



// **MARCH 2007**

**CED RESPONSES TO CONSULTATION PAPER ON THE
SIMPLIFICATION OF COSMETICS DIRECTIVE 76/768/EEC**

The Council of European Dentists represents over 300,000 dentists through 31 national dental associations. It was established in 1961 to advise the European Commission on matters relating to the dental profession, and its objectives are to promote a high level of oral health and dental care, and to represent the dental profession in the EU.

Certain dental products and preparations fall under the category of cosmetics, so the dental profession has a significant interest in ensuring that the framework for their regulation is simple and legally certain, as well as – and this is paramount – safe for consumers.

We would like to make several comments in response to the consultation paper on the simplification of the Cosmetics Directive, as follows.

// **ITEM 2: INTERNATIONAL ALIGNMENT**

The CED does not have estimates of costs stemming from international regulatory divergences. International alignment should be pursued in order to reduce costs for European businesses. In many instances, however, regulatory frameworks in Europe are stricter than elsewhere, and it is important that international alignment is not achieved at the expense of consumer safety in Europe.

// **ITEM 5: OBJECTIVE CRITERIA**

The CED does not believe that substances should be regulated according only to the application of objective criteria, independent of purpose. Any given substance may have a variety of uses on different parts of the body, and different concentrations of the substance may be appropriate for some uses on some parts of the body, but not on others. Equally, the use of some substances must be restricted to professionals in the interests of safety, whereas others may be suitable for general use. We believe therefore that the intended function, use and user of substances should continue to be taken into account for the purposes of regulating substances.



// **ITEMS 8 AND 13: MANUFACTURER'S RESPONSIBILITY AND SCRUTINY OF INDIVIDUAL SUBSTANCES**

It is very important that manufacturers be held responsible for the “uncompromised safety” of cosmetic products. The CED also understands the Commission’s desire to avoid the comprehensive assessment of individual substances. However, relying alone on manufacturers to certify the safety of their products without independent scientific scrutiny of individual substances is be problematic. Manufacturers are often under considerable commercial pressure to expedite the marketing of their products, and this may very well conflict with the need for longer-term safety assessment of the products.

The CED believes that independent scientific scrutiny of individual substances must not be reduced to only exceptional cases, as the Commission proposes. This scrutiny should be coupled with a strengthening of the principle of manufacturer’s responsibility. In order to counter the risk of manufacturers’ bias in certifying the safety of their products, random scientific checks to verify safety claims could be used.

// **ITEM 10: PRODUCT WITHDRAWAL**

The CED agrees to the need for the Cosmetics Directive to provide for clear response mechanisms in the event of non-compliance with the Directive. This should include clear rules on product withdrawal.

// **ITEM 15: “UNCOMPROMISED SAFETY”**

The concept of uncompromised safety needs to be reflected clearly in the Cosmetics Directive and in the interpretation of that Directive. To this end, the terminology of “damage”, “harm” and “undesirable effects” could be better defined.