VCI-Position on

Approach to substances of concern in the context of BPR

Background

In the context of union authorisations and national authorisations a number of questions has been raised on how substances of concern (SoC) should be handled in the authorisation process. The legal basis for this discussion is laid down in BPR[1]. Article 3(1)(f) gives the definition for substances of concern as follows:

> *(f) 'substance of concern' means any substance, other than the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the more distant future, on humans, in particular vulnerable groups, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect.*
> *Such a substance would, unless there are other grounds for concern, normally be:*
> - *a substance classified as dangerous or that meets the criteria to be classified as dangerous according to Directive 67/548/EEC, and that is present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC, or*
> - *a substance classified as hazardous or that meets the criteria for classification as hazardous according to Regulation (EC) No 1272/2008, and that is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation,*
> - *a substance which meets the criteria for being a persistent organic pollutant (POP) under Regulation (EC) No 850/2004, or which meets the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006;*

The ECHA Guidance on the BPR: Volume III Parts B+C[2] addresses the question what other "grounds of concern" are meant and makes an exhaustive proposal, which co formulants present in a biocidal product should be considered as SoC.

> *1. Classified substances that are taken into consideration when determining the classification of the product*
>
> *2. Active substances, other than those included in Annex I of the BPR, for which a draft final Competent Authority Report (CAR) (with agreed reference values) is available […] if they are present in the biocidal product at a concentration ≥ 0.1%.*
>
> *3. Substances that enhance the effect of the active substance in the product, e.g. synergists. [*
>
> *4. Substances that have been included in the […] [REACH] candidate list […] present in the biocidal product at a concentration ≥ 0.1%. […]*
>
> *5. Substances for which there are Community workplace exposure limits. […]*

[1] BPR: Biocidal Product Regulation (EU) No 528/2012

[2] Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, the relevant text can be found in the annex of this position, https://echa.europa.eu/documents/10162/23036412/biocides_guidance_human_health_ra_iii_part_bc_en.pdf

VCI points of view

The purpose of the BPR is to regulate and harmonise the making available on the market and use of biocidal products. The base hereto is a two-tiered authorisation process as it is laid down in the regulation, wherein the first step is the active substance approval, the second step is the authorisation of the biocidal product. Beside that, REACH[3] regulates the making available of substances in order to achieve a high level of protection. Active substances are considered to be registered under REACH as they are evaluated under BPR on the basis of an extensive dossier. Any other substance, that may be used in biocidal products, is covered by REACH.

The evaluation of any co-formulant in the context of biocidal product authorisation would cause a double regulation of this substance, contradictory to the OSOR principle[4]. This would not only mean a double burden for industry and evaluating competent authorities but also would cause severe problems in the context of data access and data sharing. The VCI would like to hint on the following points and arguments:

- From the VCI's perspective, the REACH and CLP Regulations should be invariably the "guardian legislation" that needs to be observed as soon as materials fall under the substance regime. Relevant substances with severe effects on human health or environment are identified under REACH[5]. Therefore, the VCI is critical of a broad definition of "substances of concern".
- From the VCI's viewpoint, the definition of substances of concern should be restricted to the criteria given in BPR 3(1)(f). The Guidance on the BPR: Volume III Parts B+C contains an exhaustive list of grounds for concern not being specified in the BPR legal text. The consideration of additional potential concerns going beyond the proposal of the Guidance would lead to lack of clarity for applicant as well as for evaluation authorities and is to avoid.
- It should be reminded, that the definition of a substance of concern in the BPR strongly is linked to an effect in the end product. If a substance does not trigger an effect in the biocidal product it thus is not meant to be an SoC.
- A restriction under REACH can restrict the manufacture, placing on the market or use of a substance as such, in a mixture or in an article. These restrictions may also relate to the use in biocidal products.
- The Safety Data Sheet (SDS) is foreseen to contain all relevant information and is subject to defined rules for the generation. As the formulator of a biocidal product acts as a downstream user he must be able to rely on the SDS of the co-formulants. On this basis the SDS for the biocidal product is generated following defined rules to comply with legal obligations. If there remain open questions on substances used as co-formulants, these questions have to be addressed under REACH.

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[3] REACH: Regulation (EG) No 1907/2006

[4] OSOR: „one substance, one registration", all information should be bundled in one data set.

[5] e.g. candidates for the (REACH) authorisation procedure and subsequent inclusion in Annex XIV.

Recommendations

The VCI strongly recommends a well-balanced consideration of co-formulants in the evaluation of biocidal products.

- **Workload**
  Some biocidal products may have a great number of co-formulants. The workload would be enormous for both applicants as well as for authorities.
- **Scope: REACH vs. BPR**
  The applicant under BPR acts as downstream user of co-formulants. As such he has to comply with obligations under REACH but has no obligation to own or to generate data of a specific substance beside the active substance. It should be sufficient to refer to available conclusions. Information on substances as co-formulants is in the scope of REACH, independent for which end product a substance is used.
- **Legal Certainty**
  The authorisation process of a biocidal product is very time-consuming, especially when product development and generation of data are taken into account. Applicants therefore need legal certainty and adequate transitional periods.
- **Know-how protection**
  The formulation of a biocidal product is an important intellectual property of the applicant and should not be published, as a matter of principle. The publication of substances contained in a biocidal product should be minimised to the essential information. A substance, for which the evaluation concludes no concern in the biocidal product thus should not be made publicly available with its content in the product.

