MANUAL ON THE SCOPE OF APPLICATION OF THE COSMETICS REGULATION (EC) NO 1223/2009 (ART. 2(1)(A))

VERSION 1.0 (NOVEMBER 2013)

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 INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA), THE EUROPEAN ORGANISATION OF COSMETIC INGREDIENTS INDUSTRIES AND SERVICES (UNITIS), AND THE EUROPEAN ASSOCIATION OF CRAFT, SMALL AND MEDIUM-SIZED ENTERPRISES (UEAPME).

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INTRODUCTION

1. **The clear determination of the scope of application of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products ("Cosmetics Regulation")[1] ("Cosmetics Regulation") is crucial for the proper implementation of the Cosmetics Regulation 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 (now replaced by the Cosmetics Regulation) 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. 2(1)(a) of the Cosmetics Regulation 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.**

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1 OJ L 342, 22.12.2009, p. 59.

2 OJ L 311, 28.11.2001, p. 67.

3 http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/guidance_doc_cosm-medicinal_en.pdf

4 OJ L 123, 24.4.1998, p. 1.

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. **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 Regulation or within the scope of application of other sectorial 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. 2(1)(a) of the Cosmetics Regulation.**

[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 Regulation.

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 mixture 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

[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

them or keeping them in good condition, falls within the scope of application of the Cosmetics Regulation.[8]

18. One condition for this substance or mixture 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 2008/121/EC on textile names[9] does not deprive the qualification of released substances for cosmetic purposes as cosmetic products. Thus, the Cosmetics Regulation 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 Regulation 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 mixture, 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 Regulation.

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.

1.4. Patches

25. **Question: Is a patch a cosmetic product?**

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

[9] OJ L 19, 23.1.2009, p. 29..

[10] OJ L 262, 27.9.1976, p. 201.

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 mixture and not an article (cf. above, chapter 1).

30. The fact that this product may fall also within the scope of application of Directive 2009/48/EC on the safety of toys[11] does not deprive it from its qualification as a cosmetic product.

1.6. Wipes

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

32. **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 Regulation.

1.7. Wig

33. **Question: Is a wig a cosmetic product?**

34. **Answer:** No. According to Art. 2(1)(a) of the Cosmetics Regulation, a cosmetic is either a substance or a mixture.

35. The Cosmetics Regulation does not define "mixture". However, the term is widely used in the regulatory frameworks for chemicals and defined as "mixture or solution composed of

[11] OJ L 170, 30.6.2009, p. 1.

[12] Cf. above, 1.1.

two or more substances" (cf., for example, Art. 2(8) of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures[13], 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,[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]).

36. Thus, since a wig is not a mixture as defined in EU law, it cannot be considered as "cosmetic product" and does not fall within the scope of application of the Cosmetics Regulation.

[13] OJ L 353, 31.12.2008, p. 1.

[14] OJ L 200, 30.7.1999, p. 1.

[15] OJ L 104, 8.4.2004.

2. APPLICATION SITE

2.1. Vagina

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

38. **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.

2.2. Ingestion (tablets)

39. **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?**

40. **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.

41. The Cosmetic Regulation defines "cosmetic product" as "any substance or mixture **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).

42. Art. 2(2) of the Cosmetics Regulation clarifies that "for the purposes of point (a) of paragraph 1, a substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product.".

43. "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'

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[16] Art. (2)(1)(a) of the Cosmetics Regulation; Cf. also the "Cosmetics/medicinal products guidance document", para. 13.

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

[18] OJ L 31, 1.02.2002, p. 1.

[19] Art. 2 Food Regulation 178/02.

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"(now replaced by the Cosmetics Regulation).

44. 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.

45. 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).

46. 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)

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

48. **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".

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[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.

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

50. 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.

51. 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 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).

52. 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.

2.4. Nasal sprays

53. **Question: Are nasal sprays cosmetics products?**

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

23 Cf. para. 28.

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

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.

54. **Answer:** No, nasal sprays are not cosmetic products due to their place of application.

55. The definition of cosmetic products covers *"any substance or mixture intended to be placed in contact with the 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*[26]*"*. The mucous membranes of the nasal cavity are not covered.

[26] Art. 2(1)(a) of Regulation (EC) No. 1223/2009.

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

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

57. **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 Regulation.

58. 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”.

59. 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" (now replaced by the Cosmetics Regulation).

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

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

61. **Answer:** The age of the person on which the substance or mixture 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 Regulation.

62. 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.

3.1.3. Bath Products for Children with a Play Value

63. **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?**

64. **Answer:** Bath products with a "play value" for children[27] 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."

65. 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.

66. 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 Regulation (i. e. requirements concerning ingredients, labelling, notification, etc).

