COMMISSION OF THE EUROPEAN COMMUNITIES

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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)

EXPLANATORY MEMORANDUM

Summary

The proposed amendment to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products has four key objectives:

- To introduce permanently and definitively a prohibition on the performance of experiments on animals for finished cosmetic products in the territory of Member States of the European Union.

- To amend the prohibition on the marketing of cosmetic products containing ingredients or combinations of ingredients tested on animal entering into force after the 30th June 2000 by introducing a prohibition on the performance of experiments on animals for ingredients and combinations of ingredients and to make mandatory use of validated alternative methods for the testing of chemicals used in cosmetic products, as soon as such methods become available. The Commission will endeavour to obtain the rapid acceptance by the OECD (Organisation for Economic Co-operation and Development) of alternative methods validated at Community level. This prohibition will enter into force three years after the implementation of the Directive by the Member States. However, the date of implementation of this prohibition 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 as offering an equivalent level of protection for the consumer.

- To revise the current legislative provisions so as to make them WTO-compliant, legally and practically enforceable. For reasons of consistency and legal certainty, the Commission intends to adopt a Commission Directive postponing the date of entry into force of the marketing ban to avoid its enforcement while a substantial modification of the basic directive is pending before the European Parliament and the Council. At international level the Commission will endeavour to ensure the mutual recognition of test data from *in vitro*/*in vivo* studies through negotiations with third countries.

- In order to improve the information provided to the consumer, 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.

This explanatory memorandum explains the background to the current legislative situation, the context of the current proposal and outlines the end result that is the intent of each specific item.

1. ANIMAL TESTING IN THE COSMETICS SECTOR

1.1. Background and current legal situation

The text of Article 4(1)(i) of Directive 76/768/EEC on cosmetic products as amended by Council Directive 93/35/EEC of 14 June 1993 (referred to as "the sixth amendment") provided that "*Member States shall prohibit the marketing of cosmetic products containing*

ingredients or combinations of ingredients tested on animals after 1 January 1998 in order to meet the requirements of this Directive".

That Article also specified that "*if there has been insufficient progress in developing satisfactory methods to replace animal testing, and in particular in those cases where alternative methods of testing, despite all reasonable endeavours, have not been scientifically validated as offering an equivalent level of protection for the consumer, taking into account OECD toxicity test guidelines, the Commission shall, by 1 January 1997, submit draft measures to postpone the date of implementation of this provision for a sufficient period and, in any case, for no less than two years, in accordance with the procedure laid down in Article 10.*".

Despite reasonable endeavours and whilst some progress had been made in the development of some alternative methods, in 1997 no alternative testing methods had been scientifically validated as offering an equivalent level of protection for the consumer. As the main objective of Directive 76/768/EEC is to protect public health, it is vital to carry out tests to assure the safety for human health of chemicals used in cosmetic formulations. A postponement of the marketing ban was put forward by the Commission in accordance with Article 4(1)(i). Commission Directive 97/18/EC, adopted on 17 April 1997, postponed the ban on the marketing of cosmetic products containing ingredients or combinations of ingredients tested on animals until 30 June 2000. Article 2 of Directive 97/18/EC did, however, provide for a reassessment of the situation.

Only three alternative methods have been validated to date, two are available for the assessment of skin corrosivity and one for the assessment of phototoxicity. Furthermore, the proposed European Parliament and Council directive amending Directive 76/768/EEC has to be adopted by co-decision procedure, and then will have to be transposed by Member States into their national law. It will take up to two years before the proposed Directive can be enforced. In the meantime the ban as foreseen by the current Directive will enter into force. Therefore, in accordance with Article 4(1)(i) of Directive 76/768/EEC and Article 2 of Directive 97/18/EC, the Commission should adopt a Directive postponing the date of the entry into force of the marketing ban. This postponement would just aim to cover the foreseeable period of time needed for this amendment to be adopted and transposed.

1.2. Objectives and constraints

When considering the issue of animal testing in the cosmetics sector, two chief objectives must be taken into consideration: consumer safety and the reduction, and wherever and as soon as possible, the elimination of animal suffering. These two considerations are the over-riding factors that must be addressed in legislative measures. However, for any measures to be effective and enforceable it is also necessary to take account of the constraints arising from compliance with international trade rules, in particular those of the World Trade Organisation (WTO).

