Manuale per l'applicazione dell'Articolo 1(1) della Direttiva 76/768 CEE

PRODOTTI *BORDERLINE*

Approvato dai Servizi della Commissione UE e dalle Autorità competenti degli Stati Membri

Commissione Europea - Direzione generale Imprese *http://ec.europa.eu/enterprise/cosmetics/html/cosm_guidance_docs.htm*

MANUAL ON THE SCOPE OF APPLICATION OF THE COSMETICS DIRECTIVE 76/768/EEC (ART. 1(1) COSMETICS DIRECTIVE)

PLEASE NOTE: the views expressed in this manual are not legally binding; only the european court of justice ("court") can give an authoritative interpretation of community law.
Moreover, this manual shall only serve as "tool" for the case-by-case application of community-legislation by the member-states. It is for the national competent authorities and national courts to assess on a case-bycase basis which regulatory framework applies.

The content of this manual and all updates are presented to the working group on cosmetic products for consultation. This group is chaired by the commission and is composed of representatives of all member states of eu and efta, the european organisation of consumers (beuc), the european federation of cosmetic products (colipa), the european federation for cosmetic ingredients (effci), the international fragrance association (ifra), the european organisation of cosmetic ingredients industries and services (unitis), and the european association of craft, small and mediumsized enterprises (ueapme).

TABLE OF CONTENTS

INTRODUCTION

1. **The clear determination of the scope of application of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[1] ("Cosmetics Directive") is crucial for the proper implementation of the Cosmetics Directive and its correct interpretation and enforcement by national competent authorities of the Member States.**

2. **With regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2] ("Medicinal products Directive"), the Commission has published a "Guidance Document on the demarcation between the cosmetic products Directive 76/768 and the medicinal products Directive 2001/83 as agreed between the Commission Services and the competent authorities of Member States" ("cosmetics/medicinal products guidance document")[3] setting out the legal rules for the demarcation between the Cosmetics Directive and the Medicinal products Directive.**

3. **Also, with regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[4] ("Biocidal products Directive"), the Commission has published such a guidance document (hereinafter the "cosmetics/biocidal products guidance document").[5]**

4. **In the course of the discussion with Member States the Commission concluded that guidance is needed which goes beyond abstract rules and addresses their actual application. To this end, a "borderline sub-group", comprised of experts from within the "working group on cosmetic products" and from other Commission Services concerned, meets on a regular basis to discuss the application of Art. 1(1) Cosmetics Directive in order to ensure a uniform approach.**

5. **This manual represents the views agreed in this group on products, or categories of products, which have raised doubts in the past.**

6. **However, please note that the views expressed in this manual are not legally binding, since only the European Court of Justice ("Court") can give an authoritative interpretation of Community law.**

7. **This manual does not relieve national competent authorities from their obligation to determine for any individual product, on a case-by-case basis, whether it falls within the scope of application of the Cosmetics Directive or within the scope of application of other sectoral legislation. The Court has repeatedly held that the national authorities, acting under the supervision of the courts, must proceed on a case-bycase basis, taking account of all the characteristics of the product.[6]**

8. **Therefore, this manual shall not "prescribe" what regulatory framework applies. Rather, it shall serve as one out of many elements supporting the national competent authorities in their case-by-case decision on individual products.**

9. **In particular, this manual does not deprive a national authority to consult with colleagues from other regulated sectors concerned in order to reach a complete view on all aspects related to a given product.**

10. **The structure of this manual shall follow the definition of "cosmetic product" as set out in Art. 1 (1) Cosmetics Directive.**

---

1 OJ L 262, 27.9.1976, p. 169, as amended; Non-official consolidated version at http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm.

2 OJ L 311, 28.11.2001, p. 67, as amended; Non-official consolidated version at http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm

3 http://ec.europa.eu/enterprise/cosmetics/html/cosm_borderline_docs.htm.

4 OJ L 123, 24.4.1998, p. 1, as amended; Non-official consolidated version at http://eurlex. europa.eu/RECH_consolidated.do.

5 "Guidance document agreed between the Commission services and the competent authorities of Member States for the biocidal products Directive 98/8/EC and for the cosmetic products Directive 76/768/EEC - Borderline between directive 98/8/EC concerning the placing on the market of biocidal product and directive 76/768/EEC concerning cosmetics products" http://ec.europa.eu/enterprise/cosmetics/html/cosm_borderline_docs.htm.

6 Cf. For example ECJ, HLH Warenvertriebs GmbH, para. 51; cf. also ECJ, C-290/90 of 20 May 1992, "Eye lotions", ECR 1992 I-3317, para. 17.

1. TYPE OF PRODUCT – SUBSTANCE OR MIXTURE

1.1. Tongue brushes releasing a preparation or a mixture

11. Question: Is a tongue brush which releases a substance or a mixture a cosmetic product?

12. Answer: A tongue brush is neither a substance nor a mixture, but an article. However, the brush may be the "vehicle" to deliver a substance or mixture to the tongue and the mucous membranes of the mouth (for example a gel). In certain cases, a substance or a mixture and a brush can be sold together.

13. This substance or mixture, if it is intended to be placed in contact with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition, may fall within the scope of application of the Cosmetics Directive.

14. If the article is built in such a way that it releases an anti-microbial substance, such as silver, for example, or activates an anti-microbial process, it may fall under the remit of Directive 98/8/EC on Biocidal Products. The relevant Implementation Manual[7] indeed states that "the combination of an article and an active substance, if the active substance is placed on the market as an inseparable ingredient of a product, shall be regarded as being under the scope of the Directive if it is intended that the biocidal active substance is released from the treated article to control harmful organisms outside the treated article (external effect) or if it is intended to only control organisms that are not harmful to the treated article itself. "

15. In any case, a decision on the qualification of the products has to be made by the national competent authorities, on a case-by-case basis, and taking into account all the relevant elements, such as the presentation of the products, the ingredients, the mode of action and the claims.

1.2. Clothes releasing cosmetic substances

16. Question: Is an item of clothing which releases substances to the skin for cosmetic purposes a cosmetic product?

17. Answer: The textile is neither a substance nor a mixture (see above). However, the textile may be the "vehicle" to deliver a substance or preparation to the human skin. This substance or mixture, if it is intended to be placed in contact with the various external parts of the human body, with a view exclusively or mainly to cleaning these external parts, to perfume them, to change their appearance and/or to correct body odours and/or to protect them or keeping them in good condition, falls within the scope of application of the Cosmetics Directive.[8]

18. One condition for this substance or preparation to be a cosmetic is thus that it is intended to be released to the body. Substances contained in the textile which are not intended to be released to the body are not cosmetic products.

19. The fact that the textile also falls within the scope of application of Directive 96/74/EC of the European Parliament and of the Council of 16 December 1996 on textile names[9] does not deprive the qualification of released substances for cosmetic purposes as cosmetic products. Thus, the Cosmetics Directive may apply alongside this Directive.

20. The fact that Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations[10] regulates the use of certain chemical substances in textiles with view of environmental and health risks does not deprive the qualification of released substances for cosmetic purposes as cosmetic products. Thus, the Cosmetics Directive may apply alongside this Directive.

1.3. Tooth picks and tooth floss

21. Question: Are tooth picks and tooth floss cosmetic products?

22. Answer: Tooth picks and tooth floss themselves are neither a substance nor a preparation, and a priori they do not fall within the definition of cosmetic products.

23. However, they may be intended to act as a "vehicle" to deliver a substance or preparation to the teeth or the gum. This substance or preparation, if it is intended to be placed in contact with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, to perfume them, to change their appearance and/or to correct body odours and/or to protect them or keeping them in good condition, may fall within the scope of application of the Cosmetics Directive.

24. This should be determined on a case by case basis, depending on the specific characteristics of the substance delivered, the quantity released and the claims, because other legislation may apply such as the Medical Devices legislation and the Medicinal Products legislation.

---

7 Manual of Decisions for Implementation of Directive 98/8/EC concerning the placing on the market of Biocidal Products, p. 68, available on http://ec.europa.eu/environment/biocides/pdf/mod.pdf

8 In any case, the rules for determining the "borderline" to medicinal products apply (cf. "cosmetics/medicinal products guidance document")

9 OJ L 32, 3.02.1997, p. 38, as amended; Non-official consolidated version at http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm.

10 OJ L 262, 27.9.1976, p. 201, as amended; Non-official consolidated version at http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm.

1.4. Patches

25. Question: Is a patch a cosmetic product?

26. Answer: The patch as such is an article and therefore not a cosmetic product. However, the substance or preparation released by the patch may be a cosmetic product if it falls under its definition. Alternatively, this substance or preparation may be a medicinal product "by presentation" or "by function" (see below, chapter 5.3.).

1.5. Washable, temporary "tattoos"

27. Question: Is a washable, temporary "tattoo" (i.e. a little picture which is moistened and subsequently projected on the skin through pressure) a cosmetic product?

28. Answer: The moistened picture may be considered as a preparation. It is intended to be placed in contact with the skin in order to change its appearance.

29. Therefore, such a product is likely to be considered as cosmetic product, provided that the moistened picture is a preparation and not an article (cf. above, chapter 1).

The fact that this product may fall also within the scope of application of Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys[11] does not deprive it from its qualification as a cosmetic product.

1.6. Wipes

30. Question: Is a wipe which releases substances a cosmetic product?

31. Answer: A wipe itself is neither a substance nor a preparation.[12] However, a wipe may be the "vehicle" to deliver a substance or preparation to the human skin. This substance or preparation, if it is intended to be placed in contact with the various external parts of the human body, with a view exclusively or mainly to cleaning these external parts, to perfume them, to change their appearance and/or to correct body odours and/or to protect them or keeping them in good condition, falls within the scope of application of the Cosmetics Directive.

1.7. Wig

32. Question: Is a wig a cosmetic product?

33. Answer: No. According to Art. 1 (1) Cosmetics Directive, a cosmetic is either a substance or a preparation.

34. The Cosmetics Directive does not define "preparation". However, the terms is widely used in the regulatory frameworks for chemicals and defined as "mixture or solution composed of two or more substances" (cf., for example, Art. 2 (1) (b) of Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations,[13] Art. 2 (1) (b) of Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[14] and Art. 2(5) of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents[15]).

35. Thus, since a wig is not a preparation as defined in Community law it cannot be considered as "cosmetic product" and does not fall within the scope of application of the Cosmetics Directive.