67. 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.

[27] Toy Safety Directive 2009/48/EC - An explanatory guidance document, Rev 1.6, Date: 11/09/2012, p. 95, available on http://ec.europa.eu/enterprise/sectors/toys/files/tsd-guidance/tsd_rev_1-6_explanatory_guidance_document_en.pdf.

3.2. Borderline with Biocides

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

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

69. **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.

70. 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";[28]
- The "Manual of decisions for implementation of directive 98/8/EC concerning the placing on the market of biocidal products."[29]

71. 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.[30, 31]

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

72. **Question: Is a mouthwash which, according to its presentation, is "antiseptic" or "antibacterial" a cosmetic product?**

73. **Answer:** A mouthwash which presents "antibacterial" or "antiseptic" claims can be qualified as a cosmetics product, a biocidal product or as a medicinal product.

74. 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 Regulation.

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[28] http://ec.europa.eu/environment/biocides/pdf/cosmetic_products.pdf.

[29] http://ec.europa.eu/environment/biocides/pdf/manualofdecisions041212.pdf.

[30] Cf. the "cosmetics/medicinal products guidance document", para. 28 (with reference to case-law of the ECJ).

[31] 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://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm).

75. The Cosmetics Regulation 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"[32], 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 Regulation. 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 Regulation, and, in particular, that the biocidal function is secondary to the cosmetic function.

76. 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[33]. A mouthwash is a medicinal product when the intended purpose is to treat or prevent oropharynx diseases.

77. 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.

[32] 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

[33] Idem.

3.3. Borderline with Pharmaceutical Products

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

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

79. **Answer:** No. The principal purpose of a cosmetic product is defined by the Cosmetics Regulation 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.[34] Joints are not external parts of the body.[35]

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

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

81. **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"[36], and that the "averagely well-informed consumer" is to be considered as the addressee of the presentation.[37]

82. A Community-definition of "disease" does not exist yet.[38] 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."[39]

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[34] Cf. the "cosmetics/medicinal products guidance document", paras 15, 16.

[35] Moreover, the principal purpose to "relieve from pain" is not a cosmetic purpose according to Art. 2(1)(a) Cosmetics Regulation (cf. also the "Cosmetics/medicinal products guidance document", para. 14).

[36] 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".

[37] 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".

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

[39] ECJ, "Delattre", paras 33-35.

83. 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

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

85. **Answer:** If a product is a medicinal product, it falls exclusively within the regulatory framework of medicinal products[40]. 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.[41] However, not any minor modification of physiological function suffices to render a product a medicinal product by virtue of function.[42]

86. 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.

87. 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.

88. 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]

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

[41] Art. 1 (2) Medicinal products Directive.

[42] 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.

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

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

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

90. **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.

91. 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.

92. 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.[44]

93. 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[45]; 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.

3.3.5. Products that make eyelashes grow

94. **Question: Are products that influence the growth of eyelashes cosmetic products?**

95. **Answer:** The question of whether such products significantly restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action has to be assessed on a case-by-case basis.

96. In assessing the proper classification of these eyelash products, one has to consider all characteristics of the product, including, for example, the presentation of the product, any promotional literature, the composition, the product's specific pharmacological, immunological or metabolic properties[46], the mode of application under normal and

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[44] Cf. cosmetics/medicinal products guidance document, para. 37-38.

[45] See entry II/372 of Annex II to Directive 76/768/EC.

[46] "It follows that products containing a substance which has a physiological effect cannot automatically be classified as medicinal products by function unless the competent administration has made an assessment, with due diligence, of each product individually, taking account, in particular, of that product’s specific pharmacological, immunological or metabolic properties, to the extent to which they can be established in the present state of scientific knowledge" (Case C‑ 140/07 Hecht‑ Pharma [2009] ECR I‑ 0000, paragraph 40).

reasonably foreseeable conditions of use, the frequency of application, the application site, the degree of penetration, and the risk which its use may entail[47].

97. The fact that a substance is used in medicinal products[48] as an active ingredient is not decisive. However, this may be an indicator for a pharmacological, immunological or metabolic action of the product.

98. On the other hand, other substances with an influence on eyelash growth may exist (or be designed), which are not used as active drug ingredients, but the product containing them could still restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action (e.g. some specially designed peptides).

99. The presentation of the product may give useful indications to the competent authorities, without, however, replacing a careful assessment of the mode of action and all the elements indicated above. For example, the claim to the effect of "eyelash growth" would indicate an intention to modify a physiological function. The absence of such claims, however, does not necessarily mean that the product does not influence eyelash growth.

3.3.6. Products for in-grown hairs

100. **Question: Are products for in-grown hairs cosmetic products?**

101. **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.

