COMMISSION OF THE EUROPEAN COMMUNITIES

COM(90) 488 final - SYN 307

Brussels, 5 February 1991

Proposal for a

COUNCIL DIRECTIVE

amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

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(presented by the Commission)

EXPLANATORY MEMORANDUM

1. Directive 76/768 was intended to approximate the laws of the Member States relating to cosmetic products in order that those products might move freely within the Community market (legal basis Article 100 of the EEC Treaty).

Articles 7 and 3 of the Directive introduced the clauses of **free movement** and **exclusive admission** respectively with a view to complete harmonization of this sector at Community level. Such a goal could not be attained without **harmonizing the safety conditions** of cosmetics and the information to be supplied to the user. The following degree of protection was therefore introduced:

- the manufacturer was
  - made responsible for the safety of these products (Article 2);
  - obliged - to comply with the lists of **authorized** (280 colouring agents, preservatives and UV filters), **restricted** (50) and **prohibited** (400) **substances** annexed to the Directive (Articles 4 and 5);
    - indicate on the packaging and the label of the product five obligatory pieces of information relating to the manufacturer or the person responsible for marketing, the nominal content, the date of minimum durability, particular precautions to be observed in use and the reference for identifying the goods (Article 6);

- **no pre-marketing procedure** (such as registration, notification or authorization) was required.

Member States could also:

- for purposes of prompt and appropriate medical treatment in the event of difficulties, require that adequate and sufficient information regarding substances contained in cosmetic products be made available to the competent authority (Article 7(3));
- if a product represented a hazard to health, provisionally prohibit the marketing of that product in its territory or subject it to special conditions (Article 12).

Lastly, a regulatory Committee was set up to adapt the annexes to the Directive to scientific and technical progress (Article 10).

Ten years after these rules were implemented, the Commission started looking into the expediency of revising the instrument referred to above in the face of persisting barriers to intra-Community trade.

Talks were held with national experts, manufacturers, consumers, scientists and animal protection groups.

2. After the second round of talks it was apparent that if national laws on cosmetics were to be harmonized Directive 76/768 would have to be amended as follows:

A. Stipulation of the information on the identity, quality, safety and efficacy of the cosmetic product to be kept available by the manufacturer in the event of a check by the competent authority. This information should not constitute a precondition for marketing, whether directly or indirectly, and should be made available only to the monitoring authority in the place of manufacture or of initial importation into Community territory.

In addition, it should be stipulated that the relevant competent authority should be apprised of the place of manufacture, for monitoring reasons, and of information necessary in the event of poisoning, for medical reasons.

B. **Transparency regarding the ingredients used in cosmetic products**. Given that:
   - the manufacturer is responsible for the safety of the cosmetic product (Article 2 of Directive 76/768);
   - the manufacturer is free to place his product on the market without any preconditions;
   - each monitoring authority in the Member State of marketing should recognize the checks carried out by its opposite numbers in the Member State of manufacture where the information referred to at A is available;
   - the user should be in a position to know the content and purpose of a product for economic reasons and to allow for individual allergies,

   it is vital that the packaging of a cosmetic product indicate the ingredients used in it and its function;

C. **Drawing-up of an inventory of the ingredients used in cosmetics**. This should enable the Commission to assess all issues relating to the use of cosmetics;

D. **A more watertight and consistent definition of cosmetics** by removing the words "exclusively or principally" and "in order to" from Article 1(1). The present definition is as follows:
   "A 'cosmetic product' means any substance or preparation intended for placing in contact with the various external parts of the human body

(epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours."

The following amendments are proposed:

1. **Deletion of the words "exclusively or principally"**. These adverbs indicate that the recognized functions of cosmetic products are of an exclusive or principal nature. This suggests that there are also functions of an accessory nature. The latter are not defined, however, which gives rise to a state of legal ambiguity as to the scope of the said definition. Deletion of these adverbs would turn the present definition into an exhaustive list and put a limit on the possible functions of the cosmetic product.