2. APPLICATION SITE

2.1. Vagina

36. Question: Is a product which is, according to its presentation, intended to be used for cleaning or lubricating the vagina a cosmetic product?

37. Answer: No. Cosmetic products are defined as intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with teeth and the mucous organs of the oral cavity[16]. This excludes the vagina.

---

11 OJ L 187, 16.7.1988, p. 1, as amended; Non-official consolidated version under http://europa.eu.int/eurlex/ lex/RECH_consolidated.do.

12 Cf. above, 1.1.

13 OJ L 200, 30.7.1999, p. 1, as amended; Non-official consolidated version at http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm.

14 OJ 196, 16.8.1967, p. 1, as amended; Non-official consolidated version at http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm.

15 OJ L 104, 8.4.2004, p. 1, as amended; Non-official consolidated version at http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm.

16 Art. 1 Cosmetics Directive; Cf. also the "cosmetics/medicinal products guidance document", para. 13.

2.2. Ingestion (tablets)

38. Question: Is a product to mask bad breath which presents itself as tablet to be dissolved in the saliva and which is ultimately swallowed a cosmetic product?

39. Answer: Apart from a possible "borderline" with medicinal products[17], this raises the question of the "borderline" between "cosmetic product" and "food". For the purpose of this manual, only the latter shall be considered.

40. The Cosmetic Directive defines "cosmetic product" as "any substance or preparation intended to be placed 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 mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition."

This definition is thus based on two cumulative aspects: the target site of application "placing on body/teeth/mucous membranes" and the "intended main (cosmetic) function" (i.e. cleaning, perfuming, changing appearance, correcting body odours, protecting, keeping in good condition).

41. Recital 5 of the Cosmetics Directive clarifies that "products containing substances or preparations intended to be ingested, inhaled, injected or implanted in the human body do not come under the field of cosmetics".

42. "Food" is defined in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ("**Food Regulation 178/02**")[18] as "any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans."[19] According to the Food Regulation 178/02, 'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. According to Art. 2 of the Food Regulation 178/02, "food" "shall not include cosmetics within the meaning of Council Directive 76/768/EEC".

43. The definition of "food" does not refer to any specific purpose of the product. Therefore, the "intended cosmetic purpose" of the product is not decisive. Rather, the decisive criterion is the target site: While the intended target site for food is the ingestion, a product which is intended to be ingested or which contains substances intended to be ingested is under no circumstances a cosmetic product.

It follows from this that the regulatory frameworks for food and cosmetics are in any case mutually exclusive and that it is crucial to determine whether a product in question or a substance contained therein is intended to be ingested.

44. This assessment has to be done on a case-by-case basis taking into consideration objective criteria, such as the presentation of the product and the usual mode of application. In this context, one may consider inter alia

– whether the preparation/substance is meant to be entirely swallowed (normally food) or whether only parts of it are swallowed "accidentally" (normally cosmetic product; for example tooth paste[20]);

– whether the preparation/substance once brought in touch with the mucous membranes or the teeth, is intended to be spit out again (normally cosmetic product; for example mouth wash preparations) or whether it is intended to be ultimately swallowed and thus ingested (normally food);

– whether the preparation/substance is absorbed by the oral mucosa (normally cosmetic product).

45. In applying these criteria to the present case, the presentation of a product in the form of a tablet which is intended to be dissolved in saliva and ultimately entirely swallowed should be seen as an important indicator that this product is intended to be ingested. Therefore, such a product is usually considered as food.

2.3. Ingestion (chewing gum)

46. Question: Is a product to keep teeth clean or to reduce bad breath which presents itself as a chewing gum a cosmetic product?

47. Answer: A chewing gum consists of a gum base (acting as a "vehicle") which releases substances and/or preparations in the mouth while it is chewed. Apart from a possible "borderline" with medicinal products[21], this raises the question whether these substances/preparations are a "cosmetic product" or "food".

48. The regulatory frameworks of food and cosmetics do not apply cumulatively.[22]

49. As shown above[23], the determination whether a substance/preparation is "food" or a cosmetic product requires an assessment whether – from the point of view of the averagely well-informed consumer – this product is "intended to be ingested". The fact that Food Regulation 178/02 explicitly includes chewing gum in the definition of food[24] does not relieve from this assessment.

50. This assessment has to take into consideration objective criteria, such as the presentation of the product and the usual mode of application. In this context, one may consider inter alia

---

17 Cf. Art. 1 (2) Medicinal products Directive.

18 OJ L 31, 1.02.2002, p. 1, as amended; Non-official consolidated version at http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm.

19 Art. 2 Food Regulation 178/02.

20 The fact that little quantities of these products are "accidentally" swallowed does not mean that they are "reasonably expected to be ingested" (Art. 2 Food Regulation 178/02). Rather, the inclusion of products which are "reasonably expected to be ingested" in the definition of food in Food Regulation 178/2002 aims at situations where products are, albeit not (yet) labelled as such, expected to be sold as food.

21 Cf. Art. 1, 2 of the Medicinal products Directive.

22 Art. 2(3)(e) Food Regulation 178/02.

23 Cf. para. 28.

24 Art. 2(2) Food Regulation 178/02.

– whether the preparation/substance is meant to be entirely swallowed (normally food) or whether only parts of it are swallowed "accidentally" (normally cosmetic product; for example tooth paste[25]);
– whether the preparation/substance once brought in touch with the mucous membranes or the teeth, is intended to be spit out again (normally cosmetic product; for example mouth wash preparations) or whether it is intended to be ultimately swallowed and thus ingested (normally food);
– whether the preparation/substance is absorbed by the oral mucuosa (normally cosmetic product).
51. More specifically, in the case of a product presented as chewing gum, one may need to assess whether the averagely well-informed consumer perceives the preparation/substance released by the chewing gum as "intended to be ingested" because:
– The preparation/substance released by the chewing gum is usually entirely swallowed and not only in parts accidentally swallowed.
The preparation/substance released by the chewing gum is – unlike the chewed gum itself ("vehicle") – usually not spitted out.

3. INTENDED COSMETIC PURPOSE

3.1. Borderline with Toys

3.1.1. Products which, according to their presentation, are destined to be used as make-up on dolls

52. Question: Are products which, according to their presentation, are destined to be used by children as make-up on children dolls, cosmetic products?
53. Answer: The question whether a substance or preparation is intended to be used with a cosmetic purpose has to be assessed on a case-by-case basis from the point of view of the reasonably well-informed consumer. In application of this principle it is likely that substances and products which are, according to their presentation, clearly only intended for their use on a doll would not fall within the scope of application of the Cosmetics Directive.
54. However, these products might fall within the scope of application of Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, which defines toys as "products designed or intended, whether or not exclusively, for use in play by children under 14 years of age".
55. According to Art.10(2), "Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children." In addition, Annex II (10) of the Toys Directive explicitly foresees that "cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.
56. Directive 2009/48/EC will apply from 20 July 2011.

3.1.2. Products which, according to their presentation, are destined to be used as make-up on children

57. Question: Are products which, according to their presentation, are destined to be used by children as make-up on children, cosmetic products?
58. Answer: The age of the person on which the substance or preparation is applied for cosmetic purposes is not a constituent part of the definition of "cosmetic product". Therefore, these products are cosmetic products and fall within the scope of the Cosmetics Directive.
59. The fact that this product may fall also within the scope of application of Council Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys does not deprive it from its qualification as a cosmetic product.
60. Directive 2009/48/EC will apply from 20 July 2011.

3.1.3. Bath Products for Children with a Play Value

61. Question: Are bath products for children which, according to their presentation, are destined e.g. to make crackling noises or colour the water of their bath, cosmetic products?
62. Answer: Bath products with a "play value" for children[26] may fall within the definition of cosmetic products if they are "intended to be placed in contact with the various external parts of the human body […] with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition."
63. If the intended purpose of the product is the playing of children (i.e. making a noise and colouring the water) and if there is no cosmetic purpose, it may fall under the definition of toys, which are "products designed or intended, whether or not exclusively, for use in play by children under 14 years of age" according to Directive 2009/48/EC. The Toys Directive already foresees provisions to ensure safety, such as CE marking and safety assessment.

25 The fact that little quantities of these products are "accidentally" swallowed does not mean that they are "reasonably expected to be ingested" (Art. 2 Food Regulation 178/02). Rather, the inclusion of products which are "reasonably expected to be ingested" in the definition of food in Food Regulation 178/2002 aims at situations where products are, albeit not (yet) labelled as such, expected to be sold as food.

26 Toy Safety Directive 2009/48/EC - An explanatory guidance document, Rev 1.2, Date: 13/09/2010, p. 95, available on http://ec.europa.eu/enterprise/sectors/toys/files/tsdguidance/ tsd_rev_1.2_explanatory_guidance_document_en.pdf

64. However, the product can be a cosmetic (for example, in cases where the skin is perfumed) and a toy, because of its "play value". If the cosmetic is also a toy, the classification as a toy does not deprive it from its qualification as a cosmetic product, which has to fully comply with the Cosmetics Directive (i. e. requirements concerning ingredients, labelling, notification, etc).
65. The classification is a case-by-case decision that the national authorities, acting under the supervision of the courts, must make, taking into account all the characteristics of the product.