102. A product that helps liberate in-grown hairs from under the skin through a mechanical or keratolitic action may be a cosmetic.

103. 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.

104. 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.

[47] "In its case-law prior to the amendment of Directive 2001/83 by Directive 2004/27, the Court indicated that, for the purpose of determining whether a product falls within the definition of a medicinal product by function, the national authorities, acting under the supervision of the courts, must decide on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail" (Case Hect-Pharma, paragraph 32).

[48] E.g. prostaglandines and their analogues.

105. 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.[49]

106. 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

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

108. **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".

109. 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."[50]

110. 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

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

112. **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,

[49] Cf. cosmetics/medicinal products guidance document, para. 37-38.

[50] ECJ, C-1121/89 of 16.04.1991, "Upjohn", ECR 1991 I-1703 (para.21-22)

correcting or *modifying* physiological functions by exerting a pharmacological, immunological or metabolic action.[51] However, not any minor modification of physiological function suffices to render a product a medicinal product by virtue of function.[52]

3.3.9. Substances applied with skin-patches

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

114. **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.

115. This has to be assessed on a case-by-case basis.[53] 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

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

117. **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 anti-inflammatory products.

118. 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.

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[51] Art. 1 (2) Medicinal products Directive.

[52] 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.

[53] Cf. Cosmetics/medicinal products guidance document, para 37-38.

119. 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

120. **Question: Are products to treat dry mouth cosmetic products?**

121. **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 cases of extreme mucosal dryness

122. **Question: Are products for moisturizing of female genital organs in cases of extreme mucosal dryness cosmetic products?**

123. **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*[54]".

124. The definition of cosmetic product explicitly refers to the external genital organs only and the vagina is clearly excluded[55].

125. 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*"[56]. 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

126. **Question: Are topical breast augmentation products cosmetic products?**

[54] Art. 2(1)(a) Cosmetics Regulation.

[55] Ref. paragraph 2.1 of this Manual.

[56] Art. 1 (2) Medicinal products Directive.

127. **Answer:** Topical breast augmentation products achieve their objective through the action of hormones[57] 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*"[58] and cannot be qualified as cosmetic products.

128. On the other hand, products only claiming to improve the breast's 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

129. **Question: Are products claiming aromatherapy cosmetic products?**

130. **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.

131. 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 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".

132. 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

133. **Question: Are products for atopic skin cosmetic products?**

134. **Answer:** According to common understanding, atopy is a type of hypersensitivity.

135. 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

[57] The use of oestrogens in cosmetic products is prohibited according to Annex II, entry 260, of the Cosmetics Regulation.

[58] Art. 1 (2) Medicinal products Directive.

classified several diseases due to atopy: acute atopic conjunctivitis, allergic asthma, atopic dermatitis, neurodermatitis, etc.

136. In light of these definitions, the products using claims related to atopy seem to fall outside of the scope of the Cosmetics Regulation. However, the use of such terms as "atopy" or “atopic skin” should be assessed on a case-by-case basis.

137. 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, bruises or blue spots

138. **Question: Are products to reduce dark circle under the eyes, bruises or blue spots cosmetic products?**

139. **Answer:** Reduction of the visibility of discoloration of the skin can be achieved either by covering it up through make-up or by acting on its causes.

140. Products to reduce the visibility of dark circles under the eyes, bruises or blue spots, such as concealers, foundations and similar products are considered cosmetics if they act only by masking or covering such discolorations.

141. On the other hand, products that act on the causes of discoloration in most cases restore, correct or modify physiological functions by exerting a significant pharmacological, immunological or metabolic action[59]. In this case they are not cosmetic products. The fact that the ingredients used are particularly suited for the claimed purpose suggests that the product is likely to fall outside the scope of the Cosmetics Regulation.

142. In order to decide definitely about the qualification, the national competent authorities should consider all the characteristics of the product, including, for example, absorption, concentration, route of administration, frequency of application, application site, and the degree of penetration.[60]

3.3.17. Skin-whitening products

143. **Question: Are skin-whitening products cosmetic products?**

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[59] Art. 1(2) Directive 2001/83/EC on Medicinal Products.

[60] Cf. cosmetics/medicinal products guidance document, para. 37-38.

144. **Answer**: yes, in principle skin-whitening is considered as a cosmetic purpose. This is confirmed by the listing of skin-whitening products in recital 7 of Regulation (EC) No 1223/2009. However, pigmentation disorders, such as melasma, chloasma and lentigo, are considered as medical conditions, and products intended to treat them fall in the scope of the Medicinal Products legislation.

