COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.7.2002
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2000/0077 (COD)

OPINION OF THE COMMISSION

pursuant to Article 251 (2), third subparagraph, point (c) of the EC Treaty, on the European Parliament's amendments to the Council's common position regarding the 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

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1. INTRODUCTION

Article 251(2), third subparagraph, point (c) of the EC Treaty provides that the Commission is to deliver an opinion on the amendments proposed by the European Parliament at second reading. The Commission sets out its opinion below on the 29 amendments proposed by Parliament.

2. BACKGROUND

– The Commission adopted it initial proposal on 5th April 2000[1].

– The Economic and Social Committee gave its opinion on 20th September 2000[2].

– The European Parliament approved the proposal with amendments in the first reading on 3rd April 2001[3].

– The Commission adopted its amended proposal on 22nd November 2001[4].

– The Council adopted its Common Position on 14th February 2002[5].

– The Commission supported the common position[6].

– The European Parliament approved the proposal with amendments in the second reading on 11th June 2002[7].

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1 OJ C 311 E, 31.10.2000, p. 134.
2 OJ C 367, 20.12.2000, p. 1.
3 OJ C 21 E, 24.1.2002, p. 104.
4 OJ C 51 E, 26.2.2002, p. 385.
5 OJ C 113 E, 14.5.2002, p. 109.
6 SEC(2002) 225.
7 Not yet published in the OJ.

3. PURPOSE OF THE PROPOSAL

The main objective of the initial proposal was to settle definitively the question of animal testing in the cosmetic sector. The main elements of the initial proposal were the introduction of a permanent and definitive prohibition to perform tests on animals for finished cosmetic products and a switch from a marketing ban of cosmetic products containing ingredients tested on animals to a ban to perform tests in the EU on animals for ingredients used in cosmetic products to comply with WTO rules. The date of implementation of this ban was foreseen three years after the date of implementation of the proposed Directive; however it could be postponed for no more than two years if there had been insufficient progress in developing satisfactory methods to replace animal testing scientifically validated.

In its amended proposal, the Commission incorporated many suggestions from the European Parliament, which aim to improve health and consumer protection. The Common Position also included these suggestions.

4. OPINION OF THE COMMISSION ON THE AMENDMENTS BY THE EUROPEAN PARLIAMENT

4.1. Amendments accepted by the Commission

- The Commission can accept in principle the first part of amendment 1 which proposes the inclusion of a reference to Directive 86/609/EEC relating to the protection of animals used for experimental and other scientific purposes. This reference is already included in recital 3 of the Common Position.

- The Commission can accept the first part of amendment 5 which requests to *"increase"* the efforts in the development and validation of alternative methods, as it is already foreseen for the implementation of the Chemical policy. Therefore, recital 6 should read as follows: *"Better coordination of resources at Community level will contribute to increasing the scientific knowledge indispensable for the development of alternative methods. It is essential, for this purpose, that the Community continue and increase its efforts and take the measures necessary for the promotion of research and the development of new methods, in particular within its Sixth Framework Programme as set out in Decision No 2002/...../EC of the European Parliament and of the Council"*.

- The Commission can accept the second part of amendment 27 which requests the addition of the following paragraph: *"The Commission shall in particular ensure the development, validation and legal acceptance of alternative test methods which do not use live animals"*.

- The Commission can accept in principle the second part of amendment 28. It would accept the principle of the listing of the recognised fragrance allergens in Annex III of Directive 76/768/EEC according to the suggested modalities (setting of threshold levels suggested by the SCCNFP). However, according to Directive 76/768/EEC, the proposed modification of Annex III has to be implemented via a Commission Directive adapting to technical progress, adopted under the comitology procedure.

4.2. Amendments rejected by the Commission

- The Commission cannot accept the second part of amendment 1 which requests the Commission to present another proposal for amending Directive 86/609/EEC. It is contrary

to the right of initiative of the Commission. The Commission has already made a declaration at the Internal Market Council of November 2001 confirming "its intention shortly to begin work on the revision of Directive 86/609/EEC".

- The Commission cannot accept amendments 2, 4, 15 and 16 dealing with the EU testing ban for ingredients. These amendments reintroduce the concept of a cut-off date for the testing ban which is contrary to the approach adopted by the Council in its Common Position supported by the Commission. They contradict the aim 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 proposed system of derogation restricted to existing ingredients is contrary to the progressive testing ban adopted in the Common Position supported by the Commission.

- The Commission cannot accept amendment 3 which deletes the prioritisation of alternative methods (according to the 3Rs principle: replacement, reduction, refinement) introduced in the Common Position supported by the Commission.

- The Commission cannot accept amendment 30 which requests the setting up of a fixed timetable for the tests within 5 years. The current scientific prospects cannot ensure the validation of the methods under development, bearing in mind that one in-vitro method has already failed at validation.

- The Commission cannot accept the second part of amendment 5 which would restrict the scope of research to non-animal alternative methods without taking into account the 3Rs principle.