3.2. Borderline with Biocides

3.2.1. Leave-on products presented as "antiseptic" or "antibacterial"

66. Question: Is a leave-on product which, according to its presentation, is "antiseptic" or "antibacterial" a cosmetic product?
67. Answer: A product which presents itself as "antiseptic" or "antibacterial" may be a biocidal product, a cosmetic product, a medicinal product or a medical device.
68. With regard to the "borderline" cosmetic products/biocidal products as defined in the Biocidal products Directive, two documents give further guidance:
• The "cosmetics/biocidal products guidance document";[27]
• The "Manual of decisions for implementation of directive 98/8/EC concerning the placing on the market of biocidal products."[28]
69. With regard to the "borderline" between cosmetic products and medicinal products "by virtue of presentation", the decision whether the product is presented as treating or preventing diseases is to be taken on a case-by-case basis. A product which presents itself as antiseptic and antibacterial products for the treatment or prevention of infection and lesions of the skin is likely to be considered as medicinal product by virtue of presentation.[29,30]

3.2.2. "Antiseptic" or "Anti-bacterial" Mouthwash

70. Question: Is a mouthwash which, according to its presentation, is "antiseptic" or "antibacterial" a cosmetic product?
71. Answer: A mouthwash which presents "antibacterial" or "antiseptic" claims can be qualified as a cosmetics product, a biocidal product or as a medicinal product.
72. If the product is intended to be placed in contact with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition, it may fall within the scope of application of the Cosmetics Directive.
73. The Cosmetics Directive allows for secondary biocidal claims like e.g. antimicrobial claim in oral hygiene products or deodorants where the primary purpose is of a cosmetic nature. As further explained by the "Guidance document on biocidal and cosmetic products"[31], article 1 (2) of Directive 98/8/EC on biocidal products excludes from its scope products that fall within the scope of other legal instruments, such as the Cosmetics Directive. In addition, it is not mentioned that biocidal claims should not be allowed for the excluded products. A biocidal claim could therefore be permitted for cosmetic products as far as it is compatible with the provisions of the Cosmetics Directive, and, in particular, that the biocidal function is secondary to the cosmetic function.
74. On the other hand, the same document also mentions that the use of the claim 'disinfection' or 'disinfecting action' as a secondary claim is not permitted because of concerns regarding the borderline of cosmetic products and medicinal products[32]. A mouthwash is a medicinal product when the intended purpose is to treat or prevent oropharynx diseases.
75. In any case, a decision on the qualification of the products has to be made by the national competent authorities, on a case-by-case basis, and taking into account all the relevant elements, such as the presentation of the products, the ingredient, the mode of action and the claims.

3.3. Borderline with Pharmaceutical Products

3.3.1. Products which, according to their presentation, are intended to exclusively or mainly relieve joint pain

76. Question: Is a product which, according to its presentation, is intended to exclusively or mainly relieve joint pain, a cosmetic product?
77. Answer: No. The principal purpose of a cosmetic product is defined by the Cosmetics Directive as "cleaning", "perfuming", "changing the appearance", "correcting body odours", "protecting", or "keeping in good condition". This principal purpose refers to external parts of the body, oral mucous membrane or teeth.[33] Joints are not external parts of the body.[34]

---

27 http://ec.europa.eu/enterprise/cosmetics/html/cosm_borderline_docs.htm.
28 http://www.europa.eu.int/comm/environment/biocides/pdf/mod_040705.pdf.
29 Cf. the "cosmetics/medicinal products guidance document", para. 28 (with reference to case-law of the ECJ).
30 Moreover, note that these products may fall within the legislation for medical devices. For the "borderline" between medicinal products and medical devices, see also the Guidelines relating to medical devices Directives (http://www.europa.eu.int/comm/enterprise/medical_devices/meddev/index.htm).
31 Guidance document agreed between the Commission services and the competent authorities of Member States for the biocidal products Directive 98/8/EC and for the cosmetic products Directive 76/768/EEC, p. 4, available on http://ec.europa.eu/environment/biocides/pdf/cosmetic_products.pdf
32 Idem.
33 Cf. the "cosmetics/medicinal products guidance document", paras 15, 16.
34 Moreover, the principal purpose to "relieve from pain" is not a cosmetic purpose according to Art. 1 Cosmetics Directive (cf. also the "cosmetics/medicinal products guidance document", para. 14).

3.3.2. Products which, according to their presentation, are intended to address "itching"

78. Question: Is a product which, according to its presentation, is intended to address itching on the skin a cosmetic product?

79. Answer: With regard to presentation, the Court has ruled that "a product expressly indicated or recommended as having therapeutic or prophylactic properties has to be regarded as a medicinal product 'by virtue of its presentation' even if it has no known therapeutic effect"[35], and that the "averagely well-informed consumer" is to be considered as the addressee of the presentation.[36]

80. A Community-definition of "disease" does not exist yet.[37] The Court has ruled that a product presented as counteracting certain conditions or sensations, such as itching is not, per se, a medicinal product. Rather, all its characteristics need to be considered: Since these sensations may have no pathological significance, "a reference to such states or sensations in the presentation of a product is not decisive."[38]

81. Thus, while itching may not necessarily be a disease in itself, itching may also be presented as a symptom of a disease. If, in the framework of a case-by-case assessment, a product appears to be presented as addressing an underlying disease, that product may be a medicinal product. The "cosmetics/medicinal products guidance document" gives guidance as to the criteria which may be looked at when considering how a product is being presented.

3.3.3. Product containing substances which restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action

82. Question: Is a product containing substances which restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action a cosmetic product?

83. Answer: If a product is a medicinal product, it falls exclusively within the regulatory framework of medicinal products[39]. A product can be a medicinal product 'by virtue of its presentation' or 'by virtue of function'.

The latter is the case, if the product is a substance or a combination of substances which are used in or administered to human beings inter alia with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.[40] However, not any minor modification of physiological function suffices to render a product a medicinal product by virtue of function.[41]

84. The question whether a product or its substance(s) restores, corrects or modifies physiological functions by exerting a pharmacological, immunological or metabolic action has to be taken on a case-by-case basis.

85. The fact that the same substance is also contained in medicinal products as active ingredient is not decisive. However, this may be an indicator for a pharmacological, immunological or metabolic action of the substance independently of the question whether the product is ingested or used topically.

86. In assessing this, one has to consider all characteristics of the product, including, for example, absorption, concentration, route of administration, frequency of application, application site, and the degree of penetration.[42]

3.3.4. Products containing substances stimulating hair growth or reducing hair loss

87. Question: Are products containing substances stimulating hair growth or reducing hair loss cosmetic products?

88. Answer: The question whether a product or its substance(s) restores, corrects or modifies physiological functions by exerting a pharmacological, immunological or metabolic action has to be taken on a case-by-case basis.

89. The fact that the same substance is not only contained in a cosmetic, but also in medicinal products as an active ingredient is not decisive. However, this may be an indicator for a pharmacological, immunological or metabolic action of the product.

90. In assessing this, one has to consider all characteristics of the product, including, for example, absorption, concentration, route of administration, frequency of application, application site, and the degree of penetration.[43]

91. In particular, the claims may give a useful indication to the competent authorities, without, however, replacing a careful assessment of the mode of action and all the elements indicated above. The claim "promoting hair growth" usually relates to pharmaceutical products, such as, for instance, those containing minoxidil, a substance that is prohibited as a cosmetic ingredient[44]; while the claim "reducing hair loss" usually relates to cosmetic products. A product "preventing hair fall", on the other hand, may be a cosmetic product.

---

35 ECJ, C-219/91, "Wilhelmus Ter Voort", ECR 1992 I-5485, para. 18, with regard to the former, slightly different-worded definition "any substance or combination of substances presented for treating or preventing disease in human beings or animals".

36 ECJ, C-227/82, "Van Bennekom", ECR 1983 3883, para 18, with regard to the former, slightly differentworded definition "any substance or combination of substances presented for treating or preventing disease in human beings or animals".

37 ECJ, C-369/88 of 21.3.1991 "Delattre", ECR 1991 I-1487, para. 12.

38 ECJ, "Delattre", paras 33-35.

39 Art. 2 (2) Medicinal products Directive, Cf. cosmetics/medicinal products guidance document, paras 12, 40- 47.

40 Art. 1 (2) Medicinal products Directive.

41 Cf. ECJ, C-1121/89 of 16.04.1991, "Upjohn", ECR 1991 I-1703, paras 21-22. Cf. Cosmetics/medicinal products guidance document paras 31-34.

42 Cf. cosmetics/medicinal products guidance document, para. 37-38.

43 Cf. cosmetics/medicinal products guidance document, para. 37-38.

44 See entry II/372 of Annex II to Directive 76/768/EC.

3.3.5. Products that make eyelashes grow

92. Question: Are eyelash products that make eyelashes grow cosmetic products?
93. Answer: No, eyelash products that make eyelashes grow (e.g. product containing bimatoprost) are likely to exert a significant influence on physiological functions.
94. They may meet the definition of medicinal products "by virtue of function", whereby the product "restores, corrects or modifies physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis".

3.3.6. Products for in-grown hairs

95. Question: Are products for in-grown hairs cosmetic products?
96. Answer: An in-grown hairs problem can be unsightly, painful, and very bothersome for men and women, but, though it may be associated to irritation and inflammation, it is not a disease.
97. A product that helps liberate in-grown hairs from under the skin through a mechanical or keratolitic action may be a cosmetic.
98. However, the question whether a product or its substance(s) restores, corrects or modifies physiological functions by exerting a pharmacological, immunological or metabolic action has to be taken on a case-by-case basis.
99. The fact that the same substance is not only contained in a cosmetic, but also in medicinal products as an active ingredient is not decisive. However, this may be an indicator for a pharmacological, immunological or metabolic action of the product.
100. In assessing this, one has to consider all characteristics of the product, including, for example, absorption, concentration, route of administration, frequency of application, application site, and the degree of penetration.[45]
101. In particular, the claims may give a useful indication to the competent authorities, without, however, replacing a careful assessment of the mode of action and all the elements indicated above. A claim referring to "soothing irritations", for example, may be associated to a cosmetic product, while claims referring to "inflammation" and "infection" are more likely to refer to medicinal products.

3.3.7. Products that make the lips swell

102. Question: Are products that plump up the lips cosmetic products?
103. Answer: Products that make lips more voluminous may in principle fulfil the definition of cosmetic products because they are intended to be placed in contact with the lips "with a view to exclusively or mainly changing their appearance".
104. However, these products may also meet the definition of medicinal products "by virtue of function", whereby the product is used or administered with a view to "restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis". The ECJ is of the opinion that: "As regards the meaning of 'restoring, correcting or modifying physiological functions', it is clear from the aim of health protection pursued by the Community legislature that the phrase must be given a sufficiently broad interpretation to cover all substances capable of having an effect on the actual functioning of the body. However, this criterion does not serve to include substances such as certain cosmetics which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions."[46]
105. Therefore, if these products act through inflammation and/or irritation (e.g. products containing capsaicin), the deliberate induction of a swelling effect could be perceived as a significant modification of one or more physiological functions in the lips, thus bringing the products under the definition of medicinal products.