2. **Deletion of "in order to" and addition of "and/or" between the last two functions**. Use of the words "in order to" creates two categories of function: principal functions (cleaning, perfuming, protecting) and secondary functions (keeping in good condition, changing appearance, correcting body odours). The need to associate a secondary function with a principal function gives riseto a contradiction with regard to Article 1(2), which refers to the indicative list of products to be considered as cosmetic products. This means that products intended exclusively to embellish or colour (so as to change appearance), such as foundation or certain hair care products, do not fall within the scope of the present definition, since their "secondary" use cannot be associated with any of the principal uses. Thus the proposal to delete the words "in order to" is intended to turn the two groups of the present definition into six individual functions, whether or not cumulative;

E. **A more consistent formulation of Article 2** by deleting the words "be liable to" and adding the words "and reasonably foreseeable". Article 2 is currently worded as follows:

"Cosmetic products put on the market within the Community must not be liable to cause damage to human health when they are applied under normal conditions of use."

The following amendments are proposed:

1. **Deletion of the words "be liable to".** The present wording ("liable to cause damage") weakens the need for cosmetic products not to cause damage to human health. It is inconsistent to accept a greater degree of risk to human health in the sale of cosmetic products than in the marketing of medicinal products intended to act upon a pathological condition. Council Directive 65/65/EEC of 26 January 1965 on proprietary medicinal products[1] does not employ this watered-down wording, but lays down in Article 5(1) that marketing authorization is to be refused "if it proves that the proprietary medicinal product is harmful in the normal conditions of use."

In addition, the proposed new measures, such as the compilation of an inventory of ingredients, stipulation of the information to be kept available for the monitoring authority and notification of the place of manufacture will provide a sufficient guarantee of harmlessness; thus the watering-down of the clause on the non-toxicity of cosmetics is inconsistent with the new measures giving it effect.

2. **Addition of the words "or reasonably foreseeable"** after the word "normal" in Article 2 so as to provide greater protection for the consumer, particularly where the cosmetic product is applied to areas close to those initially foreseen. This is already provided for in the seventh recital of the Directive.

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1 OJ No 22, 9.2.1965.

The proposal for a Council directive on general product safety (COM(89) 162 final) takes the same approach in defining "unacceptable risk" in Article 2;

F. **Extending application of the Article 10 procedure** to cover the amendment of Annexes I and VIII to the Directive, so that they can be adapted more rapidly to technological progress. It should be noted that Annex I is merely illustrative and cannot take precedence over the abovementioned Directive 65/65/EEC.

Annex I to the Directive, which sets out an illustrative list by category of cosmetic products, serves as a guideline for placing a product in the category of medicinal or cosmetic products. Given the possible overlaps between the preventive and/or physiological aspects of the definitions of medicinal and cosmetic products, it was deemed necessary to add an illustrative list of cosmetics.

There can be no overlap between medicinal and cosmetic products since the interests protected by the legislation governing medicinal products are of a higher order. Directive 65/65 introduced a system of prohibition based on the authorization, prior to marketing, of all pharmaceutical products. Directive 76/768 introduced a system to prevent abuse by establishing a list of admissible substances; cosmetic products are not subject to any procedure prior to marketing.

Directive 65/65 therefore takes precedence over Directive 76/768; Directive 76/768 can only give an indication (area of application, six functions, list in Annex I) of what might be a cosmetic product since in the last resort a product will be considered medicinal if, owing to its form and/or composition (substances used and their concentration), it is subject to a marketing authorization procedure ensuring safety, quality and efficacy.

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II

(Preparatory Acts)

COMMISSION

Proposal for a Council Directive amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

COM(90) 488 final — SYN 307

(Submitted by the Commission on 12 February 1991)

(91/C 52/06)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas legal ambiguities in Council Directive 76/768/EEC (1), as last amended by Directive 89/679/EEC (2), particularly in Articles 1 and 2, should be removed;

Whereas it has become apparent that it is desirable that data on the ingredients employed in cosmetic products be gathered with a view to the assessment of all issues relating to their use and of the resulting action at Community level with a view particularly to the establishment of a common nomenclature of ingredients used in cosmetic products; whereas the gathering of this data can be facilitated if the Commission compiles an inventory of the ingredients concerned; whereas this inventory is indicative and is not intended to constitute a definitive list of substances used in cosmetic products;

