

**PUBLIC CONSULTATION  
ON THE SIMPLIFICATION OF THE COSMETICS DIRECTIVE 76/768/EEC**

**- POSITION OF THE SECTION FOR COSMETICS OF THE CZECH  
ASSOCIATION FOR BRANDED PRODUCTS**

**Item 1**

A)

We recommend to clarify the contents of definition of „animal testing“ with regard to cosmetic products.

Reason for this is the high level of legal uncertainty, which is connected exactly with the issue of animal testing.

B)

We recommend clarification of the term „notification“.

We prefer making only one central notification (by manufacturer / importer) on the whole territory of EU, including the information for the toxicological centre (information for the purpose of emergency medical assistance).

C)

Application of Article 12

We recommend putting more precisely the definition of the process of application of Article 12, respectively more precise rules for its use.

D)

Accessibility of information according to Article 7a, section 1)

We recommend clarification of requirements for accessibility of information in the sense that it “shall be readily accessible to the competent authorities” – keeping the documentation within the scope of Article 7a, section 1) at only one place.

E)

Contents of Annex II

With regard to forbidden substances, we recommend setting their permitted levels in cases, where they are toxicologically significant.

F)

Placing on the market

For the purpose of eliminating lack of interpretation clarity with regard to the definition “placing on the market”, we recommend replacement of the current wording with Czech definition (i.e. first paid or free transfer of property rights or any importation to the custom territory of the European Communities).

G)  
PaO

In case of those categories of products, for which there must be labelled according to their contents neither PaO nor their minimum durability, we recommend mentioning their exemplary list in the text of the Annex of the Directive.

**Item 2**

If the attempt to harmonize lists of substances from Annexes from this Directive in the global scope was successful, it would substantially strengthen the position of Europe in relation to other economic competitors.

**Item 3**

We prefer changing the Directive into a Regulation.

In case of such change, the industry should be provided with sufficient time framework for adaptation of products.

At the same time, such Regulation should be in accordance with the REACH Regulation.

**Item 4**

A)

Person responsible for placing a product on the market

We recommend clarification of this definition.

B)

Article 12 – “rinse” or “leave on” products

We recommend putting the definition more precisely with regard to its potential use in accordance with Article 12.

C)

In general, we recommend clarification of definitions of the following terms:

Active substance, Cosmetic Ingredient, Cosmetovigilance, Minimum Durability, Preservative, Product Information, Prototype, Small Package, Traces and UV Filters.

**Item 5**

We recommend continuing to stick to the functions of individual substances, not to their properties.

**Item 6**

We recommend leaving the current status unchanged. Combination of various Annexes into one list would not bring any simplification, but on the contrary would cause confusion.

We recommend use of INCI names for obligatory warnings.

We recommend listing in Annex II only those substances, which represent significant toxicological risk for human health. We recommend extraction from Annex II of those substances, for which only the data are not available, because such substances can not be used for the formulae for the reason that their toxicological profile is not known.

**Item 7**

We welcome any initiative aimed at speeding up the updating of the INCI list.

We recommend abolishment of obsolete Directives for analysis of composition of cosmetic products.

**Item 8**

We recommend clarification of the contents of the definition “person responsible for placing a product on the market” (see previous requirements for putting the definition more precisely).

**Item 9**

We consider the assessment of safety risks to be a key issue.

However, the assessment should be made at a very professional level by an experienced assessor.

If such role is strengthened and clarified, it would be a step, which we would unambiguously welcome.

**Item 10**

We do not recommend any changes in this field, because there exists the General Product Safety Directive, which sets procedure for evaluation of risk and obligations of persons.

We recommend not creating any other parallel system.

**Item 11**

We welcome introduction of an all-European central harmonized system for serious cases of health damage in the form of information on serious cases provided immediately by individual companies and annual publication of consolidated anonymous database of reports in the all-European scope.

However, we recommend clarification of the contents of definition of terms “undesirable events” and “serious undesirable events”.

**Item 12**

With regard to the notification issue – see comment under Item 1.

**Item 13**

The industry is ready to discuss how existing ingredients review mechanisms at the EU level can be modified to work more effectively.

At the same time, the contents of definition of “competent authority” is unclear.

**Item 14**

The existing legislation has at its disposal sufficient tools for securing safety of products, and these tools cover to sufficient extent also the field of innovations (innovated products).

As far as the new categories of products are concerned, the mechanism for their assessment should not go behind the framework of the existing assessment system.

**Item 15**

See the argumentation in Item 14 – we resolutely disagree with any addition to the existing legislation framework in this field.

**Item 16**

We support measures of competent authorities aimed at securing that the products placed on the market were comprehensively checked from the view of their safety by a detailed and professional analysis.

**Item 17**

We do not think that introduction of broader positive lists of substances (raw materials) would increase the competitiveness of the European cosmetics industry within the global harmonization. It could be therefore stated that all relevant aspects are in this respect already sufficiently covered by the existing Annexes to the Cosmetics Directive.

**Item 18**

There is no need for a specific mechanism. Re-evaluation of substances can already now be decided at any time. Such action should however be triggered by new relevant safety information rather than by time limitations.

Jan Levora  
Executive Director  
Czech Association for Branded Products

Prague, 9 March 2007