Borderline Products in the EU: Obstacles for Manufacturers and Importers

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I. Introduction

In order to be compliant with the regulatory requirements for a specific product in the EU market, one crucial preliminary step is to identify and categorise a given product and determine to which regulatory framework it belongs. This can be a quite challenging task since there are products that lie between two categories consequently being affected by different regulatory frameworks. The term borderline product is used when a product lies on the edge of one product category and verges on another. Criteria which can lead to a product being regarded a borderline product are for example, its purpose (or intended use) and its function, in case they overlap with those of other product categories. Other relevant criteria are the product claim and the product composition (e.g. active substances) as they may advertise qualities of other product categories. Finally, the overall presentation of a product has also to be taken into account. A misleading presentation of the claim, i.e. its prominence or relevance may result in the consumer assuming that the product belongs to a certain product category, which may fall under a more stringent regulatory framework. The decision on a product's categorization must be confirmed on a case-by-case basis, considering all characteristics of the product.

Some borderline products may fall within the scope of two (or more) regulations or directives. In such a case, one of the following three options is applicable:

i. The product is regulated under both/all regulatory frameworks within scope
ii. The product is regulated under the most stringent regulatory framework
iii. A commission and/or court decision categorized the product and decided if i. or ii. applies

In the following sections examples of typical borderline products and their characteristics are presented.

II. Cosmetic and Biocidal Functions: Hand Cleaners

Article 2(1)(a) of the EU Cosmetic Product Regulation[1] describes the main purpose of cosmetic products as keeping the external parts of the human body, the teeth and the mucous membranes of the oral cavity in a clean and good condition. Due to the diversity of areas of application and wide range of product types, cosmetic products are prone to overlap with other product categories. The same applies to biocidal products. According to Article 3(1)(a) of the EU Biocidal Products Regulation[2], the main purpose of biocidal products is to destroy or control the effect of harmful organisms by any means other than mere physical or mechanical action. Although the features described do not sound similar at first glance, cosmetic products often claim functions or characteristics of biocidal products and vice versa.

In context of the current COVID-19 pandemic, the number of hygienic products placed on the EU market increased. Hand cleaners in form of gels or wipes often contain alcohol as active substance and claim both cleaning and antibacterial or antiviral functions. In order to determine whether a hand cleaner falls within the scope of the EU Cosmetic Products Regulation or the EU Biocidal Products Regulation, the primary purposes of the product is critical.

According to the borderline products manual[3] published by the working group on cosmetic products (chaired by the European Commission), prod-

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1 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (EU Cosmetics Products Regulation) [2009] OJ L 342/1

2 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (EU Biocidal Products Regulation) [2012] OJ L 167/1

3 Manual of the working group on cosmetic products (sub-group in borderline products) on the scope of application of the Cosmetics Regulation (EC) No 1223/2009 (Art. 2(1)(a)) [September 2020, version 5.2]

ucts with a primary cosmetic purpose and a secondary non-cosmetic purpose are most likely subject to the EU Cosmetic Products Regulation. This means, the main purpose of the product must be to cleanse or clean the skin.

However, it can be difficult to distinguish between a primary and a secondary purpose in case both claims seem to be equally strong or no main purpose is declared. Therefore, in 2020, two additional guidance documents were published in order to a) assist member states and industry in determining the applicable legislation for leave-on hand cleaners and hand disinfectants[4], and b) to illustrate which claims would not support the classification of leave-on hydro alcoholic hand gels as cosmetic products[5]. According to those documents, products containing a biocidal active substance marketed with any claims of biocidal activity or specific effects of reducing cross contamination would be subject to the EU Biocidal Products Regulation.

III. Cosmetic and Biocidal Functions: Sunscreen Products with Insect Repellent

Sunscreen products with insect repellent function also are typical borderline products. They protect the skin from damage caused by the sun, which is a cosmetic function. They also repel insects, which is a biocidal function. Thus, they may fall within scope of both the EU Cosmetic Products Regulation and the EU Biocidal Products Regulation. Usually, products with a primary cosmetic function and a secondary biocidal function are regulated under the EU Cosmetic Products Regulation only.

However, in case of insect repellents, the biocidal function is normally considered a primary function.

If the cosmetic function is secondary, the product will be regulated under the EU Biocidal Products Regulation only. It should be noted that Article 19(9) of the EU Biocidal Products Regulation requires that biocidal products intended for the direct application to the external parts of the human body, the teeth or the mucous membranes of the oral cavity shall not contain any non-active ingredients that may not be included in a cosmetic product pursuant to the EU Cosmetic Products Regulation.

