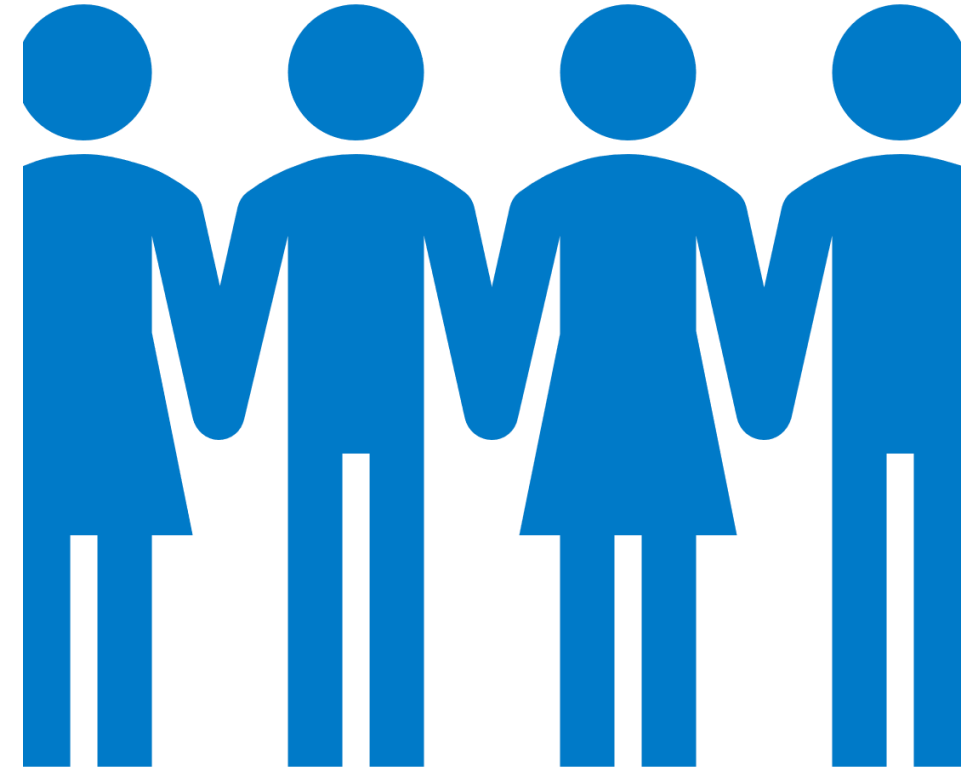


PRACTICAL EFF EXPERIENCE WITH THE NEW BPF

Meredith Theelen
Principal Regulatory Specialist - Ecolab



AGENDA

EFF Experience with the new BPF concept

1. Overall Industry BPF Experience
2. Current status EFF discussions
3. Workload impact
4. Application Coverage and Overdosing
5. Practical Impact & Solutions

OVERALL INDUSTRY BPF EXPERIENCE

- Background: The new family concept went into effect **1 OCT 2019**.
- Applicability:
 - Applies to new submissions after the activation date above.
 - For ongoing applications will apply only if the applicant agrees.
- Industry Feedback/Concerns:
 - **New Applications:** Industry has been busy defining impact on their dossiers and refining compositions based upon identifying the backbone composition.
 - Main concern is about the applicability of the new BPF concept for **previously submitted dossiers** in the evaluation phase.
 - How to handle this concept for large families that were submitted prior to the applicability date above?
 - If the applicant does not agree, how can applicants and authorities best reach a pragmatic approach that works for all?
 - **Challenge: There will be a lack of data for Phys-Chem and Efficacy data bridging that will prove near impossible to generate based upon stop-the clock and lack of official guidance.**
- Experience so far:
 - **Limited feedback** so far as very few applicants have submitted dossiers under the new concept. Additionally, guidance on Phys-Chem, EFF approach and PAR template still to be finalized.
 - Authorities are just beginning to discuss with applicants for previously submitted applications.

