E U R O P E A N E C O N O M I C A R E A

S T A N D I N G C O M M I T T E E
O F T H E E F T A S T A T E S

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EFTA WORKING GROUP ON TECHNICAL BARRIERS TO TRADE

COMMENTS BY THE EEA EFTA STATES ON THE COMMISSION PROPOSAL FOR THE SEVENTH AMENDMENT OF COUNCIL DIRECTIVE 76/768/EEC ON COSMETICS (COM (2000) 189 Final)

I EXECUTIVE SUMMARY

The EEA EFTA States have examined the Commission Proposal for a Directive of the European Parliament and of the Council amending for the seventh time Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to Cosmetics Products (COM (2000) 189 Final). The EEA EFTA States propose two amendments to the Commission Proposal as regards banning of substances for which safety cannot be assessed and the role of the OECD in the adaptation process.

II ANIMAL TESTING IN THE COSMETICS SECTOR

1. Reference is made to the proposed new *Article 4a,* which states that a definite prohibition on the use of test-methods involving animals will enter into force by 1 June 2006 at the very latest, regardless of whether alternative methods on all relevant toxicity end-points have been developed or not.

2. Taking account of the complexity of biological systems, it is not unlikely that only adapted alternative methods on some of the short-term toxic effects will be in place by the end of the transitional period. Reference is made to the following points, which have been mentioned in the Commission Proposal;

- Only three alternative (short-term toxic effect) methods have been validated to date;
- The development, validation and acceptance of alternative methods have proved to be an extremely complex scientific challenge;
- It has not been possible to time-table and schedule the necessary research into complex biological systems;
- For the long-term effects, the prospects of development and validation of in vitro methods are less promising. For those end-points it will be necessary to

rely on the use of chemicals and ingredients with established toxicological profiles, or use new chemicals which have been tested to meet regulatory requirements other than those laid out in this Directive.

3. The EEA EFTA States are concerned that the proposed ban on animal testing, regardless of alternative methods being developed, might lead to reduced consumer protection. As a result of the ban, the cosmetic industry might not be able to provide the necessary data needed by the SCCNFP to assess the safety of a given substance for use in cosmetic products.

4. In order to ensure that substances for which safety cannot be assessed are not allowed, it is proposed that the following paragraph is added to Article 4a:

> *"2. Substances, of which the safe use in cosmetic products cannot be assessed because of the requirements set out in Article 4a, 1, are not permitted with any function in products falling within the scope of this Directive*."

III THE ROLE OF THE OECD IN THE ADAPTATION PROCESS

5. With reference to the discussion of the role of the OECD, the EEA EFTA States are of the opinion that the OECD should continue to play a role in the adaptation of the new *in vitro* methods.

6. The EEA EFTA States propose to maintain the reference to the OECD toxicity test guidelines by inserting the following (italics) in the proposed new Article 4 a, 1 b, last sentence:

> "However, if there has been insufficient progress in developing satisfactory methods to replace animal testing scientifically validated as offering an equivalent level of protection for the consumer, *taking into account OECD toxicity test guidelines,* the Commission shall, by [1 June 2004], submit draft measures to postpone the date of implementation of this provision for a sufficient period, and in any case for no more than two years, in accordance with the procedure laid down in Article 10."

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