Whereas greater transparency is needed regarding the ingredients employed in cosmetics if the latter are to be placed on the market without any prior procedure and in order to obtain the necessary information on the finished product solely at the place of manufacture or of initial importation into the Community and provide better information to the consumer; whereas such transparency should be attained by indicating the product's function and by indicating the ingredients used in a cosmetic product on its packaging; whereas where for practical reasons it is impossible to indicate the ingredients and any warnings regarding use on the container or the packaging, such indications should be given on an enclosed leaflet with a suitable symbol;

Whereas, with regard to the finished cosmetic product, it should be made clear which information is to be made available to the monitoring authorities of the place of manufacture or of initial importation into the Community market; whereas this information should include all the necessary elements relating to identity, quality, safety for human health and the claimed effects of the cosmetic product;

Whereas the competent authority should be apprised of the place of manufacture, for reasons of monitoring, and of the information needed for rapid and appropriate medical treatment in case of difficulties;

Whereas assessment of the safety of use of the ingredients employed in cosmetics and of the final product must take account of the requirements of Council Directive 86/609/EEC [1] regarding the protection of animals used for experimental and other scientific purposes, and in particular Article 7 (2) thereof,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 76/768/EEC is hereby amended as follows:

1. Article 1 (1) is replaced by the following:

'1. A "cosmetic product" means any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view to cleaning them, perfuming them, protecting them, keeping them in good condition, changing their appearance and/or correcting body odours.'

2. Article 2 is replaced by the following:

'*Article 2*

Cosmetic products put on the market within the Community must not cause damage to human health when they are applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of every communication made in this regard by the manufacturer or his authorized agent or by all others responsible for placing these products on the Community market.'

3. The following Article is inserted:

'*Article 5a*

1. Not later than 31 December 1993, the Commission shall, on the basis in particular of information supplied by the Member States, compile an inventory of ingredients employed in cosmetic products.

For the purposes of this Article "cosmetic ingredient" means any chemical substance or preparation of synthetic or natural origin, except for perfume and aromatic compositions, used in the composition of cosmetic products.

2. The inventory shall contain information on:

— the identity of the ingredient, in particular its chemical name and, where appropriate, the Einecs, CAS and Colour Index numbers,

— the function(s) of the ingredient in the final product,

— where appropriate, restrictions and conditions of use and warnings which must be printed on the label.

3. The Commission shall publish the inventory and shall update it periodically. The inventory is indicative and does not constitute a list of the substances authorized for use in cosmetic products or an exhaustive list of substances used in these products.'

4. In Article 6 (1), the introductory phrase is replaced by the following:

'Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if the container and packaging bear the following information in indelible, easily legible and visible lettering, except for the information mentioned in (g) hereafter which may be indicated on the packaging alone:'.

5. Article 6 (d) is replaced by the following:

'(d) particular precautions to be observed in use, and especially those listed in the column "Conditions of use and warnings which must be printed on the label" in Annexes III, IV, VI and VII, which must appear on the container and packaging as well as any special precautionary information on cosmetic products for professional use, in particular in hairdressing. Where this is impossible for practical reasons, this information must appear on an enclosed leaflet, with either abbreviated information on the container and the packaging or the symbol given in Annex VIII referring the consumer to the information specified.'.

6. The following points (f) and (g) are added to Article 6 (1):

'(f) the function of the product, unless it is clear from the description of the product;

(g) A list of ingredients in descending order of weight at the time they are added. This list shall be preceded by an appropriate indication including the word "ingredients". Where this is

[1] OJ No L 358, 18. 12. 1986, p. 1.

impossible for practical reasons, the ingredients must appear on an enclosed leaflet, with either abbreviated information on the container and the packaging or the symbol given in Annex VIII referring the consumer to the ingredients specified. Perfume and aromatic compositions and their raw materials shall be referred to by the word "perfume". Ingredients of a concentration of less than 1 % may be listed in any order after those of a concentration of more than 1 %. Colouring agents may be listed in any order after the other ingredients.

In accordance with the Article 10 procedure, the Commission shall, no later than 31 December 1993, adopt the criteria and conditions under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients on the abovementioned list.'.

7. Article 7 (2) is replaced by the following:

'2. They may, however, require that the particulars provided for in Article 6 (1) (b), (c) and (d) be expressed at least in their own national or official language or languages; they may also require that the particulars provided for in Article 6 (1) (f) and (g) be expressed in a language easily understood by the consumer. To this end, the Commission shall adopt a common ingredients nomenclature in accordance with the Article 10 procedure.'.

