

Cosmetic products: animal experiments (7th amend. to "Cosmetics Directive" 76/768/EEC)

2000/0077(COD) - 05/04/2000 - Legislative proposal

PURPOSE: to adopt a Directive of the EP 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. **CONTENT:** The proposed Directive has 4 main aims as follows: - to prohibit the performance of experiments on animals for finished cosmetic products in the territory of the EU; - to amend the prohibition on the marketing of cosmetic products containing ingredients tested on animals entering into force after 30/06/2000 by introducing a prohibition on the performance of experiments on animals for ingredients and combination 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 of alternative methods validated at Community level. This prohibition will enter into force 3 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 2 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 EP 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; -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 so as to clarify their use. Commission Directive 97/18/EC postponed the ban on the marketing of cosmetic products containing ingredients or combinations of ingredients tested on animals until 30/06/2000. Article 2 of Directive 97/18/EC did, however, provide for a reassessment of the situation. The proposed EP and Council Directive amending Directive 76/768/EEC has to be adopted by co-decision procedure, and then will have to be transposed by the Member States into their national law. However, following the adoption of Council Decision 1999/468/EC 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 28/06/1999, 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. Thus, it is necessary to amend Article 10 to align the decision-making process. Finally, with regard to budgetary implications for the Commission, none are foreseen as a result of the provisions of the proposed Directive. It will take up to 2 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. When considering the issue of animal testing in the cosmetic 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 are the overriding 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 WTO. The prohibition in its revised form cannot be challenged under WTO rules. Therefore, the 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 EC 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 3 years after the implementation of the Directive by the Member States, regardless of whether an alternative method has been validated. 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 EU. 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 EU. Furthermore, use of an animal test that assesses the same toxic end-point will be prohibited in the EU. This will be the situation prior to OECD acceptance, and will be a major advancement in speeding up the regulatory acceptance of alternative methods. Finally, while continuing discussions with the OECD, the Commission will initiate bilateral talks on mutual recognition with third countries. Also, it will produce guidelines to include specific provisions which would require that the finished products and the ingredients have never been tested on animals, including for purposes outside the scope of this Directive.