

‘ From pre-registration to joint submission ’

Hendrik Abma

Director General

European Association of Chemical Distributors (FECC)



Commission REACH Workshop

14 April 2008



- FECC

- Pre-registration - Pre-SIEF - SIEF

- Data and cost sharing

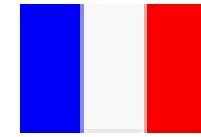
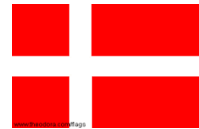
- Joint submission

Please note that the screenshot has been kindly provided by the ECHA/Commission for educational purposes.

The final version of REACH IT may present changes

National Associations 17

(including Switzerland and Norway)



Company Members 31

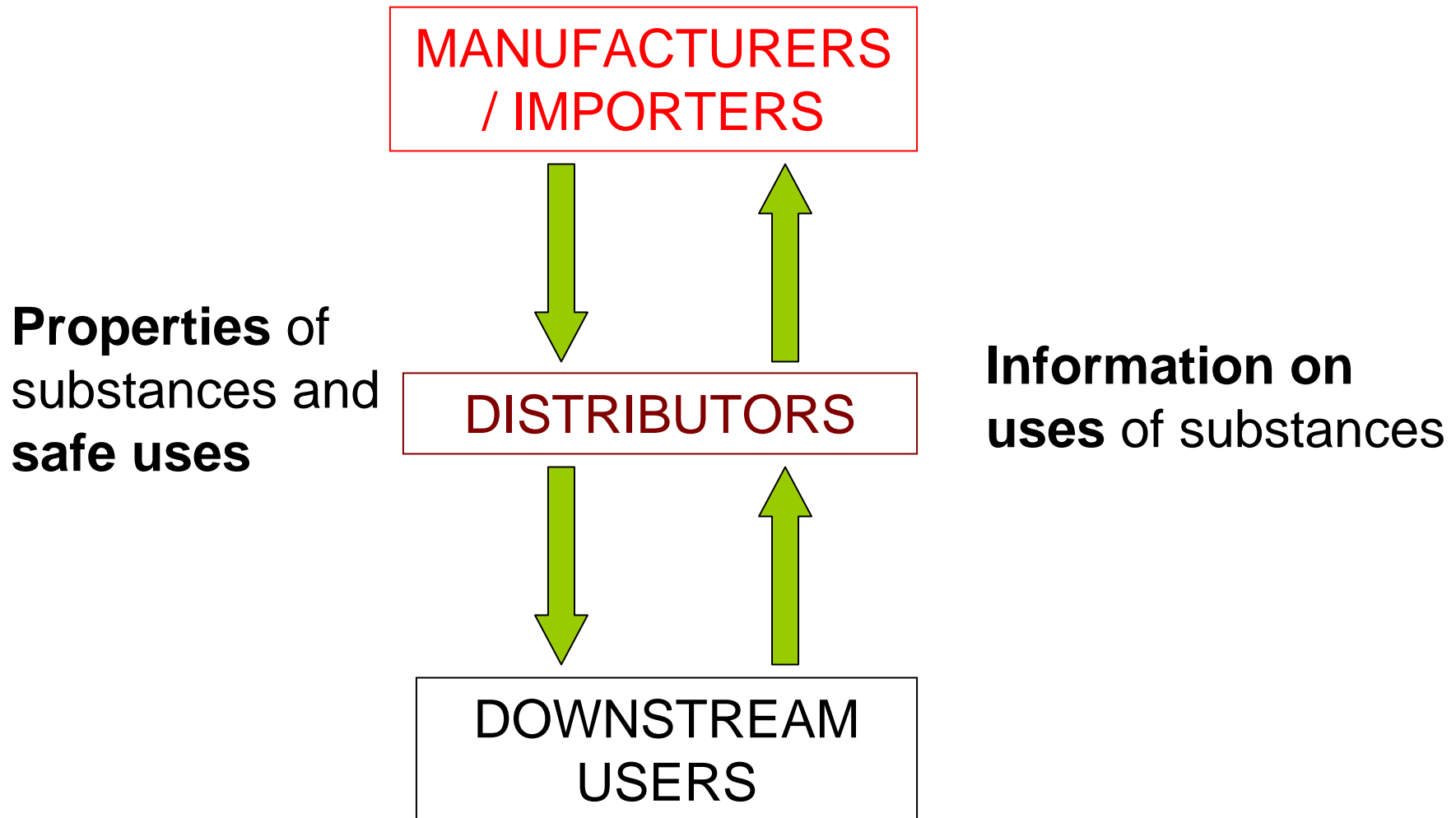
ALGOL CHEMICALS OY
AVANTEC S.A.
AZELIS S.A.
BANG & BONSONER GROUP
BIESTERFELD A.G.
BRENNTAG HOLDING GmbH & Co
BTC Europe
CALDIC BV
CAMPI Y JOVE S.A.
C.H. ERBSLÖH K.G.
DIPOL Chemical International Inc.
EIGENMANN & VERONELLI S.p.A.
GROLMAN GROUP
HARKE GROUP
Aug. HEDINGER GmbH & Co

