



NOTE FOR GUIDANCE

This document is an attempt to provide guidance in the interest of consistency, and has been drafted by the Commission services responsible for cosmetic and biocidal products with the aim of finding an agreement with all or a majority of the Member States' Competent Authorities for such products. Please note, however, that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

Subject: Borderline between the legislation for cosmetics and biocides

EXECUTIVE SUMMARY

Products supplied for cosmetic or biocidal purposes, or both, are regulated as follows:

1) Products regulated only through the cosmetics legislation

Products supplied with a main or exclusive cosmetic purpose are cosmetic products, and thus fall within the scope of the cosmetics legislation. This category includes, first of all, cosmetic products which contain preservatives for the sole purpose of preserving the cosmetic product itself, without giving a biocidal function to the product as such. Second, it includes biocidal products within the meaning of Article 2(1)(a) of the Biocidal Products Regulation, if the biocidal purpose is only secondary to a primary cosmetic purpose, or if the biocidal purpose is inherent to a primary cosmetic purpose.

2) Products regulated only through the biocides legislation

Products supplied with one single primary purpose, which is biocidal, are not covered by the definition of a cosmetic product or by the cosmetics legislation. They fall within the scope of the biocides legislation. Examples include products making claim to control public health through the control of infectious organisms, such as “disinfecting”, which would go beyond the general knowledge of personal hygiene as a contribution to public health, considering the reasonable expectations of the average consumer relating to

biocidal activity, and can include antibacterial hand gels, and antibacterial bar or liquid soaps with an additional public health claim..

3) 'Cosmetic *and* biocidal' products regulated through both the cosmetics legislation and the biocides legislation

There are products serving a primary cosmetic purpose, which serve an equally important biocidal purpose. These will be regulated by the cosmetics legislation with regard to their cosmetic purpose and by the biocides legislation with regard to their biocidal purpose. Examples include insect or jelly fish repellent sunscreens.

Some concrete examples are contained in the annex to this document, to which new examples may be added over time.

BACKGROUND AND PURPOSE OF THIS GUIDANCE

- 1) The question of product categorisation and governance of consumer products supplied with biocidal or cosmetic intentions, or both, has often been raised at both European and national level. The Member States and the European Commission have touched upon the issue in a number of guidance documents,¹ and have devoted a specific guidance document to the question.²
- 2) In light of the new Cosmetic Products Regulation (EC) No 1223/2009 ('CPR') which repealed and replaced the existing Cosmetic Products Directive 76/768/EEC ('CPD') as of 11 July 2013, as well as the new Biocidal Products Regulation ('BPR') which will repeal and replace the existing Biocidal Products Directive 98/8/EC ('BPD') as of 1 September 2013, this guidance document seeks to further harmonise the approach throughout the EU, and give practical advice to companies wishing to place consumer products on the market. It is intended to replace the guidance document referred to in footnote 2 of this document.
- 3) It is recalled, however, that guidance documents can merely give a non-legally binding indication, and do not affect the national competent authorities' obligation to determine the correct classification of a product, subject to review by the courts, on a case-by-case basis, taking account of all its characteristics.³
- 4) It is worth noting, however, that under Article 3(3) of BPR, a Member State will also have the opportunity to request the Commission to adopt a legally binding decision on the question whether a specific product or group of products is a biocidal product within the meaning of that Regulation.

LEGAL PROVISIONS ON DEFINITION AND SCOPE

- 5) The current definitions of a cosmetic product and a biocidal product respectively are contained in the CPR, and the BPD, which will be repealed and replaced by the BPR.

¹ Manual on the Scope and Application of the Cosmetic Directive 76/768/EEC (art. 1 (1) Cosmetics Directive – Version 8.0 (June 2011), available on http://ec.europa.eu/consumers/sectors/cosmetics/cosmetic-products/borderline-products/index_en.htm, Biocides Manual of decisions, available on <http://ec.europa.eu/environment/biocides/manual.htm>

² Borderline between Directive 98/8/EC concerning the placing on the market of Biocidal products and Directive 76/768/EEC concerning Cosmetic products, available on http://ec.europa.eu/environment/biocides/pdf/cosmetic_products.pdf

³ See, e.g., judgment of ECJ of 9 June 2005 in Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03, HLH Warenvertriebs GmbH & Orthica v Bundesrepublik Deutschland, paragraph 30, and the case law referred to therein.

Definition of a cosmetic product and scope of the cosmetics legislation

- 6) Article 2(1)(a) of the CPR, which does not differ substantially from the corresponding Article 1(1) of the CPD, defines a cosmetic product as follows:

"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 with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours"

- 7) Regarding the scope of the CPD, Article 1(2) of the Directive refers to an illustrative list of cosmetic products in Annex I to the Directive. A virtually identical list of products has been introduced in recital 7 of the CPR, reproduced below.

- 8) Regarding the scope of the CPR, Article 1 of the Regulation defines the scope as follows:

"This Regulation establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health."

- 9) The delimitation between the CPR and other pieces of legislation is not explicitly regulated in the operative part of the Regulation⁴. However, recital 6 of the CPR states the following:

"This Regulation relates only to cosmetic products and not to medicinal products, medical devices or biocidal products. The delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use."

- 10) As opposed to the CPD, the CPR does not contain an annex with an illustrative list of cosmetic products. Instead, recital 7 of the CPR states the following:

"The assessment of whether a product is a cosmetic product has to be made on the basis of a case-by-case assessment, taking into account all characteristics of the product. Cosmetic products may include creams, emulsions, lotions, gels and oils for the skin, face masks, tinted bases (liquids, pastes, powders), make-up powders, after-bath powders, hygienic powders, toilet soaps, deodorant soaps, perfumes, toilet waters and eau de Cologne, bath and shower preparations (salts, foams, oils, gels), depilatories, deodorants and anti-perspirants, hair colorants, products for waving, straightening and fixing hair, hair-setting products, hair-cleansing products (lotions, powders, shampoos), hair-conditioning products (lotions, creams, oils), hairdressing products (lotions, lacquers, brilliantines), shaving products (creams, foams, lotions), make-up and products removing make-up, products intended for application to the lips, products for care of the teeth and the mouth, products for nail care and make-

⁴ According to Article 2(2), however, for the purpose of the definition of cosmetic product, "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."

up, products for external intimate hygiene, sunbathing products, products for tanning without sun, skin-whitening products and anti-wrinkle products."

