



Working in a consortium

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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?

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

STRATEGY

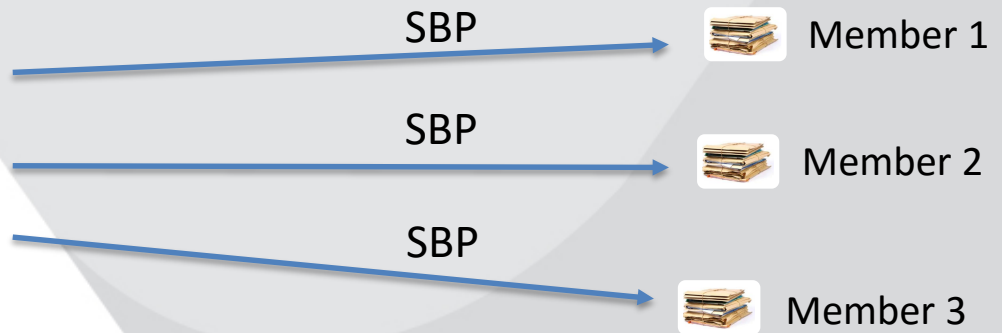


▶ Dossier Submission

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

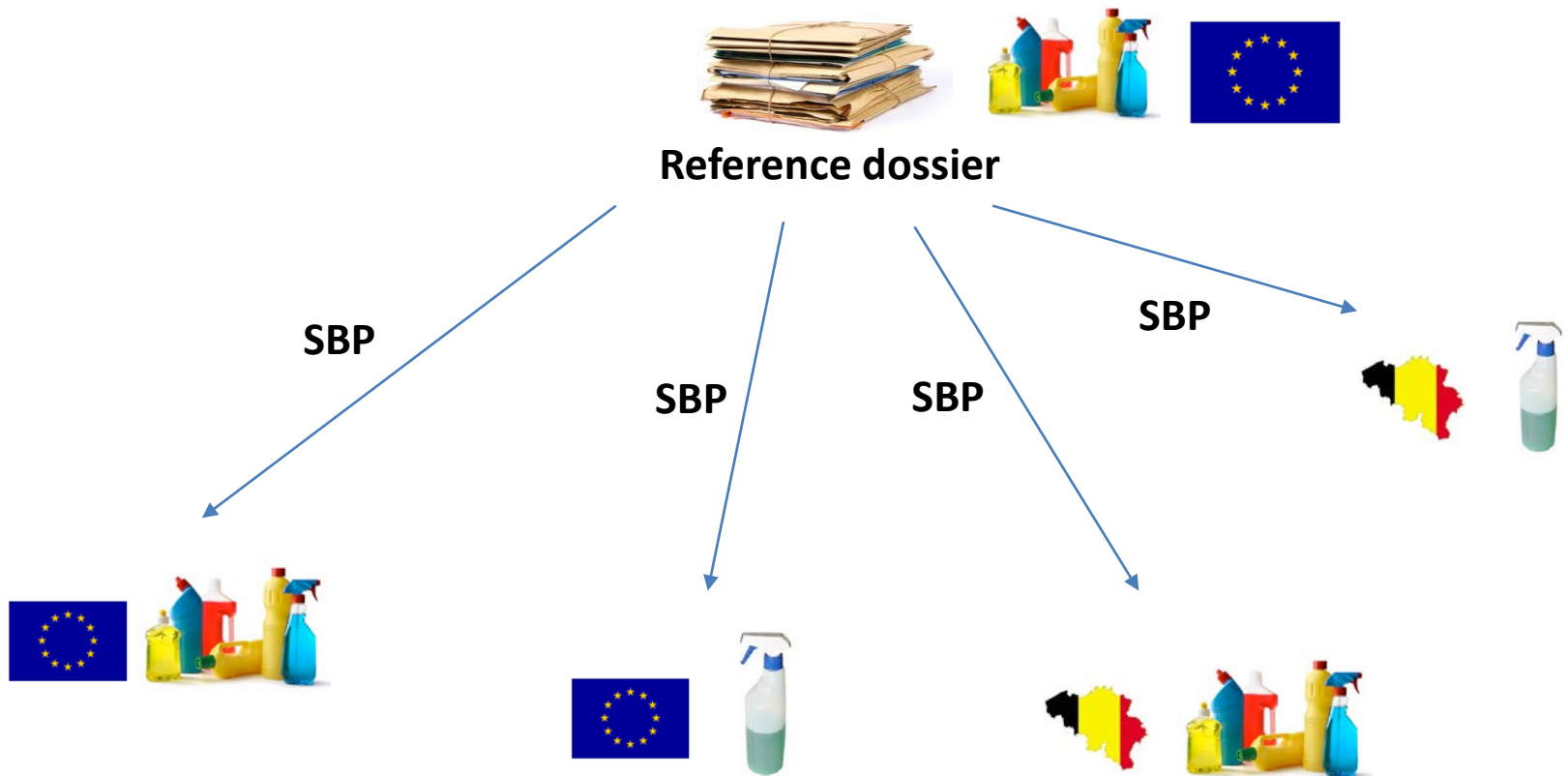


Reference Dossier submitted by
ARCHE Consortia UA or NA

