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COMMISSION RECOMMENDATION

of 7 June 2006

Establishing guidelines on the use of claims referring to the absence of tests on animals pursuant to Council Directive 76/768/EEC

(Text with EEA relevance)

(2006/406/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

HEREBY RECOMMENDS:

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (¹), and in particular the second sentence of the second subparagraph of Article 6(3) thereof,

Whereas:

- (1) Article 6(3) of Directive 76/768/EEC provides that the manufacturer or the person responsible for placing a cosmetic product on the Community market may take advantage, on the product packaging or in any document, notice, label, ring or collar accompanying or referring to the product, of the fact that no animal tests have been carried out only if the manufacturer and his suppliers have not carried out or commissioned any animal tests on the finished product, or its prototype or any of the ingredients contained in it, or used any ingredients that have been tested on animals by others for the purpose of developing new cosmetic products.
- (2) It is thus possible to claim on a cosmetic product that no animal testing was carried out in relation to its development.
- (3) It is necessary to establish guidelines aimed at ensuring that common criteria are applied in the use of such claims, that an aligned understanding of the claims is reached and in particular that such claims do not mislead the consumer or lead to unfair competition on the market between manufacturers.
- (4) Moreover, a general understanding of the provision set out in the second subparagraph of Article 6(3) of Directive 76/768/EEC within the framework of good administrative cooperation would facilitate a common implementation by control authorities. This would prevent, for instance, distortions in the internal market.
- (5) The measures provided for in this Recommendation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

For the purposes of the application of the second subparagraph of Article 6(3) of Directive 76/768/EEC, Member States should use the following guidelines.

1. Main principles

The use of claims on a cosmetic product should not mislead the consumer. The consumer should obtain the real benefit of being able to make an informed choice as a result of the 'not tested on animals' labelling claim. The information should be useful for the consumer.

The use of claims should not lead to unfair competition on the market between manufacturers and/or suppliers who use such claims as marketing tools.

2. Voluntary use of claims

Under the second subparagraph of Article 6(3) of Directive 76/768/EEC the manufacturer or the person responsible for placing the product on the market may use a claim to indicate that no animal testing has been carried out. Therefore it is not mandatory, neither for the manufacturer nor for the person responsible for placing the product on the market, to use such a claim. It is a possibility which is offered to those persons if the requirements in the second subparagraph of Article 6(3) of Directive 76/768/EEC, taking into account the present guidelines, are met.

3. Interpretation of the requirements set out in the second subparagraph of Article 6(3) of Directive 76/768/EEC

The definitions of certain terms used in the context of the present guidelines are repeated below for clarity purposes:

- 'cosmetic product' means 'cosmetic product' as defined in Article 1 of Directive 76/768/EEC,
- 'finished cosmetic product' means 'finished cosmetic product' as defined in Article 4a(3)(a) of Directive 76/768/EEC,

^{(&}lt;sup>1</sup>) OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2005/80/EC (OJ L 303, 22.11.2005, p. 32).

- 'ingredients' means any chemical substance or preparation of synthetic or natural origin, including perfume and aromatic compositions used in composition of cosmetic products (see in that respect Article 5a(1) of Directive76/768/EEC which excludes 'perfumes and aromatic compositions' only for the purpose compiling of an inventory of ingredients),
- -- 'prototype of the cosmetic product' means 'prototype' as defined in Article 4a(3)(b) of Directive 76/768/EEC,
- 'animal' means 'animal' as defined in Article 2(a) of Council Directive 86/609/EEC (¹),
- 'testing' means any tests performed in relation to the development or safety evaluation of the product or its ingredients (see in that respect Article 7a(1)(h) of Directive 76/768/EEC),
- 're-testing' means testing a product or its ingredients another time.

The requirements in the second subparagraph of Article 6(3) should be interpreted as follows:

- (a) 'no animal tests have been carried out' means that no animal test whatsoever was carried out in relation to the development or safety evaluation of a cosmetic product or its ingredients. Only the full replacement of the animal tests by an alternative method, and therefore not a reduction or a refinement of animal tests, allows the claim to be made. Furthermore, it does not matter where the test (including re-testing) is performed (in the Community or in third countries) or when the test has been performed.
- (b) 'the manufacturer and his suppliers have not carried out or commissioned any animal tests [...]' means that the manufacturer and his suppliers, including all suppliers in the supply chain:
 - have not directly carried out the animal tests,
 - have not commissioned animal tests, which means that they have not requested or paid for animal tests by means for instance of sponsorship of research by academic institutions.
- (c) The fact that the manufacturer and his suppliers should not have 'used any ingredients that have been tested on animals by others for the purpose of developing new

cosmetic products' means that the manufacturer and his suppliers should not have used ingredients for which data resulting from animal tests made by others for the purpose of developing a new cosmetic product are available for instance in scientific literature. In this context 'the development of new cosmetic product' means either the reformulation of product already on the market or the development of a totally new product (innovation). A new packaging can not be considered as a new cosmetic product.

4. Burden of proof

Any person who claims on a cosmetic product that no animal testing was carried out in relation to its development should be responsible for the claim and should be able to prove the relevance of the claim with regard to Directive 76/768/EEC.

In that context it is recalled that all relevant information for control purposes has to be readily accessible in accordance with Article 7a(1) of Directive 76/768/EEC and in particular points (d) and (h) thereof, which read as follows:

- '(d) Assessment of the safety for human health of the finished product.
 - [...]
- (h) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety evaluation of the product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of nonmember countries'.

5. Wording of claims

Any person who wishes to use a claim to indicate that no animal testing has been carried out is free to choose the wording of the claim and/or to use any pictures, figurative or other signs, as long as all the relevant requirements in Directive 76/768/EEC are fulfilled.

Done at Brussels, 7 June 2006.

For the Commission Günter VERHEUGEN Vice-President