Austrian CA

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DISCLAIMER: This document has been agreed on 3 July 2018 during the CG-30 meeting. The document CA-Nov14-Doc.5.8-Final will be updated accordingly after the conclusion of the Working Party on the Biocidal Product Family concept.

Grouping of co-formulants in biocidal product families

According Article 3(1)(s) of the BPR a biocidal product family refers to a group of products having similar uses, the same active substances, similar composition within specified variations and similar levels of risk and efficacy. In order to define what is exactly authorised within a BPF it is crucial to make clear which variations in compositions are allowed for the authorisation.

Applications for BPF can contain biocidal products with diverse compositions. At 1st and even at 2nd level of information all possible co-formulants with their concentrations ranging from 0 % to the maximum concentration can be listed. In consequence, the SPC authorised as such would mean that from a legal perspective even a product only containing the active substance and solvent could be eligible for notification. Practically speaking such case would be highly unlikely to occur, but it cannot be ruled out that a product composition will be notified which was not in the range of the initial BPF assessment.

Grouping of products into meta-SPCs (2nd level of information) and specification of miniumum concentration which is greater than zero and a maximum concentration of co-formulants at meta SPC level can avoid this situation.

To facilitate the definition of meta SPCs and to avoid excessive splitting, applicants should be allowed, when appropriate, to group co-formulants having the same function, e.g. emollients, thickeners, wetting agents and complexing agents as shown in the example below (Table 1). By declaring a range for the group of co-formulants (with the minimum concentration>0%) and the minimum = 0% and maximum concentration of each member of the group, the grouping approach avoids that a product composition will be notified which is not covered by the assessment of the BPF as authorised. It should be allowed, but not mandatory, to group some co-formulants together, provided that they:

- have the same function,
- have the same impact on the classification (i.e. resulting in the same hazard and safety statements) for the whole formulation

- have the same impact on the level of risk and efficacy of the formulation.

It should be noted that as a prerequisite for grouping a clear definition of the function of a co-formulant is needed and that grouping may not always be possible. In all cases any chosen grouping must be supported by the applicant in the dossier using sound technical arguments and where necessary data.

If grouping is applied then it is also necessary to specify if co-formulants grouped together are meant to be used in combination or if they should be used exclusively, either the one or the other.

Table 1 gives an example how grouping of co formulants following the rules as given above could look like. The example shows how Level 2 ranges are defined based on the minimum and maximum concentrations from the individual products within the meta-SPC. It is also shown how co-formulants grouped together are meant to be used, either in combination or if they should be used exclusively, either the one or the other.

Table 1 – example meta SPC

	Level 2 - Meta SPC		Level 3 - Individual Products within the meta SPC						
Function	**min(%)**	**max(%)**	1	2	3	4	5	6	7
Active Substance	0.15	0.50	0.25	0.50	0.15	0.30	0.15	0.45	0.30
Complexing Agents A and B can only be used alter-natively. The content of the complexing agent in the formu-lation should be in the range of 1.00 to 3.00	**1.00**	**3.00**							
Complexing agent A	0.00	3.00		1.00	1.50	1.00	3.00	2.50	2.50
Complexing agent B	0.00	1.90	1.90						
Thickeners A and B can be used either alter-natively or in combination. The total content of thickeners in the formulation should be in the range of 0.50 to 1.00	**0.50**	**1.00**							
Thickener A	0.00	1.00			0.1		1.00		
Thickener B	0.00	0.75	0.50	0.50	0.45	0.50		0.75	0.75
Emolients A and B can be used either alter-natively or in combination. The total content of emolients in the formulation should be in the range of 4.12 to 9.20	**4.12**	**9.20**							
Emollient A	0.00	8.70	8.00	8.00	8.70	8.00	8.00	3.00	
Emollient B	0.00	0.50	0.50						
Emollient C	0.00	4.12			0.5			4.00	4.12
Wetting Agents A and B can be used either alter-natively or in combination. The total content of wetting agents in the formulation should be in the range of 0.15 to 2.6	**0.15**	**2.6**							
Wetting Agent A	0.00	0.20		0.15	0.20				
Wetting Agent B	0.00	2.58	0.15			0.15		2.50	2.58
Wetting Agent C	0.00	1.50		0.10		0.10	1.50	0.10	
Solvent	83.7	94.13	ad 100	ad 100	ad 100	ad 100	ad 100	ad 100	ad 100