Commission Directive 95/17/EC of 19 June 1995 laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products (Text with EEA relevance)

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laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products

(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 products[(1)], as last amended by Commission Directive 94/32/EC[(2)], and in particular Article 6 (1) (g) thereof,

Whereas there is a need to specify the criteria and conditions under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients on the minimum list of ingredients which must be included on the packaging of cosmetic products, or, where this is impossible for practical reasons, on an enclosed leaflet, label, tape or card;

Whereas approval of confidentiality should not, however, impinge on the other obligations pursuant to Directive 76/768/EEC and the responsibilities arising from the Articles concerning the cosmetic product's safety, from the Annexes, and from the provisions as to the information necessary for appropriate medical treatment and the case-file to which the national monitoring authorities must have access;

Whereas approval of confidentiality should not be prejudicial to consumer safety;

Whereas the request for confidentiality must be submitted in the Member State of manufacture or initial importation into the Community market, which must also have access to the information referred to in Article 7a of Directive 76/768/EEC, as amended by Directive 93/35/EEC[(3)], for control purposes;

Whereas to be adequately assessed and monitored the request must include all the particulars necessary for identifying the applicants, for the identification and human health assessment of the ingredient as used in the cosmetic product(s) and for determining the intended use of the ingredient concerned, as well as the grounds for confidentiality and the name(s) of the product containing the ingredient;

Whereas for economic reasons and in deference to his rights the competent authority should inform the applicant, within a brief period of not more than four months, other than in

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exceptional cases, of the ruling in this case; whereas any refusal to grant confidentiality should be duly reasoned and the means of appeal and time limits clearly indicated;

Whereas in the interests of transparency and monitoring, the competent authority should allocate a registration number to each request it approves; whereas this number should replace the ingredient in the list of ingredients referred to in Article 6 (1) (g) of Directive 76/768/EEC;

Whereas all amendments to the particulars contained in the initial request must be communicated by the applicant to the competent authority, which may then withdraw its approval of confidentiality in view of those modifications, or if new information makes such a measure necessary for compelling public health reasons;

Whereas the duration of the right to confidentiality should not exceed five years, subject to the option, in exceptional circumstances, of an extension for a further three years at the most;

Whereas, in the interests of monitoring product safety and proper enforcement of the Directive, the Commission and the other Member States should be adequately informed of the decisions taken by the competent authority; whereas, on the other hand, such decisions should be recognized throughout the Community territory, except for exceptional reasons;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetics Products Sector,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive shall apply without prejudice to the other obligations arising from Directive 76/768/EEC and the responsibilities arising therefrom, in particular from Articles 2, 4, 5, 7 (3) and 7a thereof.

Article 2

Any manufacturer or his agent or person on whose account a cosmetic product is manufactured, or any person responsible for placing an imported cosmetic product on the Community market, who, for reasons of trade secrecy, wishes not to include one or more ingredients of a cosmetic product on the list referred to in Article 6 (1) (g) of Directive 76/768/EEC, shall submit a request to that effect to the competent authority referred to in Article 10 of this Directive of the Member State of the place of manufacture or initial importation, prior to placing the product on the Community market.

Article 3

The request referred to in Article 2 must include the following particulars:

(a) name or style and address or head office of the applicant;

(b) precise identification of the ingredient for which confidentiality is requested, namely:

— the CAS, Einecs and colour index numbers, the chemical name, the Iupac name, the INCI[4] name, the *European Pharmacopoeia* name, the international non-proprietary name recommended by the World Health Organization, and the common nomenclature name referred to in Article 7 (2) of Directive 76/768/EEC, where they exist,

— the Elincs name and the official number allocated to it if it has been notified pursuant to Council Directive 67/548/EEC[5] and indication of approval or refusal to approve a request for confidentiality pursuant to Article 19 of that Directive,

