Validation check list for BPR product application

The Biocidal Products Regulation 528/2012 (BPR) dictates which data and information the applicant needs to submit to the evaluating authority when applying for a product or a biocidal product family (bpf). To enable a smooth evaluation process, Ctgb has made a validation check list per discipline. In accordance to the BPR, these check lists describe the minimum of data and information that will be checked by Ctgb. Next to that, it is essential that the data and information are placed in the correct PAR and SPC template.

In the validation phase, Ctgb checks whether the submitted data and information meets the demands as described in the BPR. This means that in accordance to the BPR the data will not be evaluated during the validation. The purpose of the validation is to determine whether the submitted data can be used to start the (risk) assessment. When the dossier meets this requirement, Ctgb is able to validate or reject the dossier.

In this document the validation checklists of the disciplines APCP, Efficacy, Human Health (HH) and Environment are given.

Validation check list

Analytical methods and Physico-Chemical Properties (APCP)

What is needed for the PAR?	**Points to be checked**	**Additional information**
Manufacturers of the active substance(s)	- Are the actual plant locations filled out? - Are all sources evaluated? - If not: ask the applicant to apply for technical equivalence	
Clear composition	- Concentration ranges of active substance and co-formulants clear and consistent - Purity of active substance clear and in agreement with implementing regulation - Chemical identity of co-formulants clear - For biocidal product families (bpf): information on level 1, 2, and 3 should be presented - For bpfs: similar composition within the biocidal product family (see bpf guidance)	The risk assessment of Human Health and Environment depend on the composition. Therefore, this information needs to be checked before the start of the risk assessments.
MSDS	- Are MSDSs provided for the active substance, the product(s) and all co-formulants? - Are they in English? - Do they contain CLP classification? - Are they revised within the last 5 years?	
Co-formulants	Are co-formulants present in the product that may be active substances and/or included in annex 1 of the BPR?	SoCs are relevant for the risk assessment for Human Health and Environment.

	If so: a justification should be provided explaining why the active substance does not contribute to the efficacy of the product. The co-formulant is considered a SoC .	A justification can be supported by efficacy studies.
Support of the family structure (in case of a biocidal product family, BPF)	Is the family structure supported on level 2 (or 1)? If not → ask for it This implies that the biocidal product family is supported on level 1 or 2, not on individual product level. It is clear per physical/chemical end point why certain compositions are tested (and hence represent the bpf on level 1 or 2)?	The strategy to support the BPF can be included in the confidential annex
Formulation type	Is the formulation type correct? If so, are all technical properties provided?	
Packaging	Is the packaging information clear? Is it clear in Table 2.1.7 to which meta each package belongs? When relevant, it should be specified per packaging type if it is for prof or non-prof use If one of the packages is a spray (either trigger spray or aerosol): are spray characteristics & MMAD provided?	Information on packaging type per meta is relevant for Human Health and Environment
Shelf life	Is a shelf-life study available in the packaging material applied for? Are relevant technical properties determined before and after storage? Are all relevant substance of concern concentrations determined before and after storage? (only substances of concern that can change in concentration during storage are relevant, like for example hydrogen peroxide and acetic acid in peracetic acid dossiers)	
Waivers	Are waivers for physical chemical hazards according to the endpoint specific guidance?	
Analytical method for active substance in the product	Is validation of the analytical method for determination of the active substances in the product available? And is this method used in shelf life studies?	

Summaries in APCP section	Are the texts in the phys-chem table summaries of the study reports rather than just the conclusion?	
IUCLID	Are all APCP sections filled out? Are summaries provided, not just the conclusion?	
Study reports	Are signed studies provided for each endpoint? If only a study plan was provided is there a date mentioned when the final report will be made available for evaluation?	

Efficacy

What is needed for the PAR?	**Points to be checked**	**Additional information**
Clear PAR using template	The PAR should be written using the PAR template, which is found in ECHA website: https://echa.europa.eu/nl/support/guidance-on-reach-and-clp-implementation/formats. All sections in de PAR should be completed assessment.	
Clear and complete use description(s)	• Presence of information on: - Target organism - Comprehensive use description - Similar use (as in new BPF guidance) - Application area - Application method - Contact time - Soiling conditions during use - Dosing/concentration* - Prof/non-prof - Product Type (PT) - Preventive/curative use** - Application rate • No contradictory information *Consistent use of units (e.g. mg/kg, %, ppm), type of dilution (e.g. v/v, w/w). ** Especially relevant for preservatives.	This part is relevant for Human Health and Environment also.
Clear overview of the composition of the BPF where applicable (worst-case product)	Presence of: • Overview BPF • Clear composition of the products. • Worst-case product justification. • Uses are numbered in a logical way	The formulations are checked by the APCP expert. This part is checked by the Ctgb Efficacy expert to understand the determination of the worst case formulation, but it affects the Human Health and

