VCI Position: Biocides

REFERENCE PRODUCT IN ACTIVE SUBSTANCE DOSSIER

The authorisation regime for biocidal products under the Biocidal Products Regulation (BPR)[1] is based on a two-stage process: first, the active substance is approved, followed by the authorisation of the biocidal products containing that active substance.

The BPR, Annex II for active substances and Annex III for biocidal products, sets out in detail the information requirements that must be met.

According to Article 6(1)(b) of the Biocidal Products Regulation, an application for the approval of an active substance must include a dossier for the active substance that meets the requirements set out in Annex II, as well as a dossier for at least one representative biocidal product that meets the requirements set out in Annex III.

SUMMARY

The two-stage authorisation procedure ensures a high level of protection. Biocidal products permitted to be placed on the market in the EU are evaluated on the basis of specific data.

There is no need for an additional evaluation of extensive data on products not intended for marketing or use during the active substance authorisation process.

In practice, the requirement to provide information on a representative product as part of the active substance approval leads to considerable effort, duplication of work, unnecessary and, in some cases, very time-consuming tests, and delays. The VCI therefore calls for the requirement to submit a dossier for a representative product as part of the active substance approval to be removed.

Challenge: Data for a representative product

A basic distinction can be made between existing active substances and new active substances. Whilst biocidal products containing existing active substances are already available on the market, this is generally not the case for biocidal products containing a new active substance at the time the application for approval of that active substance is submitted. The following explains why – regardless of the differing starting points – meeting the data requirements for a product dossier poses considerable difficulties for applicants in the active substance approval process.

Existing active substances

There are various players in the biocides industry. In most cases, active substance suppliers and biocidal product formulators are different companies.

- This means that, when applying for approval of an active substance, the applicant generally does not have Annex III-compliant data on the available biocidal products of various PT.

[1] Regulation (EU) No 528/2012

- Even though, in principle, it would be possible to share data from the customer with the active substance producer, this does not usually happen, as the information is confidential business information. Another reason is that real biocidal products often contain several active substances.
- Applicants for the approval of active substances are therefore obliged to produce dummy products exclusively for the application, which are products that will never be placed on the market.
- The tests that must be carried out with these products solely to fulfil the information requirements in the active substance application are just as complex and time-consuming as those for biocidal products intended for marketing. Whilst many of the properties considered in this context are indeed relevant to the use of the biocidal product and are given special consideration during formulation, they are completely irrelevant to the assessment at the active substance level. Examples of this include long-term storage stability and metal corrosivity.

In any case, as of the date of approval, an application for authorisation, accompanied by a product dossier that meets the requirements of Annex III to the BPR, must be submitted in order to continue marketing the biocidal product containing the corresponding active substance. This ensures that a biocidal product can be assessed at short notice, even without a representative product being included in the application for approval of the active substance.

New active substances

A prerequisite for placing a biocidal product containing a new active substance on the market is a positive decision on an authorisation, which can only be applied for once the active substance in question has been approved.

- Consequently, no biocidal product may be on the market in the EU prior to the application for approval of an active substance.
- Applicants must therefore manufacture a biocidal product for each product type for which they apply. A representative product can cover only a very limited range of possible applications and formulations and does not include the wide variety of biocidal products that can be formulated using the same active substance or substances.
- Tests carried out for a product dossier on products not intended for subsequent marketing are just as complex and time-consuming as those for biocidal products intended for subsequent marketing.
- However, it is only during product development that a formulation is designed which focuses on properties such as efficacy or physical characteristics (stability, corrosiveness).
- The manufacturer of an active substance often does not have the deep specialist knowledge required to formulate a biocidal product.

Biocidal products containing a new active substance may only be placed on the market **after the evaluation has been completed**, i.e. **once authorisation has been granted**. An application for authorisation, accompanied by a product dossier that **meets the requirements of Annex III to the BPR**, is mandatory for this purpose.

Request

The requirement to submit a complete dossier for a representative biocidal product as part of an application for active substance approval ties up resources and generates unnecessary work for industry, the authorities and testing laboratories alike, without adding any value in terms of the protection of humans, animals or the environment. The manufacture, testing and evaluation of dummy products are disproportionate to the amount of additional knowledge gained. The submission of a complete dossier for a representative biocidal product for the approval of an active substance contained therein must not be a mandatory requirement in the active substance approval process – neither for initial approval nor for renewal.
Instead, it must be borne in mind that **the authorisation procedure for a biocidal product always involves a risk assessment** that takes into account the exact chemical composition and, as far as possible, realistic exposure scenarios for real products intended for the market.

Article 6(1)(b) of the Biocidal Products Regulation should therefore be amended as follows:

> *An application for approval of an active substance shall contain at least the following elements:*
> *(a) a dossier for the active substance satisfying the requirements set out in Annex II;*
> *(b) ~~a dossier satisfying the requirements set out in Annex III for at least one representative biocidal product that contains the active substance; and~~*
> *~~(c)~~ if the active substance meets at least one of the exclusion criteria listed in Article 5(1), evidence that Article 5(2) is applicable.*

This would make a significant contribution to avoiding unnecessary and duplicated work for both authorities and applicants, simplifying and speeding up processes, and reducing red tape, whilst maintaining the existing high level of protection.

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