Webinar: How to manage your BPF

Questions and answers

ECHA organised a webinar on 15 October 2020 on how to manage a biocidal product family (BPF). It gave an overview of the state of play on BPFs in the EU. It also presented practical experience gained by a national authority and industry on the revised BPF concept.

This document compiles the questions and answers from the webinar. Editorial changes have been made to improve clarity and correct spelling mistakes. Similar questions have been combined into one. Questions raising several issues have been split and separate answers have been provided. Many answers have been revised or further elaborated after the webinar to provide better explanation. This document will not be updated.

For the most up-to-date advice on biocides, contact us or refer to our support material.

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Number	Question	Answer
1.	Is the BPF guidance applicable also to submissions made before 1 October 2019?	The BPF guidance may be applied for applications submitted before 1 October 2019, if the applicant agrees.
2.	Is there any official document where it is stated that it is mandatory, also for the authorities, to have the pre-submission meeting with them before starting to work on the BPF authorisation?	Annex III to the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) (point 2, paragraph 7 of the introductory part) provides that the applicant has the obligation to initiate a pre-submission consultation. This implies that the competent authority has to provide the opportunity to the applicant to have a pre-submission consultation. In the update of the Annexes to the BPR, this paragraph will be slightly amended.
3.	Will the competent authorities be available to meet the applicant or will it be difficult, considering the workload they are facing? Considering the new BPF concept, the pre-submission should be really early on the dossier building to ensure the applicant is on the good track.	It is difficult to predict the availability of the competent authorities for meetings, as it may depend on several factors. Nonetheless, according to the revised Note for Guidance, the applicant can approach competent authorities and request a meeting. These contacts should start as soon as possible, and no later than 18 months before the expected date/deadline for the submission of the application for product authorisation.
4.	The timeline of 18 months before the expected date of submission is very early, as often at that time the future applicants not even know of the date of approval yet (if they were not involved in the active substance approval process).	The timeline of 18 months before the expected date of submission is early, but this is to ensure as far as possible that potential issues are discussed and solved well in advance before the submission of the application for product authorisation.
5.	Can you recommend a proper timeline to have a pre-submission meeting? Seeing that Member States competent authorities only accept any agreement at the earliest after a positive BPC opinion on the approval of the active substance, this leads, in general, to not earlier than approximately 18 months before the active substance approval date.	It is important that, when an agreement to act as evaluating authority is reached between the applicant and the competent authority, pre-submission meeting (or meetings) is organised as soon as possible, noting that preparatory meetings can also take place before an agreement to act as evaluating authority is reached. The sooner such meeting (or meetings) takes place, the better, so there is enough time for complex issues to be addressed. However, it depends also on the competent authorities' approach on this.
6.	About the timeline: does a meaningful pre-submission meeting with a competent authority take place only after the active substance suppliers have been included in the Article 95 list?	The possibility to have a pre-submission meeting is totally independent from the inclusion in Article 95 of active substance suppliers. Furthermore, the Article 95 requirements only apply to the biocidal products made available on the market and thus, are not a prerequisite to making a product authorisation application. It is important to have a pre-submission meeting on time and discuss with the competent authority your potential application, the timeline and

