

1 **Guidance document agreed between the Commission services and the competent**
2 **authorities of Member States for the biocidal products Directive 98/8/EC and for**
3 **the cosmetic products Directive 76/768/EEC**

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5 **BORDERLINE BETWEEN DIRECTIVE 98/8/EC CONCERNING THE**
6 **PLACING ON THE MARKET OF BIOCIDAL PRODUCT AND DIRECTIVE**
7 **76/768/EEC CONCERNING COSMETICS PRODUCTS**

8 **Introduction**

9 The determination of clear borderline between the Biocidal Products Directive
10 98/8/EC¹ (BPD) and the Cosmetic Products Directive 76/768/EEC² (CPD) is identified
11 as a crucial issue for a proper implementation of the BPD as well as of the CPD. Many
12 borderline cases have been identified so far by the competent authorities for the BPD (e.g.
13 sun bathing products containing insect repellents, shampoos that control dandruff,
14 mouthwashes with an antibacterial activity) and there is a need to give practical guidance
15 on the methodology to use to find solutions for these cases.

16 The discussion on borderline cases started in 1998 in an expert group including experts
17 from Member States' competent authorities for the BPD, the services of the European
18 Commission, as well as industry trade associations. A questionnaire on borderline cases
19 has been circulated to contact points for the Biocidal Products Directives and the
20 contributions received have been taken into account. The results have been discussed
21 during the different CA meetings of the BPD since 18 May 1999 and further
22 contribution have been received by the biocides contact points and by the service of the
23 Commission responsible for the CPD. At the CA meeting for the BPD held on October
24 2000 MSs specifically requested the Commission to produce a working document to
25 further progress on this issue.

26 This document attempts to provide guidance to Member States on borderline cases
27 between the two Directives. It will be submitted to the meetings of competent
28 authorities of the Directives involved for endorsement.

29 It has been conceived as an opinion of the Commission Services involved, however it
30 does not oblige in any way Member States to adopt the same attitude and it is not
31 legally binding since only the Court of Justice can give an authoritative interpretation of
32 existing Community law.

33 A proposal for amendments to the BPD (notably to the description of Product types in
34 Annex V) is under discussion to introduce in the legal text the agreed adjustments on
35 scope.

36 **Definition**

37 Some definitions from the BPD and CPD are reproduced here for reference.

38 **Biocidal Products (98/8/EC)**

¹ OJ L 123, 24.4.98. p. 1

² OJ L 262, 27.9.1976 p.169. Directive as last amended by Directive 2000/41/EC (OJ L 145, 20.6.2000)

39 Active substances and preparations containing one or more active substances, put up in
40 the form in which they are supplied to the user, intended to destroy, deter, render
41 harmless, prevent the action of, or otherwise exert a controlling effect on any harmful
42 organism by chemical or biological means. An exhaustive list of 23 product types with
43 an indicative set of descriptions within each type is given in Annex V.

44 **Cosmetic Product (Council Directive 76/768/EEC)**

45 A "cosmetic product" shall mean any substance or preparation intended to be placed in
46 contact with the various external parts of the human body (epidermis, hair system, nails,
47 lips and external genital organs) or with the teeth and the mucous membranes of the oral
48 cavity with a view exclusively or mainly to cleaning them, perfuming them, changing
49 their appearance and/or correcting body odours and/or protecting them or keeping them
50 in good condition.

51 The CPD has 7 Annexes covering different areas³. These annexes have relevance for
52 the classification of cosmetic products. In particular, Annex I contains an illustrative list
53 of products, which are to be considered as cosmetic products within the meaning of the
54 definition mentioned above. The other annexes regulate the use of specific substances in
55 cosmetic products, and hence indicate whether a product, based on its composition, can
56 be regarded as a cosmetic product.

57 As an additional clarification to the definition of cosmetic product, the Council and the
58 Commission made the following statement at the adoption of Council Directive
59 93/35/EEC⁴, 6th amendment of Directive 76/768/EEC, statement N° 2, referred to
60 Article 1:

- 61 (a) The Council and the Commission would point out that, in accordance with the
62 case law of the Court, the distinction between medicinal and cosmetic products
63 has to be made on a case by case basis
- 64 (b) The Council and the Commission agree that the expression "protecting or
65 keeping in good condition" does not cover prevention of disease or protection
66 against contamination or infection by micro-organisms, fungi or parasites

67 In relation to the point (b) it seems clear that if a cosmetic product shows and claims
68 "activity" as a medicinal product, it could not be regarded as a cosmetic product. A
69 product can not be both a medicinal product and a cosmetic product. Cosmetic
70 products cannot have secondary medicinal activity. A product which meets at the
71 same time the definition of a cosmetic product and the definition of a medicinal
72 product must be regarded as a medicine. The European Court of Justice has
73 established this hierarchy between the two definitions. More in general, a product
74 claiming as primary effects those mentioned in (b) can not be considered as
75 cosmetic product and it should be considered either a medicinal product or a
76 biocidal product.

