Union Authorization for a Biocidal Product Family

ECHA's Biocides Stakeholders' Day

26 September 2017 | Caroline Hall

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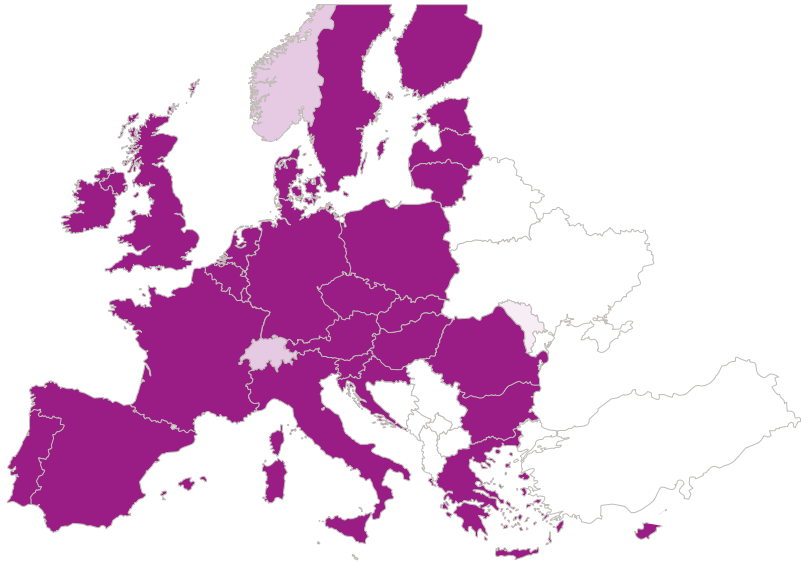
Content

1. Introduction
2. Why choosing Union Authorization of a Biocidal Product Family?
3. Challenges from an industry perspective
4. Issues during dossier preparation
5. Concluding remarks



Evonik's Involvement in Biocides Business within EU

Evonik Nutrition & Care

Products for use in the areas consumer goods, nutrition and health

- **Biocidal Actives**

Ampholyt, Chlorhexidine digluconate

Products Types 1, 2, 3 & 4

- **Current activities for UA-BPF**

Ampholyt

Products Types 2, 3 & 4

Evonik Resource Efficiency

Environmentally friendly and energy efficient systems as solutions for several industries

- **Biocidal Actives**

Hydrogen Peroxide, Peracetic Acid, Silicon dioxide

Products Types 1, 2, 3, 4, 5, 6, 11, 12 & 18

- **Current activities for UA-BPF**

Hydrogen Peroxide & Peracetic Acid

Products Types 2, 3, 4 & 5

Why choosing Union Authorization of Biocidal Product Families?

General benefits of union authorizations of biocidal product families (UA-BPF):

- Route from market in single countries to the entire EU
- Secure marketability of active substances
- Future business opportunities via change procedures
- Cost effective way for SMEs to gain access to the market
- Well defined process

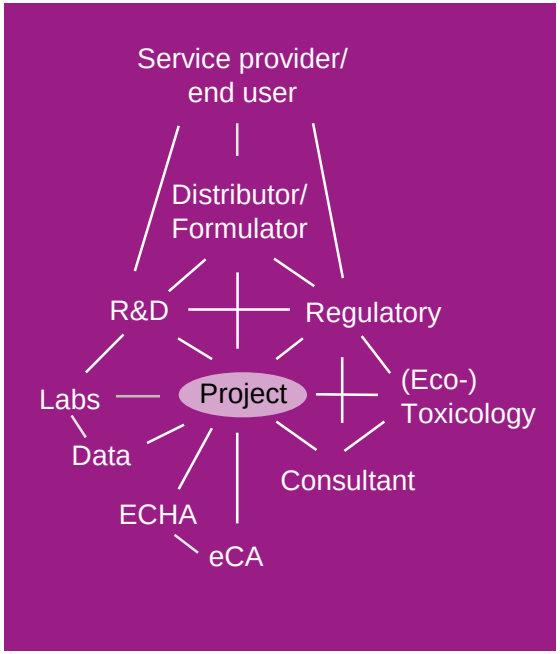
Key steps of UA-BPF

Business decision	Concept with or without onboarding of customers formulations
Development of family structure	Collection of information on products, uses and applications Generation of efficacy and physical-chemical data
Pre-submission meeting with eCA	Focus on applications, family concept and data gap filling Advise on further development of family concept by eCA
ECHA Pre-submission meeting	Declaration of intention by Applicant Clarity on family concept by ECHA and MS
Dossier preparation	Risk assessment based on efficacy and hazard of active substances and co-formulants
Evaluation and authorization	Discussions with eCA and customers

Challenges from industry perspective

Set-up of an developmental project with clear responsibilities:

- Contractual framework requires legal resources (letter of access, further contracts etc.)
- High demand on internal regulatory and R&D expertise
- Choice of partners: consultants and external labs with high level of expertise and capacities needed
- Intense communication with customers and end-users on products, uses & applications
- Product development based upon regulatory needs at a late stage



Issues during dossier preparation (1/2)

Topics	Problems
Efficacy of Disinfectants	New comprehensive guidance requires new efficacy testing. Frequently, available data does not fit to the intended application and claims.
Co-Formulants / Substances of Concern (SoC)	How to discriminate a 2nd active from a clever formulation? Definition of SoC and consequences for risk assessment, storage stability, analytics etc.
Dietary risk assessment	Appropriate guidance for professional applications is lacking.
Information on applications	Detailed information on end use is needed, but frequently not known.
Fogging	Efficacy testing of the system consisting of the active and the apparatus requires multiple testing for different systems.

Issues during dossier preparation (2/2)

Topics	Problems
Wet wipes	Carrier material requires an own metaSPC even though risk to humans and environment is lower or the same as for liquids.
Classification & Labelling	Product classification strongly influences family structure. BUT in some cases RAC decision on harmonized classification of active substances is missing.
Exposure models	Many exposure models are more than 10 years old, extremely conservative and not reflecting currents operational procedures. Furthermore, some models do not exist at all (eg. foam spraying).
IT tools	Several IT tools and data formats have to be used (R4BP3, IUCLID, SPC editor, PAR). Continuous alignment of tools, formats and labels necessary.
Publication of SPC	Details of SPC publication may contradict confidential business information.

Most important are the product applications - You can't be early enough to discuss with your customers and your active substance supplier !

"High workload & costs"

"Industry and Authorities are learning side-by-side."

"By the time you get closer to the solution you understand the complexity of the problem."

"Game changer"

"Informed customers are crucial for success."

"UA-BPF is a well defined process coordinated by ECHA."

"Work in progress"

"Challenge are the IT tools."

"Open and clear communication between eCA and Applicant needed."

"Fees are an extremely high burden."

"Key role of eCA"

Thanks !

I wish to express my personal thanks to all colleagues for their contributions - especially Wolfgang Leonhardt for his ideas and valued efforts.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Abbreviations

eCA	Evaluating Competent Authority
IUCLID	International uniform chemical information database
MS	Member State
PAR	Product Assessment Report
RAC	Committee for Risk Assessment
R4BP3	Register for biocidal products
R&D	Research and development
SME	Small and medium-sized enterprise
SoC	Substance of concern
SPC	Summary of product characteristics
UA-BPF	Union authorization of a biocidal product family