COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 22.11.2001
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2000/0077 (COD)

Amended 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 cosmetic products

(presented by the Commission pursuant to Article 250(2) of the EC Treaty)

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(Text with EEA relevance)

1. BACKGROUND

Transmission of the Proposal to the Council and the European Parliament - COM(2000) 189 final - 2000/0077 (COD) - in accordance with article 175(1) of the Treaty:	6 April 2000
Opinion of the Economic and Social Committee:	20 September 2000
Opinion of the European Parliament - first reading:	3 April 2001.

2. OBJECTIVE OF THE COMMISSION PROPOSAL

The main objective of the initial proposal was to settle definitively the question of animal testing in the cosmetic sector. The current legislative provisions providing the prohibition on the marketing of cosmetic products containing ingredients or combinations of ingredients tested on animals after 30 June 2000 (30 June 2002 following the second postponement by Commission Directive 2000/41/EC) shall be amended so as to make them WTO-compliant, legally and practically enforceable, thereby offering a genuine benefit to animal welfare.

The main elements of the initial proposal were:

- the introduction of a permanent and definitive prohibition on the performance of tests on animals for finished cosmetic products;
- a switch from a marketing ban to a testing ban WTO compliant for ingredients and combinations of ingredients used in cosmetic products. The date of implementation of this ban is foreseen three years after the date of implementation of the proposed Directive. However, it should be postponed for no more than two years if there has been insufficient progress in developing satisfactory methods to replace animal testing scientifically validated;
- a commitment that EU will take the lead in the international acceptance of alternative methods, in particular through the adoption of bilateral agreements and negotiations at OECD level;
- to allow the use of claims indicating that animal testing has not been performed. However, to ensure that such claims do not mislead the consumer, the Commission, in consultation with the Member States, will publish guidelines in order to clarify their use.

In its amended proposal, the Commission has incorporated many suggestions of the European Parliament, which aim to improve health and consumer protection.

3. COMMISSION OPINION ON THE AMENDMENTS ADOPTED BY THE PARLIAMENT

3.1. Amendments accepted in part or principle by the Commission: 1 (1st part), 2, 4, 5, 7 (2nd part), 9 to 12, 14 (2nd and 3rd parts), 15 (2nd part – with the exception of the suggested consultation of the European Parliament), 16 to 19, 23 (2nd part), 26, 30, 32 and 49 (2nd part)

The Commission can accept in principle the first part of amendment 1 and amendment 2 which propose the inclusion of a reference to Directive 86/609/EEC relating to the protection of animals used for experimental and other scientific purposes. However, the reference suggested in amendment 2 would be more relevant in recital 2 (as suggested by amendment 1) than recital 3 which relates to the testing ban for finished products. To this end, recital 2 should be amended as follows:

«Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes aims to ensure that the number of animals used for experimental purposes is reduced to a minimum. In accordance with Directive 93/35/EEC amending for the sixth time Directive 76/768/EEC, it is essential that the aim of abolishing animal experiments be pursued and that the prohibition of such experiments becomes effective on the territory of the Member States.»

The Commission can accept in principle amendments 4 and 5 subject to the following rewording:

«In order to facilitate the rapid development of non-animal alternative tests, in particular those tests which are commonly used by other sectors and specified as regulatory requirements in the Community, more coordinated action is needed at the Community and national levels, including funding of relevant scientific research.»

«The Commission has earmarked 17.5 billion Euro for the new framework programme for research and innovation in Europe over the period 2003-2006. In this context, the policy of reduction, refinement and replacement of animal tests will be continued.»

The commission can accept in principle the 2nd part of amendment 7, as all interested parties, including the NGOs, are consulted in the drafting of the guidelines, subject to the following rewording:

«In developing such guidelines, the Commission will consult all interested parties, including the relevant NGOs».