³ Annex I: Illustrative list by category of cosmetic products.
Annex II: List of substances which must not form part of the composition of cosmetic products.
Annex III: List of substances which cosmetic products must not contain except subject to restrictions
and conditions laid down.
Annex IV: List of colouring agents allowed for use in cosmetic products.
Annex V: List of substances excluded from the scope of the Directive
Annex VI: List of preservatives which cosmetic products may contain
Annex VII: List of UV filters which cosmetic products may contain

⁴ OJ L 151, 23.06.1993, p. 32

77 **Proposal for general and specific borderlines**

78 In relation to a clarification on the meaning of Article 1(2) of the BPD, the Commission
79 services' view is that products within the scope of the Directives listed in Art 1(2) are
80 excluded from Directive 98/8/EC irrespective as to whether or not the relevant Directive
81 provides for an authorization scheme or an evaluation of risks. Products covered by a
82 Directive listed in Article 1(2) can only be regulated according to the rules of this
83 Directive⁵. The CPD is listed in Article 1(2) of the BPD; therefore products within the
84 scope of the CPD are excluded from the BPD. It should be noted that in both Directives
85 "products" are defined as preparations and substances (active substances in the case of
86 the BPD).

87 Art. 1 (2) excludes from Directive 98/8/EC products that *are defined or within the scope*
88 *of the listed instruments for the purposes of the Directives* mentioned in Art. 1(2). The
89 scope of the exemption clause depends on the specific purpose of a product. When a
90 product containing a substance with biocidal activity serves a purpose regulated by a
91 Directive listed in Art. 1 (2) it is not within the scope of the BPD. However, if a product
92 containing the same substance is used for purposes not covered by the Directives listed
93 in Art. 1 (2), the BPD will apply.

94 This is the case in relation to **preservatives used in cosmetics products**, they are
95 excluded from the scope of the BPD for the specific use to preserve cosmetics, since
96 this use is specifically covered by the CPD. In fact, in its Article 3 the CPD foresees
97 specific rules for the use of preservatives in the manufacture of cosmetic products,
98 providing that only preservatives listed in Annex VI to the Directive can be used, under
99 the condition specified in the preamble and in the Annex itself.

100 If the same physical product is used to preserve for example paints or detergents, than
101 for this use it shall be authorized according to the BPD since Article 1(2) does not
102 provide for any exemption for paints or detergents.

103 It may be that some cosmetics products, which meet the relevant definition as cosmetic
104 products (Art. 1 of the CPD), can also contain active substances with biocidal activity
105 other than preservatives. In a previous note addressed to COLIPA⁶ on this subject, the
106 view of the Commission services was that "*An example could be a sun bathing product*
107 *that also contains an insect repellent as an ancillary ingredient. If such a product*
108 *exclusively or mainly has a cosmetic function within the meaning of the definition of*
109 *cosmetic product, then it clearly falls under the scope of the CPD and it will be*
110 *excluded from the scope of the BPD. From a legal point of view, a given product cannot*
111 *be a cosmetic product and a biocidal product at the same time. Either the product has*
112 *to be considered as a cosmetic product and the rules of Directive 76/768/EEC apply or*
113 *it will be a biocidal product and Directive 98/8/EC applies. The decision to classify a*
114 *product into one of the two product groups has to be taken by the competent authorities*
115 *within Member States, on a case-by-case approach, taking into account the claims, the*
116 *presentation and the ingredients of the product"*

117 The CPD is a "safety Directive", which requires that a cosmetic product put on the
118 market be safe for normal and for reasonably foreseeable conditions of use; Article 7a
119 of the CPD requires, *inter alia*, that a safety assessment be carried out by a qualified
120 safety assessor for each cosmetic product. The latter requirement addresses the safe use
121 of ingredients in cosmetic products, including those ingredients for which a

⁵ Doc.Biocides/50/99, 9 November 1999

⁶ Letter from Mr. Deboysier (DG Enterprise/E/3) of 1.07.98, ref. III/E/3/LB/lb/D(98)

122 concentration limit is not established in the annexes of the CPD. The assessment must
123 take into account the levels of exposure to the various ingredients in order to fulfill the
124 requirement contained in Article 2 of the CPD: cosmetic products put on the market
125 *must not cause damage to human health when applied under normal or reasonably*
126 *foreseeable conditions of use*⁷. The fact that no procedure of authorization had been
127 established does in no way reduce the proper assessment of all potential risks⁸.

128 The CPD allows for secondary biocidal claims like e. g. anti-dandruff claim in
129 shampoos, antimicrobial claim⁹ in oral hygiene products or deodorants and sunscreens
130 with insect repellent function. However, the use of the claim ‘disinfection’ or
131 ‘disinfecting action’ is not permitted because of concerns regarding the borderline of
132 cosmetic products and medicinal products.