1.2.1. Consumer safety

The concept of "cosmetic products" covers products for everyday use throughout life. These products must not be harmful, either immediately (for example by causing allergic reactions) or in the long term (for example leading to cancer or birth defects).

One of the primary responsibilities of both the European Commission and the Member States administrations is that of consumer safety. This responsibility is shared and met by the

European cosmetic industry which is committed to the marketing of safe products. The responsibilities of manufacturers with regards to safety are defined through the provisions of Directive 76/768/EEC. Specifically, Article 2 states that the manufacturer or person responsible for the placing on the market of the product must ensure that the product must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use. Furthermore, the provisions of Article 7a require the availability of an assessment of the safety for human health of the finished product. To assess the safety of a cosmetic product, the safety of the finished product and of the ingredients used in its composition must be assessed taking into consideration the general toxicological profile of the ingredient, its chemical structure and its level of exposure.

Directive 76/768/EEC does not specify the types of tests to be carried out, or the end-points to be assessed, as these are addressed on a case-by-case basis for each chemical and product. However, in order to comply with these requirements, it is clear that the use of data from some animal tests (whether these tests are performed for the product or the ingredient in question or whether they constitute historical data is immaterial) is necessary.

The Directive also includes a series of lists of prohibited substances, substances subject to restrictions and requirements and authorised substances. For instance, preservatives, colorants and UV filters are subject to "positive listing" in Directive 76/768/EEC and can only be used if they are listed under the appropriate annex. These lists are regularly adapted to technical progress once the Scientific Committee on Cosmetic Products and Non-Food Products (SCCNFP) has delivered its opinion on the basis of all available scientific data, and in particular the results of tests which cover the full range of toxic end-points.

For reasons of consumer safety, it is not possible to abandon safety testing, as the appearance of new substances necessitates testing for new chemical notification purposes under the provisions of Directive 67/548/EEC. Similarly, the appearance of new data on existing substances may result in the requirement for further testing of chemicals currently used in cosmetic products.

1.2.2. The reduction and elimination of animal suffering

While consumer safety must be ensured, the reduction of pain inflicted on animals during tests, of the number of tests and, wherever and as soon as possible, the elimination of animal suffering is an objective that is common to all parties involved in this issue. This aim corresponds to ethical requirements regarding respect for life, supported by public opinion and the expressed wishes of the European Parliament. This aim is also included in Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes[1].

1.2.3. Compliance with international trade rules, in particular those of the WTO

The current wording of Article 4(1)(i) of Directive 76/768/EEC specifies that the Member States must prohibit the marketing of cosmetic products containing ingredients tested on animals after 30 June 2000, whether such products are manufactured in the European Union or imported from third countries. However, WTO rules forbid any discriminatory measures between similar products. Article III.4 of the General Agreement on Tariffs and Trade

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[1] OJ L 358, 8.12.1986.

(GATT) says that imported products shall be treated no less favourably that like products of national origin. As the test method does not have any physical effect on the product, discrimination on this basis could be considered to be contrary to WTO rules, in particular Article III.4 of the GATT. In this context it is doubtful whether Article XX of the GATT 1994 could provide sufficient justification for measures of this nature.

2. PROPOSED DIRECTIVE

This proposal for a European Parliament and Council Directive takes into account the background to, the aims of, and the constraints on the current legislative situation. To take account of the need to comply with international law, the proposed amendment prohibits the performance of tests on animals on the territory of the Member States for the purpose of complying with Directive 76/768/EEC, but not the marketing of products which have been tested on animals. This represents an advancement for animal protection in the European Union. Moreover, the prohibition in its revised form cannot be challenged under WTO rules. Therefore, this prohibition will cover:

- finished cosmetic products from the date of implementation of the Directive by the Member States, and

- ingredients after publication in the Official Journal of the European Communities of an alternative method validated, or endorsed as being scientifically valid, by the European Centre for the Validation of Alternative Methods (ECVAM) and endorsed as being applicable to cosmetic products by the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP). International acceptance of such methods is no longer required though it is planned that the Commission will make efforts to secure such acceptance within the OECD and in bilateral negotiations. However, in order to achieve the highest possible degree of animal protection, some specific action has to be taken in the sector of cosmetic products. Therefore, a deadline for the prohibition on the performance of experiments on animals for ingredients is foreseen three years after the implementation of the Directive by the Member States, regardless of whether an alternative method has been validated. However, the date of implementation of this prohibition 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 as offering an equivalent level of protection for the consumer.

