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Cosmetics and biocides in the EU:
establishing the borderline

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Abstract The correct classification of a product which could be both a cosmetic or a biocide (a borderline product) is essential as this will determine the applicable legal framework. A wrong product classification can lead to product withdrawal from the market and increased costs. Among other factors, product presentation can be key in the classification of borderline products.

INTRODUCTION

Products such as antibacterial hand soap or antiseptic mouthwash are very commonly used in everyday life. But whereas hand soap and mouthwash are clearly cosmetic products, the fact that they have antibacterial or antiseptic properties might also lead to their classification as biocidal products. These can be then considered as "borderline" products between cosmetics and biocides. This article reviews the often subtle considerations required to push the classification of these products toward one side or the other of the borderline.

GENERAL OVERVIEW

Regulation (EU) No 528/2012 (1) defines a biocidal product as a product 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.

According to the Cosmetics Regulation (1223/2009) (2), a cosmetic product is 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.

These definitions clearly identify the characteristics of both product types, and differentiating between them is apparently straightforward. Some products may, however, have properties matching both definitions. In this case, the establishment of a clear borderline between a biocidal and a cosmetic product is crucial as it determines the legal framework under which a given product is to be put into the market, as they are mutually exclusive.

WHICH LEGAL FRAMEWORK TO CHOOSE?

Following a precautionary principle, the initial approach to this issue would be directly registering these borderline products as biocides, as the regulatory requirements are more strict and further controls or enquiries from national authorities would be avoided.

Nevertheless, there are financial considerations to be made. The registration of a biocidal product is complex, time-consuming and far more expensive than the notification of a cosmetic product. Additionally, the target consumer population might change depending on how the product is marketed.

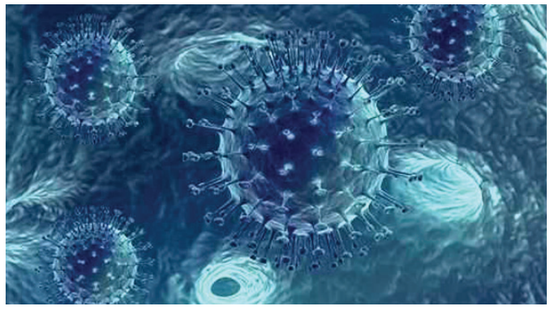
Therefore, as long as the consumer's safety is not compromised, considering the registration of the product as a cosmetic remains an option.

CONSIDERATIONS TO BE TAKEN WHEN ESTABLISHING PRODUCT CLASSIFICATION

Despite the recognition of the existence of borderline products, there is no formal legal text addressing these products in the EU.

The European Commission published its first guidance document in 2004 (3), aimed at guiding Member States on borderline cases between cosmetics and biocides. In February 2016, the second version of a manual on borderline products (including not only biocides but also toys, medicines and medical devices, among others) was completed by the Commission's sub-group on borderline products, which was published in 2017 (4). Nevertheless, none of these documents is legally binding. They should only be considered as a collection of practical cases to be used for guidance and not as the official position of the Commission.

According to the available guidance, and although **borderline products must be assessed in a case-by-case manner by the national authorities of each Member State in which the product is put into the market**, there are several steps to take into consideration when determining the classification of a product, as it is initially the product manufacturer or importer who will decide on the product's classification.



Firstly, if the product is intended to be marketed as a cosmetic, it must be intended to be applied only to an external part of the body (as defined by the Cosmetics Regulation).

Secondly, the product composition needs to be checked. If a product contains an ingredient which exceeds the concentration limits specified in the Cosmetics Regulation, it cannot be considered a cosmetic. Alternatively, if the product is to be classified as a biocide it must contain a biocidal active substance at an effective concentration. It is important to consider that the inclusion of a biocidal active substance in a product is not necessarily an impediment for its classification as a cosmetic; nevertheless, if the substance is present at a level sufficient to give the product biocidal activity, it is more likely to be considered a biocidal product. Product presentation and claims might be key factors here (see below).

Finally, we need to address the product's function. If the main function of the product is to clean, perfume, change the appearance of or protect the skin, keep it in good condition or correct body odours, then it may fall within the cosmetics regulatory framework. On the contrary, a product claiming a primary biocidal effect should clearly be considered a biocidal product. In order to clarify the product's function, presentation of the product is crucial.

PRODUCT FUNCTION AND PRESENTATION ARE KEY FOR PRODUCT CLASSIFICATION – THE IMPORTANCE OF CLAIMS

Even if the intention is that the primary function of the product is cosmetic (see definition above), this needs to be properly reflected in the presentation of the product: clear information to the consumer is crucial.

Many cosmetic products contain antibacterial ingredients and have biocidal effects (e.g. hand washes, antiperspirants, deodorants, anti-dandruff shampoos, mouth washes), and the Cosmetics Regulation allows for secondary biocidal claims to be stated. But for this biocidal action to clearly be considered a secondary function, appropriate positioning of any claims on the product label is of utmost importance. Other aspects of the product label such as font size, illustrations and layout also need to be carefully considered.

One key question is which biocidal activities can be considered as secondary to the main cosmetic functions. In general, biocidal claims are permitted in cosmetic products as long as they are not used to "imply that these products have characteristics or functions which they do not have", as stated in the EU Cosmetics Regulation. For instance, secondary biocidal claims like "anti-dandruff" in shampoos or "antimicrobial" in oral hygiene products are acceptable. Nevertheless, claiming a "disinfecting action" would trigger the classification of a product as a biocide or even as a medicine. A hand wash product whose main function is to clean, can claim a secondary antibacterial function and be classified as a cosmetic; but if the antibacterial action is intended (or implied) to be the main function, it must be then classified as a biocidal product.

Therefore, proper identification of the primary and secondary functions of borderline products, mainly through the correct design of product labelling, and careful selection of any associated claims (including advertising or testimonials), will influence the decision to classify a product as a cosmetic or a biocide.

THE FINAL STEP DECIDING PRODUCT CLASSIFICATION

As much as the suggestions above help determine which classification best applies to a given product, it is worth reminding that, in case of uncertainty, **the final decision will be taken on a case-by-case approach by the National Authorities of the Member States where the product is being commercialised.** It is to be noted that different National Authorities might have different opinions, that is, a product might be classified as a cosmetic in one Member State and as a biocide in another.

Therefore, the advisable practical procedure to find out which regime applies to a product that could be a cosmetic product claiming a secondary biocidal activity could be approaching the corresponding competent authorities within Member States. The authorities, on a case-by-case approach, taking into accounts the claims, the presentation and the ingredients of the product will decide whether it is a cosmetic product or a biocidal product. It is important to note that, despite the uncertainty, cases can be argued.

WHAT ARE THE RISKS OF INCORRECT PRODUCT CLASSIFICATION?

Proper classification of a product is of paramount importance, as an incorrect classification could lead to product recall by

the authorities, a request to redesign the product's label, a request to reformulate the product or a request to register the product under the appropriate legal framework, with all of the associated costs and delays. The associated risk with regards to consumer safety needs to be considered as well, if the intended use of the product is misunderstood by the public.

CONCLUSION

Classifying a product as a cosmetic or a biocide can be both a safety issue and a business decision. This decision needs to be based on sound arguments, and product presentation is of key importance. In the case of uncertainty, EU Member States National Authorities will decide on a case-by-case basis, based on the characteristics of the product.

REFERENCES

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About the authors

David is a specialist in mammalian toxicology, providing technical advice and support across all sectors.
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