

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

VERSION 5.0 (JUNE 2009)

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-BY-CASE 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 EUROPEAN FLAVOUR AND FRAGRANCES ASSOCIATION (EFFA), THE EUROPEAN ORGANISATION OF COSMETIC INGREDIENTS INDUSTRIES AND SERVICES (UNITIS),, AND THE EUROPEAN ASSOCIATION OF CRAFT, SMALL AND MEDIUM-SIZED ENTERPRISES (UEAMPME).

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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 products¹ (“**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 use² (“**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 market⁴ (“**Biocidal products Directive**”), the Commission has published such a guidance document (hereinafter the “**cosmetics/biocidal products guidance document**”).⁵

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://eur-lex.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

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-by-case 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. TYPE OF PRODUCT – PREPARATION OR SUBSTANCE

1.1. Wig

11. **Question: Is a wig a cosmetic product?**
12. Answer: No. According to Art. 1 (1) Cosmetics Directive, a cosmetic is either a substance or a preparation.
13. 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

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.

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,⁷ 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 substances⁸ and Art. 2(5) of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents⁹).

14. 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.

1.2. Wipes

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

16. Answer: A wipe itself is neither a substance nor a preparation.¹⁰ 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.

1.3. Clothes releasing cosmetic substances

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

18. Answer: The textile is neither a substance nor a preparation (see above). However, the textile 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.¹¹

⁷ 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.

⁸ OJ 196, 16.8.1967, p. 1, as amended; Non-official consolidated version at http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm.

⁹ 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.

¹⁰ Cf. above, 1.1.

¹¹ In any case, the rules for determining the "borderline" to medicinal products apply (cf. "cosmetics/medicinal products guidance document")

19. 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.
20. 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 names¹² does not deprive the qualification of released substances for cosmetic purposes as cosmetic products. Thus, the Cosmetics Directive may apply alongside this Directive.
21. 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 preparations¹³ 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.

1.4. Patches

22. Question: Is a patch a cosmetic product?

23. 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 Tooth picks and tooth floss

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

25. 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.
26. 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.
27. 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.

¹² 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.

¹³ 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.

2. “APPLICATION SITE”

2.1. Products which, according to their presentation, are intended to be used for cleaning the vagina

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

29. 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.¹⁴ This excludes the vagina.

2.2. Products which are presented as tablet

30. **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?**

31. Answer: Apart from a possible “borderline” with medicinal products¹⁵, this raises the question of the “borderline” between “cosmetic product” and “food”. For the purpose of this manual, only the latter shall be considered.

32. 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).

33. 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”.

34. “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**”)¹⁶ as “any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.”¹⁷ According to the Food Regulation

¹⁴ Art. 1 Cosmetics Directive; Cf. also the “cosmetics/medicinal products guidance document”, para. 13.

¹⁵ Cf. Art. 1 (2) Medicinal products Directive.

¹⁶ 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.

¹⁷ Art. 2 Food Regulation 178/02.

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".

35. 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.
36. 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 paste¹⁸);
 - 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).
37. 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. Products which are presented as chewing gum with cosmetic purpose

38. **Question: Is a product to keep teeth clean or to reduce bad breath which presents itself as a chewing gum a cosmetic product?**
39. **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 products¹⁹, this raises the question whether these substances/preparations are a "cosmetic product" or "food".

¹⁸ 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.

¹⁹ Cf. Art. 1, 2 of the Medicinal products Directive.

40. The regulatory frameworks of food and cosmetics do not apply cumulatively.²⁰
41. As shown above²¹, 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 food²² does not relieve from this assessment.
42. 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*
- 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 paste²³);
 - 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).
43. 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 spat out.

²⁰ Art. 2(3)(e) Food Regulation 178/02.

²¹ Cf. para. 28.

²² Art. 2(2) Food Regulation 178/02.

²³ 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.

3. “EFFECT SITE”

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

44. **Question: Is a product which, according to its presentation, is intended to exclusively or mainly relieve joint pain, a cosmetic product?**

45. 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.²⁴ Joints are not external parts of the body.²⁵

4. INTENDED COSMETICS PURPOSE

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

46. **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?**

47. 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.

4.2. Products which, according to their presentation, are intended to address “itching”

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

49. 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

²⁴ Cf. the “cosmetics/medicinal products guidance document”, paras 15, 16.

²⁵ 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).

therapeutic effect”²⁶, and that the “averagely well-informed consumer” is to be considered as the addressee of the presentation.²⁷

50. A Community-definition of “disease” does not exist yet.²⁸ 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.”²⁹
51. 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.

4.3. Washable, temporary “tattoos”

52. **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?**
53. 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.
54. 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).
55. 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 toys³⁰ does not deprive it from its qualification as a cosmetic product.

4.4. Leave-on products presented as “antiseptic” or “antibacterial”

56. **Question: Is a leave-on product which, according to its presentation, is “antiseptic” or “antibacterial” a cosmetic product?**

²⁶ 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”.

²⁷ ECJ, C-227/82, “Van Bennekom”, ECR 1983 3883, 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”.