The key considerations of this proposal are described below.

2.1. Finished cosmetic products testing

The proposed directive puts forward a prohibition on the performance of tests on animals for cosmetic finished products within the territory of the Member States. Given the scientific progress made to date, the safety of finished products can generally be assessed from existing knowledge on the toxicity of the ingredients and their physicochemical properties, along with the use of methods which do not involve animals. Therefore, a prohibition on the testing of finished products in the Community is seen as feasible.

This proposal would solve a problem of interpretation in the current text of Directive 76/768/EEC as to whether the phrase "ingredients or combinations of ingredients" includes

finished products and, at the same time, fulfil the commitment entered into with the European Parliament by the Commission.

2.2. Cosmetic ingredients testing

Progress has been made which makes it possible to reduce the number of animals used in experimentation and reduce the level of suffering involved, in line with the "3Rs" concept of replacement, reduction and refinement. However, the development, validation and acceptance of alternative methods have proven to be an extremely complex scientific challenge. In particular, the timetable for the various stages of the development and validation process had previously been underestimated, and progress has not been as rapid as hoped by all parties. It has not been possible to timetable and schedule the necessary research into complex biological systems.

This proposal introduces the principle of an immediate and mandatory introduction of validated alternative methods for testing cosmetic ingredients as soon as they become available.

The current Article 4(1)(i) contains a reference to the OECD and includes the phrase "*alternative methods of testing ... scientifically validated as offering an equivalent level of protection for the consumer, taking into account OECD toxicity test guidelines.*" While the Commission must make efforts to convince the OECD to accept alternative methods validated by ECVAM, experience has shown that it has sometimes taken several years for an existing method to be accepted by all OECD members. In this situation, because of the moral importance of animal welfare it is not possible to wait for such acceptance by the OECD. Action is needed at Community level given the existence of alternative methods which have been validated or endorsed as being scientifically valid by ECVAM and endorsed by the ECVAM Scientific Advisory Committee. Therefore, a new approach is put forward in the proposed directive, in that regulatory acceptance at a European level will be sufficient to permit legislative proposals for cosmetic testing in the European Union. Once a method has been validated or endorsed as being scientifically valid by ECVAM and the SCCNFP and endorsed by the Commission services, it will be published and accepted for use in the European Union. Furthermore, use of an animal test that assesses the same toxic end-point will be prohibited in the European Union. This will be the situation prior to OECD acceptance, and will be a major advancement in speeding up the regulatory acceptance of alternative methods.

Further work is required for some of those end-points that are of greatest importance to human health and to the cosmetic industry i.e. acute effects to the skin and eyes and long term systemic effects. To this end, research efforts should be intensified. Taking into account the progress made in the development of alternative methods to date, it can be reasonably expected that within five to seven years, a battery of *in vitro* tests could well be available for testing the possible short-term toxic effects of a cosmetic product. Therefore it is proposed to introduce a definitive prohibition on the performance of tests on animals for cosmetic ingredients three years after the implementation of the Directive by the Member States. However, the date of implementation of this prohibition 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 as offering an equivalent level of protection for the consumer. This prohibition, of course, does not apply to testing carried out for the purposes of meeting other regulatory requirements if the same chemical ingredient is also used in other applications (e.g. pharmaceuticals) outside the scope of Directive 76/768/EEC.

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 this Directive.

2.3. European lead in the acceptance of alternative methods and mutual recognition with third countries

It will be important to continue negotiations within the OECD to ensure a truly global acceptance of alternative methods to animal testing. The Commission will continue to work with the OECD in this respect and will endeavour to gain wider regulatory acceptance at the earliest opportunity. By taking a lead in the regulatory acceptance of validated alternative methods, it is hoped that the example set by the European Union will expedite discussions at the level of the OECD.