— where the names or numbers referred to in the first and second indents do not exist, as in the case of certain ingredients of natural origin, the name of the base material, the name of the part of the plant or animal used, and the names of the ingredient's components, such as solvents;

(c) the evaluation of the safety for human health of the ingredient as used in the finished product(s), taking into account the ingredient's toxicological profile, chemical structure and the level of exposure, as specified in Article 7a (1) (d) and (e) and Article 7a (2) of Directive 76/768/EEC;

(d) the envisaged use of the ingredient and in particular the different categories of products in which it will be used;

(e) a detailed justification of why, by way of exception, confidentiality is sought; for example:

— the fact that the identity of the ingredient or its function in the cosmetic product to be marketed has not been described in the literature and is unknown to others in the trade,

— the fact that the information is not yet in the public domain, even though a patent application has been lodged for the ingredient or its use,

— the fact that if the information were known it would be easily reproducible, to the detriment of the applicant;

(f) if known, the name of each product which is to contain the ingredient(s), and if different names are to be used in the Community market, precise details on each one of them.

If the name of a product is not yet known, it may be communicated at a later date, but at least 15 days before placing the product on the market.

If the ingredient is used in several products, one request shall suffice, provided that the products are clearly indicated to the competent authority;

(g) a statement setting out whether a request has been submitted to the competent authority of any other Member State in respect of the ingredient for which confidentiality is sought, and particulars on the outcome of any such request.

Article 4

1 After receipt of the request for confidentiality in accordance with Article 3 the competent authority shall, within a period not exceeding four months, examine the request and inform the applicant in writing of its decision. In the event of approval, the authority shall also communicate the registration number it has allocated to the product in accordance with the procedure laid down in the Annex. However, if there are exceptional reasons, the competent authority may inform the applicant in writing that an additional period of two months will be required for the examination of the request.

2 Any refusal to grant a request for confidentiality must include a statement of reasons; appeal procedures, together with their time limits, must be clearly explained to the applicant.

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Article 5

The registration number referred to in Article 4 (1) shall replace the ingredient in question in the list referred to in Article 6 (1) (g) of Directive 76/768/EEC.

Article 6

1 All amendments to the information provided pursuant to Article 3 must be communicated as rapidly as possible to the competent authority that has granted the request for confidentiality. All changes to the names of cosmetic products containing the ingredient must be communicated to the competent authority at least 15 days before those products are placed on the market under their new name.

2 Taking into consideration the amendments referred to in paragraph 1, or if new information makes it imperative to do so, particularly for compelling reasons of public health, the competent authority may withdraw its approval. In this event it shall inform the applicant of its new decision within the time limits and in accordance with the procedure referred to in Article 4.

Article 7

The decision granting the right to confidentiality shall be valid for a period of five years.

If the beneficiary of this decision considers that there are exceptional reasons justifying an extension of this period, he may submit a reasoned request to the competent authority which initially granted the request for confidentiality.

The competent authority shall decide on this new request within the time limits and under the conditions referred to in Article 4.

The confidentiality period shall not be extended by more than three years.

Article 8

1 Member States shall inform the Commission and the other Member States of their decisions to grant requests for confidentiality or to extend such approval, indicating the name or style and address or head office of the applicants, the names of the cosmetic products containing the ingredient in respect of which the request for confidentiality has been granted, and the registration number referred to in Article 4 (1).

The Commission and the other Member States may obtain, on request, a copy of the case file containing the request for confidentiality together with the decision of the competent authority. Particularly in this framework the competent authorities of the Member States and the Commission shall make arrangements to ensure proper cooperation.

2 Member States shall inform the Commission and the other Member States of their reasoned decisions to refuse or to withdraw approval of confidentiality or to refuse to extend the confidentiality period.

3 Member States and the Commission shall take the necessary measures to ensure that confidential data made known to them is not improperly disclosed.

Article 9

Member States shall recognize the decisions taken by a competent authority as to the approval of confidentiality or extension of the confidentiality period.