		the strategy to address any data gaps that may exist.
7.	For Union Authorisation applications for BPFs, there is a Pre-submission for Union authorisation managed by ECHA. Will it be at this point that the applicant's BPF structure is agreed upon across the EU? If not, when will this happen? This has to be in place at an early stage.	We confirm that it is strongly recommended to make a pre-submission via R4BP 3, before submitting an application for Union authorisation. This is followed by a pre-submission consultation among Member States and the Commission, which aims at: obtaining from Member states the confirmation that the product would have similar conditions of use across the Union; seeking confirmation that the product falls within the scope of the BPR; and identifying the appropriate Product Type(s) (PT(s)). The structure of the BPF may be commented during this consultation stage, but this is not part of the objectives of the consultation and the outcome of the consultation is only advisory.
8.	In the BPF guidance, it is indicated that a competent authority can consider in each family a maximum of two pairs of uses that are considered as non-similar. Is this something that would be agreed in the pre-submission meeting?	Yes, this issue is normally agreed during the pre-submission meeting. It is strongly recommended that the structure of the family is agreed with the competent authority before the submission of the application for product authorisation.
9.	Can ECHA be consulted after a pre-submission meeting, where there are disagreements between the applicant and the competent authority as to what is required?	ECHA is not involved in discussions between the applicant and the competent authority as far as data requirements are concerned. ECHA can be consulted in case of procedural matters for Union authorisation, if clarification is needed.
10.	Can you elaborate further about the backbone composition? "Essential" is a very vague term. If you need the ingredient to be able to mix the formulation in the tank, is it essential? If you need the ingredient to keep the active substance or other parts of the formulation stable during storage, is it essential?	Please consider the following general examples: Water, active substance and complexing agent are mixed in order to obtain a clear solution. The complexing agent is essential because otherwise a suspension would be obtained. Without a stabilizer, the shelf life might be 4 weeks. With a stabilizer 12 month. Here, the stabilizer is NOT essential for the FORMULATION of the product. It is only relevant to prolong the shelf life.
11.	Is the backbone composition at the meta-SPC level or at the BPF level?	All the products within the BPF must be similar. Accordingly, the BPF must have one backbone (at BPF level).
12.	About the BPF concept of backbone formulation, could you indicate if it can be used for an individual product? For example, if a product has different perfumes, can these be included in a single NA-APP? Similarly, a product uses the same bulk, either as a spray or as wipes. In particular, Product 1 is a spray without perfume; Product 1 is in the form	The backbone is relevant for BPFs only, not for single products. If you have products with different perfumes you have a group of products. If they are similar, they can generally be authorised as a BPF. This would require one application for authorisation (NA-APP) of a BPF in R4BP 3. If you intend to place only two products on the market (Product 1 with

	of wipes without perfume; Product 2 is a spray with perfume; and Product 2 is in the form of wipes with perfume. Is an application for BPF possible?	perfume 1 and Product 2 with perfume 2) you can apply for two single product authorisations.
13.	Could wipes and liquid/spray (despite different perfumes) be included in one BPF?	If they are similar, they can be included in one BPF.
14.	Within the backbone concept, there are only the active substance, water and surfactant(s). Can alternative surfactants be included in the group as part of the same backbone?	Generally, only the active substance and water would be considered within the backbone.
15.	Can a BPF contain surface and hand disinfectants, provided that the ingredient backbone is the same? An example are an alcoholic disinfectant, e.g. 70 % ethanol with/without perfume for surface disinfection, and hand disinfectant. Both fall under the scope of disinfection.	Please consider that PT2, PT3 and PT4 are split into several use patterns each. Therefore, the answer to your questions depends on your use patterns. Please, identify your use patterns and enter them into the matrix. However, all the other similarity criteria must be fulfilled too.
16.	Is the BPF guidance available on the grouping of co formulant under the BPF concept?	Yes, the grouping concept is part of the BPF guidance.
17.	Is the document on the definition of co-formulants used in biocidal products, prepared by the ECHA Biocidal Products Committee Analytical Methods and Physico-chemical Properties Working Group (BPC APCP WG), available?	The document has been agreed by the BPC APCP WG, but it is not publicly available yet, since it has to be presented for adoption in the Coordination Group.
18.	Would normally a PT1 use and a PT2 use be seen as similar, hence be part of the same BPF?	Please consider that PT1 consists only of use pattern 1 (#1) while PT2 is split into several use patterns. Therefore, the answer to your questions depends on your use patterns within PT2.
19.	What happens if an intended use is not included in the matrix tool for identifying similar uses? Is the matrix tool available for all PTs?	All PTs are part of the matrix. If PTs are split in several use patterns, one of the patterns is called "Other".
20.	It seems that it is basically possible to have different states into one BPF, for example powders (no co-formulant) and a simple solution, although water is neither a part of the powder or the backbone composition. Is the underlying assumption correct that powders are applied equal to concentration of solutions?	Concentrates (e.g. an active substance powder to which water is added prior to use) and the corresponding ready to use products (aqueous solution of active substance powder placed on the market) are possible within the same BPF.