8. Article 7 (3) is replaced by the following:

'3. Furthermore, a Member State may require, for purposes of prompt and appropriate medical treatment in the event of difficulties, that the qualitative and quantitative formula of the product be made available to the competent authority, which shall ensure that this formula is used only for the purposes of such treatment.

Member States shall designate that competent authority and send details thereof to the Commission, which shall publish this information in the *Official Journal of the European Communities.*'

9. The following Article is inserted:

'*Article 7a*

1. The manufacturer or his agent, provided he is established in the Community, or the person responsible for placing imported cosmetic products on the Community market, shall, for control purposes, keep the following information readily available to the competent authorities of the Member State concerned at the place of manufacture or, in the case of importation from a non-member country, at the place of initial importation into Community territory:

(a) the qualitative and quantitative formula of the product;

(b) the physico-chemical and microbiological specifications of the raw materials and the finished product and the purety and microbiological control criteria of the cosmetic product;

(c) the method of manufacture complying with the good manufacturing practice laid down by Community law or, failing that, laid down by the law of the Member State concerned;

(d) assessment of the safety for human health of the finished product. To this end, the manufacturer shall take into consideration the general toxicological profile of the ingredient, its chemical structure and its level of exposure. Should the same product be manufactured at several places on Community territory, the manufacturer may choose a single place of manufacture where this information will be kept available. With regard to this, and when so requested for monitoring purposes, he shall be obliged to indicate the place so chosen to the monitoring authority/authorities concerned;

(e) the name and address of the qualified person or persons responsible for the assessment referred to at (d). This person must have received university training in the field of natural sciences;

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

(g) proof of the effect claimed for the cosmetic product, where this is justified by the nature of the product.

2. The assessment of the safety for human health referred to in paragraph 1 (d) of this Article shall be carried out in accordance with the principles of good laboratory practice laid down in Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances (1).

3. The information referred to in paragraph 1 must be available in the national language or languages of the Member State concerned, or in a language readily understood by the competent authorities.

4. The manufacturer or his agent, provided he is established in the Community, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent national authority of the place of manufacture or of the initial importation of the address of the place of manufacture or of initial importation into the Community of the cosmetic products before the latter are placed on the Community market.

5. Member States shall designate the competent authorities referred to in paragraphs 1 and 4 and shall send details thereof to the Commission, which shall publish this information in the *Official Journal of the European Communities.*

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(1) OJ No L 15, 17. 1. 1987, p. 29.'

10. Article 8 (2) is replaced by the following:

'2. The amendments necessary for adapting to technical progress the Annexes to this Directive and the common nomenclature of ingredients used in cosmetic products shall be adopted in accordance with the same procedure, after consultation of the Scientific Committee on Cosmetology.'.

11. The Annex is added as Annex VIII.

Article 2

1. Member States shall take all necessary measures to ensure that from 1 January 1997 neither manufacturers nor importers established within the Community place on the market products which fail to comply with the provisions of this Directive.

2. Member States shall take all necessary measures to ensure that the products referred to in paragraph 1 cannot be sold or disposed of to the ultimate consumer after 31 December 1997.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1993 and shall inform the Commission thereof forthwith.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

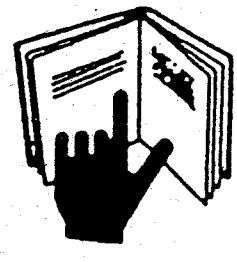
2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive.

Article 4

This Directive is addressed to the Member States.

ANNEX

Annex VIII



IMPACT ON COMPETITIVENESS AND EMPLOYMENT

I. **What is the main justification for this measure?**

The complete harmonization of the cosmetics sector aimed at by Community legislation in 1976 (basic Directive 76/768) has not been achieved: several Member States have introduced health protection measures more restrictive than those provided for in the Directive. To remedy the situation, a new system of harmonization needs to be set up, based on greater market transparency for the ingredients used in cosmetics and tighter safety rules relating to the finished product.