²⁸ ECJ, C-369/88 of 21.3.1991 “Delattre“, ECR 1991 I-1487, para. 12.

²⁹ ECJ, “Delattre”, paras 33-35.

³⁰ OJ L 187, 16.7.1988, p. 1, as amended; Non-official consolidated version under http://europa.eu.int/eur-lex/lex/RECH_consolidated.do.

57. 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.
58. 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”;³¹
 - The “Manual of decisions for implementation of directive 98/8/EC concerning the placing on the market of biocidal products.”³²
59. 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.^{33, 34}

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

60. Question: Is a skin-peeling product a cosmetic product?

61. Answer: A skin-peeling product may be a cosmetic product if it is placed in contact with the skin with a view exclusively or mainly to cleaning it, changing its appearance or keeping it in good condition. The usual criteria for delimiting the borderline to medical devices³⁵ and medicinal products³⁶ apply.
62. This assessment has to be done on a case-by-case basis. The fact that, in some linguistic versions of the Cosmetics Directive, the “illustrative list by category of cosmetic products” (Annex I Cosmetics Directive) explicitly excludes chemical peeling products for face masks (2nd indent of Annex I Cosmetics Directive) does not alter this: Annex I Cosmetics Directive is, albeit not clearly expressed in Art. 1 (2) Cosmetics Directive, only an indicative list. A peeling product is a cosmetic product if it falls within the scope of the Cosmetics Directive as defined in Art. 1(1) Cosmetics Directive.

³¹ http://ec.europa.eu/enterprise/cosmetics/html/cosm_borderline_docs.htm.

³² http://www.europa.eu.int/comm/environment/biocides/pdf/mod_040705.pdf.

³³ Cf. the “cosmetics/medicinal products guidance document”, para. 28 (with reference to case-law of the ECJ).

³⁴ 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).

³⁵ Cf. the Guidelines relating to medical devices Directives (http://www.europa.eu.int/comm/enterprise/medical_devices/meddev/index.htm).

³⁶ Cf. the “cosmetics/medicinal products guidance document”.

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

63. **Question: Are products which, according to their presentation, are destined to remove glue used to fix articles on the skin or nails cosmetic products?**

64. 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.

65. Therefore, these products fall within the scope of the Cosmetics Directive.

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

66. **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?**

67. 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.

68. Therefore, these products are not cosmetic products.

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

69. **Question: Are products which, according to their presentation, are destined to be used by children as make-up on children dolls, cosmetic products?**

70. Answer: The question whether a substance or preparation is intended to be used with a cosmetics 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 do not fall within the scope of application of the Cosmetics Directive.

71. However, these products might fall 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.³⁷ According to its Art. 2(2), “Toys may be placed on the market only if they do not jeopardize the safety and/or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children.” According to the essential requirements set out in Annex II (3) of this Directive, “toys must be so designed and constructed that,

³⁷ OJ L 187, 16.7.1988, p. 1, as amended; Non-official consolidated version under http://europa.eu.int/eur-lex/lex/RECH_consolidated.do.

[...] they do not present health hazards [...] by [...] contact with the skin, mucous tissues or eyes.” In application of these essential requirements the restrictions for certain substances as contained in the Cosmetics Directive should serve as guidance.

72. Question: Are products which, according to their presentation, are destined to be used by children as make-up on children, cosmetic products?

73. 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.

74. 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 toys³⁸ does not deprive it from its qualification as a cosmetic product.

5. ABSENCE OF PHARMACOLOGICAL, IMMUNOLOGICAL OR METABOLIC ACTION

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

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

76. Answer: If a product is a medicinal product, it falls exclusively within the regulatory framework of medicinal products³⁹. 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

77. 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.

³⁸ OJ L 187, 16.7.1988, p. 1, as amended; Non-official consolidated version under http://europa.eu.int/eur-lex/lex/RECH_consolidated.do.

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.

78. 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.
79. 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

5.2. Products reducing cellulite

80. Question: Is a product which reduces cellulite in the skin a cosmetic product?

81. 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.⁴³ However, not any minor modification of physiological function suffices to render a product a medicinal product by virtue of function.⁴⁴

5.3. Substances applied with skin-patches

82. Question: Is a product which is applied through a skin-patch cosmetic product?

83. 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.
84. This has to be assessed on a case-by-case basis.⁴⁵ 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 criteria 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.

5.4. Products that make lips swell

85. Question: Are products that plump up the lips cosmetic products?

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

⁴³ Art. 1 (2) Medicinal products Directive.

⁴⁴ 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.

⁴⁵ Cf. Cosmetics/medicinal products guidance document, para 37-38.

86. 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”.
87. 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
88. 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.

5.5. Eyelash products that make eyelashes grow

89. **Question: Are eyelash products that make eyelashes grow cosmetic products?**
90. No, eyelash products that make eyelashes grow (e.g. product containing bimatoprost) are likely to exert a significant influence on physiological functions.
91. They 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”.

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⁴⁶ ECJ, C-1121/89 of 16.04.1991, “Upjohn“, ECR 1991 I-1703 (para.21-22)