Definition of a biocidal product, and scope of the biocides legislation

11) The definition of a biocidal product and the scope of the biocidal products legislation according to the current BPD will, with the future BPR, in some parts be clarified and in other parts be amended.

12) Article 2(1)(a) of the BPD gives the following definition of a biocidal product:

"Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render-harmless, prevent the action of or exert a controlling effect on any harmful organism by chemical or biological means.

An exhaustive list of 23 product types with an indicative set of descriptions within each type is given in Annex V."

13) However, not all products falling within this definition are covered by the Directive for all purposes. Article 1(2) of the BPD stipulates the following:

"This Directive shall apply to biocidal products as defined in Article 2(1)(a) but shall exclude products that are defined or within the scope of the following instruments for the purposes of these Directives:

...

(p) [the CPD]"

14) Insofar as is relevant for the borderline between cosmetic and biocidal products, the BPR will define a biocidal product as follows:

"any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action."

15) Like the BPD, the BPR will exclude certain products which, while complying with the definition of a biocidal product, are already covered by sector-specific legislation, for the purposes covered by that other legislation. The first subparagraph of Article 2(2) of the BPR will thus read as follows:

"Subject to any explicit provision to the contrary in this Regulation or other Union legislation, this Regulation shall not apply to biocidal products or treated articles that are within the scope of the following instruments:

...

(j) [the CPR]"

- 16) The second subparagraph of Article 2(2) of the BPR will clarify that it is *only for the purposes covered by sector-specific legislation* that products can be excluded from the biocides legislation on this basis, by stipulating the following:

"Notwithstanding the previous paragraph, when a biocidal product falls within the scope of one of the above mentioned instruments and is intended to be used for purposes not covered by those instruments, this Regulation shall also apply to that biocidal product insofar as these purposes are not addressed by those instruments."

- 17) An indication of the types of biocidal products covered by the BPR is given in Article 2(1) of the Regulation, which refers to Annex V for a "list of the types of biocidal products covered by this Regulation and their description". There are two product-types in Annex V of the BPR known to be intended – like cosmetic products – for application on human skin, i.e. product-types 1, human hygiene products, and 19, repellents and attractants.

- 18) Human hygiene biocidal products covered by the BPR are described in Annex V of the Regulation as

"biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp".

- 19) Repellents and attractants covered by the BPR are described in Annex V of the Regulation as follows:

"Products used to control harmful organisms [...] by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of man or animals."

- 20) Article 19 of the BPR contains the following provision for biocidal products which are applied on the human body in the same way as cosmetics:

"Where a biocidal product is intended for direct application to the external parts of the human body (epidermis, hair system, nails, lips and external genital organs), or to the teeth and the mucous membranes of the oral cavity, it shall not contain any non-active substance that may not be included in a cosmetic product pursuant to Regulation (EC) No 1223/2009."

- 21) In the process of adopting the BPR, representatives of the cosmetics industry expressed fears that the second subparagraph of Article 2(2) of the Regulation would be taken as meaning that functions already regulated under the CPR would also be regulated under the BPR. Therefore, the following was inserted in recital 20 of the BPR:

"Where a product has a biocidal function that is inherent to its cosmetic function, or where that biocidal function is considered to be a secondary claim of a cosmetic product and is therefore regulated under [the CPR], that function and the product should remain outside the scope of this Regulation."

ANALYSIS OF THE LEGAL PROVISIONS ON DEFINITION AND SCOPE

22) Below follows an analysis of the provisions outlined above with respect to their consequences for products supplied with biocidal or cosmetic intentions, or both.

What products are covered by the cosmetics legislation?

- 23) The CPR applies to all products complying with the definition of a "cosmetic product", based on the area of application and the purposes of their use. The purpose of the product must be "*exclusively or mainly*" to clean, perfume, change the appearance, protect, keep in good condition or correct body odours. The fact that a cosmetic product may have a "main" cosmetic function allows for secondary functions, which may not be cosmetic. As a result, a product can be covered by the cosmetics legislation even if secondary, non-cosmetic claims are made, provided that it is clear, from the presentation of the product, that such claims are secondary.
- 24) Recital 7 of the CPR clarifies that no exhaustive list of cosmetic products can be drawn up in advance, and that the characterisation of products as cosmetic or not has to be determined case-by-case, taking into account all the characteristics of the product (*e.g.* overall presentation, composition, claims). For the delimitation with other legislations, recital 6 of the CPR states that *The delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use.*"
- 25) The CPR covers products for which the biocidal function is inherent to the cosmetic function, or is considered to be a secondary claim of a cosmetic product, as indicated in recital 20 of the BPR, since such products are covered by the definition of a cosmetic product.
- 26) The definition of cosmetic products points to several biocidal functions inherent to the eventual purpose of cleaning, perfuming, protecting, keeping in good condition or correcting body odours. Some examples include:
- i. Deodorants - the presence of a biocide might foster the targeted end result: the cosmetic function is one of controlling body odours caused by bacterial growth and the bacterial breakdown of perspiration. This is commonly achieved through a combination of several mechanisms; *i.e.* reduction of perspiration (antiperspirant), reduction of bacterial growth and bacterial activity, and masking of smells through perfuming. Many commonly used ingredients in deodorants support both the perfuming and the antibacterial activity (*e.g.* alcohol, farnesol as well as other fragrance compounds), aluminium salts commonly used as antiperspirants can also have moderate antimicrobial activity. Additional antimicrobial ingredients can be used to enhance the efficiency of the product, without changing its main purpose of controlling body odour.
 - ii. Anti-dandruff shampoos - dandruff is commonly caused by a combination of several causes, including sebaceous secretions, metabolic by-products of skin micro-organisms, individual factors (excessive perspiration) or dry/cold environment. Anti-dandruff shampoos act primarily by cleaning dandruff scales from the hair and the scalp through a mixture of surfactants

and keratolytic ingredients. These ingredients often also have a mild antimicrobial effect helping to control the activity of the skin organisms that contribute to dandruff formation. Other ingredients help to normalise sebum production and keratocyte proliferation. Again, many of those also affect microbial growth and activity. Certain antifungal agents can be used to control the skin microflora and provide a longer-lasting effect of clean, dandruff free hair.