At the same time as continuing discussions with the OECD, the Commission will initiate bilateral talks on mutual recognition with third countries. Mutual recognition agreements with third countries are a pivotal element of this new approach and will be essential if the actions that are proposed at Community level are to lead to a genuine reduction of animals elsewhere. The aim of these discussions will be to ensure the mutual recognition of data generated to support the safety of products or ingredients. From an European Union point of view, the Commission will push for the acceptance of data derived from *in vitro* studies, using validated alternative methods that have been conducted to fulfil the requirements of Directive 76/768/EEC. Obviously, it is important that third countries do not require the repetition of the studies using animal models due to the non-acceptance of data from *in vitro*/alternative methods. Only by this way will the European Union be able to ensure a benefit to animal welfare on a more global level. Conversely, the European Union will need to accept data from studies conducted in animals, that may be used as supporting data for cosmetic ingredients/products. Such studies would have been conducted to satisfy the legislative demands of third countries in any case. Mutual recognition is the key to this approach – it would be inappropriate for the European Union to demand the repetition of a test using an alternative methods, as this would set up a barrier to trade and may impact upon any favourable position taken upon the acceptability of European *in vitro* data. This approach also obviates the criticism that the new, WTO-compliant legislative measures on animal testing in the sector of cosmetic products simply "export" the problem. Rather, it is a genuine initiative to gain regulatory acceptance of alternative methods on a global scale.

2.4. Claims on animal tests

To improve the information provided to the consumer, this proposal also foresees the possibility for the manufacturer or the person responsible for placing the product on the market to claim that no animal tests have been carried out (directly or indirectly). However to avoid an abuse of these claims, the Commission, in collaboration with the Member States, will produce guidelines to define their use. These guidelines will need to include specific provisions which would require that the finished product and the ingredients have never been tested on animals, including for purposes outside the scope of this Directive.

The problem of the potential misleading nature of animal testing claims has already been identified in a number of Member States. The current wording of Article 6(3) of Directive 76/768/EEC as it relates to animal testing is "*Furthermore, any reference to testing on animals must state clearly whether the test is carried out involved the finished product and/or its ingredients.*". Different national interpretations of the meaning of Article 6(3) have lead to

significant disruption on the single market. Furthermore, the variety of claims used by companies within the European Union, and the even greater variety of criteria to support these claims, have led to confusion in the European marketplace on the part of consumers and regulators.

The aim of the guidelines proposed is to ensure that common criteria are applied in the use of claims relating to animal testing, that an aligned understanding of the claims is reached and in particular, that such claims do not mislead the consumer.

2.5. The cost to industry

The prohibition on the performance of experiments on animals will impose additional costs on industry, in particular on small and medium enterprises, which do not have the specific databases, knowledge or toxicology specialists to which large companies have access.

If small and medium enterprises use contract laboratories to carry out alternative tests, they will need to know when to carry out such tests and how to interpret the results. The European Cosmetic Toiletry and Perfumery Association (COLIPA) has drawn up guidelines for assessing the safety of cosmetic products which should be useful for small and medium enterprises. These should be made widely available, in electronic format whenever possible.

3. OTHER AMENDMENTS TO DIRECTIVE 76/768/EEC ON COSMETIC PRODUCTS

3.1. Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers

The Commission obtains scientific advice on the safety of cosmetic products through consultation with a scientific committee. Previously referred to as the Scientific Committee on Cosmetology, the functioning and composition of the Committee was restructured through the provisions of Commission Decision 97/579/EC. This Decision outlined the requirements for setting up the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) as one of eight new committees. This committee remains the scientific committee that will advise the Commission on matters related to the safety of cosmetic products. Therefore, Articles 8(2) and 8a(3) of Directive 76/768/EEC should refer to the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP).

3.2. Standing Committee on Cosmetic Products

The current Article 9(1) sets up a Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector. It is proposed that this Committee is renamed as the "Standing Committee on Cosmetic Products", by analogy with the titles of similar regulatory committees in other sectors.

3.3. Comitology procedure

Following the adoption of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, it has become necessary to adjust the relevant decision-making procedures. In its declaration of 28 June 1999 the Commission agreed that the necessary adjustments to the decision-making process would be made in the course of the normal revision of the legislation. Therefore, it is necessary to amend Article 10 to align the decision-making process.

4. BUDGETARY IMPLICATIONS TO THE COMMISSION

No budgetary implications to the Commission are foreseen as a result of the provisions of the proposed Directive.

5. SUBSIDIARITY AND PROPORTIONALITY

Community law already provides for an exhaustive harmonisation regarding the placing on the market of cosmetic products within the European Union, the respective rules for which are based on Article 95 of the Treaty. The only appropriate way of amending these rules is therefore through the provisions set out in Community law.

The proposed measures achieve the objectives with minimal intervention regarding regulatory and administrative requirements.

