VCI position concerning the

Authorisation of Biocidal Product Families

Background

The Biocidal Products Regulation (EU) No. 528/2012 (BPR) describes the possibility of authorising several products under one application: as product families. Article 3(1)(s) defines a biocidal product family (BPF) as "a group of biocidal products having:

i. similar uses;
ii. the same active substances;
iii. similar composition with specified variations; and
iv. similar levels of risk and efficacy".

The "Note for Guidance – Implementing a new concept of biocidal product families"[1] concretised the implementation, covering concentration ranges for variations in individual meta-SPCs[2]. After the granting of an authorisation for a BPF, the authorisation holder can add a new product, which fits into the defined ranges, to the BPF. This is done by notification at least 30 days before the placing on the market to the competent national authority or to ECHA and the European Commission, respectively.[3] Then, no further assessment is carried out. In consequence the evaluation of a BPF considers the risks to humans, animals and the environment as well as the level of efficacy of all products, which theoretically may fall in the BPF, including those products whose composition is not yet known or never will be relevant for technical reasons. However, an authorisation for a BPF only is granted if it can be established that all biocidal products of the BPF – including the purely theoretical ones – fulfil the authorisation conditions.[4]

The reason for applicants using certain degrees of freedom regarding composition is mainly due to the aim of already considering potential future substitution requirements. Given the high activity in harmonised classification (CLH process) as well as the restrictions or authorisations of substances under REACH, more and more substances are evaluated as more critical than before and thus restricted in their usability. Finally, this has an impact on the potential use of such substances in biocidal products, too. For many components, therefore, technically comparable alternatives are summed up "preventively" in one application. This allows the authorisation holder at a later moment in time to carry out certain substitutions, as they will then be required, in a fast and non-bureaucratic manner.

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[1] CA-Nov14-Doc.5.8, updated by CA-March16-Doc.4.3

[2] CA-Nov14-Doc.5.8: *"In the context of the new BPF concept a meta SPC has to be understood as the description, with a similar structure as in the SPC of a single biocidal product […] of a group of products within the BPF […]"*; SPC: "summary of product characteristics"

[3] BPR, Article 17(6)

[4] BPR, Article 19(6)

Against this backdrop, the task of the competent authorities becomes all the more difficult the more degrees of freedom in composition are to be included in the considerations. This is reflected in the first experiences with applications for BPF authorisations in industry and the evaluating authorities. For this reason, ECHA is now discussing to what extent a limitation is necessary in the formation of product families.

It is understandable that the evaluation effort should be as proportionate as possible to the fees and that the BPF structure has to allow evaluation of the BPF dossier. However, the currently discussed modifications should not undermine the BPF concept. In this position paper, the VCI addresses the points of particular importance for industry and calls for an implementation of the BPF concept that meets the practical needs of companies.

Essential variations within a biocidal product family

Highly diverse product types are subject to the same rules of the BPR. Consequently, the approaches and priorities of the various applicants are different, too.

Therefore, further discussion has to consider specific situations to find a solution that fits for all actors. Taking into account all product types (PT), the following two points are deemed essential:

- **Variations in application (i.e. several *meta*-SPCs, low variance of composition in the individual *meta*-SPC)**

  Regarding niche products for applications with a very small market, the authorisation within a BPF often is the only way to keep these products available. At present, on the market there are products for different uses for which it makes sense to be summed up in one BPF. Some examples are disinfectants with concentrates or wipes which can partly be relevant for several product types, too. This results in different exposure scenarios, for example, because of widely different concentrations when comparing the concentrate and the ready-for-use product.

  In addition to that, different uses can lead to differences in classification and risk assessment and need to be considered separately. In the BPF concept, several *meta*-SPCs would be necessary. In most cases, in the individual *meta*-SPC the variance with regard to the composition is low.