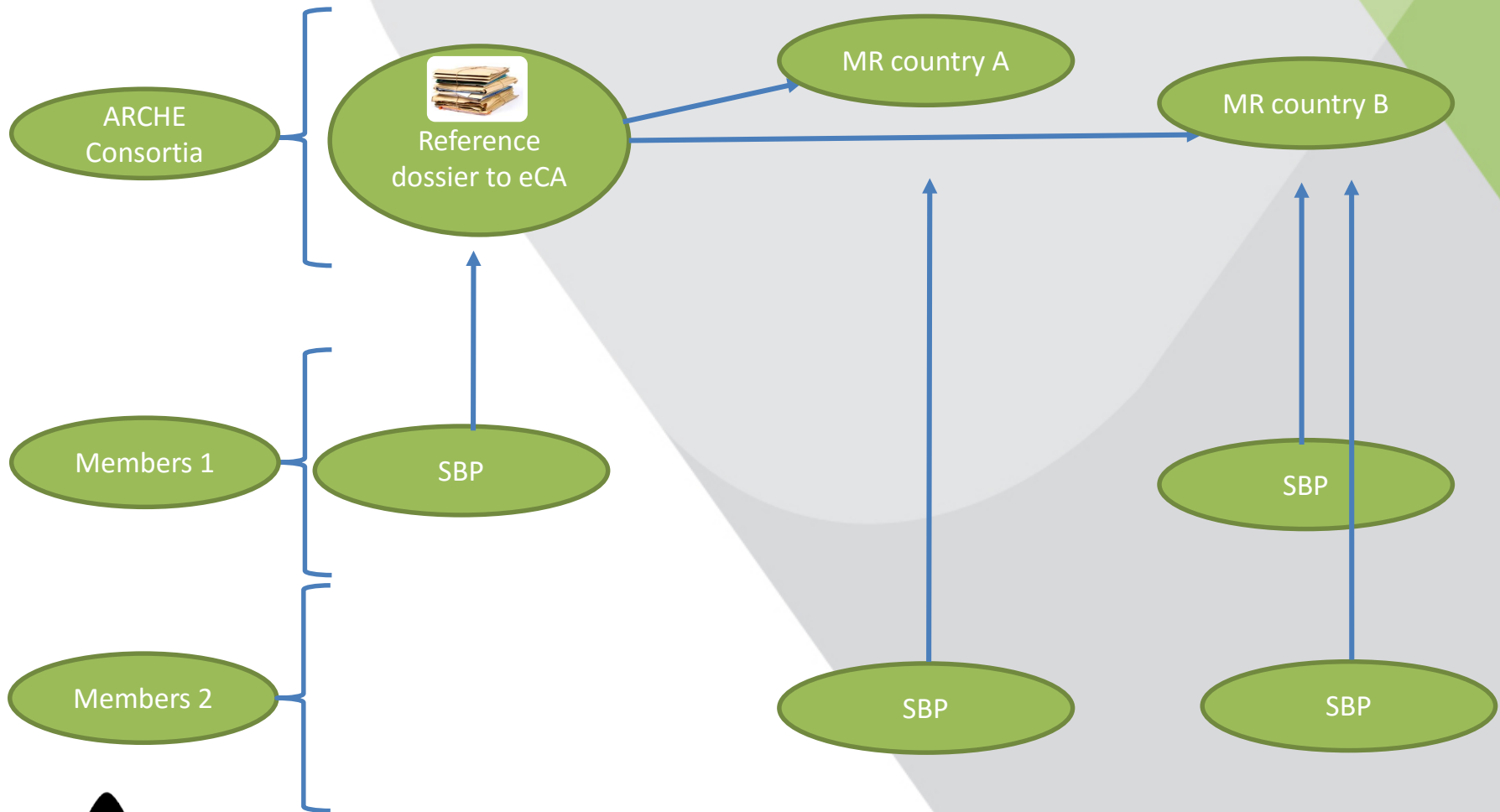


▶ Reference dossier submitted for UA

Amended SBP regulation 414/2013 (11 October 2016) makes the following options possible:



▶ Reference dossier submitted for NA



DIFFERENT STEPS IN CONSORTIUM BUILDING



▶ Different steps in consortium building



Call of interest:
Biocidal product consortia for
chlorine, permethrin+PBO, in situ PAA


By 26, 2016 – ARCHE is collecting interest in the setting-up of a voluntary consortium in order to facilitate producers, distributors and formulators of biocidal products on the market biocidal product(s).

Archer with FieldFisher for legal support are already facilitating consortia in preparation dossiers containing sodium hypochlorite, permethrin and peracetic acid and I support companies with generating product dossiers on chlorine, permethrin and PBO.