		Environment part as well.
Clear and concise summary of the efficacy studies (efficacy table)	Presence of: • Indication which use the study substantiates (nr of use and Meta SPCs). • Product/concentration tested • Test method • Test conditions (temperature, soiling, contact time, soiling) • Results (Passed log reduction, contact time, soiling, concentration) • Logical reference corresponding to test reports in IUCLID e.g. title, authors(s), year of publication etc. • All studies present in the PAR and IUCLID	
Information on resistance and mode of action active substance	Is information present and clear	
Conclusion on efficacy	Presence of: A conclusion for each use, described in conclusion on efficacy section. For each use, a textual description should be provided explaining which efficacy studies support the claims (target organisms, soiling conditions, contact time, concentration/dose, etc.) for that specific use. For a product family, a justification should be provided about the choice for the worst case product used for the efficacy testing.	

Human health (HH)

What is needed for the PAR?	**Points to be checked**	**Additional information**

Clear composition of the product/BPF	In the confidential Annex clear composition should be provided for the product or for meta-SPCs if a BPF is concerned. For Human Health (HH) risk assessment especially the following points are important: • Concentration range should be known for the active substance and co-formulants • SDSs are submitted for all components Whether the information is sufficient will be checked by the Ctgb APCP experts.	As indicated, this part is checked by the Ctgb APCP expert, but affects the HH part also. If concentrations to be considered for an assessment are not clear, we cannot evaluate the assessment for HH and the PAR is considered not valid.

Clear use description of the product/BPF	Use description in chapter 2.1.4 and SPC should be clear and specific enough to support exposure assessment and risk characterization. In support of determining whether the use description is clear, the following points can be checked during the validation phase: • Are the titles of each use included in the exposure and risk assessment clear and consistent with the proposed use? • In case of BPF, is the combination of metaSPC and corresponding uses clearly described, using an overview table where necessary? • Is the field of use specific enough to assume the worst case situation? e.g. health care institutions, restaurants, cleanroom. A cross-check with HHRA section would be necessary to check consistency. • Does the use description provide sufficient information to perform the exposure assessment, e.g.: - In case of a concentrate, the in-use concentrations are clarified for each use? - Is the application method clearly described? In case of spraying, is the spraying type and pressure specified? - Is application rate (e.g. X mL/m2) specified? - From use description is it clear how the product should be loaded or mixed to make dilutions? Please note that the points presented above are examples and does not represent an exhaustive list. Whether the use description of the product/BPF is sufficient will be checked by Ctgb Efficacy experts.	As indicated, this part is checked by the Ctgb Efficacy expert, but affects the HH part also.
In case of BPF, explanation how it fulfills the requirements of the BPF guidance	In case of BPF - an explanation should be provided how the BPF fulfills the requirements described in Ca-July19-Dec4.2-Final "Note agreed by Member States' Competent Authorities for biocidal products". This point is also checked by the other disciplines, e.g. Efficacy, but for Human Health especially the following points should be clearly described: • How the BPF fulfills the requirements "similar level of risk" • How the core assessment is defined for the BPF	

	• Whether any additional assessment (subset or extension) is needed and why. Please note the number of such subset/extension is limited to up to 3 per application • How is it checked and ensured that RMMs within one metaSPC are the same (i.e. RMMs needed for the worst case of a metaSPC are needed also for the best case of the metaSPC) • How is it checked and ensured that H- and P-statements within one metaSPC are the same (e.g. calculations were checked/read-across is applicable for the worst case and the best case of the metaSPC).	
Justification of the CLP proposal	In section 2.2.6.1 the justification of the hazard profile underlying the CLP proposal should be provided for each endpoint. If these explanations include confidential information, they may be included in confidential Annex of the PAR. Although the justification itself will not be evaluated during the validation process, several points will be checked: • Is there a toxicity study submitted? If yes is the summary included in chap 2.1.4.1 and is the study itself also submitted in IUCLID? • Is the in vivo study performed before sept. 2013 (see also art. 62 of the BPR)? • When read-across is applied, compositions of the tested formulation and the product should be compared and a (quantitive) justification for read-across should also be provided. • When the calculation rule according to the CLP is applied, it should be clear in the PAR which substances are taken into consideration, and which values (e.g. LD50, SCL, GCL) are used to determine the classifications. For acute toxicity endpoints and when using the calculations rules, ATEmix values need to be included in the PAR and the ATEmix calculations need to be included in IUCLID and in the (confidential) PAR. • In case of BPF, CLP and corresponding explanations should be at metaSPC level, and not at product level. To this end, the explanation should cover the worst case as well as the best case for each metaSPC, to ensure identical H-statements for the entire metaSPC.	
Justification of dermal absorption	In section 2.2.6.1 the justification of the dermal absorption value that is used for risk assessment	If justification on dermal absorption is

