amended 55 times. One of the key objectives of this proposal is to bring all 55 amendments together under one legal text. The Commission has chosen to present this codification in the form of a Regulation in order to facilitate and harmonise transposition of the provisions.

In addition to merging the 55 amendments into one legal text, the Commission is proposing a number of substantive changes.

Introducing a set of definitions: A set of new definitions is being proposed. The present Directive contains virtually no legal definitions resulting in legal uncertainty and inconsistent compliance. The proposal offers coherence with existing definitions particularly in the field of the free movement of good.

Glossary of ingredient names: The proposal includes a system to update the glossary of ingredient names. The glossary will contain the names of all relevant cosmetic ingredients (approximately 10 000). The names used are independent of any national language and usually much shorter than the chemical name. Thus, these names will help avoid the need for translation of the labelled list of ingredients. Further, the glossary refers to names that have global acceptance. This will help EU producers to export their goods.

Cosmetic safety assessment: Annex I of the proposal sets out the requirements for cosmetic product safety assessment in terms of content. One crucial element of the recast is clarification as to what information has to be contained in the cosmetic product safety assessment to provide evidence of the products safety.

Strengthening in-market control: The proposal strengthens the role of in-market controls, with a view to increasing imports from third countries. The proposed provisions include: defining the person responsible for products supplied to consumers from outside of the EU; a simplified, centralised and electronic notification requirement; communicating information on certain undesirable effects to a competent authority; and strengthening rules that apply to non-compliant products,

CMR Substances: A new CMR (carcinogenic, mutagenic or reprotoxic) regime is introduced. CMR substances will be classified based on their intrinsic properties ("Hazard") without taking exposure into account – i.e. future use. CMR substances are categorised into 3 categories based on the degree of evidence of the properties. Until now, CMR 1 and 2 substances were automatically banned in cosmetic products, whilst CMR 3 substances were banned unless the Scientific Committee had found the

substances to be safe for use in cosmetics. The proposal, however, intends to include a risk management regime for CMR 1 and 2 substances which allows, subject to rigid conditions, the use of these substances if they have been found to be safe by the Scientific Committee for Consumer Products.

Other changes: The proposal also: obliges the responsible person for cosmetic product safety to keep up to date report; deletes reference to the appropriate level of qualification for the manufacturers and the importers; provides for harmonised standards in the field of good manufacturing practices and sampling /analysis of cosmetic products; introduces the comitology procedure with scrutiny for granting a derogation from the animal testing regime; introduces the possibility of highlighting, on the label, the relevant address for the competent authorities; allows for the printing, on the label, a date of minimum durability by way of a pictogram; introduces the option of making use of harmonised standards to address issues of claims; introduces a clear procedure for the application of the safeguard clause; clarifies rules applying to amending the Annexes of the text; introduces the comitology procedure with scrutiny; allows for the formal objection against harmonised standards; introduces an obligation on the Member States to adopt provisions on penalties; establishes rules for the repeal of the cosmetics Directive; and deletes Annex V of the Cosmetics Directive.

From a budgetary point of view, the proposal envisages the establishment of a central electronic interface for the product notification to the competent authorities of the Member States.