



# Consortia for biocidal products

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# ▶ Outline

- Why no BP consortia under the BPD?
- Why consortia under the BPR?
- Strategy
- Different steps in consortium building
  - Pre-consortium phase
  - Consortium phase
- Conclusions

# WHY NO CONSORTIA FOR BIOCIDAL PRODUCTS UNDER THE BPD?



## ▶ Why no BP consortia under BPD?

- Consortia under BPD for AS but not BP
- Frame formulation limitations of grouping
- Not a lot of AS were approved yet, national rules apply
- Each country own authorisation schemes
- In general dossier preparation and fees not so high under transitional measures

# WHY CONSORTIA FOR BIOCIDAL PRODUCTS UNDER THE BPR?



# ▶ Why consortia under the BPR?



## Union Authorisation



80,000 €  
(+ annual fee: 10,000 €)



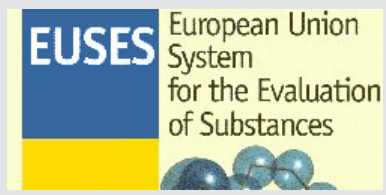
## Evaluating CA

+/- 30,000 €  
(+ annual fee: 1,170€)

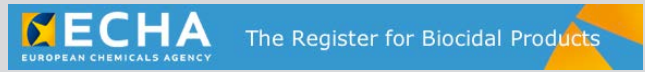


110,000 €  
(fees only)

## Dossier preparation



## Dossier submission



# ▶ Why consortia under the BPR?



20 individual authorizations

1 grouped authorization (BPF)



# ▶ Why consortia under the BPR?



## Biocidal Product Family (BPF)

- Same active substance
- Similar use
- Similar composition
- Similar levels of risk and efficacy