Directive 76/768/EEC already requires the safety assessment of products based on their intended and foreseeable use. However, the Commission can accept the principle of amendment 9 aiming to specify the safety requirements for cosmetic products intended for children, subject to the following rewording:

«Special guidance should be provided by the SCCNFP concerning the safety of products intended for children.»

The Commission can accept in principle amendment 10 and the third part of amendment 14, dealing with substances which are carcinogenic, mutagenic and toxic for the reproduction under the Dangerous substances Directive. Under Directive 76/768/EEC, cosmetic products are already required not to cause any harm to human health, the mandatory safety assessment provided by Article 7a(1) including potential mutagenic, carcinogenic or reprotoxic effects. Furthermore, this issue is already taken into account by the Commission on a horizontal basis in the proposed White Paper on the new chemical policy which plans to ban the use of substances classified in categories 1 or 2 as carcinogenic, mutagenic or toxic for reproduction under Annex 1 of Directive 67/548/EEC, except by following a procedure of authorisation providing that companies show their safe use for certain purposes. Therefore, there is no need for a specific provision in Directive 76/768/EEC.

The Commission can accept in principle the suggestions of amendments 11, 32 and 30 aiming at improving information provided to consumers regarding the minimum durability of cosmetic products, subject to the following rewording:

In the recital: *«In order to improve the information provided to consumers, cosmetic products should bear more precise indications concerning the durability of their use.»*

Article 6(1)(c) should be amended as follows:

«(c) the date of minimum durability.

The date of minimum durability of a cosmetic product shall be the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with Article 2.

The date of minimum durability shall be indicated by the date itself followed by the symbol "+". The date shall be clearly expressed and shall consist of either the month and year or the day, month and year in that order.

If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.»

The Commission can accept in principle amendment 12, the second part of amendment 23 and amendment 49 which require the information on the presence in cosmetic products of fragrance ingredients with well-recognised potential to cause contact allergy. This information will allow consumers, sensitive to these substances, to avoid cosmetic products unsuitable to them. The labelling of such ingredients through an amendment of the current Article 6.1.g) would answer the concerns. To this end, the following rewording is proposed:

In the recital: *«Certain substances have been identified as an important cause of contact-allergy reactions in fragrance-sensitive consumers. In order to ensure that these consumers are adequately informed, it is therefore necessary to amend the provisions of the Directive so as to require the mention of these substances in the list referred to Article 6(1)(g), regardless of their source or function. This information will improve the diagnosis of contact allergies in this population and will enable sensitised consumers to avoid products they may not tolerate».*

Article 6(1)(g) should be amended as follows:

«(g) a list of ingredients in descending order of weight at the time they are added. That list shall be preceded by be the word "ingredients". Where that is impossible for practical

reasons, an enclosed leaflet, label, tape or card must contain the ingredients to which the consumer is referred either by abbreviating information or the symbol given in Annex VIII, which must appear on the packaging.

The following shall not, however, be regarded as ingredients:

- *impurities in the raw materials used,*
- *subsidiary technical materials used in the preparation but not present in the final product,*
- *materials used in strictly necessary quantities as solvents or as carriers for perfume and aromatic compositions.*

Perfume and aromatic compositions and their raw materials shall be referred to by the word "parfum" or "aroma". However, the presence of substances, the mention of which is required under the column «other limitations and requirements» of Annex III, Part 1, shall be indicated in the list, irrespective of their function in the product.

Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations of more than 1 %.

Colouring agents may be listed in any order after the other ingredients, in accordance with the colour index number or denomination adopted in Annex IV.

For decorative cosmetic products marketed in several colour shades, all colouring agents used in the range may be listed, provided that the terms "may contain" or the symbol "+/-" are added.

An ingredient must be identified by the common name referred to in Article 7(2) or, failing that, by one of the names referred to in Article 5a(2), first indent.

In accordance with the procedure laid down in Article 10, the Commission may adapt the criteria and conditions under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients on the above-mentioned list provided by Commission Directive 95/17/EC of 19 June 1995 laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products.»

