VCI Position

Date of active substance approval – Periods for the authorisation of biocidal products

Legal basis

The Biocidal Products Regulation (EU) No 528/2012 regulates the making available on the market and the use of biocidal products, based on a two-tier assessment procedure:

- Assessment of the active substance and publication of an implementing regulation of the EU Commission
- Assessment of the biocidal product and authorisation

When an active substance is approved, this active substance can be placed on the market in authorised biocidal products. So-called existing active substances, i.e. substances being examined within the review programme according to Regulation (EU) No 1062/2014, can still be used in biocidal products while awaiting without authorisation pursuant to the transitional measures under Article 89. After positive evaluation of the active substance, the *"date of approval"* is stated in the implementing regulation for the approval of the active substance. By that date, the complete documentation (dossier) for an authorisation application must have been submitted for biocidal products containing the active substance at stake – if the biocidal product is to remain on the market for the duration of the authorisation procedure.

Existing situation

In the recitals of the implementing regulations for the approval of existing active substances it says that "A reasonable period should be allowed to elapse before the active substance is approved, in order to permit interested parties to take the preparatory measures necessary to meet the new requirements". This is to ensure that manufacturers of which biocidal products are already on the market and fall under the transitional measures (BPR, Article 89) have enough time to prepare product dossiers and to submit their applications for authorisation in due course, so that they are permitted to continue marketing the products without interruption.

Usually, the approval of active substances begins two years after their assessment by the Biocidal Products Committee (BPC). In practice, the timespan between the first discussion about an active substance in the BPC and publication of the implementing regulation for active substance approval in the Official Journal of the EU can vary considerably.

Example glutaraldehyde: The timespan between publication of the implementing regulation (02/10/2015) and the date of approval (01/10/2016) was under one year, because delays occurred following the first opinion of the BPC (01/10/2014).

Critical periods for ensuing applications for authorisation

Dossiers for the authorisation of biocidal products are based essentially on information from the assessment of the active substance which is published in the implementing regulation and also in the BPC assessment reports at ECHA. Preparing a dossier is appropriate not until the final documents have been published. Reference to preliminary documents (e.g. BPC opinions) involves the risk of drawing wrong conclusions from documents that cannot be reliably resorted to. Due to the lack of legal certainty, this approach is not advisable. In extreme cases, it cannot be ruled out that the Commission refuses approval of an active substance irrespective of a positive BPC opinion, so that a too hasty investment in a biocidal product dossier involves an economic risk.

For industry, short periods for preparing dossiers and submitting applications for authorisation constitute an enormous challenge for the following reasons:

- Personnel: Only with more input in terms of personnel generating and compiling data is possible. This has to be considered early in the staff planning of companies. Quite often, tasks need to be outsourced e.g. to consultants or laboratories. In such cases it should be ensured that the necessary services can be performed and completed within the prescribed periods.
- Planning of laboratory capacities: In-house as well as with external service providers, laboratory capacities need to be planned for preparing product dossiers. Otherwise, lack of available capacities can cause delays where laboratories have high capacity utilisation.
- Budget planning: The authorisation of biocidal products is linked with very high costs for the companies. These costs need to be included in the long-term planning of the respective budgets.
- Quality of product dossiers: Companies need sufficient time to prepare product dossiers completely and with great care. Due to later demands from the competent authority for further materials after dossier submission, hastily and sketchily compiled data would considerably delay the assessment process and render it more difficult.
- Union authorisation: For the Union authorisation of biocidal products a “pre-submission” to ECHA is foreseen at least six months prior to submitting the dossier. Also in this case, companies need an ensured adequate period for preparation of the dossier.

Serious consequences

For the above reasons, short periods can lead to applications for the authorisation of biocidal products not being submitted in due time by the companies. The consequences would be serious, for the market as well as for many companies:

- Products that have been established for many years cannot continue to be made available on the market 180 days after approval of the active substance. Only after evaluation of a relevant application and after granting of the authorisation these products may be placed on the market again.
- Downstream industries and operations, which use the concerned biocidal products in their products or production processes, would need to find adequate substitutes at short notice or stop production.
- Small and medium-sized enterprises (SMEs) are hit particularly hard by the short periods. They strongly depend on work from external service providers. A short-term reallocation of tasks to available staff is possible only to a very limited extent.

Moreover, a highly unequal treatment of the impacted market players is observed:

- As compared with companies that obtain approvals for active substances and also seek authorisation of biocidal products containing these active substances, companies seeking approvals solely for biocidal products are clearly more affected by short transitional periods. For identical active substances, the last-mentioned companies need a longer transitional period for preparing product dossiers as they do not have all necessary information already during the evaluation of the active substance but afterwards.
- Furthermore, the idea of European harmonisation and the equal treatment of all market players speak against different transitional periods for the various active substances.

Proposal for a solution

The BPR stipulates that the approval of active substances is granted by way of implementing regulations of the EU Commission, thus endowing the implementing regulations with a strong binding value. From our point of view, submitting applications for the authorisation of biocidal products on the basis of preliminary documents (e.g. BPC opinions) does not fulfil the relevant legal requirements. Therefore, for reasons of legal certainty the date of the approval of existing active substances needs to be linked with the date of publication of the respective implementing regulations in the Official Journal of the EU and should not depend on the discussion of the active substance in the BPC. Here, we think that a reliable and invariable period of two years would be appropriate, and we propose the date of approval to be two years after the date of publication of the implementing regulation.

In this manner, it can be ensured that an adequate period of time is available to the companies for preparing the product dossiers and for submitting their applications in the meaning of transitional measures as described in the Biocidal Products Regulation.