

VCI Position on the Draft ECHA Guidance

ASSESSMENT OF SUBSTANCES OF CONCERN IN THE AUTHORISATION PROCESS UNDER BPR

There has been a long-standing discussion about how substances of concern (SoC), as defined in Article 3(1)(f) of the Biocidal Products Regulation (BPR), should be taken into account in the authorisation procedure for biocidal products.

The new [ECHA Guidance on the BPR: Volume V – Substances of Concern](#) is intended to set out in detail how SoCs are to be identified and assessed under the BPR. The guidance is planned for publication in 2027. The VCI takes a very critical view of the draft, which is currently undergoing a consultation process. This concerns not only the required level of detail but also fundamental responsibilities. It is essential that the entire existing framework for chemicals regulation in the EU – in which REACH and CLP form the overarching framework – is taken into account!

DEMANDS

- › Completion of the Review Programme must have the **highest priority**. The new SoC Guidance should be postponed.
- › The complexity of the authorisation procedure must **not be increased** any further.
- › We call for a **balanced consideration** of co-formulants in the evaluation of biocidal products.
- › Co-formulants fall primarily within the **regulatory scope of REACH**. Any new data for these substances must be required within this legal framework.

Key Points of Criticism

Double Regulation: The Legal Framework Must be Respected

The aim of the BPR is to regulate the placing on the market and the use of biocidal products and to ensure harmonisation. This takes place through a two-tiered authorisation process, comprising the approval of the active substance and the authorisation of the biocidal product. Active substances are assessed under the Biocidal Products Regulation (EU) No 512/2012 (BPR) on the basis of a comprehensive dossier. **Any other substance used in biocidal products is already subject to general chemicals legislation.** They are subject to registration and information obligations under the REACH Regulation. The data requirements set out therein apply to them. With regard to classification, rules of the CLP Regulation apply.¹ Many aspects of the draft SoC Guidance are already regulated by the REACH and CLP Regulations. Any divergent and stricter provisions under the BPR thwart the overarching chemicals legislation and contradict the OSOA principle (One Substance – One Assessment) sought by the Commission.

- › There must be no double regulation. Data requirements for substances that are not used as active substances in biocidal products must be set out under REACH. The classification of a

¹ VCI Position on Approach to substances of concern in the context of BPR:

<https://www.vci.de/themen/chemikaliensicherheit/biozide/regelung-von-bedenklichen-stoffen-unter-bpr-vci-position-englisch.jsp>

substance falls primarily within the scope of the CLP Regulation. Classification is in the responsibility of the bodies established for this purpose and must follow the procedure defined in CLP, including the consultations provided for.

- REACH comprehensively controls the use of substances within the EU. The level of information and data required for REACH registration is appropriate to ensure the safe use of a substance within the EU. The identification of relevant hazards for physicochemical, toxicological and environmental toxicological endpoints is taken into account. As a matter of principle, this includes the use as co-formulants in biocidal products.
- Thresholds that are legally binding under CLP must also be used when classifying and assessing biocidal products.
- The applicant for the authorisation of a biocidal product receives, via the safety data sheet (SDS), all relevant information on substances used as co-formulants in the biocidal product. Additional sources of information include a harmonised classification or a clear and transparent self-classification under CLP. The applicant does not, in general, have access to studies or the relevant rights of use.
- The applicant under REACH is a downstream user and, as such, he has certain obligations laid down under REACH. Neither the applicant nor the evaluating authority under biocidal products legislation should be required to perform any additional tasks under REACH, in particular no in-depth review or supplementation of information in the REACH dossier, including the evaluation of literature, the application of QSARs and read across. This should be the responsibility of the REACH operators. We reject the explicit requirement for testing of co-formulants in the biocidal product evaluation and their dedicated evaluation under BPR.

Data Level of Detail: Balancing Costs And Benefits

In many points, the guidance calls for additional data as well as information on new and highly specific aspects. As a rule, when applying for a biocidal product authorisation, the applicant does not have data for each co-formulant that goes beyond what is included in the safety data sheet. In addition to the fundamental criticisms outlined in the previous section on double regulation, [the burden on applicants would be immense. It could result in data requirements not able to be met, not only by smaller companies.](#) It also remains unclear how the relevant data should be collected and assessed.

