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Draft

COMMISSION DIRECTIVE ../.../EC

of [...]

amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annexes IV and VI thereto to technical progress

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products¹, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Consumer Products,

Whereas:

- (1) The Scientific Committee on Cosmetic and Non-Food Products intended for consumers, replaced by the Scientific Committee on Consumer Products, (SCCP), by Commission Decision 2004/210/CE², delivered an opinion regarding the safe use of the preservative iodopropynyl butylcarbamate (IPBC) in cosmetic products concluding that the daily bioavailable intake of iodine from cosmetic products should not exceed 20% of the recommended daily intake of 150µg and that IPBC should not be used in oral hygiene and lip care products.
- (2) Considering that the list of preservatives authorised in cosmetic products should not be too limited, but that the exposure to iodine from IPBC should be not be too high, the existing entry 56 to Annex VI should be amended accordingly.
- (3) Sodium iodate and colorant CI 45425 contain iodine and are currently respectively listed under Annex VI as authorised preservative and under Annex IV as authorised colorant. In view of the absence of interest from stakeholders to defend the use of these substances and the opinion of the SCCP regarding the necessity to reduce the exposure to iodine from cosmetic products, the authorisations should be withdrawn.
- (4) Directive 76/768/EEC should therefore be amended accordingly.

¹ OJ L 262, 27.09.1976, p169. Directive as last amended by [to be introduced] (OJ L [...], [...], p. [...]).

² OJ L 66, 4.3.2004, p.45.

- (5) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes IV and VI to Directive 76/768/EEC are amended in accordance with the Annex to this Directive.

Article 2

Member States shall take all necessary measures to ensure that from [18 months from publication] no cosmetic products which fail to comply with this Directive are placed on the market by Community manufacturers or by importers established within the Community.

Member States shall take all necessary measures to ensure that those products are not sold or disposed of to the final consumer after [24 months from the publication].

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [9 months from publication] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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

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

Article 4

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

Article [...]

This Directive is addressed to the Member States.

Done at Brussels, [...]

For the Commission

[...]

Member of the Commission

ANNEX

Directive 76/768/EEC is amended as follows:

- (1) In part 1 of Annex IV, colouring agent CI 45425 is deleted.
- (2) Part 1 of Annex VI is amended as follows:
 - (a) reference number 10 is deleted;
 - (b) reference number 56 is replaced by the following:

Reference number	Substance	Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
A	B	C	d	e
"56	iodopropynyl butylcarbamate (IPBC) 3-iodo-2-propynylbutyl carbamate CAS N° 55406-53-6	a) rinse-off products: 0.02% b) leave-on products: 0.01%, except in: 1) deodorants/antiperspirants: 0.0075% 2) body lotion and body cream: 0%	Should not be used in oral hygiene and lip care products a) Not to be used in preparations for children under 3 years of age, except in bath products/shower gels and shampoo b) Not to be used in preparations for children under 3 years of age	"