	should be provided for each substance including SoCs. If these explanations include confidential information, they may be included in the confidential Annex of the PAR. Although the justification itself will not be evaluated during the validation process, several points can be checked: • If the proposed value is based on a study, the study summary should be provided. The study evaluation based on the relevant EFSA guidance (2017) should also be present. • If the proposed value is based on read-across, compositions of the tested formulation and the product should be compared using a tabular format. A justification for read-across based on the EFSA guidance (2017) should also be provided. • To use the value used in the CAR, the second bullet point above will apply. • In case of BPF- the justification for read-across should cover the entire BPF or metaSPC, i.e. the best case as well as the worst case should be covered.	insufficient, the default values as determined in the EFSA guidance on dermal absorption (2017), or 100% absorption in case of corrosive formulations will be applied.
Identification of SoCs according to the BPR guidance	In section 2.2.6.1 the following points should be clearly described regarding SoCs (substances of concern): • Are there any SoCs identified? • If not- how this was checked? • If yes – is it described for each SoC which of the 5 criteria for SoC is met? Is an explanation given for the risk assessment approach taken for each SoC (e.g. qualitative/quantitative, reference values to be used), which should be done according to Annex A of the BPR guidance Vol III Part B+C?	
Clear exposure assessment	In section 2.2.6.2 exposure assessment should be clearly described. The following points are especially checked: • In case of BPF – Is it clearly explained how the core assessment is defined, and whether any additional assessment (subset or extension) is needed and why. • If monitoring data is submitted, is the summary included in chap 2.1.4.2 and is the study itself also submitted in IUCLID?	

	In addition, also the following points will be checked: • Is the table "list of scenario" clear, and consistent with the scenario descriptions? • Are scenarios logical and reasonable to cover all possible primary exposure and secondary exposure? • In each scenario, is there a scenario description present including a brief explanation about the use of product/BPF? Is this consistent with use description included in chap 2.1.4 and SPC? • In each scenario, is it explained how the realistic worst case is determined and is this consistent with the use description included in chap 2.1.5 and SPC? • Is it explained in scenario description which guidance is followed and why? • Are all parameters used for calculations listed in the template table? • Are the calculation sheets included in Annex 3.2 where necessary? • Are calculations made for Tier 1 without PPE/RMM, and Tier2 with PPE/RMM when refinements are needed? ○ PPE or RPE needs to be prescribed as last resort. If the realistic worst case assessment results in safe use with PPE/RPE, is an best case assessment included to assess whether PPR/RPE is also considered necessary for the best case? • When exposure is considered negligible, is it explained why?	
Risk characterization	In section 2.2.6.3 risk characterization should be clearly described. The following points are especially checked: • Are the relevant reference values from CAR for the active substance and if SoCs are present are limit values listed in the table "Reference values to be used in Risk Characterization" • Local effects - The template table presented in the BPR guidance (see page 252, tables 26 and 27 of the Guidance on BPR: Vol III Parts B+C version 4.0). RMMs should be clearly described. The consideration for acceptable use should be clearly described.	

	• In case there are SoCs, is risk characterization performed also for the SoCs? • In case there are more than 1 active substances present in the formulation, is the combined exposure toxicity evaluated? In addition the following will be checked: • Are there other relevant limit values (e.g. MRL, limit in drinking water) searched and listed • Systemic effects – Are the results presented for Tier 1 and for higher Tiers, and which RMMs/PPE are accounted for the higher Tiers • When RMMs/PPE are needed they should be consistent with those included in chap 2.1.4 and SPC.	
Extra risk assessment i.e. dietary/livestock/animal/DBP where relevant	In section 2.1.6.2 and 2.1.6.3 the following need to be clearly described: • Whether dietary risk assessment is necessary, and why. This should cover whether exposure via food/drinks (water)/feed is possible or not, and why. If dietary exposure is possible, information on the available MRLs need to be included. • When dietary exposure is possible, risk assessment should be performed based on the BPR guidance where appropriate. • Whether exposure of livestock is possible and why. When exposure of livestock is possible, risk assessment should be performed based on the BPR guidance. • Whether disinfection by-products (DBPs) need to be evaluated. In section 2.2.7 it should be clearly described whether animals including domestic animals may be exposed, and why. If exposure is possible risk assessment for animals should be performed.	
ED screening/assessment performed according to the harmonized approach	An ED screening needs to be performed for all co-formulants in accordance with the procedure agreed at CG in March 2019. See appendix 'Assessment of ED properties of co-formulants' (available on this web page).	