II. **Characteristics of the businesses concerned. In particular:**

- **are there many SME?**
- **are they concentrated in regions:**
  - **eligible for regional aid from the Member States?**
  - **eligible for ERDF aid?**
- Considering that a SME has a maximum of 500 employees, 1,666 SME (turnover 7,718 milion Ecu) operate at Community level (see table at Annex I).

III. **What obligations fall directly upon businesses?**

They must indicate on the label and on the packaging the function of the cosmetic product and the ingredients used in it.
Information to be given to anti-poison centres has been reduced to a minium, i.e. the quantitative and qualitative formula.

IV. **What obligations are liable to be imposed on businesses indirectly by local authorities?**

None.

V. **Are there any special measures for SME? If so, what are they?**

None.

VI. **What is the foreseeable effect on**

- business competitiveness?

- employment?

- The disappearance of the national frontiers existing as a result of pre-marketing measures will make businesses more competitive. For the present, the files to be compiled by Community SME when they export to certain Member States (e.g. F, GR, P, ES, I) constitute a quite heavy financial burden (see the example of the French file at Annex II). By introducing transparency in the ingredients used in cosmetics, the Member States will abolish barriers connected with national files. As a result, SME's should benefit from the abolition of the very considerable burdens associated with the obligation to constitute the said national files, which are to be replaced by labelling of use and of ingredients.

  The necessary costs which will result for SME's from such labelling may in principle be minimized by the possibility of the list of ingredients appearing only on the package.

  No effect on the employment is forseen.

VII. **Have the two sides of industry been consulted?**

- opinions of the two sides

Yes.

ANNEX I

13

September 13, 1990
SC/dg

COLIPA

ESTIMATED FIGURES FOR PME IN EEC

Country :	D	B	DK	E	F	GB	GR	IR	I	NL	P	Total
Members	153	90	65	336	199	115	83	20	453	59	93	1,666
Employment ('000)	22	3.5	1.2	15	25	7	3	4	25	4.8	2.5	113
Indirect Employment ('000)	65	8	3	35	65	30	10	1.5	70	12	6.3	305.8
Turnover (million ECU)	1790	187	62	569	1620	1129	83	22	1409	245	62	7178

ESTIMATED FIGURES FOR LARGE COMPANIES IN EEC

Country :	D	B	DK	E	F	GB	GR	IR	I	NL	P	Total
Members	4	-	-	-	5	5	-	-	-	-	-	14
Employment ('000)	8	-	-	-	7	13	-	-	-	-	-	28
Indirect Employment ('000)	15	-	-	-	15	30	-	-	-	-	-	60
Turnover (million ECU)	1,406	147	48	447	1,270	887	66	17	1,108	192	49	5,637

Notes (Large Companies)

Numbers — By country on basis of head office or leading national company for US multi-nationals.

Employment — Estimate for employees active in cosmetic/toiletries sector. All big companies have other activities.

Turnover — European turnover only - assumes equal penetration in each country.

DECRET N° 77-1558 DU 28 DECEMBRE 1977

relatif à la constitution du dossier et aux transmissions préalables à la mise sur le marché d'un produit cosmétique ou d'un produit d'hygiène corporelle.

(*Journal officiel* du 25 janvier 1978.)

Le Premier ministre,

Sur le rapport du garde des sceaux, ministre de la justice, du ministre délégué à l'économie et aux finances, du ministre de l'agriculture, du ministre de l'industrie, du commerce et de l'artisanat, et du ministre de la santé et de la sécurité sociale,

Vu le code de la santé publique, et notamment son article L. 658-3 ;

Vu la loi n° 75-604 du 10 juillet 1975 modifiant le livre V du code de la santé publique et concernant la fabrication, le conditionnement, l'importation et la mise sur le marché des produits cosmétiques et des produits d'hygiène corporelle ;

Vu le décret n° 77-220 du 7 mars 1977 relatif aux déclarations incombant aux établissements de fabrication, de conditionnement et d'importation des produits cosmétiques et des produits d'hygiène corporelle, notamment son article 2 ;

Vu le décret n° 77-463 du 28 avril 1977 relatif à la présentation et à la publicité des produits cosmétiques et des produits d'hygiène corporelle,

Décrète :

Article 1er.