**BPF allows formation of consortia**

**➔ Offers flexibility**



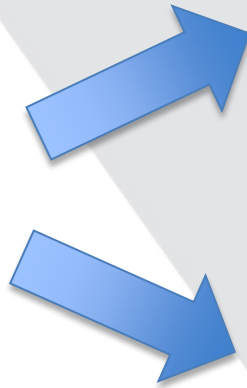
# STRATEGY



# ▶ Dossier Submission



Reference  
Dossier submitted by  
ARCHE Consortia



Union Authorisation



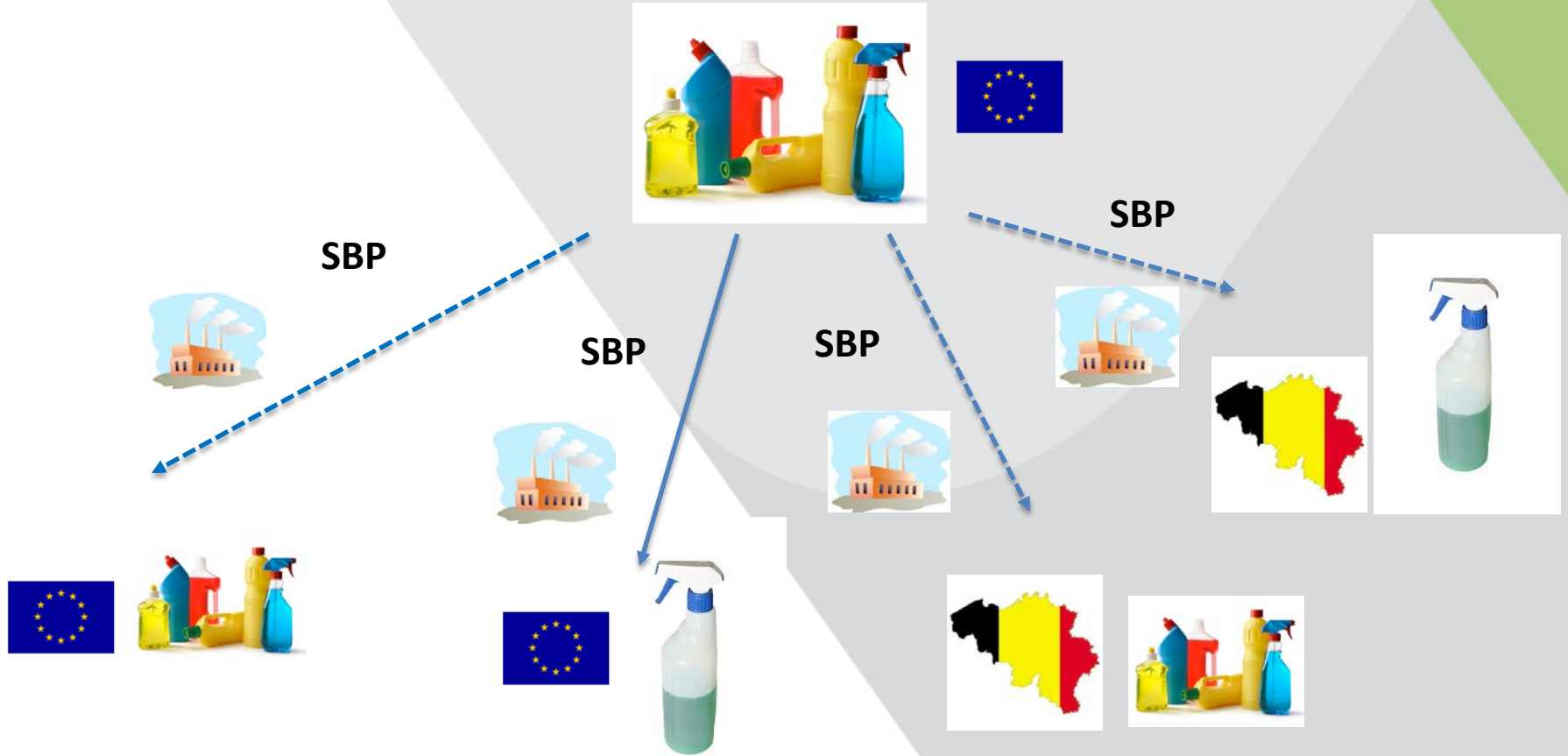
National Authorisation

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

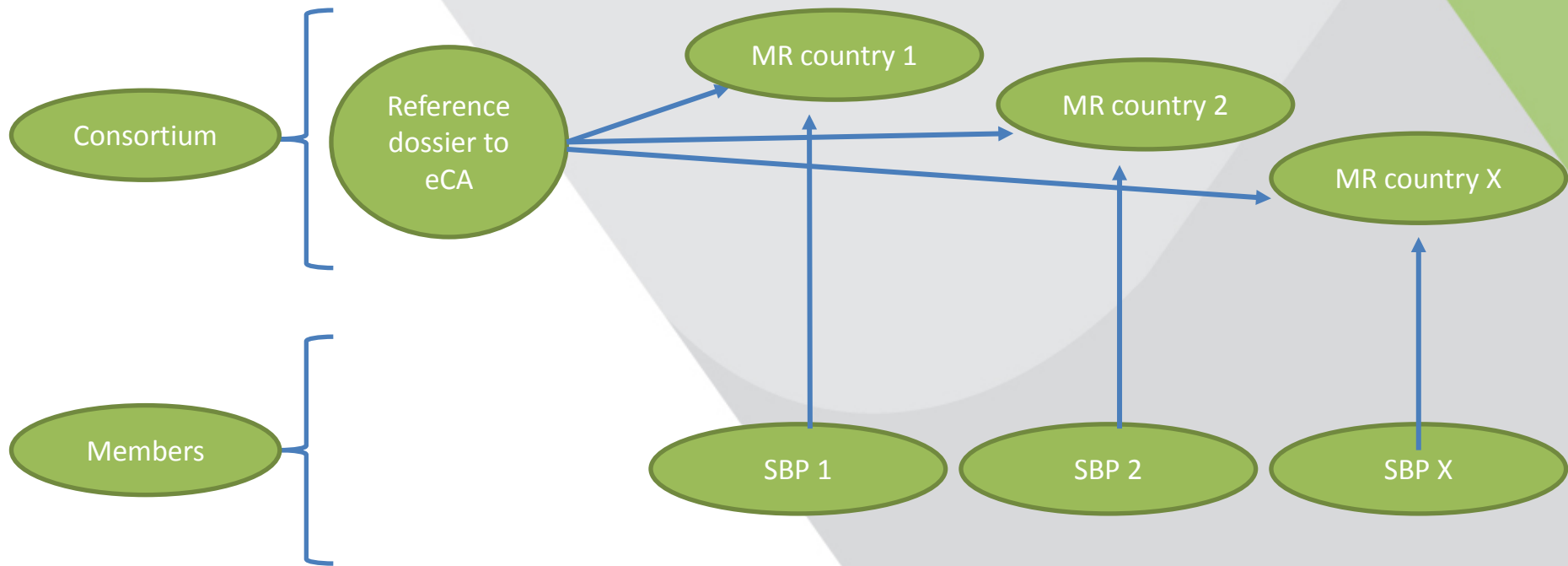
# ► Possibilities obtaining authorisation