Call of interest
AS or combination of AS

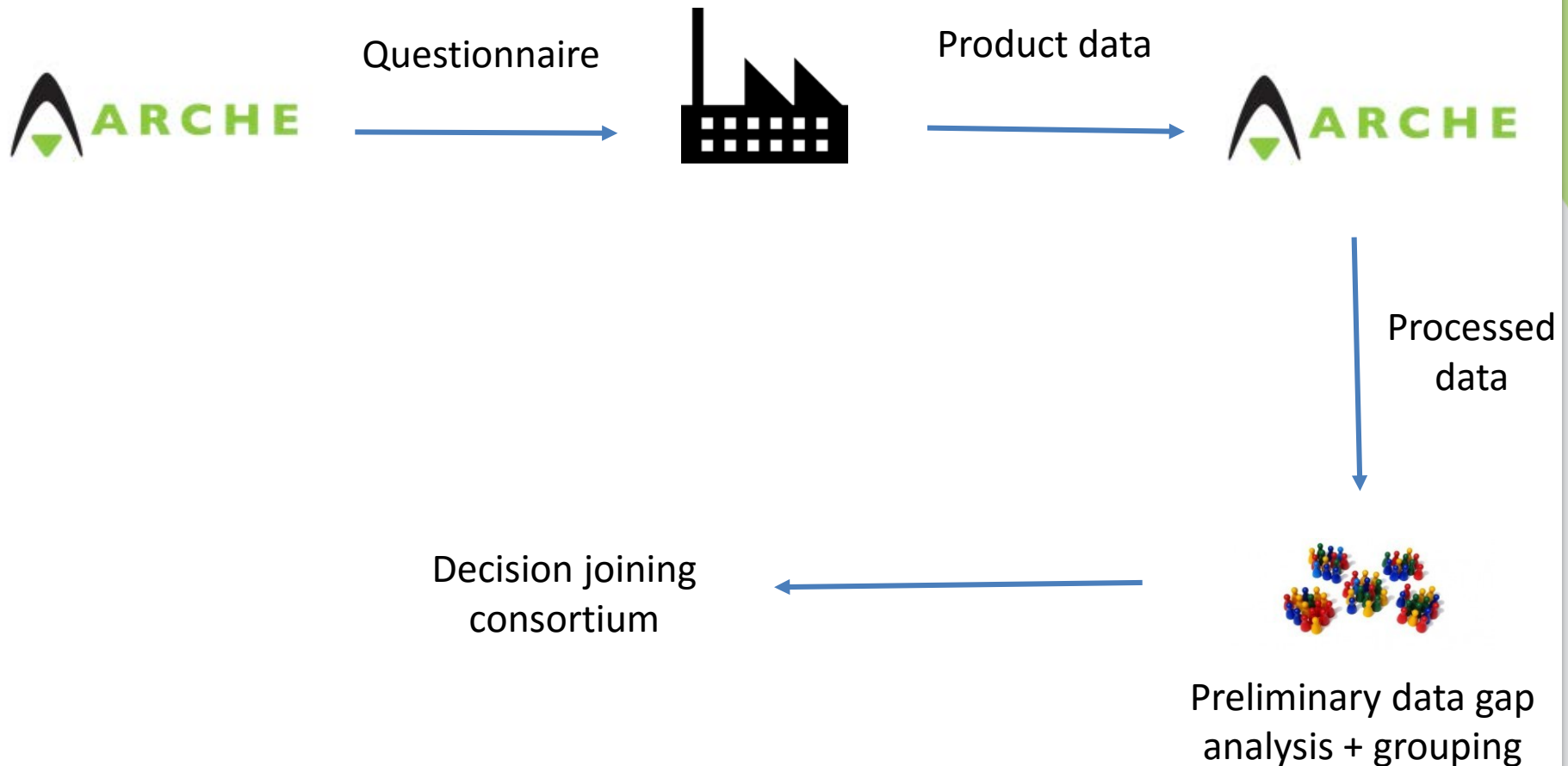


Pre-consortium phase



Consortium phase

▶ Pre-consortium phase



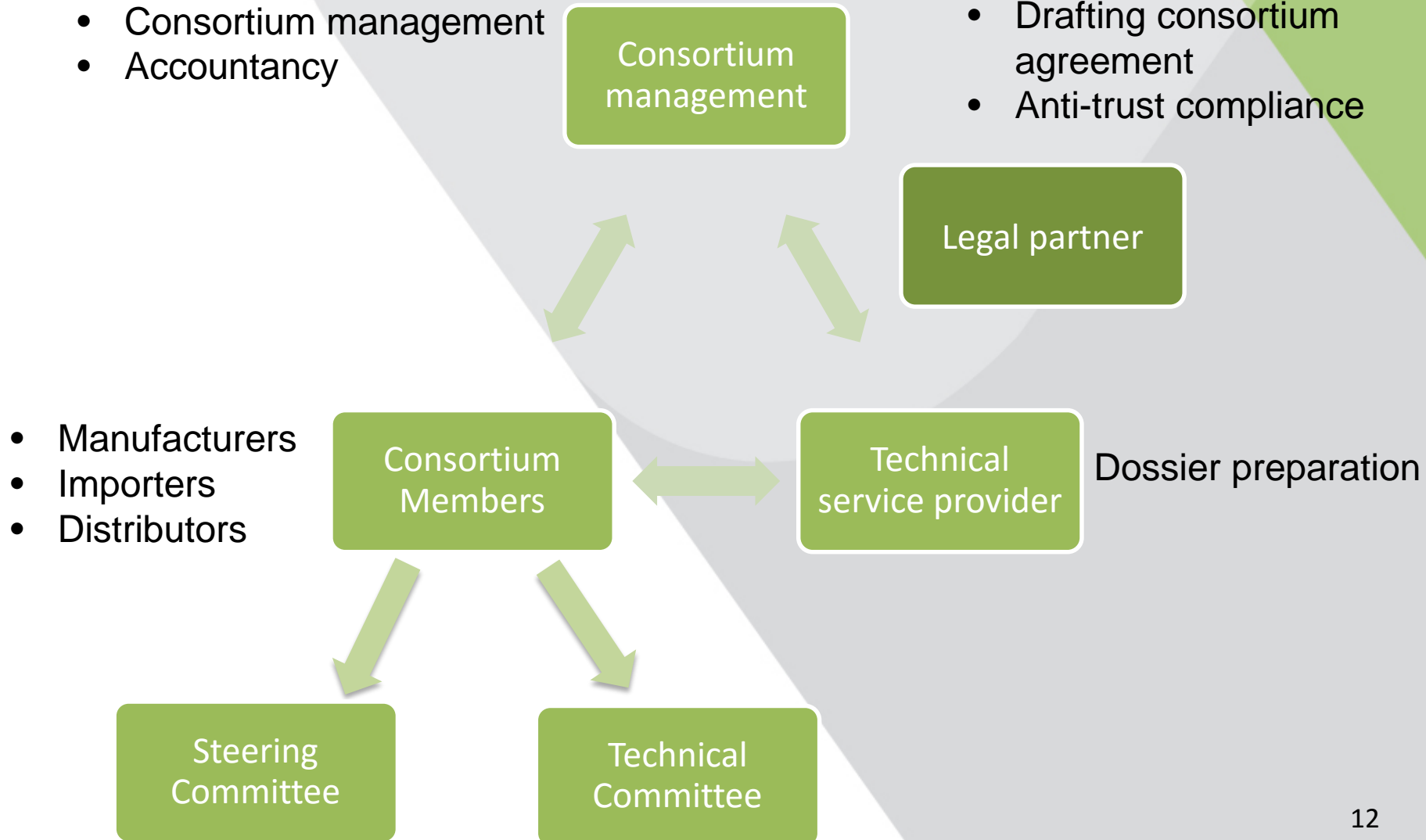