3.3.8. Products reducing cellulite

106. Question: Is a product which reduces cellulite in the skin a cosmetic product?
107. Answer: A product which reduces cellulite may be a medicinal product by virtue of function. This is the case if the product is a substance or a combination of substances which are used in or administered to human beings inter alia with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.[47] However, not any minor modification of physiological function suffices to render a product a medicinal product by virtue of function.[48]

3.3.9. Substances applied with skin-patches

108. Question: Is a product which is applied through a skin-patch cosmetic product?
109. Answer: A substance or preparation which is applied on the skin by way of a patch may be a cosmetic product or a medicinal product. Apart from issues of presentation of the product (cf. above, 4.), this depends of the question whether the substance or preparation restores, corrects or modifies physiological functions by exerting a pharmacological, immunological or metabolic action.
110. This has to be assessed on a case-by-case basis.[49]

---

45 Cf. cosmetics/medicinal products guidance document, para. 37-38.
46 ECJ, C-1121/89 of 16.04.1991, "Upjohn", ECR 1991 I-1703 (para.21-22)
47 Art. 1 (2) Medicinal products Directive.
48 Cf. ECJ, C-1121/89 of 16.04.1991, "Upjohn", ECR 1991 I-1703, paras 21-22. Cf. Cosmetics/medicinal products guidance document paras 31-34.
49 Cf. Cosmetics/medicinal products guidance document, para 37-38.

In the case of patches, consideration has to be given inter alia as to whether active ingredients enter the general blood circulation thereby modifying physiological functions to an extent that qualifies the product as medicinal product by virtue of function. On the other hand, patches may have a merely local activity on the skin without pharmacological action. One criterion to assess this may be whether the patch is occlusive or not: Occlusive patches may allow for a deeper penetration of the substance thereby making the substance systemically available.

3.3.10. Products delivered through iontophoresis or similar mechanisms

111. Question: Can products specifically intended to be delivered through iontophoresis or similar mechanisms be cosmetic products?

112. Answer: Iontophoresis and similar mechanisms are techniques which exploit a small electric charge to deliver a medicinal product or other mixtures through the skin and they are commonly used by physical therapists, for instance, for the application of antiinflammatory products.

113. Such techniques could be used for cosmetic purposes, for example plumping up lines and wrinkles, to deliver an ingredient whose penetration would be significantly increased by the above-mentioned mechanisms. If the use of device only results in a superficial penetration of the product in the epidermis, then the product is still a cosmetic and its safety should be assessed taking into account this mode of delivery. On the other hand, if the use of device induces a deeper penetration of certain ingredients, then the product could not be qualified as a cosmetic.

114. A case-by-case evaluation of all characteristics of the product, including absorption, concentration, route of administration, frequency of application, application site, and the degree of penetration, in light of the specific mode of delivery, should be carried out by the national competent authority, in order to decide on the qualification of the product.

3.3.11. Product to treat dry mouth

115. Question: Are products to treat dry mouth cosmetic products?

116. Answer: Products to treat dry mouth act by stimulating the production of saliva. This mode of action is not compatible with a cosmetic function; therefore, they are not cosmetic products.

3.3.12. Products for superficial moisturizing of female genital organ in case of dryness

117. Question: Are products for moisturizing of female genital organs in case of dryness cosmetic products?

118. Answer: Products for female genital organs may be considered cosmetic products if they are intended to "be placed in contact with the various external parts of the human body (… external genital organs) […] with a view exclusively or mainly to cleaning them, perfuming them, […] and/or correcting body odours and/or protecting them or keeping them in good condition[50]".

119. The definition of cosmetic product explicitly refers to the external genital organs only and the vagina is clearly excluded[51].

120. In addition to the site of application, one should also consider that such products may contain substances which significantly "restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action"[52]. Therefore, their qualification has to be decided on a case-by-case basis, considering all the characteristics of the product, including, for example, absorption, concentration, route of administration, frequency of application, application site, and degree of penetration.

3.3.13. Topical breast augmentation products

121. Question: Are topical breast augmentation products cosmetic products?

122. Answer: Topical breast augmentation products achieve their objective through the action of hormones[53] or hormone-like substances (e.g. phyto-oestrogens). They therefore significantly "restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action"[54] and cannot be qualified as cosmetic products.

123. On the other hand, products only claiming to improve the breast's skin firmness may be considered as cosmetic products. In any case, their qualification has to be decided on a case-by-case basis, taking into account all the characteristics of the product, including ingredients, concentration, absorption, frequency of application, and degree of penetration.

3.3.14. Products claiming aromatherapy

124. Question: Are products claiming aromatherapy cosmetic products?

125. Answer: There is no harmonized definition of aromatherapy across the EU. The intended function of such products may range from simple mood enhancing to medical treatment.

126. The term “aromatherapy” is often found on the labelling of products which contain essential oils or other plant extracts as a claim or even as part of a trademark, but is does not prevent a product to be qualified as a cosmetic if it is "a substance or mixture

50 Art. 1 Cosmetics Directive 76/768/EEC.

51 Ref. paragraph 2.1 of this Manual.

52 Art. 1 (2) Medicinal products Directive.

53 The use of oestrogens in cosmetic products is prohibited according to Annex II, entry 260, of Directive 76/768/EEC.

54 Art. 1 (2) Medicinal products Directive.

intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition".
127. In any case, a decision on the qualification of the products has to be made by the national competent authorities, on a case-by-case basis, and taking into account all the relevant elements, such as the presentation of the products, the ingredient, the mode of action and the claims.

3.3.15. Products for atopic skin

128. Question: Are products for atopic skin cosmetic products?
129. Answer: According to common understanding, atopy is a type of hypersensitivity.
130. It seems that in the general meaning, atopy and atopic dermatitis are used as synonyms in relation to cosmetic products. This makes the notion of atopy ambiguous. WHO classified several diseases due to atopy: acute atopic conjunctivitis, allergic asthma, atopic dermatitis, neurodermatitis, etc.
131. In light of these definitions, the products using claims related to atopy seem to fall outside of the scope of the Cosmetics Directive. However, the use of such terms as "atopy" or "atopic skin" should be assessed on a case-by-case basis.
132. For instance, products presented as "appropriate for/suitable to skins with atopic tendency/atopic skin" can be qualified as cosmetic products, if their purpose is to place them in contact with the various external parts of the human body (…) in order to exclusively or mainly clean them, perfume them, change their appearance and/or correct body odours and/or protect them or keep them in good condition. On the other hand, products presented as having properties to treat or prevent atopy/atopic skin cannot be qualified as cosmetic products.

3.3.16. Products to reduce dark circle under the eyes

133. Question: Are products to reduce dark circle under the eyes cosmetic products?
134. Answer: The result of reducing the appearance of dark circles under the eyes can be achieved by either covering up the darkness through make-up or by acting on the causes of the dark circles.
135. Such products as concealers, foundations and so on, that allow reducing the appearance of dark circles under the eyes are cosmetic products.
136. On the other hand, products that reduce or completely remove the darkness around the eyes may restore, correct or modify physiological functions by exerting a significant pharmacological, immunological or metabolic action.[55] Therefore, in order to decide about the qualification of such a product, one has to consider all characteristics of the product, including, for example, absorption, concentration, route of administration, frequency of application, application site, and the degree of penetration.[56]

3.4. Borderline with Medical Devices

3.4.1. Products which, according to their presentation, are intended to peel the skin

137. Question: Is a skin-peeling product a cosmetic product?
138. Answer: Skin peeling products are understood as products which remove dead cells or cell layers from the surface of the skin through mechanical or chemical action.
139. They may fulfill a cosmetic function (e. g. cleansing the skin, changing its appearance and keeping it in good condition), but may also be used in some circumstances to restore, correct or modify physiological functions of the skin (e.g. removal of scar tissue).
140. Depending on their composition and intended use, skin peeling products can increase the desquamation of isolated dead cells from the outermost skin surface or they can remove some or all cell layers of the stratum corneum.
141. Products that are intended to remove isolated cells or the top layers of the stratum corneum are not expected to significantly impact the normal skin physiology and barrier function. They can be considered as cosmetics.
142. Peelings that expose the deeper layers of the stratum corneum, or result into the complete removal of the stratum corneum significantly impact the skin physiology and barrier function. Such product could not be considered as a cosmetic product[57].
143. Therefore, in order to decide about the qualification of a skin peeling product, the competent authorities have to consider all the characteristics of the product, and, in particular the claims, the depth of peeling per application and the frequency of application.

3.4.2. Products against head lice

144. Question: Are products against head lice cosmetic products?
145. Answer: Products against head lice are not cosmetic products, because they do not have a cosmetic purpose. They are indeed not meant to "be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) […] with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting

55 Art. 1 (2) Directive 2001/83/EC on Medicinal Products.
56 Cf. cosmetics/medicinal products guidance document, para. 37-38.
57 Cf. Manual on Borderline for Medical Devices, Section 4.11, available on http://ec.europa.eu/consumers/sectors/medicaldevices/files/wg_minutes_member_lists/version1_7_borderline_manual_en.pdf

body odours and/or protecting them or keeping them in good condition[58]".
146. The qualification of anti-lice products is a borderline issue between medicinal products, medical devices and biocides.

3.5. Borderline with Other Legislations

3.5.1. Products which, according to their presentation, are defined to be used to detect plaque on teeth

147. Question: Are products which, according to their presentation, are destined to be applied on the teeth in order to subsequently detect remaining plaque, cosmetic products?
148. Answer: These substances or preparations are applied on the teeth. The question is whether they are exclusively or mainly intended to change the appearance of the teeth. While this has to be considered on a case-by-case basis, the exclusive purpose of these substances is the detection of plaque, rather than colouring the teeth. The fact that the plaque is detected by colouring certain parts of the teeth (those parts which have plaque) does not alter this assessment: the colouring effect is not the exclusive or main function, but a by-effect of the actual intended function, i.e. detecting plaque.
149. Therefore, these products are not cosmetic products.

3.5.2. Products which, according to their presentation, are destined to remove glue used to fix articles on the skin cosmetic products?

150. Question: Are products which, according to their presentation, are destined to remove glue used to fix articles on the skin or nails cosmetic products?
151. Answer: Substances and preparations which are intended to remove glue from the skin or nails are intended to cleaning them and thus have a cosmetic function.
152. Therefore, these products fall within the scope of the Cosmetics Directive.

3.5.3. Products which, according to their presentation, are intended to stimulate sexual activity

153. Question: Is a product which, according to its presentation, is exclusively or mainly intended to stimulate sexual activity more agreeable by facilitating penetration a cosmetic product?
154. Answer: No. Art. 1(1) of the Cosmetic Directive defines "cosmetic product" as "any substance or preparation intended to be placed 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 mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition." This does not entail the purpose as described above.