- Many of the issues addressed in the draft go beyond the text of the legislation. Certain criteria are explicitly described in the BPR, Article 3(1)(f). The vague provision regarding 'other grounds for concern' is interpreted very broadly in the guidance.
- Information on components with synergistic effects should be provided. However, it is not clearly defined at what point an effect is regarded as a 'synergistic effect' or how this should be dealt with. Furthermore, it should be noted that synergists are used with the aim

of enhancing efficacy against target organisms, and that this does not in itself give rise to concerns regarding other endpoints.

- Factors such as water are meant to be considered in the assessment of bioavailability.
- Overall, the impression is given that the guidance questions the classification of mixtures under CLP.
- Degradation products formed during storage are addressed. These, too, are to be assessed. However, no specific data requirements are set out.
- There is a risk that the requirements imposed by individual Member States may vary. A high level of detail could also be demanded in this regard. In any case, data requirements relating to degradation products should not be imposed under biocidal products legislation. This aspect would need to be covered by overarching legislation
- An assessment of endocrine-disrupting properties shall be made. In particular, with regard to potential environmental impacts, it is unclear what information requirements this will involve.
- A particularly critical issue is that there is no description of the conditions under which the absence of a relevant effect can be assumed. Clear criteria must be specified allowing the conclusion to be drawn that no relevant endocrine-disrupting properties are present. As the absence of an effect is not scientifically verifiable, clear criteria must be defined on the basis of which it can be determined that no relevant endocrine-disrupting properties exist.

VCI Requests

The chemical industry in Europe faces enormous pressure. The loss of technically suitable biocidal active substances means that, for an ever-increasing number of important applications, suitable substances and biocidal products **are no longer available**, or are available only to a limited extent. This can be clearly demonstrated by various examples. Innovation is largely lacking due to extreme costs and uncertainties in the processes involved.

Whilst many biocidal products have already undergone the authorisation process several times, other biocidal products for the same applications may still be marketed without authorisation, even more than 13 years after the BPR came into force. This results in a **significant market distortion**.

Continuously changing and vague requirements, which lead to inconsistent, unpredictable and overly conservative assessment approaches, additionally contribute to the excessive workload faced by assessment authorities and applicants. This further delays the review programme and **jeopardises the achievement of the BPR's objectives**.

In this situation, where the availability of biocidal products for essential industrial and public health applications is at risk, it is not appropriate to further increase the complexity of the authorisation procedure. Furthermore, there is no justification for substances already regulated under REACH to require an additional assessment when used in biocidal products. There appears to be no scientifically sound, risk-based rationale for this.

The VCI calls for a balanced consideration of co-formulants in biocidal products evaluation. **The guidance on the evaluation of SoC should be postponed** until all active substances and biocidal products have been assessed at least once.

In principle, it would be important to examine the added value that such a stringent new guideline and new data requirements would bring to the consideration of SoCs in the authorisation process. The following points must be taken into account in this impact assessment:

- » **Overarching legal framework:** REACH and CLP, occupational exposure limits and other applicable general rules establish a legal framework covering ensuring a high level of protection for human health and the environment and covering all mixtures.
- » **Workload:** Some biocidal products contain a very large number of co-formulants, which perform different functions within the product. An assessment of each single substance to the proposed level of detail would place an enormous workload on both applicants and regulatory authorities, without increasing the level of safety compared with relying solely on the information from the safety data sheet.
- » **Regulatory scope:** Applicants under the BPR act as downstream users with regard to the use of co-formulants under REACH. In this role, they must fulfil the obligations of a downstream user under REACH, however, they are not expected to generate their own data. A reference to the REACH data available from ECHA must therefore be sufficient for the assessment.
- » **Legal certainty and planning certainty:** The authorisation procedure for a biocidal product is very complex and time-consuming, particularly when product development and data collection are taken into account. Applicants therefore need legal certainty and appropriate transition periods. There must be no more changes to the procedure, no additional data requirements and no further increase in the administrative burden.

From the VCI's perspective, reference to the criteria set out in the REACH, CLP and POP Regulations, as well as assessment within the framework of these overarching chemical regulations, is entirely appropriate to ensure a robust assessment of biocidal products. Requirements, cut-off criteria and assessment principles set out in this regulatory framework must be applied when substances are used in biocidal products as well. Otherwise, multiple assessments will lead to inconsistent results, which is contrary to the objectives of the BPR, in particular the harmonisation of the market. As a general principle, the OSOA principle should be followed.

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- » 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.

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