133 Art. 1 (2) excludes from Directive 98/8/EC products that are defined or within the scope
134 of the listed instruments for the purposes of the Directives mentioned in Art. 1(2). It is
135 not mentioned that biocidal claim should not be allowed for the excluded products. A
136 biocidal claim could be permitted for cosmetic products as far as it is compatible with
137 the provisions of the CPD.

138 The use of claims on biocidal effects, is taken into account in Article 6(3) of the
139 « CPD » which states that “*Member States shall take all measures necessary to ensure*
140 *that, in the labeling, putting up for sale and advertising of cosmetic products, text,*
141 *names, trade marks, pictures and figurative or other signs are not used to imply that*
142 *these products have characteristics which they do not have. In addition, Article 7a(g)*
143 *requires that the manufacturer be able to provide proof of the effect claimed for the*
144 *cosmetic product, where justified by the nature of the effect or product.*”

145 Summarizing, the exclusion provision contained in Article 1(2) of the BPD in relation
146 to the CPD covers the following cases:

- 147 • Cosmetic ingredients – since they are within the scope of the CPD – including
148 preservatives listed in Annex VI to the CPD, under the condition specified in the
149 preamble and in the Annex itself

⁷ The example of sun protection products containing insect repellents has been quoted as a combination where intended use and function would require contradictory use instructions: the sun protection product should be applied frequently (leading to high doses of exposure), whereas the repellent should be used scarcely and at low doses. Assessment of exposure of all ingredients must result in safe use: hence, if the minimal concentration in the final product of the repellent to be effective (which must be substantiated) is such that the repeated use triggered by the application of the sun protection product leads to an unacceptably high exposure dose, this combined product is not safe in the sense of the CPD and cannot be placed on the market as a cosmetic product.

⁸ The environmental risks arising from the use of cosmetic products are not systematically addressed. However, environmental legislation regarding the use of certain substances is applicable to cosmetics as well (e.g. on ozone depleting substances, aerosols). It can be expected that the future chemicals policy will further remedy this situation to some extent.

⁹ In its opinion of 28 June 2000, the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, has endorsed the first Revision and Update of Section I of the Inventory of ingredients employed in cosmetic products, which contains 153 substances (13 in Annex III and 3 in Annex VI), which have an indicated antimicrobial function. Antimicrobial is defined as ‘helps control the growth of micro-organisms on the skin’. The inventory can be found at : <http://pharmacos.eudra.org>.

- 150 • Cosmetic products with a certain secondary biocidal activity and claim¹⁰, as long as
151 the primary function of the products is cosmetic and they comply with the
152 requirements of the CPD.

153 The critical question is, which biocidal activities can be considered as secondary to the
154 main cosmetic functions. Several examples are given in the CPD itself (such as anti-
155 dandruff shampoo and anti-microbial soaps). However, for the above-mentioned
156 example of sun lotions containing insect repellents, the biocidal function is not
157 considered to be secondary and therefore the product containing the repellent will most
158 likely be considered a biocidal product.

159 The practical procedure to find out which regime applies in case of uncertainty in
160 relation to a product that could be a cosmetic product claiming a secondary biocidal
161 activity could be the following: The person responsible for placing the product on the
162 market would approach competent authorities for cosmetic products and those
163 competent for biocidal products within Member States to know if the CPD applies. The
164 authorities, on a case-by-case approach, taking into accounts the claims, the
165 presentation and the ingredients of the product will decide whether it is a cosmetic
166 product or not. If it is concluded that it is a cosmetic product, then it is excluded from
167 the scope of the BPD. It is obvious that close co-ordination among the authorities is
168 important to come to coherent decisions.

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170 **Development of a ‘Manual of Decisions’**

171 Examples of proposed decisions by individual Member States should be sent to the
172 Commission Services responsible for the Biocidal Products Directive and those
173 responsible for the Cosmetic Products Directive. These proposals should have already
174 been agreed between the authorities responsible for the relevant Directives within that
175 Member State. The other Member States (competent authorities for biocides and
176 competent authorities for cosmetic products) will then be consulted on the proposed
177 decisions. If necessary, the Commission will also request an opinion of the Scientific
178 Committee on Cosmetic Products and Non-Food Products intended for Consumers and /
179 or the Scientific Committee on Toxicity, Ecotoxicity, and the Environment regarding
180 the risk assessment of ingredients in such products that have given reasons for concern.

181 Agreed positions will then be compiled in a ‘Manual of Decisions’. This will be located
182 on the website of the European Commission at:

183 <http://europa.eu.int/comm/environment/biocides/index.htm>

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¹⁰ Nota Bene: no therapeutic claim is allowed, as otherwise the product would be considered a medicinal product.