If both the cosmetic and the biocidal purposes are of relevance then both regulations need to be taken into consideration. As mentioned before, the EU Biocidal Products Regulation shall not apply to biocidal products that are within the scope of the EU Cosmetic Products Regulation. Nonetheless, the European Commission published a note for guidance[6], which contradicts this view. According to the notes of guidance, sunscreen products with insect repellent function have to comply with both regulations. The same criteria apply to sunscreen products with repellent effects for jellyfish or other harmful organisms.

IV. Medical and Biocidal Functions: Insect Repellents

Some insect repellents claim to have a medical function, such as the prevention of diseases that might be transmitted by certain insects. This raises the question whether they fall within the scope of the EU Biocidal Products Regulation or rather of the medical legislation. Article 1(2) of the EU Medicinal Product Regulation[7] describes medicinal products as substances or combinations of substances, which have (amongst others) properties for treating or preventing disease in human beings. According to Article 2(1) of the EU Medical Devices Regulation[8], medical devices can also serve the purpose of disease prevention.

Thus, the manual[9] on borderline and classification on the community regulatory framework for medical devices discusses the case of an insect repellent, which claims to prevent diseases transferred by mos-

4 Guidance on the applicable legislation for leave-on hand cleaners and hand disinfectants (gel, solution, etc.) [2020]

5 Technical document on the scope of application of the Cosmetics Regulation (EC) No 1223/2009 (Art. 2(1)(a)), product claims of leave-on hydro alcoholic hand gels in the context of COVID-19 pandemic agreed by the Sub-Working Group on Borderline Products [2020]

6 European Commission note for guidance on borderline between the legislation for cosmetics and biocides [2013] CA-Jul13-Doc.5.1.h

7 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (EU Medicinal Products Directive) [2001] OJ L 311/1

8 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (EU Medical Devices Regulation) [2017] OJ L 117/1

9 Manual on borderline and classification on the community regulatory framework for medical devices [2018] Version 1.19

quitoes, and is intended for the use on human skin. The manual concludes that the product's primary purpose is to repel insects, which is a biocidal function. Furthermore, the product does not have an effect on the human body, but on the insects. Therefore, the product falls within the scope of the EU Biocidal Products Regulation. As mentioned earlier, for biocidal products intended for the direct application to the human skin, restrictions on certain ingredients defined by the EU Cosmetic Products Regulation must be considered. Please note however that, when defining the claim of a biocidal product it should be considered that its purpose is to protect humans, animals, materials or articles against harmful organisms, by the action of the active substances contained in the biocidal product and not the prevention of diseases as such. Therefore such claims can be considered misleading.

V. Medical and Cosmetic Functions: Skin Discolouration

Other borderline products sit on the fence between the EU Medicinal Products Regulations and the EU Cosmetics Regulation. Besides treating or preventing diseases, medicinal products also restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action (Article 1(2) of the EU Medicinal Products Regulations). Many medicinal products are applied directly to the human skin in form of lotions, creams or ointments and thus, resemble many common types of cosmetic products. Furthermore, medicinal products may advertise cosmetic functions, such as moisturizing the skin. Cosmetic products on the other hand sometimes claim functions, which may be regarded of medicinal nature, such as soothing skin irritations.

Often the mode of action of a product is crucial for the decision whether the product falls under the scope of a certain regulation or is excluded from the scope. For example, products that lighten the colour of dark circles under the eyes can operate in different ways. Make-up products cover dark circles in order to hide them. Such products do not exert any pharmacological, immunological or metabolic action and fall within the scope of the EU Cosmetic Products Regulation. Other products reduce the dark circles by acting on the cause of the discolouration. Such products are regulated under the EU Medicinal Products Regulations as they penetrate the skin layers and restore, correct or modify physiological functions.

According to the borderline products manual[3] published by the working group on cosmetic products, skin-whitening products fall within the scope of the EU Cosmetic Products Regulation as long as the purpose of the product is not associated with the treatment of pigmentation disorders. Skin conditions such as melasma, chloasma and lentigo are considered medical conditions. Therefore, products treating pigmentation disorders are regulated under the EU Medicinal Products Regulation.

VI. Conclusion

Categorizing a product can be challenging but is essential. Determining the product category, identifying the regulatory requirements that apply, rectifying the claims, if required, and registering or notifying the product under the correct regulation or directive will ensure product compliance and pay off in the long run. Falsely categorizing or wrongly claiming and presenting a product may lead to unnecessary costs in product registration or notification and a delay in placing the product on the market. In case a product is placed on the market but is registered or notified under the wrong regulatory framework, authorities might request a product recall and impose sanctions against the product manufacturer or the person responsible for marketing the product.

The European Commission has published several manuals and guidelines addressing borderline product cases in a variety of different legislations. It is highly recommended to consult such documents and stay informed about the developments in the regulatory world.