Reference dossier UA

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# ▶ Reference dossier: NA and Mutual Recognition



MR Fees can be shared among members  
SBP independent when approved

# DIFFERENT STEPS IN CONSORTIUM BUILDING



# ▶ Different steps in consortium building

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

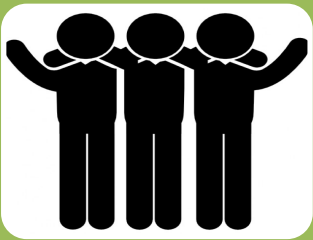
July 26, 2016 – ARCHE is collecting interest in the setting-up of a voluntary consortium in order to facilitate producers, distributors and formulators of biocidal products on the market biocidal product(s).

FieldFisher for legal support are already facilitating consortia in preparation of dossiers containing sodium hypochlorite, permethrin and peracetic acid and FieldFisher 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

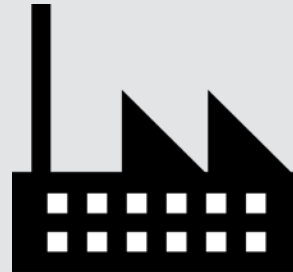


# ▶ Pre-consortium phase

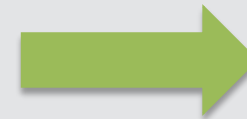
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Questionnaire



Product data



Processed data



Solid database

Pre-submission meeting



Data gap analysis + preliminary grouping





# ▶ Pre-consortium phase: grouping

BPF: three-levels of information

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## LEVEL 1

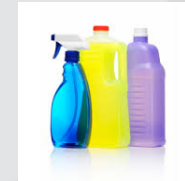
- Formulation type
- PT might vary
- Contain the same AS



Family

## LEVEL 2

- Same classification, H&P statements
- Common set of RMMs
- Similar uses
- Common set of first aid instructions, disposal, storage and shelf-life