21.	Can a concentrate product (not to be used as such but only upon dilution) and the respective diluted ready-to-use product be part of the same BPF?	Yes, this is possible, but all the other similarity criteria must be fulfilled too.
22.	It is possible to submit an application for a BPF with PT3-PT4 uses with similar compositions?	Please consider that PT3 and PT4 are split into several use patterns each. Therefore, the answer to your questions depends on your use patterns. Please, identify your use patterns and enter them into the matrix.
23.	Regarding the worst-case product, can we imagine to have a worst-case for efficacy, one for physical-chemical properties and one for human health/environment?	Yes. Please, consider the BPF guidance for details (paragraph 55, page 12).
24.	How to consider the worst-case scenario for a product that can be used either neat (for certain uses) or diluted (for other uses)?	One would identify one worst-case composition. However, within the assessment one would consider for each use in the SPC applied for (e.g. brushing-neat and spraying with 10% solution) the corresponding in use concentration.
25.	Will there be a harmonized approach amongst Member States competent authorities with regards to worst-case assessments? Some competent authorities define the worst-case composition (WCC) over the whole BPF, whilst others break it down to a meta-SPC level, i.e. several meta-SPC-based WCCs. What is the impact on the BPC WG discussions for Union authorisations?	The BPF guidance is meant to ensure a harmonised approach among Member States. The guidance clearly defines "(53) In order to ensure a manageable size, the BPF must be defined by one core assessment…" and "(55) The assessment is based on one worst-case composition." If the guidance is not followed, this will be discussed among Member States during agreement on the SPC.
26.	Could you please also explain if the core assessment established for the human health and the environment risk assessment must be the same?	Different WCCs can be used for human health and environment.
27.	Could you please explain if the core assessment for the human health risk assessment must be common to the different scenarios or can there be a core assessment (a different core assessment) per scenario?	Please, consider slide 16 of Thilo Walther's presentation. There is one worst-case composition for human health risk assessment that is used for the assessment of each use/scenario.
28.	If a BPF contains products with a substance of concern that requires a risk assessment, do those products need to be placed in a separate meta-SPC?	There might be a need to present products in a separate meta-SPC (e.g. if a substance of concern triggers a different classification). Please, consider also slide 15 and 16 of Thilo Walther's presentation. In any case, there will be only one assessment.

29.	A human health/environment risk assessment is based on the worst-case. Why is information required on the best-case and what is the purpose of the best-case?	Please, consider section 4 of the BPF guidance. It is in your own interest to know the best-case composition in order to ensure one consistent set of risk mitigation measures (RMMs) per use.
30.	A human health/environment risk assessment only considers active substances and substances of concern and is calculated on a substance specific approach. Why is the definition of other co-formulants indicated and how should a best- and worst-case concentration of a co-formulant be defined, if the substance has no impact on the assessment?	Please, consider slide 17 of Thilo Walther's presentation. For example, the binder content of your products might be relevant, even if it is not a substance of concern.
31.	If a single worst-case assessment is done, how is an aggregate exposure assessment then performed as part of the risk assessment? Is the worst-case assumed across all use patterns? If so, this would be far too conservative and will never pass.	Further discussions are needed to clarify this aspect.
32.	In normal industry manufacturing, it is not possible to create dummy products easily to cover all variants for efficacy testing. How to fulfil the requirements?	The best approach would be to create a pilot batch or laboratory sample with proper Certificates of Analysis and traceable record keeping, to ensure that mixing specifications are met. This approach is ideally agreed with the competent authority either in a pre-submission meeting or subsequent help desk questions.
33.	Regarding the presentation of Ecolab: Creating a dummy product for efficacy testing seems possible, but how to deal with potential difficulties when formulating a non-real life dummy product (e.g. insolubility of ingredients, flocculation, phase separations)?	Excellent question and one which will be difficult to answer as Ecolab raised the exact concern. This will require case-by-case consultation with the competent authority to help define the exact agreed upon formulatable dummy formulation for assessment purposes.
34.	From the experience gained by industry, are 18 months sufficient to be able to provide all needed test (if to be redone), if the worst-case composition needs to be adapted after the pre-submission meeting with the competent authority?	It might be theoretically possible to generate the data (depending upon laboratory capacity and availability), but the impact on shelf-life and risk assessments will prove difficult, if not near impossible, to meet within 18 months.
35.	Apart from the Note for Guidance, are there any additional guidelines on how to select the worst-case product for stability and efficacy testing? If so, is there any draft available and when will it be published? When will the guidelines be mandatory? Will they have to be	A document on the selection of the BPF worst-case product for efficacy testing has been agreed at the ECHA Biocidal Products Committee Efficacy Working Group (BPC EFF WG) and at the BPC, and is available at echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/efficacy.