- iii. Toothpastes and mouthwashes are generally intended to maintain the teeth and/or oral cavity in good condition by cleaning and perfuming the teeth and gums, correcting bad odours and perfuming the oral cavity. The control the oral microflora is inherent to the cosmetic benefits of oral care products, and is achieved not only by removing bacteria, but also through the antibacterial properties of surfactants, flavour ingredients (e.g. menthol) or preservatives. The microflora-control properties of these products can be further enhanced by other ingredients with antimicrobial activity when these are permitted for use in cosmetics.

27) ,In addition, a cosmetic product with secondary non-cosmetic claims will remain exclusively in the scope of the CPR, provided its main intended function remains cosmetic. The product must be assessed on a case-by-case basis to determine whether any such non-cosmetic claims are secondary, and hence do not deprive the product of its character as a cosmetic. Examples of non-cosmetic claims that may in certain cases be considered as secondary include "antibacterial" or "antimicrobial" claims on soaps, mouthwashes and deodorants, provided that the primary function of the product is still of a cosmetic nature, and not disinfection.

What products are covered by the biocides legislation?

28) A product complies with the definition of a biocidal product in BPD and BPR only if the product *as such* is intended to control harmful organisms. This means that, while preservatives in themselves are biocidal products, the mere fact that a cosmetic product *contains* a preservative does not in itself make the cosmetic a biocide. Under the CPR, preservatives may only be used in cosmetic products if they have been included in the positive list in Annex V of the Regulation following an independent safety assessment by the Scientific Committee for Consumers Safety (SCCS). This positive list (Annex V of the CPR) also provides restrictions to ensure their safe use.

29) The basic principle of the BPD remains the same in the BPR: the biocides legislation covers products complying with the definition of a "biocidal product", but not all such products.

30) That is because many of the products typically supplied with the intention to kill harmful organisms and thus complying with that definition, such as plant protection products or medicines, were already governed by sector-specific legislation before the general biocides legislation was adopted, and the general biocides legislation never intended to impose double regulation of such products *when their intended biocidal purposes were already covered* by the sector-specific legislation.

31) However, some of these "biocidal products" having intended purposes which were already covered by a sector-specific piece of legislation can also have *other* intended

purposes which are *not* covered by the sector-specific legislation. These are commonly referred to as "dual use" or "dual purpose" products because they have two distinct functions. According to its Article 1(2), BPD only excludes dual purpose products "for the purposes of [the sector-specific] Directives". In other words, for purposes *not* regulated by the sector-specific Directives, BPD still applies. In the area of plant protection products, it has long been common ground that, already based on BPD, dual purpose products thus have to comply with the plant protection products legislation for the purpose of their use as plant protection products, and with the biocides legislation for the purpose of other biocidal uses.⁵ With the introduction of the second subparagraph of Article 2(2) of the BPR, it was made clear that the principle of double regulation of dual purpose products applies in relation to all the sector-specific pieces of legislation listed in the first subparagraph of Article 2(2) of the BPR.

Can a product fall under both the definitions of cosmetic and biocidal product?

- 32) The biocides legislation gives a broad definition of a biocidal product, defining it as any product supplied with a biocidal intention, be it primary or secondary. While excluding certain products, *i.e.* cosmetics, from its *scope* for certain purposes, the legislation does not exclude those products from the *definition* of a biocidal product.
- 33) The cosmetics legislation defines a cosmetic product as a substance or mixture [...] with exclusively or mainly a cosmetic purpose. However, a product with a main cosmetic purpose may also be supplied with other purposes, such as a biocidal purpose. Those products are not excluded from the definition of a cosmetic product.
- 34) In consequence, a product with a cosmetic purpose which is also supplied with a biocidal intention will constitute both a "cosmetic product" within the definition of the cosmetics legislation and a "biocidal product" within the definition of the biocidal products legislation. The question which legislation is applicable on such '*cosmetic and biocidal*' products is explored below.

Are products falling under both the definitions of 'cosmetic' and 'biocidal' product definitions excluded from the scope of the cosmetics legislation?

- 35) Recital 6 of the CPR states that the regulation does not apply to "biocidal products". Taken literally, this would mean that any cosmetic product which also complies with the broad definition of a "biocidal product" in the biocides legislation, *i.e.* any cosmetic product which is also supplied with a biocidal intention, would *not* be covered by the CPR. However, this interpretation is not supported in the operative parts of the CPR, in particular not in Article 1, which makes it clear that the CPR applies to "any cosmetic product". Furthermore, this interpretation would deprive the

⁵ See, e.g., *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 plant protection products Directive 91/414/EEC on: Borderline between Directive 98/8/EC concerning the placing on the market of Biocidal product and Directive 91/414/EEC concerning the placing on the market of plant protection products*, available on http://ec.europa.eu/food/plant/protection/evaluation/borderline_en.htm

exclusion in Article 2(2)(j) of the BPR, which applies to "biocidal products ... that are within the scope of ... [the CPR]", of its purpose.

- 36) Therefore, it must be considered that a product supplied mainly with a cosmetic purpose is covered by the scope of the CPD and the CPR, even if it is also falls within the definition of a "biocidal product".

Are products falling under both the definitions of 'cosmetic product' and 'biocidal product' excluded from the scope of the biocides legislation?

- 37) As indicated above, the introduction of the second subparagraph of Article 2(2) of the BPR made it clear that the principle of double regulation of dual purpose products applies in relation to all the sector-specific pieces of legislation listed in the first subparagraph of Article 2(2) of the BPR and hence also in relation to the CPR. In other words, 'cosmetic and biocidal' products are included in the scope of the BPR, if they are intended to be used for purposes not covered by the cosmetics legislation.

- 38) Recital 20 of the BPR clarifies that biocidal functions that are inherent to a product's cosmetic function and secondary biocidal claims of a cosmetic product are covered by the CPR, and that the respective secondary function and the product itself should remain out of the scope of the BPR. This is in line with the explanation given in Recital 6 of the CPR which clarifies that the delimitation between cosmetic products and biocidal products "follows in particular from the detailed definition of cosmetic products".

- 39) Where a biocidal function of the product is not already inherent to its cosmetic purpose, the critical question for the delimitation between both product categories is therefore whether an intended biocidal purpose can indeed be considered to be secondary.

Which products are regulated through which legislation?

- 40) As shown above, the definitions of the scope of the cosmetics and biocides legislation respectively leave a large room for interpretation. When examining in individual cases which legislation applies, several aspects should be taken into account.