58 Art.1 of Directive 76/768/EEC.

Raccomandazione della Commissione (2006/406/CE)

Linee guida sull'uso di dichiarazioni relative all'*assenza di sperimentazioni animali* ai sensi della direttiva 76/768/CEE del Consiglio

7 giugno 2006 (Testo rilevante ai fini del SEE)
(**Commissione UE (2006)** *Gazzetta ufficiale dell'Unione europea* 10.6.2006 **IT L 158** 18-19)

La Commissione delle Comunità Europee, visto il trattato che istituisce la Comunità europea, vista la direttiva 76/768/CEE del Consiglio, del 27 luglio 1976, concernente il ravvicinamento delle legislazioni degli Stati membri relative ai prodotti cosmetici (**1**), in particolare l' articolo 6, paragrafo 3, secondo comma, seconda frase, considerando quanto segue:

1) In virtù dell' articolo 6, paragrafo 3, della direttiva 76/768/CEE, il fabbricante o il responsabile dell' immissione di un prodotto cosmetico sul mercato comunitario può attirare l' attenzione delle Comunità europee, sulla confezione del prodotto o su qualsiasi documento, foglio di istruzioni, etichetta, fascetta o cartellino che accompagna o si riferisce a tale prodotto, sul fatto che quest'ultimo è stato sviluppato senza fare ricorso alla sperimentazione animale, solo a condizione che il fabbricante e i suoi fornitori non abbiano effettuato o commissionato sperimentazioni animali sul prodotto finito, sul suo prototipo, né su alcun suo ingrediente e che non abbiano usato ingredienti sottoposti da terzi a sperimentazioni animali al fine di ottenere nuovi prodotti cosmetici.
2) Di conseguenza è possibile dichiarare sui prodotti cosmetici che essi non sono stati ottenuti attraverso sperimentazioni su animali.
3) È necessario stabilire linee guida al fine di assicurare l'applicazione di criteri comuni nell'uso di tali dichiarazioni e la loro interpretazione univoca, in particolare per evitare che esse traggano in inganno il consumatore o generino concorrenza sleale sul mercato tra i fabbricanti.
4) Inoltre, nel quadro di un buon rapporto di cooperazione amministrativa, una concezione generale della disposizione di cui all' articolo 6, paragrafo 3, secondo comma, della direttiva 76/768/CEE, ne faciliterebbe un' applicazione comune da parte delle autorità di controllo. Ciò eviterebbe, ad esempio, che la concorrenza nel mercato interno venga falsata.
5) I provvedimenti di cui alla presente raccomandazione sono conformi al parere del comitato permanente per i prodotti cosmetici,

RACCOMANDA

Ai fini dell' applicazione dell' articolo 6, paragrafo 3, secondo comma, della direttiva 76/768/CEE, gli Stati membri si attengono alle seguenti linee guida.

1 Principi fondamentali

L'uso di dichiarazioni su un prodotto cosmetico non deve trarre in inganno il consumatore. Quest'ultimo deve trarre un beneficio reale dal fatto di poter scegliere il prodotto con piena cognizione di causa, per effetto della presenza sull' etichetta della dicitura «non testato su animali». L'informazione deve risultare utile per il consumatore.
L'uso di tali dichiarazioni non deve generare concorrenza sleale sul mercato tra i fabbricanti e/o i fornitori che le utilizzano come strumenti di marketing.

2 Uso volontario di dichiarazioni

In virtù dell' articolo 6, paragrafo 3, secondo comma, della direttiva 76/768/CEE, il fabbricante o il responsabile dell' immissione del prodotto sul mercato può utilizzare una dichiarazione per indicare che non si è fatto ricorso alla sperimentazione animale. Non è dunque obbligatorio, né per il fabbricante né per il responsabile dell' immissione del prodotto sul mercato, utilizzare tale dichiarazione; è una possibilità offerta loro qualora, tenendo conto delle presenti linee guida,
vengano soddisfatte le prescrizioni di cui all' articolo 6, paragrafo 3, secondo comma, della direttiva 76/768/CEE.

3 Interpretazione delle prescrizioni di cui all' articolo 6, paragrafo 3, secondo comma, della direttiva 76/768/CEE

Si rammentano di seguito, per motivi di chiarezza, le definizioni di alcuni termini usati nel contesto delle presenti linee guida:
- per «prodotti cosmetici» si intendono i «prodotti cosmetici» di cui alla definizione dell'articolo 1 della direttiva 76/768/CEE,
- per «prodotto cosmetico finito» si intende il «prodotto cosmetico finito» di cui alla definizione dell' articolo 4 bis, paragrafo 3, lettera a), della direttiva 76/768/CEE,
- per «ingredienti» si intende qualsiasi sostanza chimica o preparazione di origine sintetica o naturale, inclusi i composti odoranti e aromatici, che rientri nella composizione dei prodotti cosmetici (cfr. a tale riguardo l' articolo 5 bis, paragrafo 1, della direttiva 76/768/CEE che esclude i «composti odoranti e aromatici» solo per quanto riguarda la compilazione di un elenco degli ingredienti),
- per «prototipo del prodotto cosmetico» si intende il «prototipo» di cui alla definizione dell'articolo 4 bis, paragrafo 3, lettera b), della direttiva 76/768/CEE,
- per animale«si intende l'»animale di cui alla definizione dell' articolo 2, lettera a), della direttiva 86/609/CEE del Consiglio (**2**),

(**1**) GU L 262 del 27.9.1976, pag. 169. Direttiva modificata da ultimo dalla direttiva 2005/80/CE della Commissione (GU L 303 del 22.11.2005, pag. 32)
(**2**) GU L 358 del 18.12.1986, pag. 1

- per «sperimentazioni» si intende qualsiasi sperimentazione effettuata relativamente allo sviluppo o alla valutazione della sicurezza del prodotto o dei suoi ingredienti [cfr. a tale riguardo l' articolo 7 bis, paragrafo 1, lettera h), della direttiva 76/768/CEE],
- per «nuove sperimentazioni» (re-testing) si intende la ripetizione della sperimentazione di un determinato prodotto o ingrediente.

Le prescrizioni di cui all' articolo 6, paragrafo 3, secondo comma, vanno così interpretate:

a) «non si è fatto ricorso alla sperimentazione animale» significa che i prodotti cosmetici o i loro ingredienti non sono stati oggetto di sperimentazioni su animali in fase di sviluppo o di valutazione della sicurezza. Si possono usare le dichiarazioni soltanto qualora si ricorra a metodi alternativi che non comportino l' impiego di animali, dunque non nel caso di una riduzione o di un perfezionamento delle sperimentazioni su animali. Non hanno importanza, inoltre, il luogo (se nella Comunità o in paesi terzi) o la data in cui la sperimentazione (compreso il «re-testing») è stata effettuata;

b) «il fabbricante e i suoi fornitori non hanno effettuato o commissionato sperimentazioni animali […]» significa che il fabbricante e i suoi fornitori, compresi tutti i fornitori della catena di approvvigionamento:
   - non hanno effettuato direttamente le sperimentazioni animali,
   - non hanno commissionato sperimentazioni animali, ossia non le hanno richieste né pagate tramite, ad esempio, finanziamenti di ricerche compiute da istituzioni accademiche;

c) il fatto che il fabbricante e i suoi fornitori non devono aver «usato ingredienti sottoposti da terzi a sperimentazioni animali al fine di ottenere nuovi prodotti cosmetici» significa che il fabbricante e i suoi fornitori non devono aver usato ingredienti per i quali sono disponibili, ad esempio nella letteratura scientifica, dati ricavati da sperimentazioni animali effettuate da terzi al fine di ottenere nuovi prodotti cosmetici. In tale contesto «lo sviluppo di nuovi prodotti cosmetici» indica la riformulazione del prodotto già presente sul mercato o lo sviluppo di un prodotto totalmente nuovo (innovazione). Un nuovo tipo di confezione non può essere considerato un nuovo prodotto cosmetico.

4. **Onere della prova**

Chiunque dichiari sui prodotti cosmetici che essi non sono stati ottenuti attraverso sperimentazioni su animali deve assumersi la responsabilità della dichiarazione, e deve essere in grado di provarne la pertinenza con riferimento alla direttiva 76/768/CEE. In tale contesto si rammenta che tutte le informazioni pertinenti a fini di controllo devono essere prontamente accessibili, conformemente all' articolo 7 *bis*, paragrafo 1, della direttiva 76/768/CEE, in particolare le lettere d) e h), le quali
recitano:

«d) la valutazione della sicurezza per la salute umana del prodotto finito.
[…]
h) i dati concernenti le sperimentazioni animali effettuate dal fabbricante, dai suoi agenti o dai suoi fornitori relativamente allo sviluppo o alla valutazione della sicurezza del prodotto o dei suoi ingredienti, inclusi gli esperimenti sugli animali effettuati per soddisfare i requisiti legislativi o regolamentari di paesi non membri.»

5. **Formulazione delle dichiarazioni**

Chiunque desideri usare una dichiarazione per indicare che non si è fatto ricorso alla sperimentazione animale è libero di sceglierne la formulazione e/o di utilizzare qualsiasi immagine, segno figurativo o di altro tipo, purché vengano rispettate tutte le pertinenti prescrizioni della direttiva 76/768/CEE.

Fatto a Bruxelles, il 7 giugno 2006.

Per la Commissione
Günter VERHEUGEN
Vicepresidente

RESTRIZIONE ALL'USO PROFESSIONALE

nella Direttiva Cosmetici 76/768/CEE

Commissione Europea - Direzione generale Imprese
http://ec.europa.eu/enterprise/cosmetics/html/cosm_guidance_docs.htm

***** ORIGINAL *****

Guidance Note

THE RESTRICTION TO "PROFESSIONAL USE"

in the Cosmetics Directive 76/768/EEC

PLEASE NOTE

- *This document provides guidance as to the meaning of the restriction to professional use in the cosmetics directive 76/768.*
- *To develop this guidance note 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 8 December 2005. this group is chaired by the Commission and is composed of representatives of all Member States, of EU and EFTA, The European Organisation of Consumers (BEUC), European Federation of Cosmetic Products (COLIPA), European Federation For Cosmetic Ingredients (EFFCI), European Flavour and Fragrances Association (EFFA), and European Organisation of Cosmetic Ingredients Industries and Services (UNITIS).*
- *A general consensus was reached on these guidelines.*
- *Please note also that this guidance note addresses the concept of "restriction to professional use" as used in the annexes to the cosmetics directive at the date of this document. Obviously, these views may evolve and change in the light of future developments and this guidance note may be adapted accordingly.*
- *The views expressed in this guidance note are not legally binding; only the European Court of Justice ("Court") can give an authoritative interpretation of Community law.*

Version 1.0 (December 2005)

1 BACKGROUND

1. Council Directive 76/768 of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products ("Cosmetics Directive") provides in Article 4 that "[…] Member States shall prohibit the marketing of cosmetic products containing […] substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down".