	applied also for on-going applications?	The document is not mandatory and is meant to provide recommendations on how to select the BPF worst-case product for efficacy testing. Applicability should be in line with the overall applicability of the BPF Note for Guidance.
36.	With the focus on backbone composition and WCCs, only theoretical products are assessed. However, as most products are existing for many years, only data (physical-chemical properties, efficacy) on actual products is available. How to deal with that?	According to Article 19(6) of BPR, the assessment must consider the whole potential range of products within the BPF. Accordingly, a BPF can only be authorised if any potential product fulfils the authorisation criteria. Therefore, appropriate data must be provided (if necessary, data on potential products). In order to profit from studies already available, one should design the BPF applied for in a way that it includes only relevant existing products and as little variations in composition as possible.
37.	For a family with 4 products, same active in water, same application method (nebulization), I have been asked to submit 4 phase 2, step 2 efficacy tests, because "very specific mode of application". Is there any explanation for that?	This is a very specific aspect which cannot be tackled without further information. Your question can not be answered during the webinar. Send us your question using our contact form: echa.europa.eu/contact
38.	There is still a lot of "CA interpretation" during evaluation, because we lack clear guidance.	Thank you for the feedback, we take note of it.
39.	Must testing for physical-chemical properties/stability and efficacy always be on the same formula? Can you still apply with the whole bundle of physical-chemical properties /stability tests if already available for each product (and avoid to find out a WCC for this part)?	You have to identify one appropriate biocidal product for "physical-chemical properties/stability" and one for "efficacy". They might be the same, but they must not be the same. Concerning physical-chemical properties/stability tests, there is no requirement for similarity in the BPR. However, given that the composition must be similar, you should be able to choose studies for one or a small number of products, in order to cover the whole potential range of your BPF.
40.	There is not much information in the literature regarding what will be a co-formulant positively or negatively affecting efficacy. Could the authorities create a document with co-formulants which they think will have a positive effect and ingredients which will have a negative one?	The approach, presented in the document on the selection of the BPF worst-case product for efficacy testing (agreed at BPC EFF WG and BPC), does group many co-formulants. The approach provides overall direction of what would be considered positively or negatively influencing efficacy.

41.	According to the BPR, the applicant shall notify the authority 30 days before placing to the market the product in the BPF. If the applicant does not hear from the authority about its notification within the 30 days, how the applicant should act?	According to Article 17(6) of the BPR, if the composition of a new product falls within the established ranges of the BPF, the authorisation holder only needs to notify the product to the authorities 30 days before placing the new product on the market. Notifications for placing the product on a national market must be sent to the relevant competent authority who has granted a national authorisation for a BPF. In the case of a Union authorisation the notification must be sent to ECHA and the Commission. All notifications must be sent through R4BP 3. For a national authorisation, where the competent authority does not object to the notification within the 30-day period referred to in Article 17(6) of the BPR, the product can be placed on the market. For Union authorisation, on receipt of the notification by the authorisation holder, ECHA verifies that the information provided is complete and in line with the terms and conditions stipulated in the authorisation granted for the BPF. If this is not the case, ECHA invites the authorisation holder to amend the notification accordingly. Once this verification is finalized (approximately within 30 days from the receipt of the notification), ECHA informs the authorisation holder.
42.	An increasing number of authorities are refusing to take new dossiers (product and active substances) which could mean a discrimination of companies because market access will become blocked. How is this in line with competition law and what will be done to increase capacities at authorities' side?	In the CA meeting it is regularly discussed what is the state of play of active substances and biocidal product procedures. In those discussions, the Commission highlights that competent authorities have to live up to their responsibilities included in the BPR. If necessary, the Commission may apply the available mechanisms to address the lack of respect of the provisions in the BPR.
43.	It sounds that there are now thousands of products because of the 2014 guidance. It is simply that these products are on the market. How should they be authorized now, is their assessment still ongoing?	In the CA meeting the applicability of the BPF guidance has been discussed and it was agreed that the guidance would apply for new applications submitted as of 1 October 2019. It may be applied for applications before that date, if the applicant agrees.
44.	Is there a template for the competent authority to sign, agreeing to evaluate an application for product authorisation?	Yes, the competent authority has the template.
45.	Many competent authorities denied to organise a first meeting to discuss a BPF structure and worst-case approaches, upfront to the active substance decision. Competent authorities should not be surprised that they do not get good dossiers, if they see the approach for the first time only one year before submission. What can applicants do here to improve their	The applicant is fully responsible for the content and quality of the dossier.