- 41) First, compliance with the biocides legislation on top of the cosmetics legislation for one single product represents a significant burden for companies. This burden would come in addition to the requirements under the CPR and the CPD to prepare a product information file, including a cosmetic product safety assessment, label the product according to the CPD/CPR rules, and notify it. The interest of avoiding this burden calls for applying both the cosmetics and biocides legislations to the same product only in exceptional cases.

- 42) There are, however, cases where double regulation is justified. An example worth mentioning is that of sunscreens that are also insect, or jelly fish, repellents. These products are cosmetics by virtue of having a cosmetic purpose, *i.e.* the function as a sunscreen. They must comply with the CPR, including its composition requirements, whereby UV-filters are explicitly authorized after an independent safety assessment by the SCCS, and with the requirements regarding efficacy and claims addressed in

Commission Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto (2006/647/EC)⁶.

- 43) At the same time, the repellent properties of such products can be essential for the user and imply risks to humans and the environment. Those properties are not addressed by the cosmetics legislation, and can hardly be regarded as merely secondary. Such products should therefore also have to comply with the biocides legislation for the purpose of the repellent function.
- 44) Second, the biocides legislation offers a high level of protection of human health and the environment in providing for a rigorous mechanism of peer reviewed evaluation of every active substance, and authorisation of every product, before placing on the market. Furthermore, there are important factors taken into account in an evaluation made according to BPD or the BPR which are not routinely addressed under the CPD or the CPR, such as target organism resistance and effects on the environment.
- 45) The difference can be explained by two inherent characteristics which biocidal products are more likely to present than cosmetic products: Their potential dangers for public health and the environment, as well as their potential importance for the protection of public health, beyond what is expected from a cosmetic product. The regulatory regime for biocides appears to have been shaped to be more rigorous in certain aspects than that for cosmetics. In order to fulfil the aim of protecting public health and the environment, it can therefore be necessary to apply the biocides legislation in dubious cases.⁷
- 46) In particular, where a biocidal product is supplied with a claim to protect public health through a control of infectious organisms, which would go beyond the general knowledge of personal hygiene as a contribution to public health, considering the reasonable expectations of the average consumer, , that function is likely to be of primary importance, in which case the product has to be regulated under the biocides legislation. On the other hand, a public health claim relating to a function that has nothing to do with biocidal action, such as that of protecting the skin from the sun, does not attribute a primary biocidal function to a product.
- 47) Solutions to some initial concrete cases based on these principles discussed in this paper are proposed in the annex to this document. The annex is intended to be a living document, where new examples can be added as they become known.

⁶ OJ L 265, 26.9.2006, p. 39.

⁷ For an analogy, see Judgment of the Court of 21 March 1991 in Case C-60/89, ECR 1991, Page I-01547, where the Court clarified that where a given product is supplied with the intention of providing certain health benefits, and falls within the definition of two product categories (in that case cosmetics and medicinal products) of which one is subject to more rigorous rules because of its implications for public health (in that case the medicinal products legislation), the product in question may have to be made subject to the rules of the latter category.



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EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate A – Green Economy
ENV.A.3 - Chemicals

SPECIFIC CASES OF COSMETIC-BIOCIDE LEGISLATION BORDERLINE

Listed below are some concrete illustrative examples of products which could fall under both the “cosmetics” and “biocidal” products definitions, as well as suggested applicability of the legislation in question.⁸ This Annex is not intended to discuss products which are considered as medicinal products, since, according to Article 2(1) of Directive 2001/83/EC, the classification as a medicinal product always takes precedent over any other product classification, and hence the borderline between the cosmetics and biocides legislation will never be relevant for a product which may fall within the definition of a medicinal product.

The list has been established solely on the basis of product claims. Claims may be a strong indication of the intended product function and consumer perception, and will therefore help in forming a preliminary assumption on a product's regulatory status. However, **it is important to assess all the characteristics of the product, including not only the claims, but also its overall presentation, the purposes of its use, and its composition, on a case by case basis before making a final decision.**

⁸ The list of examples was originally provided in a guidance document drafted by the Irish competent authorities for biocides and cosmetics, but the conclusions have been modified.

Mouthwashes and toothpastes

These products are usually intended for application on the teeth and the mucous membranes of the oral cavity with a view mainly to cleaning them, perfuming them, and/or keeping them in good condition. They will therefore usually constitute cosmetic products within the meaning of the CPD and the CPR.

In some cases, these products claim to be supplied with a biocidal function. In this case, it needs to be assessed whether :

- the biocidal function is inherent to the cosmetic purpose, or
- a claimed biocidal function of the product, that is not inherent to delivering its cosmetic benefits, is presented as the main function of the product. In this case, the product is no longer a cosmetic and will have to comply only with the BPD and the BPR; or
- the cosmetic function remains the main function and a claimed biocidal function that is not inherent to the product's cosmetic benefit is presented as a secondary function. In this case, the product is a cosmetic product that remains exclusively regulated by the CPD and the CPR, and not by the BPD and the BPR;

Table 1: Examples of presumed classification for mouthwash and toothpaste products

Labelled Claim	Presumed product classification and applicable legislation, based solely on the claim
Protect teeth; protects teeth and gums; helps protect teeth from decay; protect tooth enamel	Cosmetic – protection function in line with the definition of a cosmetic. The product will have to comply with the CPD or the CPR.
Keep teeth and gums in good condition	Cosmetic – function of keeping in good condition is in line with the definition of a cosmetic. The product will have to comply with the CPD or the CPR.
Assists in protecting against cavity formation; Assists in guarding against cavities	Cosmetic - protection function in line with the definition of a cosmetic. The product will have to comply with the CPD or the CPR.
Antibacterial	Antibacterial is a biocidal function. However, control of the oral microflora is at the same time an inherent property of all oral care products. The term “antibacterial” on cosmetics is not understood as the control of infectious organisms but as a controlling action on the oral microflora by suppressing to some degree unwanted bacteria.