145. In order to achieve the cosmetic whitening effect, several substances may be legally used.

146. Other substances - such as hydroquinone, mercury compounds and glucocorticoids (e. g. clobetasol propionate) – are banned when used in cosmetic skin-whitening products. In this case, if skin-whitening products are marketed as cosmetics, they are illegal cosmetics.

147. Some skin-whitening products containing hydroquinone and glucocorticoids, although marketed as cosmetics, may actually qualify as medicinal products[61].

3.3.18. Products to relieve tired swollen and heavy legs

148. **Question: Are topical products to relieve tired, swollen or heavy legs cosmetic products?**

149. **Answer:** No, leave-on products presented as relieving tired, swollen or heavy legs are considered as intending to address minor peripheral circulatory disorders and therefore cannot be qualified as cosmetics.

150. However, leave-on products with a primary cosmetic function (e. g. a moisturizer) which are also presented as refreshing, cooling, soothing for the legs could be qualified as cosmetic products, if they do not significantly restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.

151. A case-by-case evaluation of all characteristics of the product, including the ingredients, the mode of action, the degree of penetration, and the claims should be carried out by the national competent authority, in order to decide on the qualification of the product.

3.3.19. Anti-wrinkle products

152. **Question: Are anti-wrinkle products cosmetic products?**

153. **Answer:** Yes, in principle anti-wrinkle products can be cosmetic products. This is confirmed by the listing of anti-wrinkle products in Annex I to Directive 76/768/EEC and recital 7 of Regulation (EC) No 1223/2009.

[61] See point 7 of the Introduction to this Manual.

154. However, some products presented as anti-wrinkle may significantly restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action. In that case, they would not qualify as cosmetics.

155. 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, for example, the presentation of the product, any promotional literature, the composition, the product's specific pharmacological, immunological or metabolic properties , the mode of application under normal and reasonably foreseeable conditions of use, the frequency of application, the application site, the degree of penetration, and the risk which its use may entail.

156. In order to achieve the anti-wrinkle effect, several substances are typically used and have different modes of action.

157. Some substances - such as tretinoin[62] (all-trans retinoic acid), gerotine[63] (spermine), phenol[64] and progesterone[65] are banned when used in cosmetic products. In this case, if anti-wrinkle products containing these ingredients are marketed as cosmetics, they are illegal cosmetics.

[62] Annex II, 375.

[63] Annex II, 411.

[64] Annex II, 1175.

[65] Annex II, 194..

3.4. Borderline with Medical Devices

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

158. **Question: Is a skin-peeling product a cosmetic product?**

159. **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.

160. 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).

161. 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.

162. 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.

163. 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[66].

164. 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*

165. **Question: Are products against head lice cosmetic products?**

166. **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,*

[66] Cf. Manual on Borderline for Medical Devices, Section 4.11, available on http://ec.europa.eu/consumers/sectors/medical-devices/files/wg_minutes_member_lists/version1_7_borderline_manual_en.pdf

changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition[67]".

167. The qualification of anti-lice products is a borderline issue between medicinal products, medical devices and biocides.

[67] Art. 2(1)(a) of the Cosmetics Regulation

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

168. **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?**

169. **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.

170. 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?

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

172. **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.

173. Therefore, these products fall within the scope of the Cosmetics Regulation.

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

174. **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?**

175. **Answer:** No. Art. 2(1)(a) of the Cosmetic Regulation 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.

3.5.4. Cosmetic kits

176. **Question: Are cosmetic kits cosmetic products?**

177. **Answer:** There are several types of 'cosmetic kits':

- Kits with components to be mixed based on clear instructions, *e.g.* soap chips to be mixed with a coloring mixture and a fragrance mixture, or a cream base to be mixed with a perfuming mixture, are considered as finished cosmetic products. Therefore, the cosmetics legislation applies, and the kits must be assessed, labeled, notified, *etc.*, by the responsible person as multi-component cosmetic products. The CLP Regulation does not apply because of an exception for finished products in the form of cosmetics[68]. If the consumer is supposed to add any ingredient that is not in the kit (e.g. water or honey), to the 'recipe', this should be taken into account by the responsible person in complying with the Cosmetics Regulation.

- Kits of substances and mixtures, which are not linked to specific instructions on how to make a finished cosmetic product from them, and where the components are not cosmetic products on their own, are not cosmetics. For these kits, the CLP Regulation[69] applies for the components. If the substances and mixtures are then mixed and placed on the market as finished cosmetic products, the cosmetics legislation applies and the manufacturer becomes a responsible person.

[68] Art. 1, 5. (c) of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures foresees that*:*

"This Regulation shall not apply to substances and mixtures in the following forms, which are in the finished state, intended for the final user:

[…] (c) cosmetic products as defined in Directive 76/768/EEC".

[69] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.