2. A number of substances listed in annex III contain in the section "restrictions" the entry "professional use", which is listed either in column 'c' ("field of application and/or use"(**1**)) or in column 'e' ("other limitations and requirements"(**2**)). A list of all substances subject to professional use is annexed to this note.

3. For the purpose of this document these entries shall be termed "restriction to professional use".

4. The restriction to professional use is complemented in column f ("conditions of use and warnings which must be printed on the label") with the wording "for professional use only".(**3**)

(**1**) Ref.-no. 2a, 2b, 8, 9, 10, 14, 15a, 15b, 22, 64 of annex III. Note, however, that these entries are not necessarily linked to Art. 6 (1) d 1st sentence, 2nd part. Rather, this provision concerns additional "precautionary information on cosmetic products for professional use, in particular in hairdressing" which may need to be labelled on products for professional use (cf. ECJ, Case C-169/99 Schwarzkopf, of 13.9.2001, ECR 2001 I-5901, paras 29-30).

(**2**) Such as ref. no. 94, 95 of annex III.

(**3**) One exception is reference no. 3 (Oxalic acid, its esters and alkaline salts), where "professional use" is referred to only in the column "Conditions of use and warnings which must be printed on the label".

(**4**) Cf. for example, the opinion on strontium peroxide, adopted by the scientific committee in its plenary session of 7 October 1992, in the plenary meeting of 25 June 1993, and in the plenary meeting of 10 December 1993. More recently, cf. the opinion on Benzoyl Peroxide and Hydroquinon (SCCNFP/0486/01).

5. The restriction to professional use stems in some cases from the fact that industry, when submitting the safety dossier, asks for evaluation of this ingredient exclusively for the use by professionals, such as hairdressers.(**4**)
6. This guidance note attempts to provide guidance as to the meaning of the restriction to professional use. Its content has been the result of intensive discussion with representatives of Member States and representatives of industry.

7. In some cases products may also be marketed as "products only for professionals", "professional products", "professional line" etc. as part of a marketing strategy, without a regulatory obligation to this restriction in the Cosmetics Directive. This guidance note does not address restrictions based on marketing considerations but addresses only the restriction to professional use as a regulatory obligation stemming from the Cosmetics Directive.

2. THE PURPOSE OF THE RESTRICTION TO PROFESSIONAL USE

8. The main objective of the Cosmetics Directive is safeguarding public health while ensuring the free market for cosmetic products.(**5**)

9. In order to attain this objective the Cosmetics Directive exhaustively (**6**) harmonises the labelling provisions for products placed on the Community market. The Cosmetics Directive also regulates ingredients of cosmetic products through banning, restricting or authorising.

10. The restriction to professional use contributes to this objective (**7**); it ensures that products which:
    - contain certain substances (**8**) or
    - contain substances in a higher concentration than for general use (**9**) or
    - do not contain certain warnings which are obligatory when used by the consumer (**10**) are used by a professional only.

11. A professional is generally assumed to have a certain degree of professional education and/or professional experience. In particular, a professional usually:
    - is more familiar with the risks for health of a specific substance or its concentration in a cosmetic product than a consumer;
    - has more expertise (eg professional expertise) in applying cosmetic products correctly on the consumer – this is in particular the case for substances which are used on the nails or on the hair but which must not get in contact with the skin;
      and
    - disposes of more information on the product/its ingredients.

    Finally, it is usually easier to inform professional users then the general public about the correct use of a cosmetic product.

12. For the sake of completeness, it shall be mentioned here that some substances restricted to professional use also have to bear warnings that aim at protecting the professional. (**11**) The principal aim of the Cosmetics Directive is the safeguarding of human health, no matter if the final product is applied by the consumer or by a professional. However, the *restriction* of a product to professional use does not have as its purpose to *protect* the health of the professional. The warnings aiming at protecting the professional are a *consequence*, not a *cause* for the restriction to professional use.

3. THE MEANING OF THE RESTRICTION TO PROFESSIONAL USE

13. The Cosmetics Directive does not define the terms "professional use" means (**12**); nor has the case-law of the European Court of Justice

(**5**) Cf. Cosmetics Directive, recitals 2-4.

(**6**) The European Court of Justice has ruled on various occasions that the Cosmetics Directive "provides exhaustively for the harmonisation of national rules on the packaging and labelling of cosmetic products" and that Member States are hindered to adopt additional rules in this respect (Case C-220/98 Lifting [2000] ECR I-117, paragraph 23; Cf. also Case C-150/88 Parfümerie-Fabrik 4711 v Provide [1989] ECR 3891, paragraph 28; Case C-315/92 Verband Sozialer Wettbewerb v Clinique Laboratories and Estée Lauder [1994] ECR I-317, paragraph 11).

(**7**) In this respect, the restriction to professional use can be considered as a 'concretisation' of Art. 2 Cosmetics Directive which sets out the basic principle that "a cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling [and] any instructions for its use […]" (emphasis added).

(**8**) Cf. annex III, ref.-no. 3, 64, 94, 95.

(**9**) Cf. annex III, ref.-no. 2a, 2b, 15a, 15b.

(**10**) Cf. annex III, ref.-no. 8, 9, 10, 14, 22.

(**11**) Cf. annex III, ref.-no. 10 and 64 ("wear suitable gloves"). In this respect, cf. the opinion of the scientific opinion on glyceryl monothioglycolate, where the scientific committee stated in its conclusion: "Better occupational hygiene precautions should help to reduce the incidence of hypersensitivity to the compound in hairdressers. Hairdressers need to be instructed to handle this type of permanent wave with greater care and follow the directions already in legal force. Direct skin contact should be avoided. Gloves and improved handling technique may lead to a decrease in the frequency of sensitization." (opinion adopted at the plenary meeting of 9 March 1994).

(**12**) It shall be mentioned here that a number of other legislation act of the Community refer to „professional use", such as in the biocidal products Directive 1998/8, and the General products safety Directive 2001/95. However, in neither of these Directives the term is defined.

(**13**) Note, however, that the ECJ has discussed the restriction to professional use obiter dicta in Case C-169/99 Schwarzkopf, of 13.9.2001, ECR 2001 I-5901, paras 29-30. This case, however, concerned the question how the warnings for professionals, which are contained on products restricted to professional use, are to be labelled according to Art. 7 (1) d 1st sentence of the Cosmetics Directive.

addressed this issue in relation to the Cosmetics Directive (**13**) or in relation to other Community legislation.

14. In the light of the purpose and wording of the restriction to professional use a "professional" **is any person who, in exercising his/her professional activity, utilises cosmetic products**.
15. Moreover, the wording "for professional use" (**14**) indicates that the restriction extends to the *use* of the product: thus, **the cosmetic product has to be *used*, eg. *applied, and not merely sold,* by a professional**.
16. This definition applies no matter if the restriction to professional use is listed in column 'c', 'e' or 'f' of Annex III.

4. ENFORCING THE RESTRICTION TO PROFESSIONAL USE

17. A Directive, such as the Cosmetics Directive, is binding only as to the result to be achieved, but leaves to the national authorities the choice of form and methods.(**15**) In transposing and applying the Cosmetics Directive and the restriction to professional use, national authorities are free to choose the forms and methods in order to ensure that the final result (here: the product is only used by professionals) is achieved.
18. These forms and methods might include:
    - National rules providing that the products containing the ingredients in question may only be used by a professional;
    - National rules providing that products containing the ingredients in question must only be sold to professionals for their own use.
19. The restriction to professional use is unlikely to be achieved if the product is merely labelled accordingly and available to the general public, including consumers in retail shops.

5. THE IMPACT OF THE RESTRICTION TO PROFESSIONAL USE ON THE DISTRIBUTION OF COSMETIC PRODUCTS

20. The Cosmetics Directive does not directly address the distribution (**16**) of cosmetic products within the Community. In this respect, the Cosmetics Directive is similar to 'New Approach' Directives which, in general, do not include provisions regarding distribution.(**17**) This is also why, as far as obligations for distributors are concerned, the General Product Safety Directive (EC) 2001/95 applies.(**18**)
21. However, the above shows that – depending on the forms and methods Member States apply to achieve the result - the transposition of the Cosmetics Directive may have an indirect effect on the distribution of a cosmetic product in the Community: This may be the case, for example, if a Member State chooses to achieve the result by prohibiting the sale of products restricted to professional use in retail shops.

ANNEX: Substances restricted to professional use according to Cosmetic Directive 76/768

Annex, Reference no.	Substance
III, 2a	Thioglycollic acid and its salts[19] (if between 8% and 11% ready for use, pH 7 to 9,5)
III, 2b	Thioglycollic acid esters[20] (if between 8% and 11% ready for use, pH 6 to 9,5)
III, 3	Oxalic acid, its esters and alkaline salts[21]
III, 8	m- and p-Phenylenediamines, their N-substituted derivatives and their salts; Nsubstituted derivatives of o-Phenylenediamines[22], with the exception of those derivatives listed elsewhere in this Annex (if label does not contain the warning set out in column f litt (a) 1.)
III, 9	Methylphenylenediamines, their N-substituted derivatives and their salts[23], with the exception of substance No 364 in Annex II (if label does not contain the warning set out in column f litt (a) 1.)
III, 10	Diaminophenols [24] (if label does not contain the warning set out in column f litt (a) 1.)
III, 14	Hydroquinone[25] (if label does not contain the warning set out in column f litt (a) 1.) Hydroquinone when used as artificial nail systems.
III, 15a	Potassim or sodium hydroxide[26] (if with between 2% and 4,5% by weight).
III, 15b	Lithium hydroxide[27] (if with between 1,2% and 4,5% by weight
III, 22	Resorcinol[28] (if label does not contain the warning set out in column f litt. (a) 1).
III, 64	Strontium Peroxide[29]
III, 94	Benzoyl peroxide[30]
III, 95	Hydroquinone methylether[31]

(**14**) FR: *usage* professional; DE: gewerbliche *Verwendung*

(**15**) Treaty establishing the European Community, Art. 249 (3).