CURRENT STATUS EFF

- **Background:** Starting at the end of 2019, discussions within the BPC EFF WG meetings started to develop a proposal for determining the worst-case test product for efficacy of a disinfectant within a BPF (authored by DE).
- **Intention of the proposal:**
 - **Solve issues** currently identified during BPF evaluation
 - Help apply BPF family concept regarding **worst-case** formulation
- **Industry position:**
 - While industry understand the intention of the proposed approach and its alignment with the new BPF concept, we are concerned about the overall implications of employing such an approach.
 - While **authorities' assessment will be reduced**, this will lead to a **high impact on workload for industry** and contract labs to conduct additional studies beyond straight-forward product testing/assessment (i.e. bridging studies)
 - High potential for **overdosing**.
 - Severe **limitations** to the size of BPFs rendering the concept unusable for industry.
 - Potential for **huge limitation of variability of products** offered on the European market
 - Impact for industry to need to submit **more dossiers** to overcome limitations thus **increasing the workload** for all.

WORKLOAD IMPACT:

Worst case test product strategy / new BPF concept

	BPF	BP 1	BP 2	BP 3	BP 4
AS	1-2%	1%	1%	1%	2%
Surfactant	0-1%	1%	-	-	-
Thickener A	0-2%	-	2%	-	-
Thickener B	0-2%	-	-	2%	-

Full set of studies
Bridging studies

AS
Surfactant
Thickener A
Thickener B

BP 5 *
1%
-
-
-

Tiered approach
• Bacteria, yeast
→ 2 x 2 = 4 Studies
+ 2 x 3 Bridging studies

BP 6
1%
-
2%
2%

*assuming this can be considered as worst case test product

IND comments:

- This approach does **reduce** amount of data to be reviewed by **authorities**; however,
- For transitional registration, individual product data must be submitted.
- **Industry will now need to generate additional studies:**
 - Bridging studies
 - Full assessment of potential dummy products
- Additional impact on:
 - Capacity of contract labs
 - Long wait times (pandemic) will put **stop-the-clock at risk**

APPLICATION COVERAGE AND OVERDOSING:

Worst case test product



	<u>use</u>	<u>Target organism</u>	<u>Contact time</u>
<u>Use 1</u>	Surface <u>disinfection</u> - <u>spraying</u>	<u>Bacteria, yeast</u>	5 min
<u>Use 2</u>	Surface <u>disinfection</u> - <u>spraying</u>	<u>viruses</u>	10 min
<u>Use 3</u>	Surface <u>disinfection</u> - <u>wiping</u>	<u>Bacteria, yeast</u>	5 min



Every use will be assessed with worst case test product!

Every use will be assessed with worst-case product:

- We assess this to mean that the **worst-case** will **determine the dose** for the entire family. This concept renders the family concept in general useless for applicants.
- Not every application requires the same dose even within the same PT and application.
- Example: PT2 surface disinfection terminal disinfection vs. detergent-disinfectants.
- There will be **structural overdosing** for terminal disinfectant applications.
- Use of dummy products creates **high concentration demand** for applications where the product is not even marketed. This approach is not representative of application in realistic conditions and it may prove instable.

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Worst case test product for a disinfectant BPF

b a u a :

PRACTICAL IMPACT & SOLUTIONS

IMPACT:

- Family concept will become so narrow it forces companies to produce more biocidal dossiers increasing the workload for both industry and authorities.
- Use of dummy products creates super formulas that are excessively difficult to pass against creating unrealistic restrictions on dosing values, leading to overdosing and potential further risk assessment concerns.
- Family size restrictions may lead industry to largely reduce the variability of disinfectants on the market.
- The cost burden for testing may restrict the ability of smaller companies to compete.

SOLUTIONS:

- Allow for worst-case assessment with consideration to allow:
 - Worst-case should be based off existing formulations within the family to allow for realistic formulations.
 - Subsets of different concentration levels within the min-max active substance concentration ranges should be allowed determining multiple worst-case formulations on a case-by-case basis.
 - Product specific claims so long as they contain higher levels of the active substance and include the easier-to-test-against lower-tiered organisms.

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