	dossiers?	
46.	How long is the average time taken from submission to approval for the 16 families approved so far?	The average time for granting the authorisation is a little over 3 years
47.	In terms of mutual recognition procedure: must every concerned Member State approve of the BPF agreed with the reference Member State? With such little experience, how will you avoid that Member States differ in the way they interpret the BPF guidance?	For the time being, experience is still limited and case-by-case considerations may apply.
48.	If the evaluation of a BPF is now limited to "one core assessment", can the premium in fees compared to a single biocidal product application now be justified? This can run into tens of thousands of euros (ignoring Union authorisation annual fees). What about the evaluating competent authority fees? BAuA charges 50k Euros for a single BP and 75k for a BPF. Many Member States double their single biocidal product cost for a BPF, can this now be justified on workload?	It is up to the applicant to consider what marketing strategy is the most appropriate for its range of products. Fees are only one of the parameters that can be taken into account. The fees payable to the evaluating competent authorities may vary between the competent authorities and are established in the national legal acts of each Member State.
49.	Is there any expected update of the SPC editor for BPF with more than 100 meta-SPC? How many meta-SPCs can be handled by the tool?	The SPC Editor does not have an explicit limit on the number of meta-SPCs that can be handled. However, experience showed that BPF with many meta-SPC and many products are processed more slowly. Regardless of the capacity of the SPC Editor to handle a certain number of meta-SPC, it is important for both the preparation of the applications and their assessment that the structure of the BPF is kept at a manageable size from the content point of view. If the BPF structure is too complex, it is difficult to be handled.
50.	Is there any official step in the BPR process to discuss also other factors, like the socio-economic analysis or consequences for downstream users (like for chemicals in CARACAL after the RAC opinion)?	In the context of product authorisation, any possible negative impact of non-authorising a biocidal product could be taken into account in several situations (e.g. derogations according to Articles 19(5) and 37(1) of the BPR).
51.	Will there be a revision of the wording of the BPF guidance? Many parts of the guidance seem to be incomprehensible both for authorities and industry.	The BPF guidance is relatively recent and experience on its application is still limited. Accordingly, a revision is not considered for the time being. However, if such a need is identified by the CA meeting the guidance will be revised.

52.	Will the supporting document for BPFs be updated to fit better to the BPF guidance document? Will the new document also reflect the formulation level (based on raw materials) and the level of final product (e.g. after reactions)? This is not currently implemented.	Yes, the supporting document to provide the overview of the BPF has been updated and is available at echa.europa.eu/support/dossier-submission-tools/r4bp/supporting-documents.
53.	When do you expect the newest PAR and BPF overview templates to be available?	We expect to make them publicly available on the ECHA website in the first half of 2021.
54.	When will it be mandatory to use the templates then? Copy-pasting takes time, in addition to the normal workload on a BPF dossier, whilst the old format normally has been filled in parallel to dossier preparation.	The timeframe to start using the revised PAR templates and confidential annexes by applicants and competent authorities for new applications for product authorisation, is 6 months after publication on the ECHA website. They could be used for existing applications on a voluntary basis, if considered useful. The timeframe to start using the BPF overview template is 3 months after publication on the ECHA website. Applicants can use it earlier, on a voluntary basis.
55.	Is the material of this webinar available?	The material (video recording, presentations and Q&A) is available on the ECHA website at echa.europa.eu/support/webinars.