



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.02.2002

SEC(2002) 225 final

2000/0077 (COD)

**COMMUNICATION FROM THE COMMISSION
TO THE EUROPEAN PARLIAMENT**

pursuant to the second paragraph of Article 251(2) of the EC Treaty

concerning the

**common position of the Council on the adoption of a European Parliament and Council
Directive amending for the seventh time Council Directive 76/768/EEC on the
approximation of the laws of the Member States relating to cosmetic products**

**COMMUNICATION FROM THE COMMISSION
TO THE EUROPEAN PARLIAMENT**

pursuant to the second paragraph of Article 251 of the EC Treaty

concerning the

common position of the Council on the adoption of a European Parliament and Council Directive amending for the seventh time Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

1. BACKGROUND

- The above mentioned proposal [COM(2000) 189 final] was adopted by the Commission on 5th April 2000 and then transmitted to the Council and the European Parliament.
- The European Parliament approved the proposal with amendments in the first reading on 3rd April 2001.
- The Commission's amended proposal [COM(2001) 697 final] was adopted on 22nd November 2001 and then transmitted to the Council and the European Parliament.
- The Council reached a political agreement with majority on 26th November 2001 and adopted its Common Position on 14th February 2002.
- The Economic and Social Committee gave its Opinion on 20th September 2000.

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 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.

3. COMMENTS ON THE COMMON POSITION

3.1. General

The Council's Common Position corresponds with the Commission's amended proposal, especially concerning the provisions to improve health and consumer protection. However, concerning the issue of animal testing, the Council has made changes to the Commission proposal.

3.2. Fate of the Amendments

Of the 31 amendments adopted by the European Parliament, the Commission has accepted in principle 14 amendments and part of 7 other amendments.

The Commission has accepted the inclusion of amendments aimed at improving health and consumer protection, by providing consumers with more relevant information, through the improvement of safety requirements for some categories of products such as products for children and intimate hygiene products, the requirement for a minimum durability date for all cosmetic products or the introduction of a labelling system for allergenic fragrance ingredients.

On the contrary, even if sharing the objective to reduce animal pain inflicted during experimentation, the Commission could not accept amendments contrary to its primary objective to provide European citizens with the highest level of safety and its international commitments. It rejected the amendment proposing the reintroduction of the marketing ban, as such a ban is not in conformity with WTO-rules. The Commission could not accept the reduction of the time limit for a full testing ban on ingredients, as it is contrary to its key objective of consumer protection and public health.

3.3. The Common Position of the Council

The Common Position of the Council has been adopted with a qualified majority.

The Common Position of the Council includes most amendments of the European Parliament aiming at improving health and consumer protection, already included in the Commission amended proposal. Furthermore, as requested by the European Parliament, it includes specific provisions on substances classified as carcinogenic, mutagenic or toxic for reproduction.

Concerning the issue of animal testing, the Council shares the aim of abolishing animal testing as soon and whenever possible. However, the Common Position incorporates a new approach.

Concerning the EU testing ban on ingredients, the Council has rejected the idea of any fixed cut-off date for its total implementation, as it would compromise the health and safety of consumers. The Common Position provides for a stepwise approach, based on the 3 Rs principle (replacement, refinement and reduction) and links the progressive implementation of such a testing ban to the availability of alternative methods, including those which reduce the number of animals used or diminish their suffering. In addition, it reinforces the regulatory framework to ensure that scientifically validated alternative methods are effectively used when they exist.

Concerning the marketing ban, the Common Position provides a marketing ban on cosmetic products when the final product or its ingredients have been subject to animal testing, but links the progressive implementation of such a ban to the existence of alternative testing methods accepted at international level within the framework of the OECD, to reinforce the multilateral character of the measure.

3.4 Position of the Commission towards the Common Position

Concerning the EU testing ban on ingredients, linked to the availability of alternative methods and without any cut-off date, the Commission can endorse this solution, offering a genuine benefit to animal welfare while safeguarding consumer health. This improvement can only reinforce the role of the EU as leader in research in the development of alternative methods based on the 3 Rs principle. It will lead to the management of animal testing within the EU, without compromising the primary objective to provide European citizens with the highest possible level of safety in all products that they use.

Concerning the proposed marketing ban, linked to the acceptance at OECD level (i.e. of a multilateral international organisation which would function in this case as an international standardising body) and excluding any cut-off date, it reduces the risk of a challenge under the dispute settlement system of the WTO. However, the OECD is an organisation with a very limited membership (currently 30 members out of the 144 of the WTO). Limiting the creation of acceptable alternative methods to the OECD can thus create a problem, unless it is ascertained that the OECD is the only international body where this issue could be disciplined. Moreover, as the developments of alternative testing methods within the OECD would only involve such a limited number of countries, in light of WTO law and jurisprudence, the Directive should envisage some further reasonable period of time between the approval of alternative methods and the entry into force of the marketing ban in the EC in order to allow either other WTO Members, which are not party to the OECD, to accept and implement these alternative methods, or the Community to initiate negotiations with them on the application of these alternative methods. Such approach is more in line with the Community international obligations and the EU position to continue its current efforts for a co-ordinated animal welfare policy at international level.

Therefore the Commission can accept the overall approach foreseen in the Common Position.

4. CONCLUSION

The Commission supports the Common Position, which is in line with many items of its amended Proposal and fulfils the public health and consumer protection, taking into account its international obligations.

5. DECLARATION OF THE COMMISSION

Statement by the Commission for the minutes of the Internal Market Council of 26 November 2001:

«The Commission confirms its intention shortly to begin work on the revision of Directive 86/609/EEC¹ 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.»

¹ OJL 358, 18.12.1986, p. 1.