HSH GROUP
IMCD GROUP B.V.
KRAHN CHEMIE GmbH
NORDMANN RASSMANN GmbH & Co
OMYA AG
ORKA d.o.o.
PENTA CHEMIKALIEN GmbH & Co KG
QUIMIDROGA S.A.
QUIMITECNICA.COM S.A.
R2 GROUP A/S
SAFECEM EUROPE GmbH
TENNANTS DISTRIBUTION Ltd.
TER HELL group
UNIVAR Europe Ltd
WARWICK INTERNATIONAL GROUP LTD.
WELDING

Associate Members 12

- ❑ Observer seat at **REACH CA**
 - ❑ Round table on pre-registration, March 2008
 - ❑ Presentation to the **ECHA**, Feb. 2007
 - ❑ Testing of the Navigator and REACH IT
 - ❑ Participation in Commission REACH workshops
 - ❑ REACH Implementation Projects (**RIPs**):
 - 3.1: Registration and Overall Guidance
 - 3.2: Chemical Safety Assessment and Report
 - 3.4: Data and cost sharing
 - 3.5: Downstream users obligations
 - 3.6: GHS
-
-

REACH will affect the entire supply chain and will make the chemical distributors play a crucial role



Chemical Distributors may have different roles in REACH...

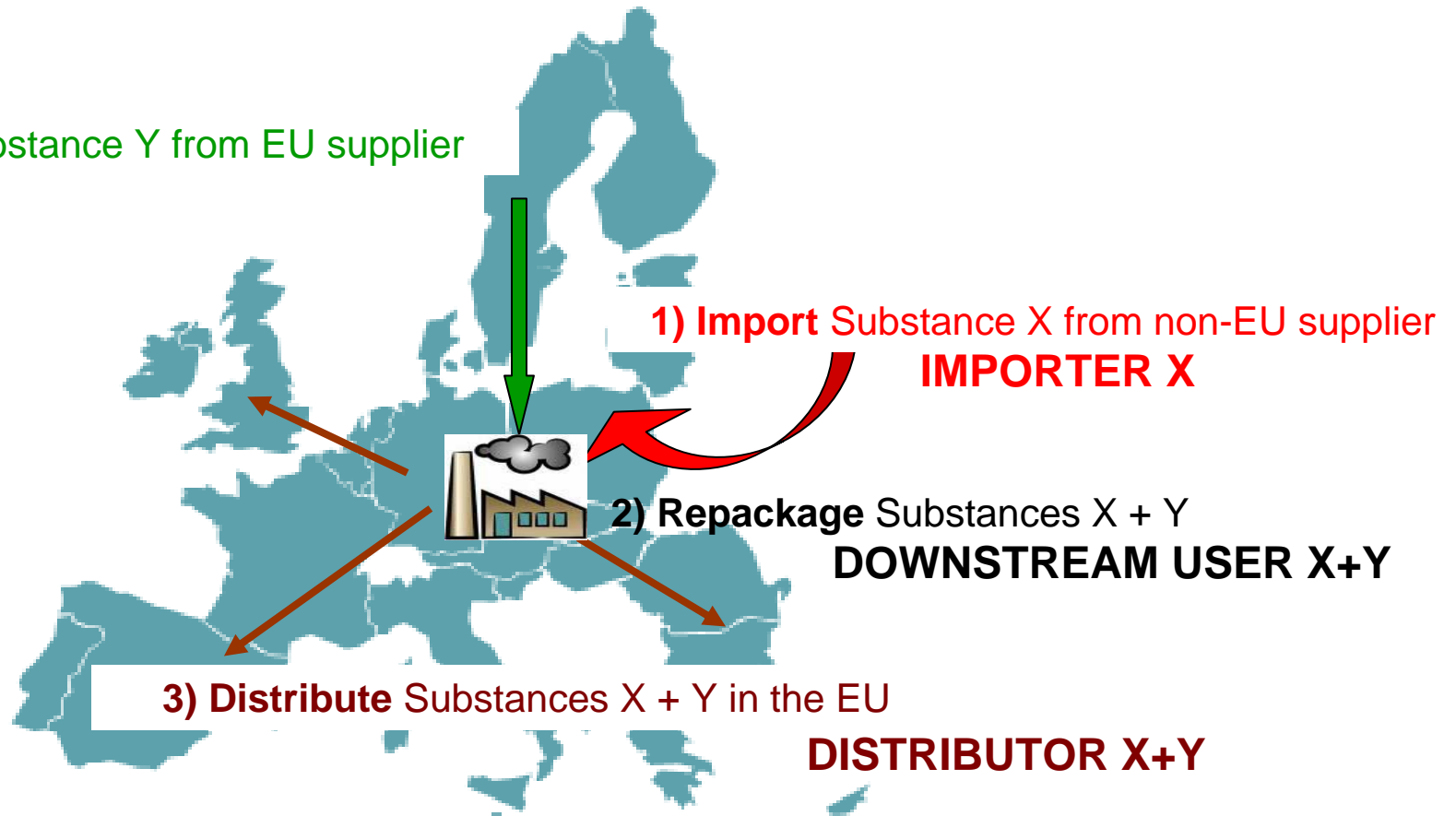
- ❑ Importer/Manufacturer: import into the EU (or manufacture) a substance or a substance in a preparation in 1 or more tonnes/year

- ❑ Distributor: only stores and places on the market a substance, on its own or in a preparation, for third parties

- ❑ Downstream user: uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities, e.g. formulation, dilution, re-packaging, etc

Different roles for the same company

1) Buy Substance Y from EU supplier



When a company pre-registers for the first time a substance, a pre-SIEF page is created.