	<p>If it is clear from an assessment of all product characteristics that the product makes claims of human hygiene through control of infectious organisms, and hence claims to protect public health through biocidal action which would go beyond the general knowledge of personal hygiene as a contribution to public health considering the reasonable expectations of the average consumer in the market in question, the product cannot be considered as cosmetics and will have to comply exclusively with the BPD and the BPR.</p> <p>In the absence of any such claim, and if the assessment of all product characteristics shows that the main intended (and understood) function of the product is to clean, perfume, control body odours and/or keep the oral cavity in good condition, the product is a cosmetic product with a secondary biocidal function and will have to comply exclusively with the CPD and the CPR.</p>
Kills bacteria	<p>To kill bacteria is a biocidal function. However, control of oral microflora is at the same time inherent of all oral care products.</p> <p>If, however, it is clear from an assessment of all product characteristics that the product makes claims of human hygiene through the control of infectious organisms, and hence claims to protect public health through biocidal action which would go beyond the general knowledge of personal hygiene as a contribution to public health considering the reasonable expectations of the average consumer in the market in question, the product would usually not be considered as a cosmetic and will have to comply exclusively with the BPD and the BPR. The classification of this product would rather become an issue of borderline between the pharmaceutical products and biocides.</p> <p>In the absence of any such claim, and if the assessment of all the characteristics of the product shows that the main intended (and understood) function of the product is to perfume and/or control body odours, or keep in good condition, the product is a cosmetic product with a secondary biocidal function and will have to comply exclusively with the CPD and the CPR.</p>

<p>Kills up to 99.9% of bacteria</p>	<p>Because of the specific reference to a numerical reduction of bacteria, and depending on the overall presentation of the product, an average consumer could perceive and associate this claim with the prevention of infections. If not a medicine, then a product bearing such a claim would likely be a biocide – the product claims to serve a biocidal purpose.</p> <p>Even if the claim is presented as a secondary claim/function, it makes clear reference to human hygiene through disinfection/control of infectious organisms, and hence to public health protection through biocidal action, which would go beyond the general knowledge of personal hygiene as a contribution to public health considering the reasonable expectations of the average consumer in the market in question. In this case, the biocidal function is likely to be considered as the main function to which the cosmetic function has become secondary. In consequence, the product would likely be excluded from the scope of the CPD/CPR, and would need to comply with the BPD and the BPR.</p>
<p>Antiviral and words having the same meaning</p>	<p>Because of the specific reference to viruses, and depending on the overall presentation of the product, an average consumer could perceive and associate this claim with the prevention of infections. If not a medicine, then a product bearing such a claim would likely be a biocide – the use of the word ‘antiviral’ points to a biocidal (if not medicinal) function.</p> <p>Even if the claim is presented as a secondary claim/function, it makes clear reference to human hygiene through disinfection/control of infectious organism, and hence to public health protection through biocidal action, which would go beyond the general knowledge of personal hygiene as a contribution to public health considering the reasonable expectations of the average consumer in the market in question. In this case, the biocidal function is likely to be considered as the main function to which the cosmetic function has become secondary. In consequence the product would be excluded from the scope of the CPD/CPR, and would need to comply with the BPD and the BPR.</p>
<p>Antifungal and words having the same meaning</p>	<p>Because of the specific reference to fungus, and depending on the overall presentation of the product, an average consumer could perceive and associate this claim with the prevention of infections. If not a medicine, then a product bearing such a claim would likely be a biocide – the use of the word ‘antifungal’ points to a biocidal (if not medicinal) function.</p>

	<p>Even if the claim is presented as secondary, it makes clear reference to human hygiene through disinfection/control of infectious organisms, and hence to public health protection through biocidal action, which would go beyond the general knowledge of personal hygiene as a contribution to public health considering the reasonable expectations of the average consumer in the market in question. In this case, the biocidal function is likely to be considered as the main function to which the cosmetic function has become secondary. In consequence the product would be excluded from the scope of the CPD/CPR, and would need to comply with the BPD and the BPR.</p>
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Shaving gels

These products are usually considered to be cosmetics, since their main function is usually that of changing the appearance of the skin, while at the same time protecting it and keeping it in good condition. They will therefore usually constitute cosmetic products within the meaning of the CPD and the CPR.

In some cases, these cosmetic products might claim to be supplied with biocidal purposes. In this case, it needs to be assessed if

- the biocidal function is inherent to the cosmetic purpose, or
- a claimed biocidal function of the product, that is not inherent to delivering its cosmetic benefits, is presented as the main function of the product. In this case, the product is no longer a cosmetic and will have to comply only with the BPD and the BPR, or
- the cosmetic function remains the main function and a claimed biocidal function that is not inherent to the product’s cosmetic benefit is presented as a secondary function . In this case, the product is a cosmetic product that remains exclusively regulated by the CPD and the CPR but not by the BPD and the BPR.

Table 2: Examples of presumed classification for shaving gel products

Labelled Claim	Presumed product classification and applicable legislation, based solely on the claim
Helps prevent dry and tight skin	Cosmetic - function is in line with the definition of a cosmetic in that the product is protecting the skin from the effects of shaving and, as such, protecting the skin, which is the purpose of a cosmetic product. The

	product will have to comply with the CPD or the CPR.
Helps prevent skin redness associated with shaving'	Cosmetic - function is in line with the definition of a cosmetic in that the product is protecting the skin from the effects of shaving and, as such, protecting the skin, which is the purpose of a cosmetic product. The product will have to comply with the CPD or the CPR.
Reduces shaving rash/ skin burn due to shaving	Cosmetic - function of reducing here is in line with the definition of a cosmetic in that the product is protecting the skin from the effects of shaving and, as such, protecting the skin which is the purpose of a cosmetic product. The product will have to comply with the CPD or the CPR.
Soothes skin whilst shaving	Cosmetic – function in line with the definition of a cosmetic in that the product is protecting the skin. The product will have to comply with the CPD or the CPR.
Reduces skin redness due to shaving	Cosmetic - function of reducing here is in line with the definition of a cosmetic in that the product is protecting the skin from the effects of shaving and, as such, protecting the skin which is the purpose of a cosmetic product. The product will have to comply with the CPD or the CPR.
Shave cream/gel that kills 99.9% of facial bacteria	<p>Because of the specific reference to a numerical reduction of bacteria, and depending on the overall presentation of the product, an average consumer would likely perceive and associate this claim with the prevention of infections. A product bearing such a claim would likely be a biocide - the product is supplied with a biocidal purpose.</p> <p>Even if the claim is presented as secondary, it makes clear reference to human hygiene through skin disinfection/control of infectious organisms, and hence to public health protection through biocidal action, which would go beyond the general knowledge of personal hygiene as a contribution to public health considering the reasonable expectations of the average consumer in the market in question.. In this case, the biocidal function is likely to be considered as the main function to which the cosmetic function has become secondary. Therefore the product would be excluded from the scope of the CPD/CPR, and would need to comply with the BPD and the BPR.</p>

Deodorants

In general, antiperspirant and deodorant products are classified as cosmetics by virtue of their main function of perfuming the skin and correcting body odours. They will therefore usually be classified as cosmetic products within the meaning of the CPD and the CPR.

