CONUSBAT
Internationalization Regulatory Services
EU Regulatory Update
For Cosmetics, Personal Care
Fine Chemicals & Borderline Products

Reviewing Regulatory Approaches for 'Borderline Products' to Cosmetics

- A Simplified Biocidal Product Authorization -

The definition for borderline products is given on the website of the EU Commission's Directorate General, which is responsible for the cosmetics' regulation, the DG Growth. Stated there is the following: 'Sometimes it may be unclear whether a particular product is a cosmetic product under cosmetics legislation or whether it falls other sectorial legislation. In the case of these "borderline products", the decision on a product's classification must be taken on a case-by-case basis'[1].

Products borderline to cosmetics may be falling under medicinal products legislation, medical devices, general products or biocides, etc. A decision on what regulatory framework applies is to be based on taking into account all relevant factors relating to the product's presentation and function, nature and quantity of the ingredients, the product application, dosage and use specification, presentation of the product, claims, etc..

Depending on the product factors of presentation and function, a hand sanitizer may be falling under cosmetics, medicinal or biocides legislation.The EU's regulatory framework for biocides changed in 2013 to Regulation (EU) 528/2012 (Biocidal Products Regulation [BPR])[2]. The BPR applies with a transitional period for certain provisions and will repeal the Biocidal Products Directive (Directive 98/8/EC).

Biocidal products require pre-market authorization, which usually entails a comprehensive and expensive approach. In cases where products are borderline to cosmetics but where the product claims request that biocidal legislation is to be applied, a 'Simplified Product Authorization' may be reviewed, which the regulatory framework provides for. Support for the decision on applicable regulatory framework is given in guidance documents issued by the EU Commission[1&3]; the simplified compliance is further described on the European Chemicals Agency (ECHA) website[2].

A simplified authorization procedure generally aims to encourage the use of biocidal products that are less harmful for the environment, human and animal health. To be eligible for the simplified authorisation procedure a biocidal product must comply with all of the following conditions:

- All the active substances contained in the biocidal product appear in Annex I of the BPR & comply with the specified restrictions
- The product does not contain any substance of concern or nanomaterial(s), but is sufficiently effective
- The handling of the biocidal product & its intended use do not require personal protective equipment

If all of these conditions are met, the applicant seeking authorization should submit an application to ECHA through R4BP 3, the electronic biocides submission tool, indicating which Member State competent authority will evaluate the application. Where a simplified authorization is granted, the biocidal product may be made available on the market in other Member States without the need for mutual recognition. The authorization holder, however, needs to notify each relevant Member State 30 days before placing the product on its territory. This notification is also done in R4BP 3.

ECHA provides ongoing webinars on the implementation of the Biocidal Products Regulation. This Wednesday, 9. November (11.00-12.00, GMT +2 [Helsinki, Finland]), a webinar addresses the topic: 'Same Biocidal Products Application Process and the new Family SPC' concept, which are additional possibilities for the submission of biocidal product applications.

Further Links:

1) EU Commission: ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en
2) BPR / ECHA: echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr
3) Borderline Guidance: ec.europa.eu/DocsRoom/documents/13033/attachments/1/translations

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CONUSBAT Regulatory Services: Our expertise lies in EU legislation as well as in global compliance support for cosmetics, personal care, fine chemicals & the borderline industries. We provide safety assessments, substance inventories (SIs), registration dossiers, representation, i.e., REACH Only Representative (OR), Responsible Person (RP). We cooperate with strategic global regulatory partners for the core sectors we service.

CONUSBAT didn't write the regulation; our job is keeping you compliant with it!

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