VCI-POSITION

Biocides: Extension of the Review Programme beyond 2024

During the CA meetings in March and June 2023 an extension of the review programme and thoughts towards an accelerated finalisation of the active substance evaluation were discussed. Due to multiple aspects the finalisation of the review programme is an important issue for the biocides industry as applicant and data owner.
VCI therefore would like to address some important points mentioned in the relevant CA documents *CA-March23-Doc.5.2* and *CA-June23-Doc.5.2*.

Development of Guidance

CA-March23-Doc.5.2 *- 2.(5) […]*
the mains reasons for the delays are the lack of resources allocated in Member States, delays of applicants in submitting additional data, complex technical questions on specific dossiers that need to be resolved first, evolution of technical guidance, and the adoption of new scientific criteria for the determination of endocrine disrupting properties which triggered the need for further data and further assessments.
CA-June23-Doc.5.2 *– 2. ii On the application of new guidance document the views were split, […]*
and *- iv On the opportunity to provide new information to show a safe use: one Member State considers that the opportunity should still be given to applicant to provide new information when the unacceptable risk identified results from the application of new guidance posterior to the submission of the previous information by the applicant.*

VCI-Opinion: We agree that there were numerous questions included complex technical aspects that required guidance to ensure harmonised implementation. However, it has to be kept in mind, that fulfilling new data requirements takes a certain amount of time to generate the respective results. Lab capacities are needed, necessary samples for testing need to be provided. For this reason, we are in favour of finalising the active substance approval process based on the original data sets as far as possible and to consider new guidance in a second step in the renewal process. Data requirements for the initial approval should be kept as simple as possible. This includes the principle of “one safe use“: The original dossier contains one safe use under the conditions applicable at the time. Changes in the BPR guidance on risk assessment should not be considered. If absolutely necessary for granting an approval in terms of fairness it should be possible to add data for showing a new safe use.
The lack of resources of member states is a severe problem for applicants. It is relevant not only for the finalisation of the Review Programme but for applications for new active substances and biocidal products as well. It thus has i.e. a strong negative impact on innovation. At the moment, for new dossiers such as for product authorisation, it is hardly possible to find a competent authority willing to accept a dossier for Union authorisation due to capacity issues. We favour a

primary focus on the finalization of the review programme as a core task without delaying new dossier/change submissions. The further development of guidance and other refinement aspects should be postponed. Nevertheless, the applicants should be given the realistic chance to improve a dossier if late in the process a data gap is identified in order to maintain the level playing field in comparison to the already approved dossiers (with data re-submissions).

Workload: Initial evaluation and renewal on top

CA-March23-Doc.5.2 *- 2.(8): The renewal of approval of various active substances for various products-types now runs in parallel, while, due to the delays referred to above, not all active substances have been assessed under the review programme for the same product-types. This does not allow an holistic view on the properties of active substances for the same PT, and does not ensure a level-playing field for economic operators on the market.*

VCI-Opinion: The parallel processes for initial approvals and renewals for the products of the same product type result in a severe market distortion. At the current situation, authorised and non-authorised biocidal products of the same product-types are sometimes legally available on the market in parallel for more than 10 years. This market distortion particularly burdens companies that produce "niche products" for special requirements but is an issue for all companies who want to comply with the complex requirements. Under certain circumstances, the consequences for companies can extend to their withdrawal from the market. We thus agree with the Commission's view that there is no level playing field and need for action. Nevertheless, it is of high importance not to prematurely decide a non-approval/non-authorisation.

Information on ED-properties

CA-March23-Doc.5.2 *- 2.1. (11): […] Member States must have requested the necessary information to the applicants, who must have already generated the required data or already launched the generation of the required data. The responsibility to provide all required data to allow a conclusion on the application for approval lays on applicants.*

CA-June23-Doc.5.2 *– 2.2.1. (11): Would Member States support setting a common date of 31 December 2025 (when all missing data on ED must be submitted by applicants? […] 31 December 2025 still leaves more than 2 years to provide data, which means a total of more than 7 years after the adoption of the ED criteria (in 2017). […] After 31 December 2025, the evaluation of the concerned dossier would either have to continue based on the available data, or when requested data have not been submitted by applicants, the provisions of Article 11 of the Review Regulation ([1]) and of Article 9(1)(b) of the BPR ([2]) would be applied by Member States, ECHA and eventually the Commission.*

([1]) Absence of data is considered as a withdrawal of the applicant.

([2]) The BPR states that: **The Commission shall, on receipt of the opinion of the Agency referred to in Article 8(4), either**: …. (b) in cases where the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2), are not satisfied **or where the requisite information and data have not been submitted within the prescribed period**, **adopt an implementing decision that an active substance is not approved.**

VCI-Opinion: It is important to remember that the information requirements on ED were not legally clear until the amendment of the BPR annexes II and III in 2020. From then on, test proposals could be made, and data generated. Besides, laboratory capacities are limited. Thus, the data required for the ED assessment could not be made available at an early stage. In addition, the responsibility for a potential delay cannot lie solely with the applicant, as vertebrate studies are not allowed to be performed without an official request from the authority. Discussions between authorities and applicants on which study has to be performed take time. In this process all available data has to be taken into account and literature needs to be reviewed carefully. Prior to starting a study, a notification of the test proposal and the agreement of the authority are necessary and, in most cases, required by the labs. A non-approval based on a lack of ED-study results is not justified.