(**16**) The terms "distribution" is not defined in the Cosmetics Directive. For the purpose of these guidelines, however, distribution shall be defined as the supply of a cosmetics product subsequently to its placing on the Community market (cf. Guide to the implementation of directives based on the New Approach and the Global Approach, p. 23, under: http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/document/1999_1282_en.pdf)

(**17**) "Guide to the implementation of Directives based on the New Approach and the Global Approach", p.23

(**18**) Cf. Article 5 (2), (3), (4) General Product Safety Directive 2001/95. See also the "Guidance Document on the Relationship Between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety" for more details (http://pharmacos.eudra.org/F3/cosmetic/cosm_borderline_docs.htm)

(**19**) When used in hair waving and straightening products. (**20**) When used in hair waving and straightening products. (**21**) Restricted to gair care products.

(**22**) Restricted to oxidizing colouring agents for hair dyeing. (**23**) Restricted to oxidizing colouring agents for hair dyeing.

(**24**) Restricted to oxidizing colouring agents for hair dyeing. (**25**) When used in oxidizing colouring agents for hair dyeing.

(**26**) When used in hair straighteners. (**27**) When used in hair straighteners. (**28**) When used in oxidizing colouring agents for hair dyeing.

(**29**) Restricted to rinse-off hair care preparations. (**30**) Restricted to artificial nail systems. (**31**) Restricted to artificial nail systems.

Implementazione pratica dell'Articolo 6(1)(c) della Direttiva Cosmetici
(Legge 713/86 Art 8 (1)(c))

ETICHETTATURA SULLA DURATA DEI PRODOTTI

'Periodo di tempo dopo l'apertura' (PAO)

***** ORIGINAL *****

Practical implementation of Article 6(1)(c) of the Cosmetics Directive (76/768/EEC) **(1)**

LABELLING OF PRODUCT DURABILITY: "PERIOD OF TIME AFTER OPENING"

06/02/2006
Commissione Europea - Direzione generale Imprese *http://ec.europa.eu/enterprise/cosmetics/html/cosm_guidance_docs.htm*
04/ENTR/COS/28 Révisé

Under article 6(1)(c) of the Cosmetics Directive (76/768/EEC) it is foreseen:

"(….) Indication of the date of durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product can be used without any harm to the consumer. This information shall be indicated by the symbol given in Annex VIIIa followed by the period (in months and/or years)".

Further to the adoption of the Directive 2003/15/EC which has modified the Cosmetics Directive (76/768/EEC), 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 [19 April 2004]. This group is chaired by the Commission and is composed of representatives of all Member States, EFTA, BEUC, the 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. A general consensus was reached on these conclusions.

The comments expressed in this Communication **are not legally binding**, since only the Court of Justice can give an authoritative interpretation of Community law.

As quoted above, according to article 6(1)(c) the indication of the date of durability is not mandatory for cosmetic products with the minimum durability of more than 30 months.
However there shall be **an indication of the period of time after opening** for which the product can be used **without any harm to the consumer**.
It is this new provision that is the object of comments below.

When the mention of the period of time after opening has to be made available

By requiring the labelling of a period after opening, the Article 6(1)(c) of the Cosmetics Directive (76/768/EEC), aims to provide useful information to consumers. **(2)**
It can be assumed from article 6(1)(c) that the period **after opening must be labelled when after its opening the deterioration of the product may lead to harm to the consumer**.

A product can be seen as being harmful to the consumer when, in accordance with Article 2 of the Cosmetics Directive, it can cause damage to human health.

The deterioration may be linked to:
- the deleterious effect of micro-organisms and/or
- physico-chemical degradation that would lead to :
  - harm to the consumer or
  - the decrease of efficacy when the modification of the efficacy can affect the safety of the product according to human health (e.g. U.V protection of sun products)

(1) As last modified by European Parliament and Council Directive 2003/15/EC.OJ L 66, 11.03.2003, p.26.

(2) Recital (14) of Directive 2003/15/EC reads as follow: "In order to improve the information provided to consumers, cosmetic products should bear more precise indications concerning their durability for use."

A variety of **relevant methods** may be used to support the period indicated on a product, including those used during product development, since there is no officially sanctioned methodology that could be used.

Examples of sources of information for assessing a product's PaO may include:

- microbiological challenge tests
- stability data
- analytical data (e.g. preservative analysis)
- type of packaging
- experience with similar formulations and products
- consumer habits and practices.

For the purpose of Article 6(1)(c), the opening of the product may be considered as occurring when the consumer opens the product for use for the first time.
Anyway, in the case of products sensitive to deterioration by micro-organisms, the person responsible for placing the product on the Community market should consider **measures to avoid the opening of the product before it reaches the final consumer**.

The mention of the period after opening seems not to be relevant when there is:

a. - **no physical opening** of the product as is the case for products presented in containers where there is no possibility of contact between the product in the container and the external environment (e.g. sealed pressurised containers),
b. - **no period after opening** as is the case for single-use products, which are designed to be used only once.

c. - **no risk of harm to the consumer**, as there is no risk of deterioration that could lead to, in accordance with Article 2 of the Cosmetics Directive, damage to human health.

What information needs to be labelled

The "**period after opening**" is indicated by the open-jar symbol adopted by the Commission on 5 September 2003 (**3**). The period of time is expressed in months and/or in years, inside or alongside the symbol. The choice of the position of this number should be made in order that it is easily legible as required by article 6.1 of Cosmetics Directive.

Without prejudice to Article 7 (2), if the period of time is in months, it may be indicated by a number followed by the full word "month" or, for example by the abbreviation "M", the letter "M" standing for "Menses" (i.e. months in Latin).
The "period after opening" needs to be printed on primary and secondary packaging (i.e. the container and its carton if any).

How the information should be explained to the consumer
It seems appropriate that steps are taken to ensure that **consumer fully understands** the meaning of the new open-jar symbol and the accompanying abbreviation ("M") that could appear on cosmetic products.

According to industry and Member States, they intend to disseminate this information (e.g. brochures) to consumers through consumer associations, distributors and retailers' information on public authorities' websites etc.…

(**3**) Commission Directive 2003/80/EC, OJ L 224 of 06.09.2003, p. 27.

Linea Guida della Commissione UE

COMPOSIZIONE ED EFFETTI INDESIDERATI DEI PRODOTTI COSMETICI

Da rendere facilmente disponibili ai consumatori

21/08/2006
Commissione Europea - Direzione generale Imprese
http://ec.europa.eu/enterprise/cosmetics/html/cosm_guidance_docs.htm

***** ORIGINAL *****

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 Directive (**1**).
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

(**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;" […].

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*".
- 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) 2$_{nd}$ 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 package (**2**).

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.
- 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.

(**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%".

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.

Campo di applicazione dell'Articolo 1(1) della Direttiva 76/768 EEC

COLORANTI COSMETICI

Dicembre 2006
Commissione Europea - Direzione generale Imprese
http://ec.europa.eu/enterprise/cosmetics/html/cosm_guidance_docs.htm

***** ORIGINAL *****

THE 'RESTRICTED FIELDS OF APPLICATION' FOR COLORING AGENTS IN ANEX IV *to Cosmetics Directive 76/768/EEC* (Art.1(1) Cosmetics Directive)

PLEASE NOTE This document provides guidance 'Fields of application' in annex IV to Cosmetics Directive 76/768/EEC.

- *This guidance note was presented to the "working party cosmetic products" on 24 october 2006. this group is chaired by the commission and is composed of representatives of all member states, of eu and efta, beuc, the 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. a general consensus was reached on this guidance note.*
- *The views expressed in this guidance note are not legally binding; only the european court of justice ("court") can give an authoritative interpretation of community law.*

1. BACKGROUND

1. Council Directive 76/768 of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[1] ("Cosmetics Directive") provides in Article 4(1)(d) that "[…] Member States shall prohibit the marketing of cosmetic products containing […] colouring agents listed in Annex IV, Part 1, used outside the conditions laid down […]".

2. Annex IV to Cosmetics Directive 76/768/EEC provides for a "list of colouring agents allowed for use in cosmetic products". The allowed use refers to different fields of applications:
   - Column 1: "Colouring agents allowed in all cosmetic products";
   - Column 2: "Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of the eyes, in particular eye make-up and eye make-up remover";
   - Column 3: "Colouring agents allowed exclusively in cosmetic products intended not to come into contact with the mucous membranes";
   - Column 4: "Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin".

3. Columns 2-4 introduce restrictions for the use of colouring agents. For the purpose of this guidance note, these provisions shall be named "restricted fields of application".

4. With the exception of the term "cosmetic product", the Cosmetics Directive does not define any of the terms applied in the restricted fields of application[2]; nor has the Court addressed this issue in relation to the Cosmetics Directive.

5. This guidance note attempts to provide guidance as to the meaning of the restricted fields of applications.

1 OJ L 262, 27.09.1976, p. 169, as amended.

2 It shall be mentioned here that a number of other legislative acts of the Community refer to terms applied in the restricted fields or application – however, without defining them. One example is the term„ mucous membranes" which is used in in Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1, as amended).

2. THE PURPOSE OF THE RESTRICTED FIELDS OF APPLICATION

6. The main objective of the Cosmetics Directive is safeguarding public health while ensuring the free market for cosmetic products.[3]
7. In particular, Art. 2 Cosmetics Directive provides that "a cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use […] as well as any other indication or information provided […]".[4]

8. The restricted fields of application aim at concretising this obligation for colouring agents. They ensure that certain colouring agents are not used in certain cosmetic products, as these cosmetic products are generally assumed:
   • to lead to a relatively high exposure to certain cosmetic ingredients; or
   • to get in contact with sensitive parts of the human body, such as eyes or mucous membranes.

3. THE MEANING OF THE RESTRICTED FIELDS OF APPLICATION

9. In the light of Art. 2 Cosmetics Directive and the purpose of the restricted fields of application, the terms used therein should be interpreted as follows:

3.1. "Intended" field of application

10. Columns 2-4 refer to the "intended" field of application. In the light of Art. 2 Cosmetics Directive, a product is "intended" to come into contact with certain parts of the human body if this contact occurs while the product is "applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use […] as well as any other indication or information provided".