- The Commission cannot accept amendment 6, which requests the Commission to present another proposal, being contrary to the right of initiative of the Commission.

- The Commission cannot accept amendments 7, 13 and 31 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 contrary to the approach adopted by the Council in its Common Position, i.e. the introduction of a progressive marketing ban subject to the previous acceptance of alternative methods at OECD level, in order to reduce the risk of a challenge under WTO. The suggested marketing ban is in contradiction with the purpose of the Commission to avoid a unilateral action by the Community. It is not in conformity with WTO rules and is likely to be challenged. The Commission will pursue its effort to promote rapid international acceptance of alternative methods at OCDE level. Having noted the concerns of 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 conducted in a multilateral forum. Such a unilateral action 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 is not

endangered. Only a co-ordinated approach at international level will improve animal welfare, and on a wider scale.

- The Commission cannot accept the additional requirement of compulsory labelling "tested on animals" required by amendments 7 and 22. Such amendment is not proportionate and may raise concerns, among others under the TBT agreement, since most imported products would bear this mention.

- The Commission cannot accept amendments 8 and 23 dealing with the use of claims relating to animal testing. These are contrary to the intention of the Commission 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 amendment 9 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. Safety requirements for some categories of products such as products for children and intimate hygiene products have already been reinforced through a new provision.

- The Commission cannot accept amendments 10, 11, 14 and 18 leading to a general ban which is contrary to the principle of risk assessment set up in Directive 76/768/EEC. The Common Position has already introduced specific provisions regarding substances which are carcinogenic, mutagenic and toxic for reproduction (CMR), taking into account the latest scientific opinion, in line with the principle of risk assessment. The Commission shares the Parliament's objective to prevent risks to consumer health due to CMR-substances in cosmetic products. Directive 76/768/EEC already regulates the use of CMR-substances in cosmetic products in a sectorial manner. Restrictions of use or bans are imposed by the overriding safety and product information requirements and by specific regulation of such substances in the annexes of this Directive. Even if the Commission accepts the principle that ingredients which are classified as CMR-substances, categories 1 and 2 should in general not be used in cosmetics, it wishes to ensure that this regulatory approach is consistent with the cosmetics legislation and the approach of the White Paper on Chemical Policy. Furthermore, this issue has already been considered 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 following a procedure of authorisation providing that companies show their safe use for certain purposes. This approach will be incorporated into the future proposals for a new Community legislation on chemicals. The provisions concerning CMR-substances in cosmetics should be consistent with that approach.

- The Commission cannot accept amendment 12 dealing with ingredients potentially allergenic. Recital 11 of the Common Position already specifies the measures requested for fragrance allergens, i.e. information to consumer through labelling, as suggested by the relevant Scientific Committee.

- The Commission cannot accept amendment 17 dealing with the definition of finished products. This definition has already been reconsidered in the Common Position with the aim of achieving a consistent and coherent legislation.

- The Commission cannot accept amendments 19 and 26 aimed 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 amendments 20 and 29 dealing with the durability of cosmetic products. The provisions on the minimum durability date have already been reconsidered in order to provide the consumer with helpful information in a coherent and proportionate manner. The suggestion for a symbol is been considered in the whole reflection on this issue; however, the open-jar is not considered as the more appropriate.

- The Commission cannot accept amendment 21 and the first part of amendment 28, which aim to achieve a full ingredient listing, including perfume composition. Such a full labelling of all fragrance ingredients would neither be feasible nor helpful to sensitised consumers or dermatologists and would be disproportionate to the anticipated risks. The SCCNFP has expressed the opinion that fragrance ingredients have to be considered as an important cause of contact allergy and have identified 26 fragrance ingredients, which correspond to the most frequently recognised allergens. Information should be provided to consumers about the known presence in cosmetic products of fragrance ingredients with well-recognised potential to cause contact allergy. The Common Position has already introduced the legal basis to allow the labelling of such ingredients by amending the current Article 6.1.g). It cannot accept the deletion of this modification suggested in amendment 21 which would withdraw the legal basis for requesting the labelling of fragrances with potential allergenic effects as requested in the second part of amendment 28. Furthermore, according to Article 8(2) of Directive 76/768/EEC, the modification of Annex III proposed in amendment 28 has to be implemented via a Commission Directive adapting to technical progress, adopted under the comitology procedure.

- The Commission cannot accept amendment 24 dealing with the product information, the current legislation already specifies that the information is accessible for control authorities for control purposes.

- The Commission cannot accept amendment 25, suggesting additional data on animal tests performed should 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 tested once 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 first part of amendment 27 which requests an annual report. The requirement for a report every 3 years aims to provide a better overview of the progress made and align it to the Report requested in the framework of Directive 86/609/EEC, taking into account available resources.

5. CONCLUSION

Pursuant to Article 250(2) of the EC Treaty, the Commission amends its proposal as set out above.