Working in a consortium

An Ghekiere

26 September 2017, ECHA Biocides Stakeholders’ Day
Outline

• Why are consortia for biocidal products new?
• Strategy
• Steps in consortium building
  – Pre-consortium phase
  – Consortium phase
• General findings
• Conclusions
## Why are consortia for BP new?

<table>
<thead>
<tr>
<th>Biocidal Products Directive (BPD)</th>
<th>Biocidal Products Regulation (BPR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consortia for AS but not BP</td>
<td>Consortia for AS and BP</td>
</tr>
<tr>
<td>Frame formulation limitations of grouping</td>
<td>Biocidal product family more flexibility for grouping</td>
</tr>
<tr>
<td>Cost not so high under transitional measures (limited AS approved yet)</td>
<td>Cost very high</td>
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<tr>
<td>In general dossier preparation not so complex</td>
<td>Often no in house knowledge or capacity for complex dossier preparation</td>
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<td></td>
<td>Amended SBP Regulation 11 October 2016</td>
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</tbody>
</table>
STRATEGY
Dossier Submission

Each consortium member own authorisation number via Same biocidal products application, Regulation (EU) No 414/2013

Reference Dossier submitted by ARCHE Consortia UA or NA

SBP → Member 1
SBP → Member 2
SBP → Member 3
Reference dossier submitted for UA

Amended SBP regulation 414/2013 (11 October 2016) makes the following options possible:
Reference dossier submitted for NA

MR Fees can be shared among members
SBP independent when approved
DIFFERENT STEPS IN CONSORTIUM BUILDING
Different steps in consortium building

- **Call of interest**
  - AS or combination of AS

- **Pre-consortium phase**

- **Consortium phase**
Pre-consortium phase

- Questionnaire
- Product data
- Processed data
- Decision joining consortium
- Preliminary data gap analysis + grouping
Consortium agreement

• Drafted by legal partner
• Review by members during pre-consortium phase
• Agreement between members
• Indicates the start of the consortium
Consortium: structure

- Secretary
- Consortium management
- Accountancy

Consortium Members

- Manufacturers
- Importers
- Distributors

Consortium management

- Drafting consortium agreement
- Anti-trust compliance

Legal partner

Technical service provider

Dossier preparation

Steering Committee

Technical Committee
Consortium: steps dossier preparation

Data gap analysis
- Inventory of tests
- Review of existing data
- Waivers/expert statements

Testing
- Develop testing strategy
- Selection of labs
- Testing

IUCLID dossier
- Input studies/waivers
- Administrative data requirements
- Attachments

Risk assessment
- Environmental
- Human
- SoC
- Product assessment report

SPC
- Creation metaSPCs/product SPCs

January 7, 2016
Timeline

- Call of interest
- Start Pre-consortium
- Start Consortium
- Dossier preparation
- Submission
- +/- 2 years
- BPC opinion
- Date of AS approval
Ongoing ARCHE consortia

- Call of interest
- Pre-consortium phase
- Consortium phase
- Submitted

- NaOCl
- NaCl
- H₂O₂
- Peracetic acid
- Permethrin
- In situ PAA
- Chlorine
- See next slide

See next slide
Call of interest

Will be published beginning of October 2017:

<table>
<thead>
<tr>
<th>Active substance</th>
<th>PT</th>
<th>BPC opinion expected</th>
<th>Expected submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium dichloroisocyanurate dihydrate (NaDCC)</td>
<td>2, 3, 4, 5</td>
<td>April 2018</td>
<td>April 2020</td>
</tr>
<tr>
<td>Pyrethrins and pyrethroids</td>
<td>18, 19</td>
<td>June 2018</td>
<td>June 2020</td>
</tr>
<tr>
<td>Hydrogen peroxide</td>
<td>11, 12</td>
<td>June 2018</td>
<td>June 2020</td>
</tr>
</tbody>
</table>
General findings

• Consortia for BP still new, need some explanation
• Little reaction of MS
• MS ask additional information for MR (templates LoA AS and products)
• Additional LoA to the AS dossier required for reference dossier although all members have an individual AS LoA
• Pre-submission meeting is very important and must be duly prepared
General findings

- MR fees higher than expected
- Many avoid UA due to high annual ECHA fee
- Current discussions on similar use, composition & risk and acceptable size of BPFs can result in even higher fees and bigger administrative burden for companies and authorities
- Flexible evaluation fees based on the size of the family or on actual time spent good approach for BPF dossiers
CONCLUSIONS
Conclusions

- Consortia are highly cost saving
- SME often only option
- Still many uncertainties (big BPF, requirements)
- Consortia – BPF - UA – SBP still new, but is supported by EC, ECHA and MS
- Reduces the high workload for authorities
an.ghekiere@arche-consulting.be

www.arche-consulting.be