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- Identification no. in the EU Transparency Register: 15423437054-40
- The VCI is registered in the “public list on the registration of associations and their representatives” of German Parliament (Deutscher Bundestag).

The VCI represents the politico-economic interests of around 1,700 German chemical companies and German subsidiaries of foreign businesses. For this purpose, the VCI is in contact with politicians, public authorities, other industries, science and media. The VCI stands for over 90 percent of the chemical industry in Germany. In 2018 the German chemical industry realised sales of 203 billion euros and employed ca. 462,500 staff.

Annex

Excerpt from Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017

Identification of Substances of Concern

A substance of concern (SoC) is defined in Art 3(f) of Regulation (EU) No. 528/2012/EC or the Biocidal Product Regulation (BPR) as follows:

Article 3 (f) 'substance of concern' means any substance, other than the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the more distant future, on humans, in particular vulnerable groups, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect. Such a substance would, unless there are other grounds for concern, normally be:

- a substance classified as dangerous or that meets the criteria to be classified as dangerous according to Directive 67/548/EEC, and that is present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC, or

- a substance classified as hazardous or that meets the criteria for classification as hazardous according to Regulation (EC) No 1272/2008, and that is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation

- a substance which meets the criteria for being a persistent organic pollutant (POP) under Regulation (EC) No 850/2004, or which meets the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006;

Therefore, a SoC is a co-formulant in a biocidal product which meets at least one of the conditions specified in Art 3(f) of the BPR, i.e. a classified co-formulant present in the biocidal product above the respective specific or generic concentration limit of Directive 1999/45/EC and/or the CLP Regulation and thus, leading to its classification. However, as it can be seen from Art 3(f) of the BPR, the legal text is vague on what constitutes a SoC on the basis of "other grounds for concern". It has been proposed that in addition to the three cases (three indents in the [ ] box above) of clearly defined SoCs specified in Art 3(f) of the BPR, the following co-formulants present in a biocidal product should be considered as SoCs:

1. Classified substances that are taken into consideration when determining the classification of the product according to Directive 1999/45/EC, Article 3(3) or according to Article 11(2) of the CLP Regulation. It should be noted that impurities might affect the classification of any such substances. This criterion partly overlaps with the requirements of Art 3(f) of the BPR. Ultimately, this criterion will additionally identify classified co-formulants that contribute, by additivity, to the classification of the biocidal product. It is noted that since the additivity principle of Directive 1999/45/EC or CLP Regulation applies only to acute toxicity and irritation/corrosivity, SoCs identified by this

criterion would be co-formulants classified for these endpoints, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves, but that together with other co-formulants/active substance(s) contribute to the classification of the product. Conversely, as the additivity principle of Directive 1999/45/EC or CLP Regulation does not apply to the other toxicological hazards under the scope of these legislations, co-formulants classified for these other hazards, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves are not considered SoCs on the basis of this criterion. Concentrations for classified substances taken into consideration when determining the classification of the product are specified in the relevant legislation (Directive 1999/45/EC and CLP Regulation).

2. Active substances, other than those included in Annex I of the BPR, for which a draft final Competent Authority Report (CAR) (with agreed reference values) is available (including draft final CARs for Product Types other than the one of the actual biocidal product under evaluation). This criterion identifies other active substances in the biocidal product that act as co-formulants (e.g. in-can preservatives). It is noted that active substances (acting as co-formulants in a product) should be regarded as SoCs because, due to their intrinsic biological activity, they are likely to possess toxicological activity. It is also noted that as many active substances do not hold harmonised classifications under the CLP Regulation, they may fail to be identified as SoCs by the first two indents of Art 3(f) of the BPR. These substances should be considered SoCs if they are present in the biocidal product at a concentration ≥ 0.1%.

3. Substances that enhance the effect of the active substance in the product, e.g. synergists. For such substances, critical information/data shall relate to the interaction between the active substance and the synergist, not only to the synergist itself. In such situations, an appropriate evaluation of the risks posed by the active substance in the presence of the synergist rather than an evaluation of the risks posed by the synergist itself should be undertaken. A generic concentration cut-off value (for their presence in a product) applicable to all synergists cannot be specified. On a case-by-case basis, a synergist should be considered a SoC, if it is present at a concentration that enhances the toxicity of the active substance, as indicated by the available data.

4. Substances that have been included in the list (the candidate list) established in accordance with the REACH Regulation, Article 59(1) or fulfil the criteria for inclusion in the candidate list, if not already covered by the criteria of Article 3(f) of the BPR. These substances should be considered SoCs if they are present in the biocidal product at a concentration ≥ 0.1%. It is noted this criterion will ultimately capture, over and above the clearly-defined SoCs specified in Art 3(f) of the BPR, endocrine disruptors (EDs) and substances with hazards of equivalent concern to CMR 1A or 1B (under the CLP Regulation).

5. Substances for which there are Community workplace exposure limits. A generic concentration cut-off value (for their presence in a product) applicable to all such substances cannot be specified. This should be determined on a case-by-case basis depending on the hazard profile, potency and exposure potential of the substance.