▶ Consortium agreement

- 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

- Drafting consortium agreement
- Anti-trust compliance



- Manufacturers
- Importers
- Distributors

▶ 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

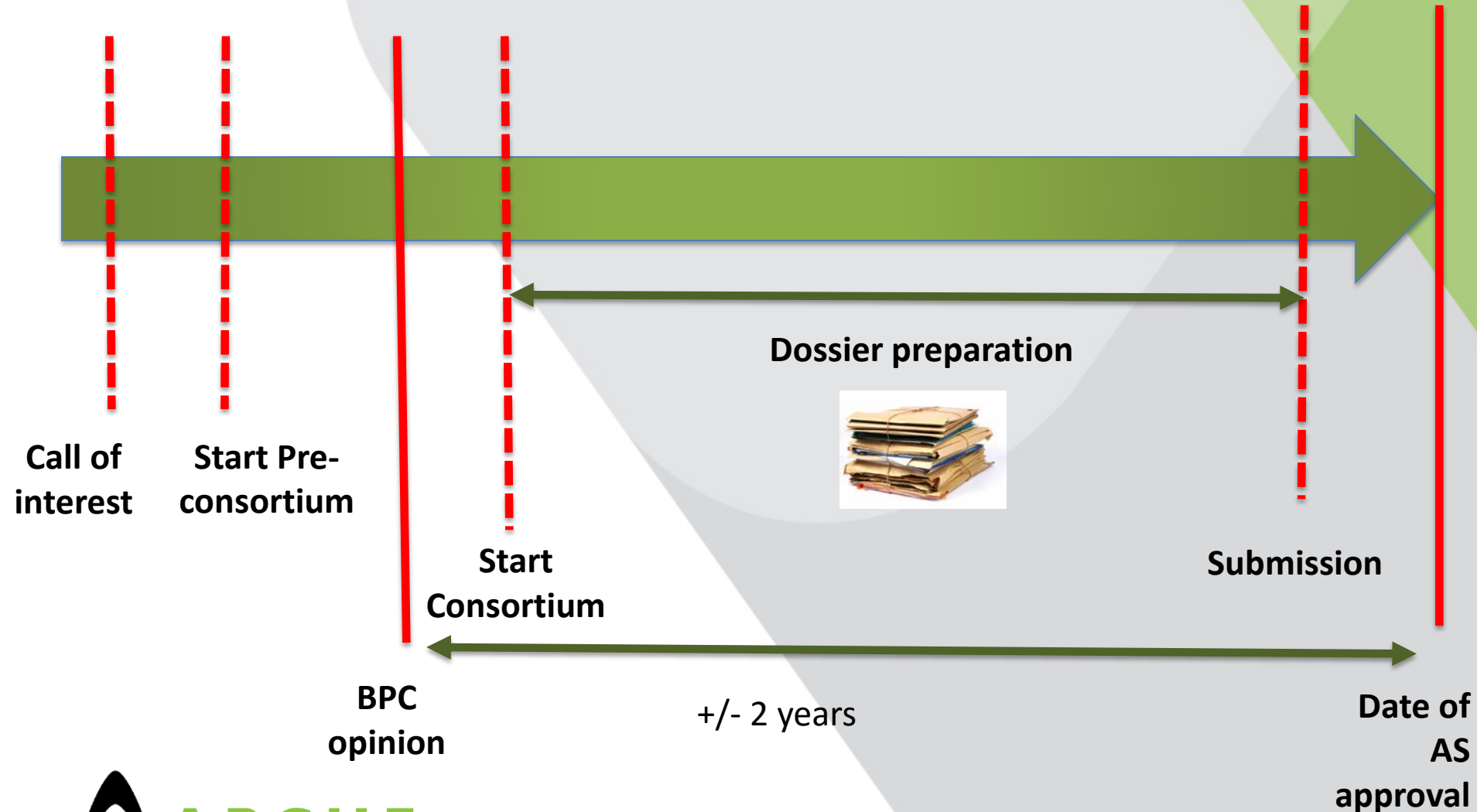
- Environmental
- Human
- SoC
- Product assessment report

