Cosmetics: development, validation and legal acceptance of alternative methods to animal experiments. 1996 report

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OBJECTIVE: this third annual Commission report (1996) on the development, validation and legal acceptance of alternative methods to animal experiments in the field of cosmetics reviews the situation on the eve of the date by which the Commission has to present draft measures postponing the date for the ban on animal testing if alternative methods have not been scientifically validated (1 January 1998). SUBSTANCE: the report comprises two parts. The first describes the objectives and anticipated constraints concerning legal acceptance on the eve of the date (1 January 1998) from which the ban on cosmetic products containing ingredients or combinations of ingredients tested on animals is due to be introduced. The second part is more scientific and describes the initiatives taken with a view to the development, validation and legal acceptance of alternative methods. (1) Objectives and constraints: two principal objectives are pursued: - the safety of cosmetic products with regard to human health: in this connection the basic 'Cosmetics' Directive (93/35/EEC) requires manufacturers, as from 1 January 1995, to keep certain information on product safety readily accessible to the competent authorities. It also establishes a system of lists of prohibited products, products subject to certain limitations and authorized products. These lists are regularly adapted to technical progress. The Commission believes that a blanket ban on the use of new substances would not obviate the need for tests. Furthermore, putting a stop to innovation in this area would spell ruin for many SMEs; - reduction/elimination of animal suffering: the Commission recognizes the fact that it is a question of ethical imperatives, even though tests of this type account for a mere 0.03% of all animal tests. However, it feels that the use of human volunteers cannot in itself replace animal tests across the board. The constraints which have to be taken into account concerning acceptance of alternative methods fall into two categories: - compatibility with the rules of international trade (especially WTO rules): any measure that leads to banning products from third countries because they have been tested on animals is likely to prove incompatible with these rules. The Commission is therefore proposing to review the basic 'Cosmetics' Directive in order to resolve this problem; - the interests of SMEs must be safeguarded, particularly with regard to jobs created in this sector. (2) Existing and expected results: a distinction must be made between ingredients (and/or combinations of ingredients) and finished cosmetic products: - ingredients/combinations of ingredients: the report notes that no alternative method offering an equivalent degree of protection are available as yet, nor are they expected to become available by 1 January 1998. However, alternative methods should progressively become available in the domains pertaining to percutaneous absorption and local risks to the eye and skin: photoirritation, eye irritation and skin irritation (same conclusions as the 1995 report - see COS0505). By contrast, in the case of tests relating to systemic effects, there is no hope of replacing animal testing in the foreseeable future, although the reduction in the number of animals used for tests should continue; - finished cosmetic products: after 1 January 1998 it will be possible to evaluate these products without animal testing as a result of available knowledge on the safety of their ingredients. However, the report notes that there are grounds to fear toxic effects as a result of interaction between ingredients or where skin penetration by ingredients is facilitated by the vehicle used. In such cases animal testing is likely to remain necessary. (3) Conclusions: while research has made progress, no alternative test methods have yet been scientifically validated and accepted. The situation is unlikely to change before 1 January 1998. The Commission is therefore proposing: - postponement of the ban on products tested on animals until 30 June 2000, - presentation of draft measures before 1 January 2000, taking account of progress made by that date, - promotion of research into and validation of alternative methods, - dissemination among SMEs of testing methods for finished products which do not involve the use of

animals, - presentation of a proposal banning animal testing for finished cosmetic products as of 1 January 1998 (to be adopted by the Codecision Procedure with the European Parliament; also covers aspects relating to products from third countries).