The Commission would accept the principle of the listing of the recognised fragrance allergens in the Annex III according to the modalities suggested in amendment 49 (setting of threshold levels suggested by the SCCNFP), in line with the proposed amended Article 6(1)(g). However, according to Article 8(2) of Directive 76/768/EEC, the proposed adaptation of Annex III, part 1, has to be done via a Commission Directive adopted under the comitology procedure. Therefore, such technical adaptation should be done after the final adoption of the Directive amending Article 6(1)(g), which would give the legal basis for such a technical adaptation.

The Commission can accept to consider the principle of an introduction of a derogation to the full testing ban for safety reasons proposed by the second part of amendment 15 (with the exception of the suggested consultation of the European Parliament), to ensure the key objectives of consumer protection and public health, taking into account of the expected progress in developing satisfactory methods to replace animal testing. However, the system of

such derogation restricted to existing ingredients should be reviewed to be implemented in a non-discriminatory manner.

The Commission can accept in principle amendment 16 regarding the definition of finished products, subject to the following rewording: *«A "finished cosmetic product" shall mean the cosmetic product in its final composition, as placed on the market and made available to the final consumer.»*

The Commission can accept in principle the second part of amendment 14, amendments 17, 18 and 19, which require additional information to be included in the Annual Report made by the Commission, taking into account that the work done at OECD level is already part of the existing Annual Report. However, in order to ensure a substantive evaluation of the progress made and the collection of appropriate data, it is proposed to present the report on a three-year basis. Therefore, the following rewording of the provision dealing with the Report is proposed:

«Every three years the Commission shall present a report to the European Parliament and the Council. That report shall contain:

a) an account of the progress in the development, validation and legal acceptance of alternative methods to those involving experiments on animals. It shall contain precise data on the number and type of experiments relating to cosmetic products carried out on animals. The Member States shall be obliged to collect that information in addition to collecting statistics as laid down by Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes;

b) an account of the progress made by the Commission in its efforts to obtain acceptance by the Organisation for Economic Cooperation and Development (OECD) of alternative methods validated at Community level, and to obtain, within the framework of bilateral agreements with third countries, recognition of the results of tests carried out in the Community using alternative methods so as not to obstruct the export of cosmetic products for which such methods have been used;

c) an account of the progress made in international fora, in particular the World Trade Organisation, to enhance the protection of animal welfare;

d) an explanation of how the economic and competition needs, of small and medium enterprises in particular, have been taken into account in the implementation of Article 4a.»

The provisions of the Directive already require the safety assessment of cosmetic products based on their intended and foreseeable use. However, to give particular attention to cosmetic products for children and intimate hygiene products, the Commission can accept in principle amendment 26 subject to the following rewording: *«(d) assessment of the safety for human health of the finished product. To that end, the manufacturer shall take into consideration the general toxicological profile of the ingredient, its chemical structure and its level of exposure. He shall, in particular, take into consideration the specific exposure characteristics of the areas on which the product will be applied or of the population for which it is intended. In particular, there shall be a specific assessment for cosmetic products intended exclusively for use on children under the age of three and for cosmetic products intended exclusively for use in intimate hygiene.»*

3.2. Amendments not accepted by the Commission: 1 (2nd part), 3, 7 (1st part), 13 and 14 (1st part), 15 (1st part), 20 and 21, 23 (1st part), 27 and 28, 36 and 37, 39, 43, 47 and 49 (1st part)

The Commission cannot accept the second part of amendment 1 and amendment 36, which request the Commission to present other proposals, being contrary to the right of initiative of the Commission.

The Commission cannot accept amendment 3 and the first part of amendment 15 dealing with the EU testing ban for ingredients. The Commission cannot accept the deletion of the postponement which aims to ensure the key objectives of consumer protection and public health, taking into account the expected progress in developing satisfactory methods to replace animal testing scientifically validated as offering an equivalent level of protection for the consumer. The Commission has to ensure a high level of consumer protection and therefore to keep the possibility to postpone in case of lack of validation of key alternative methods for this sector.