Le responsable de la mise sur le marché de tout produit cosmétique ou de tout produit d'hygiène corporelle assure la constitution, le dépôt et la mise à jour du dossier prévu à l'article L. 658-3 du code de la santé publique. Il est tenu de faire connaître le lieu de dépôt du dossier au préfet du département où se trouve l'adresse ou le siège social mentionné à l'article 1er b du décret du 28 avril 1977 susvisé.

Article 2.

Le dossier est établi en langue française. Il comporte les éléments suivants :

1° Nom ou dénomination sociale et adresse du ou des établissements fabriquant le produit et nom, fonctions et qualification

professionnelle de la ou des personnes responsables désignées dans la déclaration prévue à l'article L. 658-2 du code de la santé publique ;

2° Nom ou dénomination sociale et adresse du ou des établissements conditionnant le produit ; nom, fonctions et qualification professionnelle de la ou des personnes responsables désignées dans la déclaration prévue à l'article L. 658-2 du code de la santé publique ;

3° Nom ou dénomination sociale et adresse du ou des établissements important le produit ; nom, fonctions et qualification professionnelle de la ou des personnes responsables désignées dans la déclaration prévue à l'article L. 658-2 du code de la santé publique ;

4° Dénomination du produit ;

5° Classement du produit dans les catégories prévues par la liste mentionnée à l'article 2 *e* du décret du 7 mars 1977 susvisé ;

6° Usage et mode d'emploi du produit ;

7° Formule intégrale du produit, conformément aux dispositions des articles 4 et 6 du présent décret, ou s'il s'agit d'un parfum liste et dosage des supports et des produits prévus aux articles L. 658-5 et L. 658-6 du code de la santé publique entrant éventuellement dans sa composition ;

8° **Méthode utilisée et résultats des essais** prévus par l'article L. 658-3 du code de la santé publique ;

9° **Conditions de fabrication du produit** : formule de préparation comportant la mention des substances utilisées, y compris des substances intermédiaires pouvant ne pas se retrouver dans le produit fini ; description du mode et des conditions de fabrication ; désignation des lieux de fabrication totale ou partielle du produit ;

10° **Condition de contrôle des matières premières et des lots de produit fini** . description des techniques de contrôle physico-chimique et, s'il y a lieu, de contrôle de propreté bactériologique ; mention des résultats obtenus par application de ces techniques lors de leur mise au point ; désignation des lieux de contrôle et de stockage du produit ;

11° Modalités d'identification des lots de fabrication ;

12° Précautions particulières d'emploi du produit ;

13° Description de la méthode utilisée pour déterminer la durée de conservation du produit ; résultats obtenus avec indication précise du délai de péremption lorsque celui-ci est inférieur à trois ans ;

14° Indication des différents types de présentation des unités de vente du produit et de leur contenance, des matériaux entrant dans la composition des récipients ; spécimens ou reproductions des notices, récipients et emballages ;

15° Justification de la transmission prévue à l'article 5 du présent décret.

Article 3.

Chacun des éléments mentionnés à l'article précédent porte l'indication de la date à laquelle il a été établi.

Toute modification apportée au dossier fait l'objet d'un rectificatif daté.

Les éléments modifiés sont maintenus au dossier.

Article 4.

Pour l'application du présent décret, on entend par formule intégrale du produit l'indication de la composition qualitative et quantitative de ce produit, exprimée par la désignation de toutes les substances entrant dans sa composition, avec la mention du pourcentage de chacune d'elles.

Les substances chimiques doivent être désignées par leur dénomination usuelle et leur dénomination scientifique, accompagnée de leur formule chimique développée et, lorsqu'elle existe, par leur dénomination commune internationale recommandée par l'Organisation mondiale de la santé, suivie de la mention DCI.

Les substances d'origine végétale ou animale doivent être désignées par leur dénomination usuelle accompagnée de l'indication de leur mode d'obtention.

Toutefois, lorsqu'un produit cosmétique ou un produit d'hygiène corporelle contient une composition parfumante, les seules indications relatives à cette dernière sont la liste et le dosage des supports et des produits mentionnés aux articles L. 658-5 et L. 658-6 du code de la santé publique entrant éventuellement dans sa composition.

Article 5.

A la diligence du responsable de la mise sur le marché, la formule intégrale du produit est déposée contre récépissé ou adressée par lettre recommandée avec demande d'avis de réception, aux centres de traitement des intoxications désignés par l'arrêté prévu à l'article L. 658-3 du code de la santé publique.

