HAPPY FAMILIES

Richard Elsmore and Samantha Wright of JSC International review the Product family options under the Biocidal Product Regulation.

The Biocidal Products Regulation (BPR)[1] regulates the availability and use of biocidal products within the EU. It aims to harmonize data requirements and assessment processes for biocidal active substances and products, while ensuring protection for humans and the environment.

The BPR has replaced the Biocidal Products Directive (BPD)[2] since September 2013. The BPR introduces a number of new concepts that impact how biocidal products and active substances are regulated. For example, under the BPD, frame formulations allowed similar biocidal products to be grouped together. With the BPR, this concept has been broadened and expanded through the introduction of product families.

Product families vs frame formulations

The BPD frame formulation allowed similar biocidal products, containing the same active substances of the same specifications, to be assessed together. Their compositions were to present only variations from a previously authorized biocidal product, which did not affect the level of risk associated with them and their efficacy. In this context, a variation allowed a reduction in the percentage of the active substance, and/or an alteration in percentage composition of one or more non-active substances, and/or the replacement of one or more pigments, dyes or perfumes, by others presenting the same or a lower risk, and which did not decrease its efficacy. Because of these restricted variations, the Directive tended only to have limited use.

Now, under the BPR, the product family is defined as a group of biocidal products having:

(i) Similar uses
(ii) Same active substances
(iii) Similar composition with specified variations (including all other co-formulants; not just pigments, dyes or perfumes)
(iv) Similar levels of risk and efficacy.

The text also provides that *the assessment of the biocidal product family conducted according to the common principles for the evaluation of dossiers for biocidal products set out in Annex VI of the BPR shall consider the maximum risks to human health, animal health and the environment and the minimum level of efficacy over the whole potential range of products within the biocidal product family.*

> “BIOCIDICAL PRODUCTS WITHIN A PRODUCT FAMILY SHOULD HAVE SIMILAR USES AND THE SAME ACTIVE SUBSTANCE.”

To summarize, biocidal products within a product family should have similar uses and the same active substances. Variations in the composition or the replacement of non-active substances should be specified, but may not adversely affect the level of risk or significantly reduce the efficacy of the products (Table 1).

Frame formulation (BPD)	Biocidal product family (BPR)
Specifications for a group of biocidal products having the ***same use and user type***	Group of biocidal products having similar uses
– must contain the ***same active substances of the same specifications***	– the active substances of which have the same specifications
– and their compositions must present only ***variations from a previously authorized biocidal product*** which do not affect the level of risk associated with them and their efficacy	– and presenting specified variations in their composition which do not adversely affect the level of risk or significantly reduce the efficacy of the products
– a reduction in the percentage of the ***active substance*** and/or	– a reduction in the percentage of one or more active substances may be allowed, and/or
– an alteration in percentage composition of one or more non-active substances and/or	– a variation in percentage of one or more non-active substances, and/or
– the replacement of one or more ***pigments, dyes, perfumes*** by others presenting the same or a lower risk, and which do not decrease its efficacy	– the replacement of one or more non-active substances by other specified substances presenting the same or lower risk
– the ***classification*** of any product within the frame formulation ***should normally be the same*** (Ref Note for Guidance on Frame Formulations Competent Authority meeting; *NfG on FF – CA-Feb11-Doc.6.1.a*)	– the product family can have different classification and labelling (C&L), but the hazard and precautionary statements must be the same for all products covered by one meta-SPC
– each component is specified with its allowable ***concentration range*** (*NfG on FF – CA-Feb11-Doc.6.1.a*)	– the quantitative composition shall indicate a minimum and maximum percentage for each active and non-active substance, where the minimum percentage indicated for certain substances may be 0%

Table 1 – Comparison of concepts of ‘frame formulation’ and ‘biocidal product family’[3]

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How to develop a product family

The product family is structured using the concept of a 'meta-SPC' (Summary of Product Characteristics). Because it contains products with different classifications and features (e.g. first aid measures), it is important to group products together in a meta-SPC.

All products within a meta-SPC have:

a) Similar compositions within a specified variation, which fall within the specified variations for components and concentrations ranges of the whole BPF
b) Similar uses resulting from the risk and efficacy assessment, which are associated to a common set of risk management measures (RMMs). However, products within a meta-SPC can have different RMMs and instructions for use linked to each authorized use (e.g. to a different user category or application method)
c) The same hazard and precautionary statements
d) A common set of first aid instructions, disposal, storage and shelf life.

A biocidal product family can consist of one or more meta-SPCs, with the number in the product family being carefully considered to allow post-authorization notifications.

A biocidal product family can include different user categories, target organisms, application methods, application rates, and frequency and fields of use. It can also include products containing more than one existing active substance or belonging to more than one product type. By definition, products belonging to a product family must have a similar composition within specified variations. Although the co-formulants may be included in the product family composition at 0%, all active substances contained in a biocidal product family have to be present in each product (content ≠ 0).