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission[2],

Having regard to the opinion of the Economic and Social Committee[3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) Council Directive 76/768/EEC[4], as last amended by Commission Directive 2000/11/EC[5], has comprehensively harmonised the national laws relating to cosmetic products. The main objective of the Directive is to protect public health. To this end it is indispensable to carry out certain toxicological tests to evaluate the safety of cosmetic products for human health.

(2) In accordance with 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.

(3) The safety of finished cosmetic products can already be assessed from knowledge about the safety of the ingredients which they contain and by methods which do not involve the use of animals. Therefore animal tests on finished cosmetic products should be prohibited.

(4) It will progressively but slowly be possible to ensure the safety of the ingredients and combinations of ingredients used in cosmetic products, at least for the acute effects, without recourse to animal experiments, by using alternative methods validated at Community level, or approved as being scientifically validated, by the European Centre for the Validation of Alternative Methods (ECVAM). After consulting the

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2 OJ C , , p. .
3 OJ C , , p. .
4 OJ L 262, 27.9.1976, p. 169.
5 OJ L 65, 14.3.2000, p. 22.

Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) as regards the applicability of the validated alternative methods to the field of cosmetic products, the Commission will have immediately to publish the validated or approved methods recognised as being applicable to such ingredients. In order to achieve the highest possible degree of animal protection, a deadline has to be foreseen, when a definitive prohibition should be introduced. However, the date of implementation of this prohibition should be postponed 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.

(5) All efforts must be made to ensure that the ethical requirement of animal welfare is recognised world-wide. To this end, the Commission should endeavour to obtain the rapid acceptance by the Organisation for Economic Co-operation and Development (OECD) of alternative methods validated at Community level. Furthermore, in the framework of bilateral agreements with third countries, the Commission should make efforts to obtain 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.

(6) It should be possible to claim on a cosmetic product that no experiment on animals was ever carried out on the finished cosmetic product and/or its ingredients and combinations of ingredients including for the purposes outside the scope of Directive 76/768/EEC. The Commission, in consultation with the Member States, should produce guidelines with the aim of providing clarity and practical guidance to the cosmetic industry, European regulators and above-all the consumer with respect to claims relating to animal testing within the cosmetic sector. These guidelines should aim to ensure that common criteria are applied in the use of claims and that an aligned understanding of the claims is reached, and in particular that such claims do not mislead the consumer.

(7) Since the measures necessary for the implementation of this Directive are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[6], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Council Directive 76/768/EEC is hereby amended as follows:

1. Article 4(1)(i) is deleted.

2. The following Article 4a is added:

"Article 4a

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6 OJ L 184, 17.7.1999, p. 23.

1. Member States shall take all necessary measures to prohibit the performance on their territory of animal tests in order to meet the requirements of this Directive:

   (a) for tests performed on finished cosmetic products [from 1 December 2001];

   (b) for tests performed on ingredients or combinations of ingredients, as soon as an alternative method has been published by the Commission, after endorsement of its scientific validity by the European Centre for the Validation of Alternative Methods (ECVAM) and the ECVAM Scientific Advisory Committee, following consultation of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, and in any case [from 1 December 2004]. 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, 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.

2. For the purposes of this Directive, "finished cosmetic product" means the cosmetic product intended to be supplied in its existing state to the final consumer.

3. The Commission shall present an annual report to the European Parliament and the Council on progress in the development, validation and legal acceptance of alternative methods to those involving experiments on animals until the entry into force of the prohibition referred to in paragraph 1(b). That report 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. The Commission shall pay particular attention to the development, validation and legal acceptance of experimental methods which do not use live animals.".

3. Article 6(3) is amended as follows:

   a) The last sentence of Article 6(3) is deleted.

   b) The following second subparagraph is added:

"Furthermore, the manufacturer or the person responsible for placing the product on the Community market may only 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 provided neither the finished product, nor its prototype, nor any of the ingredients contained in it have ever been the subject of such tests including for purposes outside the scope of this Directive. The Commission, in consultation with the Member States, shall for this purpose publish guidelines on the implementation of this principle.".

4. In Article 8(2) and Article 8a(3), the title "Scientific Committee on Cosmetology" is replaced by the title "Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers".

5. In Article 9(1), the title "Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector" is replaced by the title "Standing Committee on Cosmetic Products".

6. Article 10 is replaced by the following text:

"Article 10

1. The Commission shall be assisted by the Committee.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.".

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than [1 December 2001]. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the third day following that of its publication in the *Official Journal of the European Communities.*

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

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DOCUMENTS

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