Biocidal Product Risk Assessments and Their Relation to Efficacy

By Mark Worthington

Under the EU BPR regulation, as part of the preparation of a biocidal product authorisation dossier, it is essential that your biocidal products are assessed for their safety to the environment and human health. Without a safe use, your product won’t receive an authorisation, even if it is currently on the market prior to approval of the active. At the same time you also need to demonstrate that your product is efficacious. If your product doesn’t “do what it says on the tin” then it also won’t receive an authorisation.

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But, did you know that risk assessment and efficacy are closely linked? With an ever increasing emphasis for protection of people and the environment, the line between achieving a safe use while maintaining good efficacy is becoming thin. But what to determine first, the efficacious range or the safe use range?

By definition, biocides all have the potential to be harmful to the user and/or the environment as a consequence of their use. Ideally, therefore, it is best to establish if your product would be safe before you invest in efficacy studies. If the risk assessment indicates an unacceptable risk, you may then need to consider making changes and performing efficacy testing at a lower product application/frequency rate and/or lower active concentration, which the risk assessment indicates would be safe. Determining the safe use scenario with modelling is far more cost effective than a battery of efficacy tests to determine the lower end of the efficacious range, only to discover later that this doesn’t give a safe use.

A ‘case study’ can be used to illustrate the point above:

A company is considering the development of an insecticide product containing 1% of insecticide A. The company wants to know if this would be ‘safe’ for humans and the environment before investing in efficacy testing, so decides to perform a preliminary risk assessment using appropriate emission scenarios for their chosen application type.

After risk assessment, it is clear that 1% of insecticide A is considered safe for human health, but not for the environment if applied and used as intended. In order to achieve an acceptable risk to the environment the amount of insecticide A applied has to be reduced. This can be achieved by reduction of the concentration of insecticide A in the product and/or reduction of the application rate of
the product whilst bearing in mind how the product is applied. Efficacy testing would then need to be performed to assess if the product would still work at this much lower concentration of active and/or lower product application rate. If proven to be efficacious, the company can then reduce the amount of active in their formulation, thus lowering both the manufacturing cost and the exposure to the user and the environment. The efficacy testing only needs to be performed once, a further cost saving. Clearly this is an attractive strategy to follow.

Eurofins can assess the potential human and environmental risks posed by your current/intended product(s) to determine if you already have the right balance between effectiveness and safety or whether you need to consider further options. In addition to this, we can advise if your product contains ‘substances of concern’. These also need consideration for product authorisation and may need to be risk assessed, providing appropriate information is available.

So, as soon as the last* biocidal active substance in your product is approved (or has a positive BPC opinion), we would advise that you prepare a preliminary risk assessment as a priority – you might be surprised how useful it could be when determining the future strategy of your biocidal product(s). It could change your plans and ideas about how you intend to formulate/test and market the product, saving you money in the process.

If you need any further advice on this area, we are happy to be of assistance! Please contact Mark Worthington with any queries

*not including ‘silent’ actives such as in-can preservatives