If such products are marketed with antibacterial or any other biocidal claims, it needs to be assessed whether:

- the biocidal function is inherent to the cosmetic purpose, or
- a claimed biocidal function of the product, that is not inherent to delivering its cosmetic benefits, is presented as the main function of the product. In this case, the product is no longer a cosmetic and will have to comply only with the BPD and the BPR,
- the cosmetic function remains the main function and a claimed biocidal function that is not inherent to the product's cosmetic benefit is presented as a secondary function. In this case, the product is a cosmetic product that remains exclusively regulated by the CPD and the CPR but not by the BPD and the BPR;

Table 3: Examples of presumed classification for antiperspirant and deodorant products

Labelled Claim	Presumed product classification and applicable legislation, based solely on the claim
Correct body odour; Mask body odour	Cosmetic – function in line with the definition and purpose of a cosmetic product with respect to correcting body odour and perfuming the body. The product will have to comply with the CPD or the CPR.
Protects against sweat; Masks sweat	Cosmetic – function in line with the definition and purpose of a cosmetic product with respect to correcting body odours. The product will have to comply with the CPD or the CPR.
Reduces the signs of sweating	Cosmetic – function in line with the definition and purpose of a cosmetic product with respect to changing their appearance and correcting body odour. The product will have to comply with the CPD or the CPR.
Minimise the effects of sweating	Cosmetic – function in line with the definition and purpose of a cosmetic product with respect to correcting body odour and perfuming. The product will have to comply with the CPD or the CPR.
Eliminate bacteria	To eliminate bacteria is a biocidal function. However, control of skin microflora is at the same time inherent to delivering the deodorant effect.

	<p>If the assessment of all the characteristics of the product shows that the main intended (and understood) function of the product is to perfume and/or control body odours, including through antibacterial action, the product is a cosmetic product with a secondary biocidal function and will have to comply exclusively with the CPD and the CPR.</p>
Antimicrobial	<p>Antimicrobial is a biocidal function. However, control of skin microflora is at the same time an inherent property of all deodorant products. The term “antimicrobial” on cosmetics is usually understood to mean a controlling action on the skin microflora by suppressing to some degree unwanted microbes.</p> <p>If the assessment of all product characteristics shows that the main intended (and understood) function of the product is to perfume and/or control body odours or other cosmetic function, including through antibacterial action, the product is a cosmetic product with a secondary biocidal function and will have to comply exclusively with the CPD and the CPR.</p>
Antibacterial	<p>Antibacterial is a biocidal function. However, control of skin microflora is at the same time an inherent property of all deodorant products. The term “antibacterial” on cosmetics is usually understood to mean a controlling action on the skin microflora by suppressing to some degree unwanted bacteria.</p> <p>If the assessment of all product characteristics shows that the main intended (and understood) function of the product is to perfume and/or control body odours, or other cosmetic purpose, including through antibacterial action, the product is a cosmetic product with a secondary biocidal function and will have to comply exclusively with the CPD and the CPR.</p>

Hand and body cleaning wash-off products: bar and liquid soaps, foams and liquids

Products in this category are cosmetics where the function of the product is primarily to cleanse or clean. If such products are marketed with any claims of biocidal activity or specific effects of reducing cross-contamination, they can also be considered as biocides.

If such products are marketed with antibacterial or any other biocidal claims, it needs to be assessed whether:

- the biocidal function is inherent to the cosmetic purpose, or

- a claimed biocidal function of the product, that is not inherent to delivering its cosmetic benefits, is presented as the main function of the product. In this case, the product is no longer a cosmetic and will have to comply only with the BPD and the BPR,
- the cosmetic function remains the main function and a claimed biocidal function that is not inherent to the product’s cosmetic benefit is presented as a secondary function. In this case, the product is a cosmetic product that remains exclusively regulated by the CPD and the CPR but not by the BPD and the BPR;

Table 4: Examples of presumed classification for hand and body rinse-off products

Labelled Claim	Presumed product classification and applicable legislation, based solely on the claim
Physically clean / visually clean	Cosmetic – the function is in line with the definition and purpose of a cosmetic product with respect to cleaning and improving the appearance of the hands or body. The product will have to comply with the CPD or the CPR.
Daily use, suitable for dry, and sensitive skin	Cosmetic – function in line with the use of a cosmetic product to clean and freshen the hands or body without acting as an irritant. The product will have to comply with the CPD or the CPR.
Unique antibacterial formulation	<p>The product appears to be supplied with a biocidal purpose. However, control of skin microflora is at the same time an inherent property of all surfactant based hand and body wash products.</p> <p>The term “antibacterial” on cosmetics is usually understood to mean a controlling action on the skin microflora by suppressing to some degree unwanted bacteria.</p> <p>If it is clear from an assessment of all product characteristics that the product is mainly intended to protect public health through biocidal action, which would go beyond the general knowledge of personal hygiene as a contribution to public health considering the reasonable expectations of the average consumer in the market in question, the product cannot be considered as a cosmetic and will have to comply exclusively with the BPD and the BPR.</p> <p>In the absence of any such claim, and if the assessment of all product characteristics shows that the main intended (and understood) function of the product is to clean, the product is a cosmetic product with a secondary biocidal function and will have to comply exclusively with the CPD and the CPR.</p>

