Cosmetics and biocides in the EU: establishing the borderline

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) defnes 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 organs or with the teeth and the mucous membranes of the oral cavity or with the teeth and the mucous membranes of the oral cavity to improve the condition or correct defects.

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 fnancial considerations to be made. The registration of a biocidal product is complex, time-consuming and far more expensive than the notifcation 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 fnrst 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 personal care products) was completed by the Commission’s sub-group on borderline products, which was published in 2017 (4).

However, 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 ofcial 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. Firstly, the product manufacturer or importer 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 defned by the Cosmetics Regulation).

Secondly, the product composition needs to be checked. If a product contains an ingredient which exceeds the concentration limits specied in the Cosmetics Regulation, it cannot be considered a cosmetic. Alternatively, if the product is a biocidal product, it must contain a biocidal active substance at an efective concentration. It is important to consider that the inclusion of a biocidal active substance in a product is not necessarily an impediment for its classifcation as a cosmetic; nevertheless, if the substance is present at a level suficient 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 or of protect the skin, keep it in good condition or correct body odour, then it may fall within the cosmetics regulatory framework. On the contrary, a product claiming a primary biocidal efect 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 defnition 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 thus biocidal efects (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 positioning also need to be carefully considered.

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


About the authors

David is a specialist in mammalian toxicology, providing technical advice and support across all sectors. He has extensive and broad experience from working in industry and government departments in toxicological research, and in the areas of industrial chemical and agrochemical risk assessment. Prior to joining TSGE, David was a senior toxicologist at the UK Pesticides Safety Directorate. He has also held a parttime position as lecturer in toxicology at Leeds Beckett University. David has a degree in Toxicology and Pharmacology and has a PhD in Toxicology. He is a Diplomate of the American Board of Toxicology and also holds European Registered Toxicologist status.

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