The Commission cannot accept the first part of amendment 7 and amendment 47 dealing with the use of claims relating to animal testing. These are contrary to the intention of the Commission proposal to avoid the use of such claims that mislead consumers by giving them the impression that none of the ingredients contained in the products have been tested on animals whilst such tests have necessarily been performed on almost every ingredient at least once by someone. The aim of the Commission is to avoid misleading claims and give complete information to consumers. The details should be dealt with in the production of guidelines where all interested parties will be involved.

The Commission cannot accept amendments 13, 21 and 28 aiming at publishing all data concerning each cosmetic product in the Inventory. Such information is part of the product information required for the effective in-market control system established by the 6th amendment to ensure free movement of goods while ensuring consumer safety. This is not the purpose of the Inventory of cosmetic ingredients published by the Commission. Furthermore, such a proposal would raise concerns in terms of industry property rights and trade secrecy, and could lead to unfair competition, while not improving consumer information.

The Commission cannot accept amendment 20 and the first part of amendment 23, which aim to achieve a full ingredient listing, including for perfume composition. Such a full labelling of all fragrance ingredients would neither be feasible or helpful to sensitised consumers or dermatologists and would be disproportionate to the anticipated risks. Furthermore, these amendments are in contradiction with amendment 12, the second part of amendment 23 and amendment 49, aiming at introducing a labelling system for the fragrance ingredients with well-recognised potential to cause contact allergy, that the Commission has accepted in principle.

The Commission initial proposal provided a switch from the marketing ban to an EU testing ban WTO-compliant, legally and practically enforceable, thereby offering a genuine benefit to animal welfare. The Commission cannot accept amendment 37 and the first part of amendment 14 reintroducing the marketing ban as and when alternatives are available, with a definitive date after which no products can be marketed if tested on animals, whether or not there are validated alternatives. It is not in conformity with WTO-rules and likely to be challenged. As already stated in recital 5 of the initial proposal, the Commission will pursue its effort to promote rapid international acceptance of alternative methods at OCDE level. Having noticed the concerns of the public opinion, it will stimulate discussions on trade and animal welfare in a multilateral forum. A unilateral Community ban on marketing would be

contrary to the policy of a multilateral approach to animal welfare trade issues. The Community has taken a position that discussions on trade and animal welfare (and other PPMs issues) should be done in a multilateral forum. A unilateral action by the Community such as the proposed marketing ban would undermine this multilateral approach. The Commission underlines its commitment to the use of international standards as a basis for measures which have a trade impact. The Community would be in contradiction with its international commitments to accept the results of tests carried out on animals in third countries because of the mutual acceptance of data agreement. Furthermore, considering the development of alternatives, the time scale suggested for its implementation is not realistic. It should take into account the development and international acceptance of alternative methods to ensure that consumer safety would not be endangered. Only a co-ordinated approach at international level would improve animal welfare, and on a wider scale.

The Commission cannot accept amendment 27, suggesting additional data on animal tests performed to be included in the product information required for each cosmetic product put on the market. This additional requirement obliging the manufacturer to check if any of the ingredients used have been once tested on animals somewhere in the world is impossible to fulfil, and could raise concerns under the TBT agreement (Article 5.2.3).

The Commission cannot accept the additional requirement of a compulsory labelling "tested on animals" required by amendments 37 and 39. Such amendment is not proportionate and may raise concerns, among others under the TBT agreement, as most imported products would bear this mention.

The Commission cannot accept amendment 43 aiming to avoid use of fragrances in some categories except when they fulfil specific purposes. The suggested ban would be contrary to the principles of necessity and proportionality. The Commission has already accepted to reinforce safety requirements for some categories of products such as products for children and intimate hygiene products, as suggested by amendment 26.

3.3. Amended proposal

Having regard to Article 250, paragraph 2, of the EC Treaty, the Commission amends its proposal as indicated above.

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DOCUMENTS

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