SPC

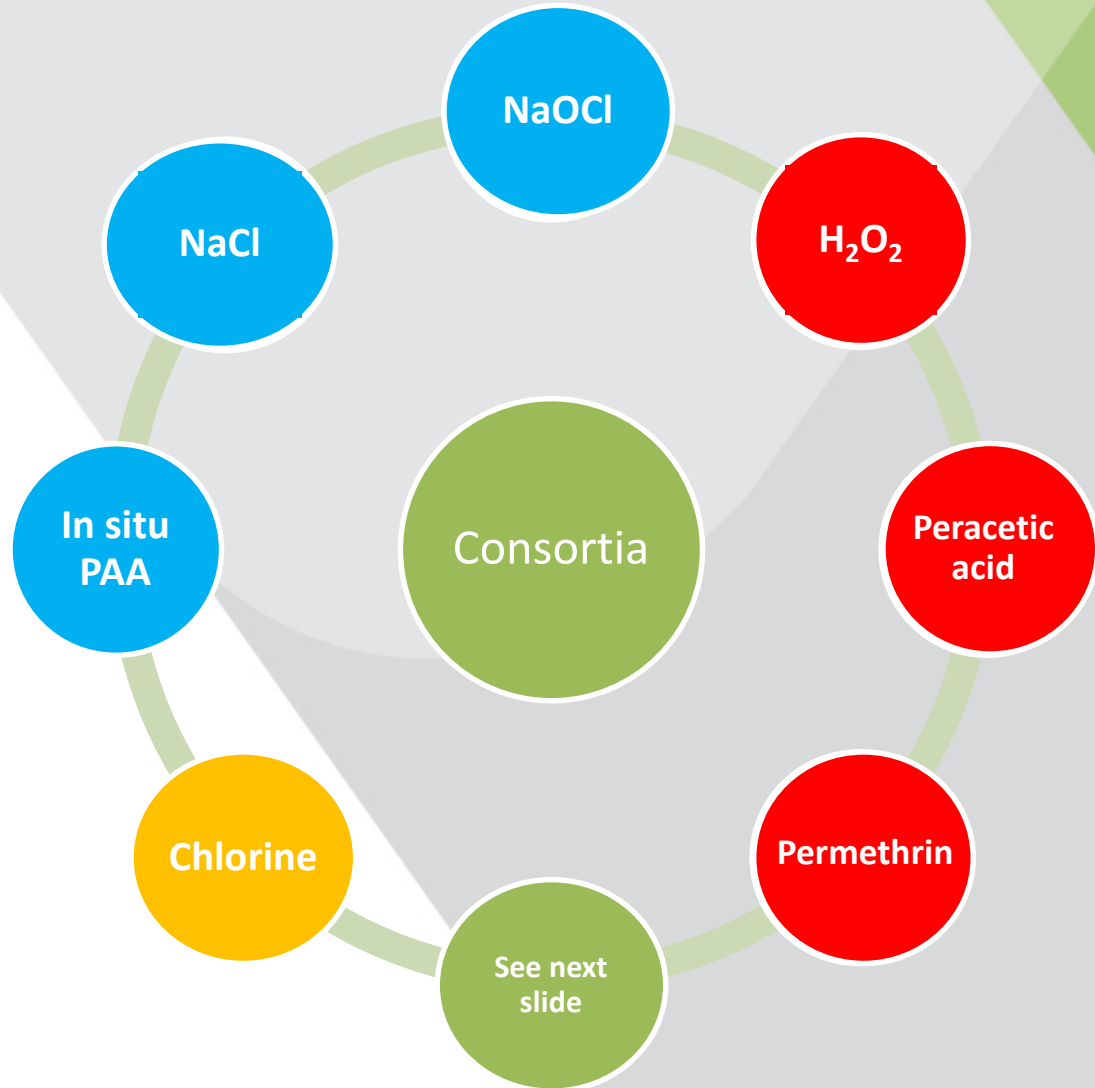
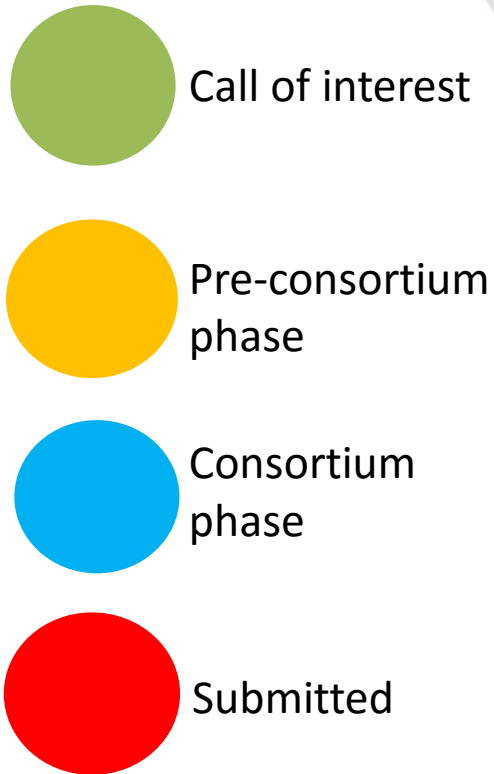
- Creation metaSPCs/product SPCs

January 7, 2016

▶ Timeline



▶ Ongoing ARCHE consortia



▶ Call of interest

Will be published beginning of October 2017:

Active substance	PT	BPC opinion expected	Expected submission
Sodium dichloroisocyanurate dihydrate (NaDCC)	2, 3, 4, 5	April 2018	April 2020
Pyrethrins and pyrethroids	18, 19	June 2018	June 2020
Hydrogen peroxide	11, 12	June 2018	June 2020

GENERAL FINDINGS



▶ 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



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