

Composition and undesirable effects of cosmetic products to be made easily accessible to the public - practical implementation of article 7a(1)(h) 2nd paragraph of Council directive 76/768/EEC

Under article 7a (1)(h) 2nd paragraph of Council Directive 76/768/EEC, hereinafter called the Cosmetics Directive, it is foreseen:

“Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, Member States shall ensure that the information required under (a) and (f) shall be made easily accessible to the public by any appropriate means, including electronic means. The quantitative information required under (a) to be made publicly accessible shall be limited to dangerous substances covered by Directive 67/548/EEC.”

Points (a) and (f), mentioned in this paragraph, refer to:

(a) the qualitative and quantitative composition of the product; in the case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier;

(f) existing data on undesirable effects on human health resulting from use of the cosmetic product.

Further to the adoption of European Parliament and Council Directive 2003/15/EC which has modified the Cosmetics Directive in order to introduce this transparency aspect, it seems appropriate to ensure a uniform implementation of this requirement in order to allow a smooth functioning of the internal market. To this purpose, the Commission set up a sub-working group composed of representatives of Member States and stakeholders.

The sub-working group presented its conclusions to the working group on cosmetic products on 22 June 2005. This group was chaired by the Commission and was composed of representatives of all Member States, EFTA, BEUC, European Organisation of Consumers, Colipa, European Federation of Cosmetic Products, EFFCI, European Federation for Cosmetic Ingredients, EFFA, European Flavour and Fragrances Association and Unitis, European Organisation of Cosmetic Ingredients Industries and Services. Following comments received from stakeholders a new version of these conclusions was drafted, which is reflected in this document.

The content of this document **is not legally binding**, since only the Court of Justice can give an authoritative interpretation of Community law.

When is this information to be made available?

All the information concerned is already accessible to the competent authorities of the Member States under the specific requirements of article 7a (1) of the Cosmetics Directive¹.

¹ “The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market shall for control purposes keep the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with Article 6 (1) (a):
(a) the qualitative and quantitative composition of the product; in the case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier; [...]
(f) existing data on undesirable effects on human health resulting from use of the cosmetic product;” [...]

The key difference is that some of the information must also be made easily accessible to the public on their request.

Who needs to make the information accessible to the public?

The obligation to make the information mentioned in article 7a (1)(a) and (f) easily accessible to the public is clearly with the cosmetic manufacturer, his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market. This person has also to keep this information readily accessible to competent authorities. Member States have to ensure that these obligations are fulfilled.

What information needs to be made accessible to the public?

➤ Qualitative and quantitative composition of the product (Article 7a (1) (a))

In accordance with article 7a (1)(h) 2nd paragraph, Member States shall ensure that, without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, qualitative and quantitative information, which the manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market has kept, for control purposes, readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with article 6 (1), is made easily accessible to the public.

Qualitative composition: the list of ingredients of the product

It must be pointed out that ingredients means any chemical substance or preparation of synthetic or natural origin, including perfume and aromatic compositions used in composition of cosmetic products (see in that respect Article 5a (1) of Cosmetics Directive which excludes 'perfume and aromatic compositions' only for the purposes of the compiling of an inventory of ingredients).

Article 6 (1)(g) provides that the list of ingredients has to be labelled at least on the packaging of cosmetic products. It also provides that impurities in the raw materials used, subsidiary technical materials used in the preparation but not present in the final product, and materials used in strictly necessary quantities as solvents or as carriers for perfume and aromatic compositions are not ingredients.

For aromatic compositions and perfumes:

- Article 6 (1)(g) provides that *“perfume and aromatic compositions and their raw materials shall be referred to by the word ‘perfume’ or ‘aroma’. However, the presence of substances, the mention of which is required under the column ‘other limitations and requirements’ in Annex III, shall be indicated in the list irrespective of their function in the product”*.
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- However, article 7a (1)(a) provides that “in the case of perfume compositions and perfumes”, information concerning the qualitative and quantitative composition of a product consists in “the name and code number of the composition and the identity of the supplier”. Still, in accordance with article 7a (1)(h) 2nd paragraph, in order to not compromise, in particular, commercial secrecy or intellectual property rights, access to this information may be refused.