	The results should be reported clearly in the PAR.	
In case of BPF, clear overview of the BPF	In case of BPF - structure of the BPF needs to be clearly described, using tables to provide an overview. For human health the reason for the proposed BPF structure should be clear and in addition especially the following points should instantaneously be clear for each metaSPC: • Concentration range of active substance and SoCs • Relevant uses • Relevant exposure scenarios for each use • CLP proposal covering the whole range of the metaSPC • Identified SoCs • Packaging	This part is checked by the Ctgb APCP and Efficacy expert as well, but affects the HH part also.

Environment

What is needed for a PAR?	**Points to be checked**	**Additional information**
Clear PAR using template	The PAR should be written using the PAR template, which is found in ECHA website: https://echa.europa.eu/nl/support/guidance-on-reach-and-clp-implementation/formats. All sections in de PAR should be completed assessment.	The template needs to be followed to ensure that all aspects of the risk assessment are addressed (e.g. identification of substances of concern, ED-assessment of the co-formulants, and aggregated exposure and risk).

Clear use description of the product/BPF	Use description in section 2.1.4 and SPC should be clear and specific enough to support the environmental exposure assessment and risk characterization and vice versa. The following points are especially checked: • Is it clear from the environmental exposure assessment which of the applied exposure scenarios covers a certain authorized use and why? • Are all parameters required for the exposure assessment also included in section 2.1.4 and the SPC? • Is, if applicable, the application rate (e.g. X mL/m^2) specified in the environmental section of the PAR? • Is it clearly indicated in the environmental section of the PAR which meta SPC is considered worst-case for an exposure scenario? • Are RMMs clearly described and does the quantitative or qualitative risk assessment for the environment indicate that the RMMs are expected to be effective? • Is "the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment" completed and in line with the proposed H- and P-statements?	
In case of BPF, clear overview of the BPF	In case of BPF - structure of the BPF needs to be clearly described, using tables to provide an overview. For environment especially the following points should instantaneously be clear for each meta SPC: • Concentration range of active substance and SoCs • Relevant uses • Relevant exposure scenarios for each use • CLP proposal • Identified SoCs • Packaging	
Clear effect assessment	Are studies with the product (if any) added to IUCLID and summarized in the relevant sections of the PAR including the values to be applied in the risk assessment?	

	Note that additional studies with the active substance with the intention to update the assessment report and agreed List of Endpoints will not be evaluated by the Ctgb when submitted along with product dossiers. The owner of the active substance dossier should inform ECHA and discuss how to add the submitted new endpoint to the List of Endpoints.	
Justification of the CLP proposal	In section 2.2.8.1 the justification of the CLP proposal should be provided. If these explanations include confidential information, they may be included in confidential Annex of the PAR. • When the calculation rule according to the CLP is applied, it should be clear in the PAR which substances are taken into consideration, and which Ecotox endpoints (e.g. LC50, NOEC) are used to determine the classifications. • New scientific insight with regard to the chronic toxicity of a substance needs to be applied for substances with a Harmonised classification (Annex VI of 1272/2008) according to ATP00, 01 or 02. At the time of Annex VI insertion, this chronic information was not yet available. • When read-across is applied compositions of the tested formulation and the product should be compared and a justification for read-across should also be provided. • In case of BPF, the explanations should be at the meta SPC level, and not at each product level. The explanations should cover both the worst case and the best case for each meta SPC, to ensure identical H-statements for the entire meta SPC.	
Identification of SoCs according to the BPR guidance	In section 2.2.8.1 the following points should be clearly described regarding SoCs (substances of concern): • Are there any SoCs identified based on Annex C of the BPR guidance Vol IV environment - Part B+C (2017)? • If yes, please explain briefly the risk assessment approach taken for each SoC (e.g. qualitative/quantitative, endpoints to be used) and include this risk assessment in sections 2.2.8.2 and 2.2.8.3	

Assessment of disinfection by products	In section 2.2.8.3 the risk characterization of disinfection by products should be clearly described. The following point is especially checked: Is the formation of disinfection by products relevant and are these assessed?	
ED screening/assessment performed according to the harmonized approach	An ED screening needs to be performed for all co-formulants in accordance with the procedure agreed at CG in March 2019. See appendix 'Assessment of ED properties of co-formulants' (available on this web page). The results should be clearly reported in the PAR.	
Submission of additional data indicated in section 2.3.4 or 2.4 of the assessment report(s) of the active substance(s)	In the assessment report(s) of the active substance(s) it is indicated whether further tests or studies for the active substance(s) or the "dummy biocidal product" evaluated as the representative biocidal product are required and the dates at which these shall be submitted and to who. These data need to be submitted by the applicant together with the request for authorization of the product or product family. A summary of each study and the study reports are added to IUCLID.	