<p>Germ Kill</p>	<p>The product appears to be supplied with a biocidal purpose. However, control of skin microflora is at the same time an inherent property of all surfactant based hand and body wash products.</p> <p>If it is clear from an assessment of all product characteristics that the product makes claims of human hygiene through controlling infectious organisms on skin, and hence claims to protect public health through biocidal action which would go beyond the general knowledge of personal hygiene as a contribution to public health considering the reasonable expectations of the average consumer in the market in question, the product cannot be considered as a cosmetic and will have to comply exclusively with the BPD and the BPR.</p> <p>In the absence of any such claim, and if the assessment of all product characteristics shows that the main intended (and understood) function of the product is to clean, the product is a cosmetic product with a secondary biocidal function and will have to comply exclusively with the CPD and the CPR.</p>
<p>Kills 99.9% of bacteria</p>	<p>Because of the specific reference to a numerical reduction of bacteria, and depending on the overall presentation of the product, an average consumer could perceive and associate this claim with the prevention of infections. A product bearing such a claim would likely be a biocide – the product clearly makes a claim of human hygiene through skin disinfection/control of infectious organisms , and hence a claim to protect public health through biocidal action.</p> <p>In this case, the biocidal function would go beyond the general knowledge of personal hygiene as a contribution to public health considering the reasonable expectations of the average consumer in the market in question. The biocidal function would therefore need to be considered as the main function to which the cosmetic function has become secondary. In consequence, the product would be excluded from the scope of the CPD/CPR, and would need to comply with the BPD and the BPR.</p>
<p><i>Antibacterial</i></p>	<p>The product appears to be supplied with a biocidal purpose. However, control of skin microflora is at the same time an inherent property of all surfactant based hand and body wash products.</p> <p>The term “antibacterial” on cosmetics is usually understood to mean a controlling action on the skin microflora by suppressing to some degree unwanted bacteria.</p> <p>If it is clear from an assessment of all product characteristics that the product is mainly intended to protect public health through biocidal action, which would go beyond the general knowledge of personal hygiene as a contribution to public health considering the reasonable expectations of the average consumer in the market</p>

	<p>in question, the product cannot be considered as a cosmetic and will have to comply exclusively with the BPD and the BPR.</p> <p>In the absence of any such claims, and if the assessment of all product characteristics shows that the main intended (and understood) function of the product is to clean, or provide another cosmetic function, the product is a cosmetic product with a secondary biocidal function and will have to comply exclusively with the CPD and the CPR.</p>
<i>Natural antibacterial</i>	<p>The product appears to be supplied with a biocidal purpose. However, control of skin microflora is at the same time an inherent property of all surfactant based hand and body wash products.</p> <p>The term “antibacterial” on cosmetics is usually understood to mean a controlling action on the skin microflora by suppressing to some degree unwanted bacteria.</p> <p>If it is clear from an assessment of all product characteristics that the product is mainly intended to protect public health through biocidal action, which would go beyond the general knowledge of personal hygiene as a contribution to public health considering the reasonable expectations of the average consumer in the market in question, the product cannot be considered as a cosmetic and will have to comply exclusively with the BPD and the BPR. By virtue of Article 69(2) of the BPR, biocidal products must not be labelled as "natural", and this claim will therefore have to be taken off the label in order for product authorisation to be granted.</p> <p>In the absence of any such claim, and if the assessment of all product characteristics shows that the main intended (and understood) function of the product is to perfume and/or control body odours, the product is a cosmetic product with a secondary biocidal function and will have to comply exclusively with the CPD and the CPR.</p>
Hygienically clean	<p>The claim refers to cleaning. It should be assessed if the function ‘hygiene’ needs to be considered as biocidal.</p> <p>The term hygiene has a broad spectrum of meaning which ranges from simple cleanliness to disinfection, depending on the context in which it is used.</p> <p>In the context of cosmetics, the term normally refers to ‘personal hygiene’, i.e. measures and products for cleaning the body and keeping it in good condition.</p>

	<p>In a context of classical biocidal products, the term ‘hygiene’ may be more easily understood as ‘disinfected’.</p> <p>It is therefore important to look at all product characteristics and in particular its presentation.</p> <p>If it is clear from an assessment of all product characteristics that the product is mainly intended to protect public health through biocidal action, which would go beyond the general knowledge of personal hygiene as a contribution to public health considering the reasonable expectations of the average consumer in the market in question, the product cannot be considered as a cosmetic and will have to comply exclusively with the BPD and the BPR.</p> <p>In the absence of any such claims, and if the assessment of all product characteristics shows that the main intended (and understood) function of the product is to clean, the product is a cosmetic product and will have to comply exclusively with the CPD and the CPR.</p>
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Hand and body gels, hand and body wipes and other leave-on products

These products can be classified as cosmetic or biocidal depending on their function, composition, mode of action and label claims. If such products claim to have an ‘antibacterial’ or similar effect, or if they make claims of having a biocidal action or specific effects of reducing cross-contamination, then one of the functions would in any event be biocidal.

It needs to be assessed whether:

- the biocidal function is inherent to the cosmetic purpose, or
- a claimed biocidal function of the product, that is not inherent to delivering its cosmetic benefits, is presented as the main function of the product. In this case, the product is no longer a cosmetic and will have to comply only with the BPD and the BPR,
- the cosmetic function remains the main function and a claimed biocidal function that is not inherent to the product’s cosmetic benefit is presented as a secondary function. In this case, the product is a cosmetic product that remains exclusively regulated by the CPD and the CPR but not by the BPD and the BPR.

It should be noted, however, that in the case of leave-on products, it is more likely that the product will have a disinfecting action, as the removal of dirt will not be as efficient as in the case of a rinse-off product. In addition, these products are often presented as implicitly preventing the spread of diseases.

In this case, therefore, it is all the more important that all the characteristics of the product, including the expected perception of the consumer, are taken into account.

Table 5: Examples of presumed classification for hand and body leave-on cleaning products

Labelled Claim	Presumed product classification and applicable legislation, based solely on the claim
Hand cleaner	Cosmetic – the function is in line with the definition and purpose served by a cosmetic product. The product will have to comply with the CPD and the CPR.
Physically clean / visually clean	Cosmetic – the function is in line with the definition and purpose of a cosmetic product with respect to cleaning and improving the appearance of the hands or body. The product will have to comply with the CPD and the CPR.
Antibacterial	Biocide – the product clearly makes a claim of human hygiene through skin disinfection, and hence a claim to protect public health through biocidal action. In this case, the biocidal function is likely to be considered as the main function to which the cosmetic function has become secondary. In consequence, the product would be excluded from the scope of the CPD/CPR, and would need to comply with the BPD and the BPR.
Kills a wide range of germs	Biocide – the product clearly makes a claim of human hygiene through skin disinfection, and hence a claim to protect public health through biocidal action. In this case, the biocidal function is likely to be considered as the main function to which the cosmetic function has become secondary. In consequence, the product would be excluded from the scope of the CPD/CPR, and would need to comply with the BPD and the BPR.
Kill bacteria	Biocide – the product clearly makes a claim of human hygiene through skin disinfection, and hence a claim to protect public health through biocidal action. In this case, the biocidal function is likely to be considered as the main function to which the cosmetic function has become secondary. In consequence, the product would be excluded from the scope of the CPD/CPR, and would need to comply with the BPD and the BPR.