Different formulation types may belong to the same biocidal product family, provided differences in composition do not significantly affect overall conclusions from the risk assessment and efficacy evaluation. The risk assessment would be completed for the worst case product for human health and the environment (usually the most hazardous with maximum risk) and the worst case product for efficacy (usually the lowest active concentration thereby providing the minimum level of efficacy). The risk assessment must cover the range of products and all uses within the product family. However, where the assessment on the basis of an overall 'worst case' for the entire biocidal product family is not possible, the assessment may be focused at a meta-SPC level, taking into consideration the composition of the products and the different uses described in each meta-SPC.

Chemistry, Toxicology, Ecotoxicology, Fate and Efficacy are data requirements for a biocidal product family authorization. However, careful consideration of the products in the family may allow options to read-across from one product to all others within the family, with only specific individual testing required for certain endpoints.

It is necessary to specify if liquid formulations include water-based liquid, solvent liquids or emulsions and both concentrate and ready-to-use products can be incorporated into the same biocidal product family.

Products belonging to one family can have different classification and labelling, but the hazard and precautionary statements must be the same for all products covered by one meta-SPC. The products can also have different RMMs but each meta-SPC should have its own set of RMMs in order to facilitate the post-authorization notification of new products belonging to that meta-SPC.[4]

Options for authorization

The authorization decision will include a 'Biocidal Product Family SPC', which will be made available in the R4BP3 system (the central hub through which all biocides applications are made) and disseminated by ECHA, so they can be found by inspectors or the general public when searching by the product authorization number or trade name(s) of the products as they are made available on the market.

The information of the biocidal product family is presented in three levels plus details for dissemination (Table 2).

Submission of the biocidal product family dossier is via R4BP3 for either Union Authorization or National Authorization followed by Mutual Recognition. In both instances an evaluating Member State should be contacted to confirm they are happy to accept the dossier for evaluation. The evaluation of the biocidal product family shall follow the timings specified in the BPR Article 30.

1st level	2nd Level	3rd Level	Product Specific SPC (for dissemination)
General information: • Proposed family name • Product type(s) • Authorization holder, product manufacturer(s), active substance(s) manufacturer(s) • Formulation type(s) • Product family composition range	Meta-SPC containing the description of a group of products within the BPF having: • Product names • Family authorization number, including the suffix identifying the meta-SPC • PT(s) of the meta-SPC • Specific composition range for the meta-SPC • Hazard and precautionary statements • Intended uses, instructions for use, RMM's and other directions that are use-specific • General directions for use and disposal that are valid for all intended uses • The particulars of likely direct or indirect effects, first aid instructions, emergency measures to protect the environment • Conditions of storage and shelf-life of the product	• List of all product names included in the meta-SPC with authorization number and product specific suffix	• Authorization conditions will be the same as those in the meta-SPC with the exception of the full formulation details • Full formulations will be available on R4BP3

Table 2· – Information presented for a biocidal product family

New products in the family

Once the biocidal product family is authorized, it is possible to place new products on the market that can belong to the biocidal product family but were not identified in the original authorization.

A notification system can be used by the authorization holders to inform competent authorities that they intend to place on the market new products. The notification is completed via R4BP3 and requires the submission of the full formulation of the proposed new product, the trade name, the suffix to add to the authorization number and the meta-SPC to which the new product belongs. The notification is only a 30-day process before a new product can be placed on the market. This should be completed for each member state where the product is authorized if application was through mutual recognition.

The notification process is not required when the variation in composition concerns only pigments, perfumes and dyes within the permitted variations of the existing product family range.

Product Family Consortia

The product family concept has benefits that will allow companies to work together as consortia under the BPR. These benefits, which can offer significant cost savings, were not available under the BPD. By applying for Union Authorization (UA) for a Product Family reference dossier, individual consortia members are able to apply for UA or, following the recent amendment of the Same Biocidal Product Regulation,[5,6] apply for individual member state authorization for their products.

However, it is recognised the biocidal product consortia may not be the best option for all companies and products, with individual biocidal product families remaining the route chosen by many companies.

Summary

The BPR product family approach offers companies the benefit of reducing regulatory costs through grouping products together into families.

The product family can contain products within differing product types and different types of users (e.g. professional and non-professional). It may also contain differing application methods (e.g. wipes, sprays). The ability to vary the concentration of non-active substances (down to 0%) allows for considerable formulation variations to be accommodated.

It is highly recommended that pre-submission meetings are held with the chosen evaluating member state well in advance of dossier submission, allowing time to discuss the approach foreseen by the applicant and possible issues.

The combination of the Biocidal Product Family, Union Authorization and the Same Biocidal Product Regulation may offer companies lower cost authorizations through working together in consortia, although it is recognised that this approach may not suit all companies and products and may not always result in 'Happy Families'.

REFERENCES

1. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.
2. Council Directive 98/8/EC of 16 February 1998, Official Journal of the European Communities, 24 April 1998, L123/1.
3. Taken from Note for Guidance on handling the transfer from frame formulations to biocidal product families. European Commission CA-Sept13-Doc.6.2.c-Final
4. Note for Guidance on implementing the new concept of biocidal product families. European Commission CA-Nov14-Doc.5.8-Final.
5. Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.
6. Commission Implementing Regulation (EU) No 2016/1802 of 11 October 2016 amending implementing Regulation (EU) No 414/2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.