MetaSPC

## LEVEL 3

- Exact composition
- Specific use
- Specific RMMs



Product

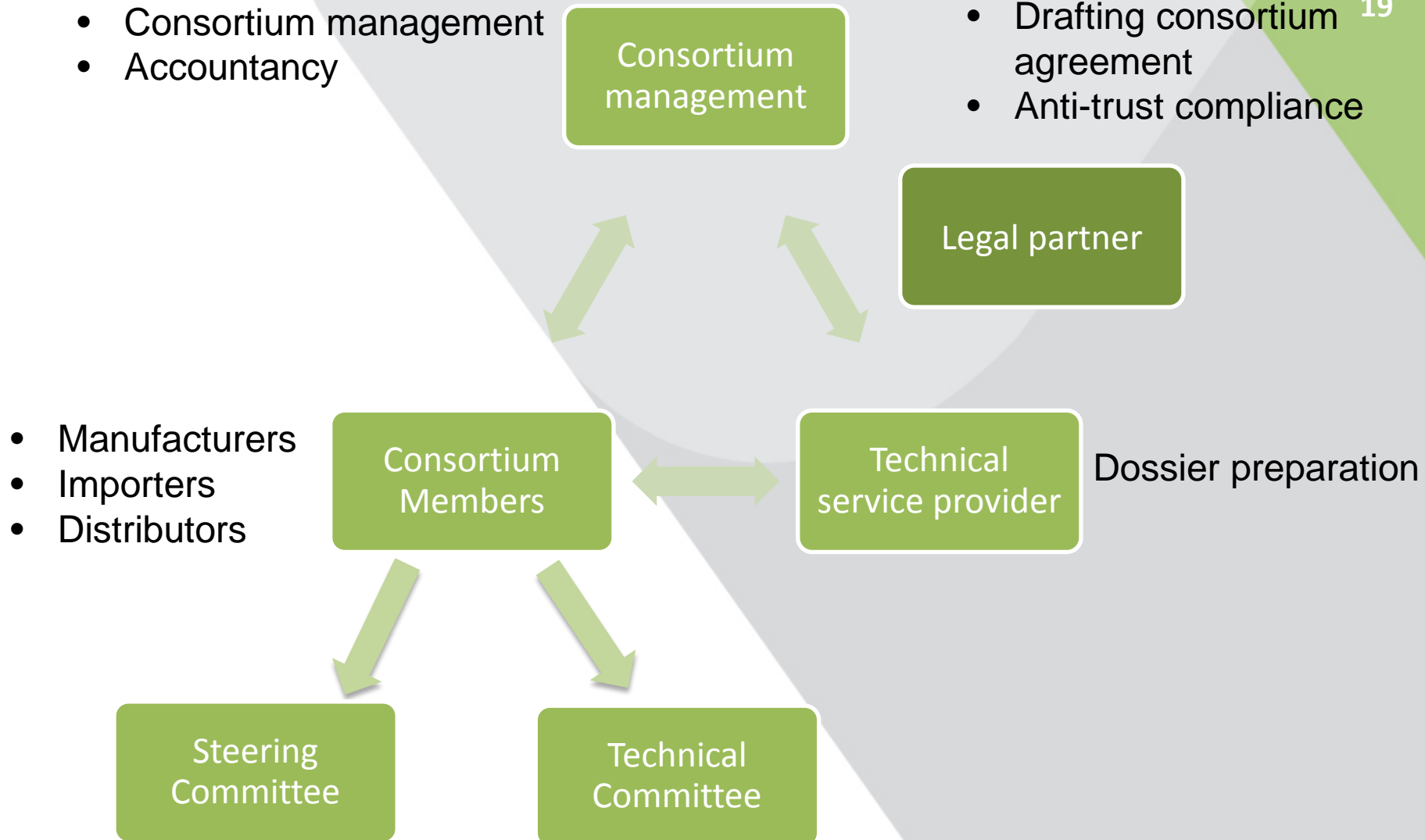
# CONSORTIUM PHASE



# ▶ Consortium: structure

- Secretary
- Consortium management
- Accountancy

- Drafting consortium agreement <sup>19</sup>
- Anti-trust compliance



- Manufacturers
- Importers
- Distributors

# ▶ Consortium agreement

- Drafted by legal partner
- Thorough review by members during the pre-consortium phase
- Agreement between members
- Indicates the start of the consortium

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# ▶ 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