Antiviral	Biocide – the product clearly makes a claim of human hygiene through skin disinfection, and hence a claim to protect public health through biocidal action. In this case, the biocidal function is likely to be considered as the main function to which the cosmetic function has become secondary. In consequence, the product would be excluded from the scope of the CPD/CPR, and would need to comply with the BPD and the BPR.
Kills viruses Virokill	Biocide – the product clearly makes a claim of human hygiene through skin disinfection, and hence a claim to protect public health through biocidal action. In this case, the biocidal function is likely to be considered as the main function to which the cosmetic function has become secondary. In consequence, the product would be excluded from the scope of the CPD/CPR, and would need to comply with the BPD and the BPR.
Hand/body sanitizer	Biocide – the product clearly makes a claim of human hygiene through skin disinfection, and hence a claim to protect public health through biocidal action. In this case, the biocidal function is likely to be considered as the main function to which the cosmetic function has become secondary. In consequence, the product would be excluded from the scope of the CPD/CPR, and would need to comply with the BPD and the BPR.
Disinfection of hands/other body parts	Biocide – the product clearly makes a claim of human hygiene through skin disinfection, and hence a claim to protect public health through biocidal action. In this case, the biocidal function is likely to be considered as the main function to which the cosmetic function has become secondary. In consequence, the product would be excluded from the scope of the CPD/CPR, and would need to comply with the BPD and the BPR.
Hygienically clean	<p>The product is presented with a function of cleaning. It should be assessed if the function ‘hygiene’ needs to be considered as biocidal.</p> <p>For leave-on products, it should be assessed if the claimed cleaning function is actually present.</p> <p>The term hygiene has a broad spectrum of meaning which range from simple cleanliness to disinfection, depending on the context in which it is used.</p> <p>In the context of cosmetics, the term normally refers to ‘personal hygiene’, i.e. measures and products for</p>

	<p>cleaning and keeping in good condition of the body.</p> <p>In a context of classical biocidal products, the term ‘hygiene’ may more easily be understood as ‘disinfected’.</p> <p>It is therefore important to look at all the characteristics of the product, and in particular its presentation.</p> <p>If it is clear from an assessment of all product characteristics that the product is mainly intended to protect public health through biocidal action, which would go beyond the general knowledge of personal hygiene as a contribution to public health considering the reasonable expectations of the average consumer in the market in question, the product cannot be considered as a cosmetic and will have to comply exclusively with the BPD and the BPR.</p> <p>In the absence of any such claims, and if the assessment of all product characteristics shows that the main intended (and understood) function of the product is to clean,, the product is a cosmetic product and will have to comply exclusively with the CPD and the CPR.</p>
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8.6 Face washes

These products can be classified as cosmetic or biocidal based on composition and labelling claims made. For example, a product marketed with a claim to ‘alleviate skin dryness’ might be acceptable as a cosmetic depending on how the product is presented. Should biocidal claims be made, and should they be important enough to deprive the product of its character as a cosmetic, the product would be excluded from the CPD/CPR, and hence have to comply with BPD/BPR.

Table 6: Examples of presumed classification for face wash products

Labelled Claim	Presumed product classification and applicable legislation, based solely on the claim
Keeps the skin in good condition	Cosmetic – the function claimed is in line with the definition and purpose served by a cosmetic. The product will have to comply with CPD and the CPR.
Assists in protecting against blemish formation; Enhance/improve the	Cosmetic – the function to assist in protecting against blemishes is in line with the purpose of keeping the skin in good condition and enhancing the appearance. The product will have to comply with the CPD and the CPR.

appearance of the facial area	
Assists in protecting against blackheads	Cosmetic – the function to assist in protecting against blackheads is in line with the purpose of keeping the skin in good condition. The product will have to comply with the CPD and the CPR.
Protects the skin against excess oil	Cosmetic – the function to protect is in line with the definition of a cosmetic and with the purpose of keeping the skin in good condition. The product will have to comply with the CPD and the CPR.
Protect the skin	Cosmetic – the function to protect is in line with the definition of a cosmetic. The product will have to comply with the CPD and the CPR.
Cleansing wash/scrub; Protecting wash/scrub	Cosmetic - the function to protect is in line with the definition of a cosmetic and with the purpose of keeping the skin in good condition. The product will have to comply with the CPD and the CPR.
Antibacterial	<p>The product appears to be supplied with a biocidal purpose. However, control of skin microflora is at the same time an inherent property of all surfactant based face / body wash products.</p> <p>The term “antibacterial” on cosmetics is not understood as ‘disinfecting’ or killing 99.9% of bacteria. It means a controlling action on the skin microflora by suppressing to some degree (but not totally) unwanted bacteria.</p> <p>If it is clear from an assessment of all product characteristics that the product is mainly intended to protect public health through biocidal action, which would go beyond the general knowledge of personal hygiene as a contribution to public health considering the reasonable expectations of the average consumer in the market in question, the product cannot be considered as a cosmetic and will have to comply exclusively with the BPD and the BPR.</p> <p>In the absence of any such claim, and if the assessment of all product characteristics shows that the main intended (and understood) function of the product is to clean, the product is a cosmetic product with a secondary biocidal function and will have to comply exclusively with the CPD and the CPR.</p>

Sun block with insect repellent

A sun block with insect repellent has two distinct functions which are both important to protect public health: to protect the skin from the harmful effects of the sun – addressed through the cosmetics legislation – and to repel insects – addressed through the biocides legislation. Since the sun blocking function is primary, the product is a cosmetic covered by the cosmetics legislation. However, the biocidal function of repelling insects is also primary, and therefore not covered by the cosmetics legislation. The product will therefore have to comply with both the biocides legislation and the cosmetics legislation.

The same reasoning would also apply to other sunscreen products claiming repellent effects for other harmful organisms, such as jellyfish.