- **Variations in composition (i.e. few *meta*-SPCs, high variance of composition in the individual *meta*-SPC)**

  In order to meet the different needs of customers, often similar products are made available on the market which differ in the single components of their formulations. Those products should be packed in one BPF in order to reduce the effort and to carry out the authorisation process reasonably. Examples are products of different colours. The variation of the content of different colour pastes should be possible in defined concentration limits.

  Given the similarity of uses (user categories, exposure scenarios), the risk assessment for many of those product variations is similar or the same. In

consequence, such product families typically consist of only one or very few different meta-SPCs. However, within this single or individual meta-SPC, many variations in composition can be described.

Starting points for solutions / Demands

The evaluation of product families requires pragmatic approaches. Therefore, it is essential to limit the assessment to “worst cases”. The evaluation of each individual product within a BPF would mean a disproportionate and unnecessary effort for those involved.

In order to reduce the complexity of a BPF and thus to facilitate the evaluation process, it would be helpful to group certain co-formulations according to their technical function. For example, a concentration range could be stated for the technical function (e.g. “solvent”) and chemical substances or mixtures suitable for this purpose could be described and then approved. This would allow to focus on those product variations which can really become relevant in practice at a later stage – while not covering purely theoretical product variants. Furthermore, applicants should concretely describe and specify as many as possible of the individual product variants, which they really want to market later on, in their respective composition.

For many products, the authorisation within a BPF is the only economically viable option to remain on the market. Moreover, this way of authorisation is greatly important for small businesses such as small and medium-sized enterprises (SMEs). In practice, their products often are covered by suppliers’ applications for a BPF. We do not see any alternative to authorisation within product families to keep such important products on the market.

Therefore, it must be possible to allow different meta-SPCs within one BPF if the variations in composition are summarised and described in a meaningful manner and in detail – so that the respective risk and efficacy can be well estimated based on the submitted data. In the individual case, this must be conclusive, comprehensible and workable. By those means, niche products and products with special requirements e.g. to their efficacy spectrum could be kept on the market.

At present, many applicants are trying to pre-empt potential future mandatory substitution for individual components already when applying for BPF authorisation. This causes a considerable level of complexity regarding the product composition which is not necessarily relevant, at least not at the moment in time when the applications are made. In principle, it would be appropriate to apply for changes in the formulation by using the option of a “change” (Implementing Regulation (EU) No 354/2013 on changes of biocidal products [...]) just when it is really necessary. The Regulation fundamentally distinguishes between *“minor changes”* and *“major changes”*.

While a *“minor change”* would be a fast and cost-effective alternative to covering potential formulation changes within a BPF, the procedure of a *“major change”* is often time consuming and involves high fees. Therefore the latter is not suitable for rapid changes in formulation.

From our viewpoint, it is not clearly defined what is included in a *"minor change".* Thus considerable uncertainties remain and lead to applicants including possible variations in the BPF – as the allegedly safer route for authorising such future products which become necessary due to limitations under other pieces of legislation, restrictions, classifications or authorisations. An unambiguous definition of *"minor change"* together with a broad and legally sound application of this principle would bring significant reduction in the number of *meta*-SPCs and in the variations proposed by applicants within product families. Thus, changes, which primarily focus on maintaining a comparable efficacy of the products within a BPF should generally be understood as *"minor changes"*. The subsequent change in composition of an authorised biocidal product should be brought in a more practice-oriented shape. Thus it would support a voluntary optimisation of the risk potential of biocidal products by the authorisation holder.

Furthermore, we consider a *"pre-submission"* meeting between the applicant and the evaluating authority as essential, where the framework conditions for a BPF are bindingly defined. Before the submission of the dossier, both the structure of the family and the data situation have to be discussed between these parties. This allows to identify any need for changes at an early stage and to respond to them in good time. Where necessary, the meeting should also address later discussions with the other authorities involved, e.g. within Union authorisations or mutual recognition. For industry and competent authorities, this course of action would enable more reliable planning. A further development of the IT tools regarding the possibility to copy already entered items of information would enormously facilitate the work of applicants and competent authorities and save much time.

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