New Guidance

CA-March23-Doc.5.2 *- 2.2.2.(20)b: […] It should be reconsidered whether there are valid reasons to apply new technical guidance developed by ECHA to already submitted applications, or whether new guidance should no longer be applied to review programme applications still under the evaluation phase in the Member States.*

VCI-Opinion: We are in favour to evaluate the initial approval on the basis of the original data and the original evaluation principles. Certain uses therefore should not be excluded from approval due to open questions. Not evaluated questions should be taken up in the renewal process. Only at this stage new data should be considered. The consideration of even smaller changes in already planned tests is very problematic.

Decoupling BPR and CLH processes

CA-March23-Doc.5.2 *- 2.2.2.(20)d: Suspension of the progress of dossiers pending a RAC opinion on the harmonised CLH of the substance when the harmonised classification concerns an exclusion criteria…*

CA-June23-Doc.5.2 *– 2. (12) Suspension of the progress of dossiers pending a RAC opinion on the harmonised CLH of the substance when the harmonised classification concerns an exclusion criteria, mutagen category 2: it is proposed to no longer await the outcome of the RAC opinion on this matter. The ECHA BPC is entitled by the BPC to make evaluation of biocidal active substance and set up its conclusions as regards to CMR properties, and related exclusion criteria.*

VCI-Opinion: We recognise the dilemma between the different timelines in CLP and BPR processes. Nevertheless, we acknowledge the competence of the RAC as a scientific committee and the legal process under CLP. The CLP process leads to more reliability and more harmonisation, including the possibility to comment through public consultation. After the decision on a harmonised classification every market actor must apply the foreseen classification at the same deadline. This means a more reliable comparability and a more transparent market situation.

Taking over the role of participant

CA-March23-Doc.5.2 *- 2.2.2.(23): As already referred in previous discussions in the CA meeting, the Commission will propose to remove the possibility to take-over the role of participants in the review programme following a first withdrawal: interested economic operators had large amount of time to manifest their support or joining the current applicant to support an active substance. Such possibilities have been unique to the biocides area. No new application should be accepted in the review programme 20 years after its start.*

CA-June23-Doc.5.2 *– 2. (13) Modifications of the Review Regulation: Taking-over mechanism: the provisions for taking over the role of participant will be removed for the Review Regulation. The Commission will start preparing a modification of the Delegated Regulation in this respect.*

VCI-Opinion: We reject the proposal to repeal completely the possibility to take over the role of the participant. Especially for active substances, for which Article 95 suppliers are listed and for which biocidal products are still on the market, this proposal could have grave consequences. Market actors are likely to rely on one participant in the RP. In addition, only in case of the withdrawal of the previous participant in the review programme a new participant can take over the role. If this participant stops supporting the substance and no other company is allowed to take over the role of the review programme participant, this may have great consequences for multiple actors in the supply chain as well as for the users including the need to give up the business.
The possibility of taking over must therefore remain in any case, so that companies that produce the active substance as e.g. Article 95-supplier or who use it in biocidal products as customers of listed suppliers cannot be forced to leave the market.

Conclusions and Requests

We welcome the open discussion on the extension of the review programme and the considerations on acceleration and measures to finalise the programme.
From our point of view there are three central issues that should be taken into account.

⬢ Improving focus – evaluation without new guidance

The application of new guidance and the discussion on further new guidance must be stopped at once and not only after 2024. This focus would promote a level playing field while allowing authorities to focus evaluation. We doubt that in the end the application of new guidance for a part of the approvals and authorisations is more beneficial than the application of older approaches to all of them.
We agree that certain topics need to be discussed and new developments should be considered. However, we are in favour to postpone new or more detailed requirements to a later stage when all active substances have passed the initial process.
Besides, authority's capacities are an important issue. Not only the evaluation in context with the approval of existing active substances under the Review Programme needs to be done. The number of applications for authorisation will further increase with the number of active substances approved. In addition to that, innovation only is supported, when new products may be placed on the market. Refinements in formulations, that may be implemented by changes of valid authorisations must be an easy and feasible possibility.

⬢ Granting level playing field

We observe that market distortion is more and more increasing. For the same use, there are products that are legally on the market but have never gone through the BPR evaluation process side by side with products that are already in the authorisation process for the second time. Thus, the burden on companies in terms of time and costs is very unequal.
Considerations of hard stops[1] for comparable substances or products in cases where applicants have little or no influence on is not fair and cannot be justified.

⬢ Considering data protection

According to Article 95(5), the data protection periods for existing active substances end on 31 December 2025 at the latest. Any further considerations must take into account that data which were not part of the original dossier should be protected beyond that date.[2] A fair and appropriate approach must be found, which also includes appropriate cost sharing for new studies on old active substances.

[1] ChemicalWatch in Existing Union authorisations for iodine-based biocidal products to remain valid, on 19 July 2023, about information by the commission: "While existing authorisations will remain valid, the authorities will not grant any new applications for iodine-based products. This will also affect those currently being processed."

[2] VCI Position on Data Protection under BPR

Contact: Dr. Evelyn Roßkamp
Product Safety
Science, Technical and Environmental Affairs
P +49 (69) 2556-1962| **E** rosskamp@vci.de

German Chemical Industry Association
Mainzer Landstrasse 55
60329 Frankfurt, Germany

www.vci.de | www.ihre-chemie.de | www.chemiehoch3.de
LinkedIn | Twitter | YouTube | Facebook
Data protection rules | Compliance-Guideline | Transparenz

- Identification no. in the EU Transparency Register: 15423437054-40
- The VCI is registered with registration no. R000476 in the Lobbying Register for the Representation of Special Interests vis-à-vis the German Bundestag and the Federal Government.

The VCI and its sector associations represent the interests of around 1,900 companies from the chemical-pharmaceutical industry and related sectors vis-à-vis politicians, public authorities, other industries, science and media. In 2022, the VCI member companies realized sales of ca. 260 billion euros and employed nearly 550,000 staff.