S'il s'agit d'un parfum, le responsable de la mise sur le marché dépose ou adresse auxdits centres, dans les mêmes conditions, la liste et le dosage des supports et des produits mentionnés aux articles L. 658-5 et L. 658-6 du code de la santé publique entrant éventuellement dans la composition du parfum.

Toute modification apportée aux indications ainsi fournies doit être transmise auxdits centres dans les mêmes conditions, préalablement à la mise sur le marché du produit modifié.

Les transmissions prévues au présent article sont faites sous double enveloppe. Les documents transmis sont contenus dans l'enveloppe intérieure cachetée portant extérieurement la dénomination de vente du produit.

Un arrêté du ministre chargé de la santé détermine le modèle d'imprimé à utiliser pour assurer les transmissions prévues au présent article.

Article 6.

Lorsqu'un produit cosmétique ou un produit d'hygiène corporelle contient un composant délivré par un fournisseur exclusif et responsable qui a refusé d'en communiquer la formule intégrale au responsable de la mise sur le marché du produit, ce dernier peut, par dérogation aux dispositions de l'article 4 du présent décret ne mentionner dans la formule du produit que la dénomination de vente dudit composant. Cette mention doit être complétée :

— par l'indication du nom ou de la dénomination sociale et de l'adresse du fournisseur de ce composant ;
— par la justification de la transmission faite par le fournisseur, de la formule intégrale de ce composant au ministre chargé de la santé et aux centres de traitement des intoxications ;
— par un document, établi par le fournisseur, contenant les indications relatives au composant qui permettent au responsable de la mise sur le marché du produit de satisfaire aux dispositions des articles L. 658-5, L. 658-6 du code de la santé publique et à celles du décret du 28 avril 1977.

Le fournisseur exclusif et responsable du composant en transmet la formule intégrale au ministre chargé de la santé et aux centres de traitement des intoxications désignés par l'arrêté prévu à l'article L. 658-3 du code de la santé publique. Il leur transmet toute modification apportée à ces formules. Ces transmissions sont effectuées dans les conditions et selon les formes prévues à l'article 5 du présent décret.

Article 7.

Dans chaque centre de traitement des intoxications habilité à recevoir le dépôt des formules intégrales des produits cosmétiques et des produits d'hygiène corporelle ou de leurs composants le chef du centre prend toutes dispositions utiles pour que les formules ne soient accessibles qu'à lui-même ou aux personnes qu'il a désignées pour en assurer la garde.

Les formules déposées ne sont communiquées qu'aux autorités chargées d'enquêtes ou, sur demande motivée, aux autres centres de traitement des intoxications habilités à recevoir cette communication par arrêté du ministre chargé de la santé.

Les communications prévues à l'alinéa précédent sont faites par le chef du centre ou par les personnes désignées pour assurer la garde des formules ; elles sont consignées sur un registre qui mentionne la dénomination commerciale du produit, la date, le destinataire et le motif de la communication.

Article 8.

Le ministre chargé de la santé prend toutes dispositions utiles pour que les formules des composants qui lui sont communiquées en application de l'article 6 ne soient accessibles qu'aux personnes désignées par lui pour en assurer la garde ou aux autorités compétentes pour prendre connaissance du dossier prévu à l'article L. 658-3 du code de la santé publique.

Article 9.

Le garde des sceaux, ministre de la justice, le ministre délégué à l'économie et aux finances, le ministre de l'agriculture, le ministre de l'indutrie, du commerce et de l'artisanat et le ministre de la santé et de la sécurité sociale sont chargés, chacun en ce qui le concerne, de l'exécution du présent décret, qui sera publié au *Journal officiel* de la République française.

Fait à Paris, le 28 décembre 1977.

RAYMOND BARRE.

Par le Premier ministre :

Le ministre de la santé et de la sécurité sociale,
SIMONE VEIL.

Le garde des sceaux, ministre de la justice,
ALAIN PEYREFITTE.

Le ministre délégué à l'économie et aux finances,
ROBERT BOULIN.

Le ministre de l'agriculture,
PIERRE MÉHAIGNERIE.

Le ministre de l'industrie,
du commerce et de l'artisanat,
RENÉ MONORY.

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