# ▶ Consortium: Steps in dossier preparation

## Data gap analysis

- Inventory of tests
- Review of existing data
- Waivers/expert statements

## Testing

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## IUCLID dossier

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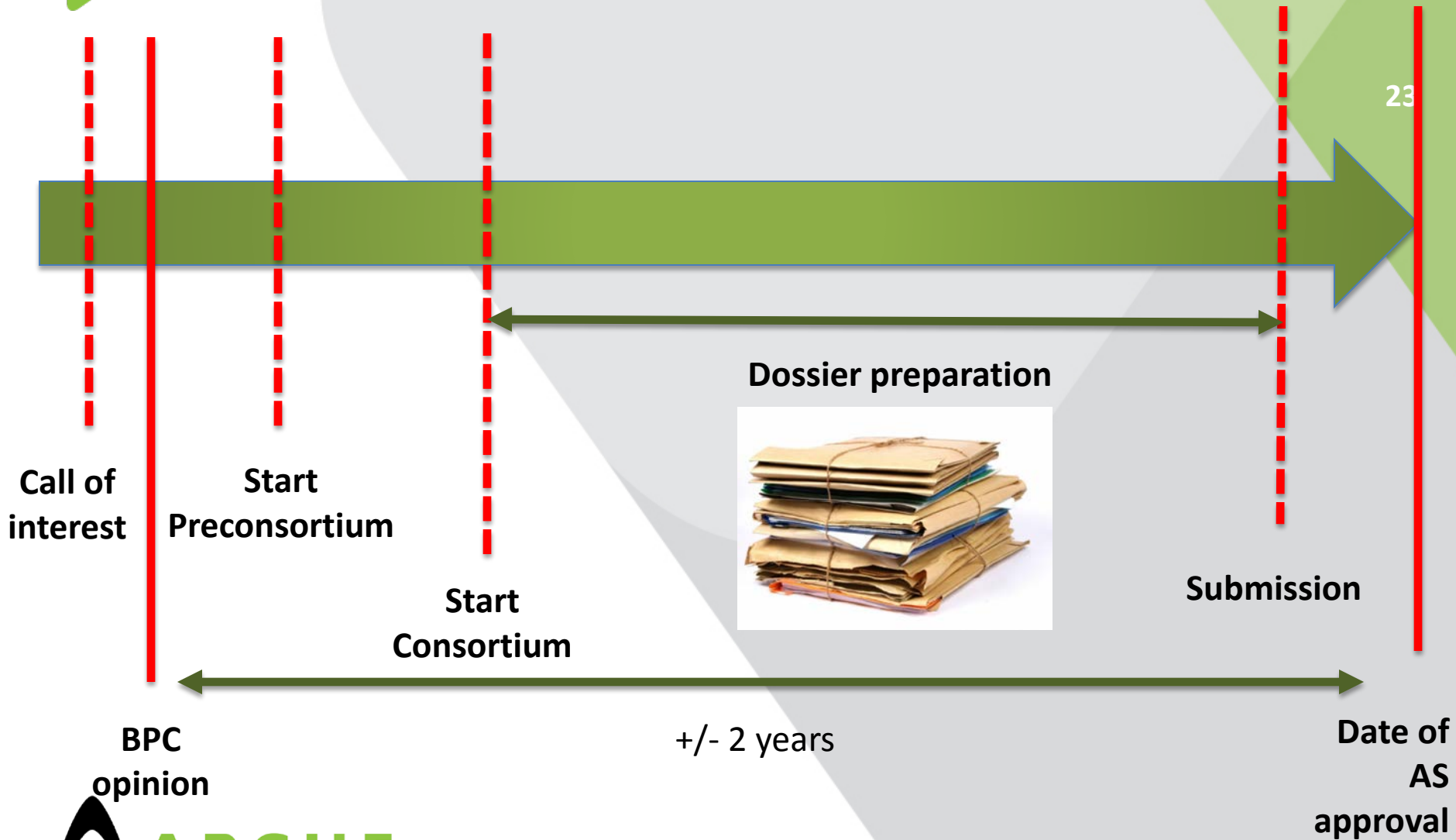
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- Environmental
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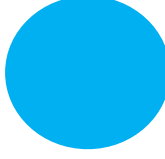
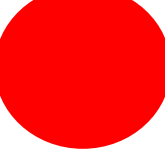
## SPC