11. This includes to some extent the possibility that a cosmetic product is applied wrongly or that a cosmetic product accidentally comes in contact with certain parts of the human body, as long as this is "normal or reasonably foreseeable".

3.2. "Mucous membranes"

12. Column 3 refers to "mucous membranes": Colouring agents listed in column 3 are not allowed in cosmetic products intended to come into contact with them.

13. In the light of Art. 1 Cosmetics Directive, the term "mucous membranes" includes all mucous membranes which are external parts of the body and the mucous membranes of the oral cavity.

3.3. "Product intended to come into contact only briefly with the skin"

14. Column 4 refers to an "only brief contact with the skin": Colouring agents listed in column 4 are exclusively allowed in cosmetic products intended to come into contact only briefly with the skin.

15. In the light of Art. 2 Cosmetics Directive, a product intended to come into contact only briefly with the skin is a product whose duration of contact with the human body is short, if applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use as well as any other indication or information provided.

16. Examples for such products are products presented as rinse-off products.

4. ENFORCING THE RESTRICTED FIELDS OF APPLICATION; ADMINISTRATIVE COOPERATION

17. In applying the restricted fields of application, decisions are to be taken by competent national authorities on a case-by-case basis. However, it is crucial for national competent authorities to inform each other about their approach to the restricted fields of application in order to ensure the functioning of the internal market. The Commission does encourage administrative cooperation with a view to exchange information on decisions taken by national competent authorities.

Brussels, December 2006

3 Cf. Cosmetics Directive, recitals 2-4.

4 Emphasis added

Direttiva 76/768/EEC

ETICHETTATURA DEGLI INGREDIENTI COSMETICI

Febbraio 2008
Commissione Europea - Direzione generale Imprese
http://ec.europa.eu/enterprise/cosmetics/html/cosm_guidance_docs.htm

***** ORIGINAL *****

LABELLING OF INGREDIENTS
in Cosmetics Directive 76/768/EEC

Update February 2008

PLEASE NOTE This document provides guidance regarding labelling of ingredients in Cosmetic Directive 76/768/EEC.

- *This guidance note was presented to the "working party cosmetic products" on 13 june 2007 and revised on at the working group of February 2008. This group is chaired by the Commission and is composed of representatives of all Member States, of EU and EFTA, BEUC, the European Organisation of Consumers, COLIPA, European Federation of Cosmetic Products, EFrCI, European Federation for Cosmetic Ingredients, EFFA, European Flavour and Fragrances Association, Unitis, European Organisation of Cosmetic Ingredients Industries and Services and UEAPME, European Association of CRAFT, Small and Medium-sized Enterprises. A general consensus was reached on this guidance note.*

- *The views expressed in this guidance note are not legally binding; only the European Court of Justice ("court") can give an authoritative interpretation of Community Law.*

1. Legal provisions

Article 6 paragraph 1 (g) of Directive 76/768/EEC provides that:

"A list of ingredients in descending order of weight at the time they are added. That list shall be preceded by the word 'ingredients'. Where that is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain the ingredients to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII, which must appear on the packaging.

The following shall not, however, be regarded as ingredients:
- *impurities in the raw materials used,*
- *subsidiary technical materials used in the preparation but not present in the final product,*
- *materials used in strictly necessary quantities as solvents or as carriers for perfume and aromatic compositions.*

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***". [Bold added]

In Annex III, part 1 to the Cosmetics Directive, for 26 entries (from 67 to 92)[1] it is then mentioned that "***the presence of the substance must be indicated in the list of ingredients referred to in Article 6 (1)(g) when its concentration exceeds:***
- ***0.001 % in leave-on products***
- ***0.01 % in rinse-off products.***" [bold added]

The parts in bold were introduced by directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council directive 76/768/EEC, so called 7th amendment.

1 Situation on 13.06.2007

Recital 15 of this directive provides that:
"Certain substances have been identified as an important cause of contact-allergy reactions in fragrance-sensitive consumers. In order to ensure that such consumers are adequately informed, it is therefore necessary to amend the provisions of Directive 76/768/EEC to require that the presence of these substances be mentioned in the list of ingredients. This information will improve the diagnosis of contact allergies among such consumers and will enable them to avoid the use of cosmetic products which they do not tolerate".

2. Interpretation

Some Member States expressed worries that those provisions would be misinterpreted and that the presence of those 26 substances would be then wrongly labelled.

All ingredients have to be listed on the labelling, whatever is their concentration, except:

- those which shall *not be regarded as ingredients* (impurities in the raw materials used, subsidiary technical materials used in the preparation but not present in the final product or materials used in strictly necessary quantities as solvents or as carriers for perfume and aromatic compositions).
- those which are *perfumes, aromatic compositions and their raw materials*, which shall be referred as 'parfum' or 'aroma'[2]. *However* for the 26 substances their presence should be mentioned when it is specified under the relevant entries in Annex III to the Cosmetics Directive. This requirement is linked with presence limit of the substance in the product (limit of 0.001% in leave-on products and of 0.01 % in rinse-off products.) It concerns the use of those substances as perfumes, aromatic compositions and their raw materials in order to avoid the generic mention 'parfum' or 'aroma' for this type of use.
- the same logic applies for cases where ingredients are not supposed to be labelled. It is the case for substances which are parts of a mixture (for example botanical extracts and essential oils). For the 26 substances their presence should be mentioned when it is specified under the relevant entries in Annex III to the Cosmetics Directive. This requirement is linked with presence limit of the substance in the product (limit of 0.001% in leave-on products and of 0.01% in rinse-off products.). It concerns the presence of those substances in mixtures in order to avoid that only the name of the mixture is mentioned.

2 Minutes of the Standing Committee of 14-15 February 2005, point 6 Labelling of cosmetic products (ingredients, aroma, parfum) request from Hungary
"COM explained that in 1995 Member States agreed to use the terms 'ingredients', 'aroma' and 'parfum' without translation for the application of article 6 introduced in the Cosmetics directive by the 6th amendment (05-ENTRCOS-06)
HU requested that this agreement is reiterated between the 25 Member States, as when new Member States transposed the 'acquis communautaire' in cosmetic field they are bound by the current wording of article 6.
No Member States expressed any restriction on such reiteration of the agreement, therefore it was concluded that:
- *the term 'ingredients' will be used to refer to ingredients,*
- *the term 'parfum' will be used to refer to perfume compositions and*
- *the term 'aroma' will be used to refer aromatic compositions.*

No translation of those terms would be necessary".

Campagna UE per il Consumatore sui Prodotti Solari

Nuovi pittogrammi per informare il consumatore sui danni causati dall'esposizione solare

Luglio 2007
Commissione Europea - Direzione generale Imprese
http://ec.europa.eu/health-eu/news/sun_uv_en.htm

***** ORIGINAL *****

New pictogrammes to inform consumers on dangers linked to sun exposure

The **Pictograms** in this page have been developed for this purpose. A number of authorities and stakeholders in the EU Member States are starting to promote their use. Any organisation can use them. They can be downloaded for free from this site for display at points of sale and consumption (beaches, pools, marinas, mountain huts, etc.).

1. Protect yourself!
2. Use sunscreen products correctly!
3. More information

Protect yourself!

Sunscreen products cannot deliver total protection from UV radiation. ***Every product lets some of the UV radiation through***. This holds also true for products claiming to be a "sun block" or to offer "total protection". Therefore:

Avoid excessive sun exposure at peak hours

Keep yourself well covered, including hat, T-shirt, and sun glasses

Avoid direct sun exposure for babies and young children
Avoiding UV radiation is most essential for children. The more a baby or child is overexposed to UV radiation, the higher is the risk of skin-cancer later in life. Therefore, babies and children should best not be exposed to direct sunlight at all:

Use sunscreen products correctly!

There are two types of ultraviolet (UV) radiation reaching the earth: UVB and UVA. UVB radiation is the cause of "sun-burn". UVA radiation causes premature skin ageing and interferes with the human immune system. Both types of radiation are important contributors to the skin-cancer risk.

Use sunscreen products that offer sufficient protection for your skin
The sun protection factor (SPF) is a score used to describe the 'strength' of the product to protect against "sun–burn", i.e. mainly UVB radiation. It is important to know that an SPF over 50 does not increase the protection against sun burn and UVB radiation for normal skin. If a product is applied correctly (see below), a ***SPF of category "medium" (i.e. SPF 15, 20 or 25)*** suffices to protect a person with normal skin from sun burn. Only if a product is applied in insufficient quantity would a higher category be required.

Apart from UVB-protection (expressed with the SPF), your sunscreen product should protect also against UVA radiation: As the SPF mainly refers to sunburn, sunscreen products with only UVB-protection may provide a false sense of safety because they still let hazardous UVA radiation reach the skin.

Use sunscreen products generously
It is important to know that sunscreen products have their full effect only if used in ***sufficient quantities***: to protect the whole body of an average-seized adult, a quantity of 35 grams of the sunscreen product needs to be applied. This is a quantity equal to approximately six filled tea spoons. Currently, consumers usually use only half of this quantity, which reduces protection by even more than half.

Re-apply sunscreen products frequently
It is crucial to re-apply sunscreen products frequently, especially after swimming, bathing or towelling in order to maintain the original protection. However, it is not possible to extend the protection time through continuous re-application of the sunscreen product. Once the efficacy of the applied product has been exhausted, re-application of the product leads to an accumulation of exposure to UV radiation and thus to over-exposure.

More information

Rules for labelling of sunscreen products in the EU

More information in your country:

Bulgaria Ministry of Health	**Nederlands** - Verstandig zonnen - Zonnetips - Gouden Regels	**Sweden** SOLinformation
Denmark - Skru ned for solen - Solcreme og selvbruner/selvbrunerkabiner: Miljøstyrelsens kosmetikguide	**Norway** Kreft foreningen	**United Kingdom** - Sunsmart - Sunsense
France - Soleil – mode d'emploi - Guide de la protection solaire	**Finland** - Radiation and Nuclear Safety Authority - Finnish Meteorological Institute - Finnish Cancer Organisations	**Poland** UVAgaslonce
Belgium - French version: soleilmalin - Dutch version: veiligindezon	**Slovak republic** Public Health Office of the Slovak Republic	
Germany Haut.de	**Spain** El sol	