Biocides

When is a biocide not a biocide? – when it is a cosmetic!

The term 'Biocide' is derived from *bios*, the Greek word meaning 'life' and the Latin *caedere* meaning to kill, so literally something that is capable of 'killing life'. The term is used to describe a diverse range of chemicals that are used to control harmful organisms (typically, but not exclusively, microorganisms). Biocides include products like disinfectants, preservatives and chemicals used to control microbial growth on surfaces, plus other products such as insecticides, repellents and rodenticides.

Historically the regulation of biocidal products and the active substances that they contain has varied considerably across Member States within the EU, with some products being regulated and others not. This was considered a barrier to free trade within the EU and resulted in the implementation of the Biocidal Products Directive (BPD) in 1998. The objectives were to harmonise the regulation of biocidal products throughout the EU; to provide a high level of protection for humans, animals and the environment; and to ensure that products are sufficiently effective against target species.

The Biocidal Products Directive was repealed and replaced by the Biocidal Products Regulation (BPR) which has applied since 01 September 2013. The move to the BPR has resulted in major changes to the biocide market within Europe, introducing, for example, new administrative processes, exclusion and substitution criteria for active substances and the regulation of articles treated with biocidal products.

The BPR does, however, retain the two stage evaluation process originally introduced by the BPD. The first phase of the evaluation involves the hazard and risk assessment of active substances with the intention of declaring EU wide approval of substances for their specified use(s). The assessment of all active substances notified into the process was originally expected to be completed over a 10 year period finishing in 2010. However, the scale and complexity of the process required an extension, initially to 2014, but subsequently to the end of 2024, in part to recognise the additional impact of the BPR on the process timing. It is important to note that, while active substances remain under evaluation, the existing national rules for regulating biocidal products remain in force in each Member State with only certain aspects of the BPR having effect. The second phase of the evaluation requires biocidal products containing EU approved active substances to be authorised in Member States where those products are placed on the market. Application for authorisation must be submitted for all existing biocidal products by the official Approval date for the active substance which is set in the substance Approval Regulation. For products that are based on more than one active substance, it is the Approval date for the last active substance in the product to be approved that triggers the deadline for the application for authorisation.
Biocidal products on the EU market should only contain approved active substances, or active substances being supported for approval through the EU review process. It is also a requirement of the BPR that, after 01 September 2015, only biocidal products consisting of, containing, or generating a relevant substance, can be made available on the EU market if the substance supplier or product supplier is included in the approved supplier list (Article 95 list) for the product type to which the product belongs. This list is regularly updated by the European Chemical Agency (ECHA) and is publicly available on the ECHA website.

We are now at the stage where many of the active substances that are used in consumer products are completing their evaluation and obtaining EU approval. This is triggering the process for authorising commonly used products such as antibacterial trigger sprays, household disinfectants, household insecticides and bleach based toilet care products. Also many of the preservatives used in household products are now being approved and since the BPR regulates treated articles, only articles treated with biocidal products containing approved preservatives (or those remaining under evaluation) can be placed on the EU market and specific labelling requirements introduced by the BPR must be followed.

Companies placing personal care products on the market should consider the border that can exist between cosmetic product regulation and biocide regulation and this topic has been hotly discussed for many years. This is relevant to products that claim an antibacterial action and the prominence, strength and specifics of the claim will determine whether the product will trigger regulation as a cosmetic or as a biocide. While there is guidance available, its interpretation can be subjective and 'grey areas' often remain that require decisions to be made on a case-by-case basis by regulators.

Preservatives that are used in personal care products are not considered to be within the scope of the BPR. Article 2 (j) of the BPR specifically excludes biocidal products or treated articles that are within the scope of the EU Cosmetics Regulation (EC) No 1223/2009. Such exemption includes a product which 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 Cosmetics Regulation.

The Cosmetics Regulation places the responsibility on the manufacturer or importer for the safety of the product and this is supported by restriction of some substances in Annexes II and III. Moreover, substances which are intended to be used as preservatives should be listed in Annex V of the Cosmetics Regulation in order to be allowed for this use. Interestingly some preservatives were not supported under the BPD/R but are listed in Annex V. Because of this they can be used in cosmetic products but cannot be used for the preservation of household products. While this fact is now widely known it has caught out some companies in the past.

Understanding the scope of the BPR in relation to cosmetic products and the process of product authorisation under the BPR can be complex. The amount of time and resource that will need to be allocated should not be underestimated and it is likely that companies will require specialist regulatory advice and support. It is important to be aware of regulatory deadlines that apply to products and to take advantage of the time that is made available for companies to support their products in order to stay on the market within the EU.

About the author

RICHARD ELSMORE
Managing Director
JSC International Limited (an ERM Group Company)
Harrogate, United Kingdom

Richard Elsmore *(ERM Partner and Managing Director of JSC International Limited) and is based in Harrogate in the UK. Richard has over 30 years' experience of working within the Chemical industry. He has a first degree and PhD in Microbiology from Cardiff University and also an MBA in Financial Studies from Nottingham University; he is a Chartered Biologist and a Fellow of the Royal Society of Biology.*

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