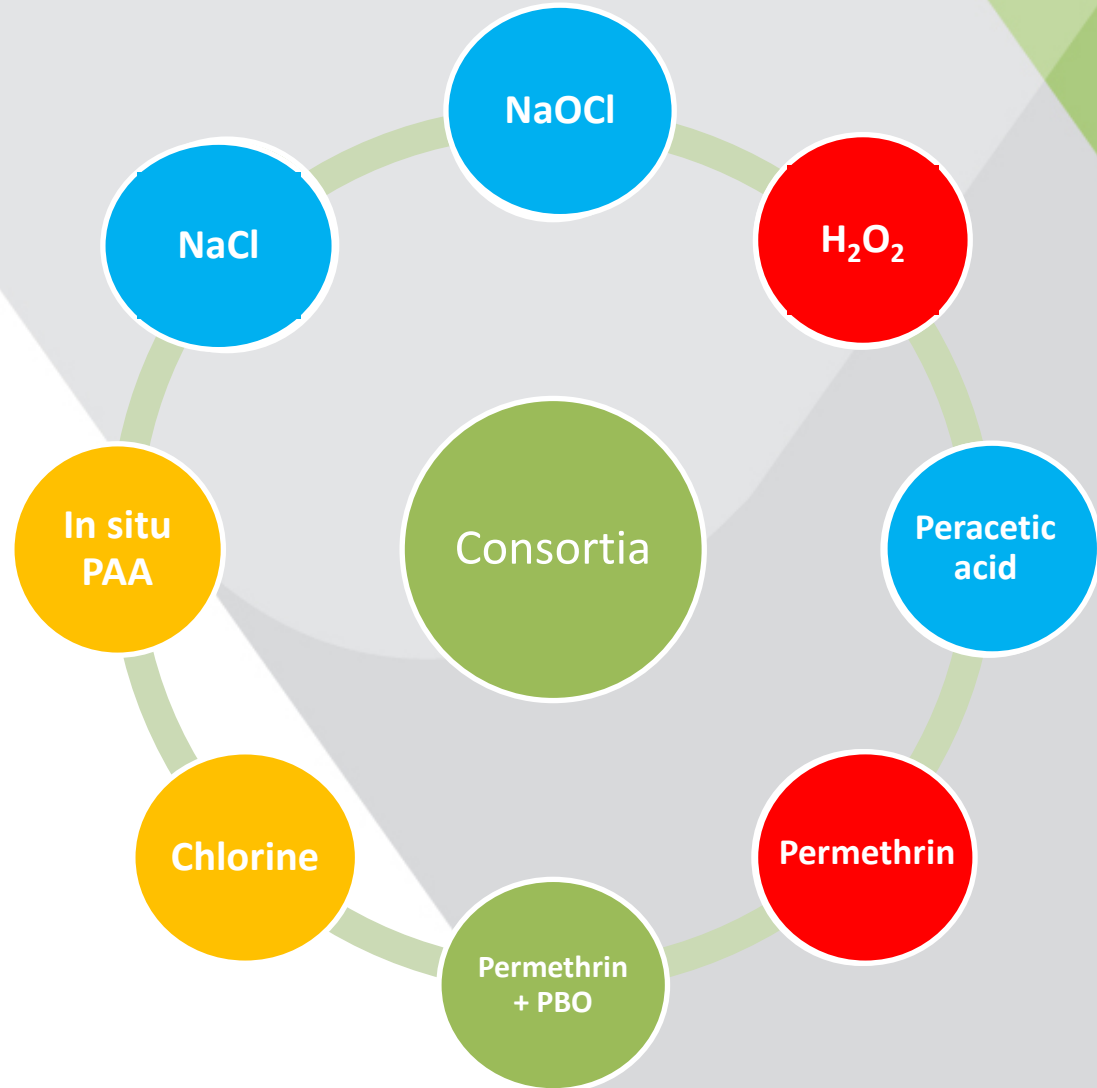
- Creation metaSPCs/product SPCs

# ▶ Timeline



# ▶ Ongoing ARCHE consortia

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





# ▶ Lessons learnt

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- Little reaction on MR of many MS
- Concept consortia for BP still new
- MR fees higher than expected
- Many members want to avoid ECHA annual fee for UA
- MS ask additional information for MR (templates LoA AS and products)
- LoA ARCHE Consortia
- Little difficulties working in group

# CONCLUSIONS

## ► Conclusions

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- Consortia are highly cost saving
- SME often only option but still high costs
- Still many uncertainties (big BPF, requirements)
- Consortia – BPF - UA – SBP still new, no authorisation yet but is supported by ECHA and MS
- Reduces workload for authorities



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