Quantitative composition:

The quantitative information to be made publicly accessible is limited to those substances which are classified as ‘dangerous’ under the provisions of Directive 67/548/EEC.

In accordance with article 7a 1(h) 2nd paragraph this shall include substances listed in Annex I of Directive 67/548/EEC and, if it is the case, those that are not yet listed in that Annex I but that are classified as ‘dangerous’ in accordance with article 6 of the above-mentioned Directive 67/548/EEC as reported in the material safety data sheet (MSDS) which is made available to the cosmetic manufacturer. In accordance with the above-mentioned article 7a (1)(h) 2nd paragraph, when necessary, in order to not compromise commercial secrecy or intellectual property rights, the value can be rounded up and indicated as “<x %” or, alternatively, concentration ranges can be used (x-y%).

The quantitative information ought to be consistent with the ingredients’ respective positions in the list on the product’s package².

➤ Data on undesirable effects related to the product (Article 7a (1) (f))

In accordance with article 7a (1)(h) 2nd paragraph, Member States shall ensure that, without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, undesirable effects, which the manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market has kept, for control purposes, readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with article 6 (1), are made easily accessible to the public.

- An “undesirable effect” is an adverse effect on human health that occurs from the normal or reasonably foreseeable use of a cosmetic product (as it results from article 2 of the Cosmetics directive). Undesirable effects accessible to the public do not include, for example, those resulting from abuse or misuse of the product and those related to associated items, such as the packaging.
- Examples of undesirable effects are: irritant and allergic effects, cosmetic acne, phototoxic effects, photosensitivity, anaphylactic shock and itching.

² Article 6.1(g) provides that must be indicated on the container or at least on the packaging “a list of ingredients in descending order of weight at the time they are added” and that “ingredients in concentrations of less than 1% may be listed in any order after those in concentrations of more than 1%”.

- All undesirable effects reported to the companies should be included when the company gives information to the public.
- Appropriate information on the frequency and nature of undesirable effects linked to the product placed on the market of the Member States must be provided.
- The companies have the possibility to inform the public if undesirable effects have been substantiated or not, i.e if the causal link between the product and the undesirable effect has been proved.
- The companies have the possibility when informing the public to additionally compute a value for the number of undesirable effects per 1.000.000 units placed on the market.

How should the information be made accessible to the public?

The information outlined above has to be made accessible to the public on request but it does not have to be published.

The Commission considers that members of the public who wish to access this information will have one or more of the following options:

- To write to the company,
- To telephone the company,
- To visit the company's website.

In accordance with article 6 (1) (a), the label of every cosmetic product placed on the EU market must bear the name or style and the address or registered office of the manufacturer or the person responsible for marketing the cosmetic product who is established within the Community. Moreover, in order to facilitate public access to the relevant product information, industry has made known to the Commission that it has created a central public directory of companies placing cosmetic products on the EU market. Please find enclosed the hyperlink to the directory:

European Directory of public access

<http://www.european-cosmetics.info>

The directory is made available on the internet and contains company names and contact details (address, phone, fax, email, website). The directory is a central listing of contact points, designed to enable public to locate the companies, and is not the source of the information itself. Companies themselves will reply directly to the public.

For companies that do not have consumer help-line numbers or websites, the public will always have the option of writing to the address indicated on the package.

In order to make the information easily accessible to the public, the party responsible for answering a request for information according to article 7a (1)(h) 2nd paragraph, should ensure

that an answer is given promptly without unnecessary delay taking into account the nature and the volume of the information.

If a member of the public does not receive an answer from the company or if they consider that the answer is not complete, they can complain to competent authorities who will then contact the competent authorities of the Member State concerned.

The answer should be in a language easily understood by the public.

Companies should keep a record of all requests and answers given.