Subsequent pre-registrants of the same substance will be added to this page.

Potential registrants:

- Manufacturers and importers
- Third party Representatives
- Only Representatives

Other participants:

- Data holders
(Downstream users and others) - *Voluntary*
 - Early registrants - *Mandatory*
-
-

PRE-SIEF AND SIEF FORMATION



REACH logo

Contact | Site map | Search | Print version |

English (en) ▾

You are connected as: j.doe@ccc on behalf of The Chemical Company, Inc. - Logout

Company > pre-SIEF > View > 202-049-5

Pre-SIEF definition

Caution:

The Agency does not take any legal liability or responsibility for information shared over this page.

Please note that the participants of this site have not had their identity checked.
By using this site you agree not to disclose any of the information you see to third parties.

EC number: [202-049-5](#)

Substance name: [naphthalene](#)

Substances to read-across:

[203-000-0 naphthalene](#) [58-08-2 coffeein](#)

Information from the SIEF formation facilitator

Dear colleagues,

for the substance naphthalene there will be a SIEF for data exchange available following the link
<http://naphthalene.SIEF-Portal.eu>

Best regards

PRE-SIEF partnership

Company name	Partnership type	Facilitator	Deadline / Tonnage band	Information from member	Contact person name
The Chemical Company, Inc.	Potential registrant	<input type="checkbox"/>	Over 100 tonnes 01/2/2010	info field ...	Jane Doe details ...
Chemicals Association	Potential registrant	<input type="checkbox"/>	1 to 10 tonnes 01/05/2010	info field ...	John Smith details ...
Les Usine Chimiques	Potential registrant	<input type="checkbox"/>		info field ...	Jean Dupond details ...
Chem Lawyers	Potential registrant	<input type="checkbox"/>		info field ...	John Grisham details ...
La chimie du Brabant	Third party - MI < 1 tonne / year			info field ...	Anne Delacourt details ...
Painting factory	Third party - Downstream user			info field ...	Jack Down details ...

Pre-SIEF discussions on sameness of substance



Agreement on same substance



SIEF Formation



Data sharing



Joint submission

Recommendation:

Issues to consider during first discussions:

- ❑ Confidentiality
- ❑ Scope of the cooperation
- ❑ Who will be the lead registrant?
- ❑ Agreement on joint submission and cost sharing
- ❑ Will the SIEF facilitator/Lead Registrant be compensated
- ❑ Legitimate possession
- ❑ Competition law rules apply! *REACH should be without prejudice to the full and complete application of the Community competition rules.*

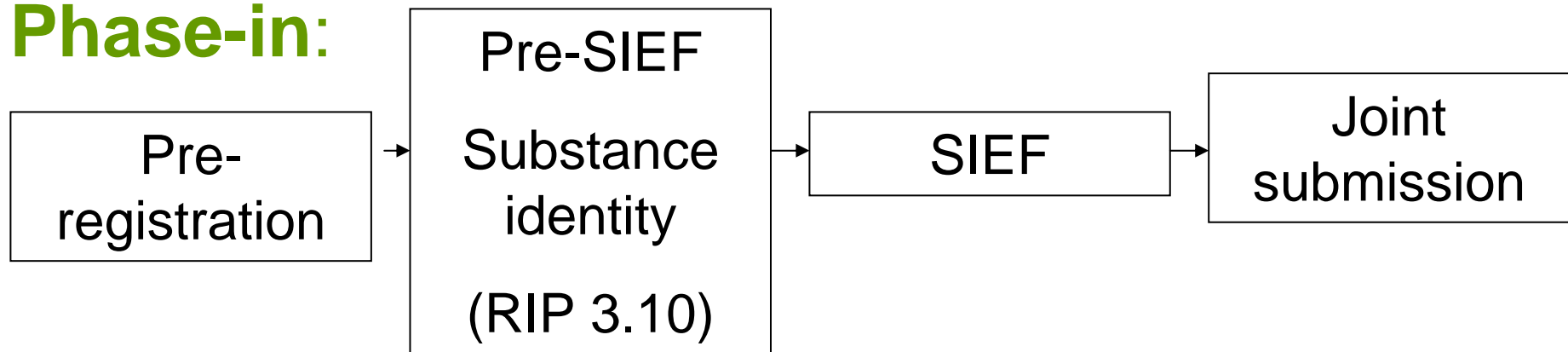
DATA SHARING: Issues to consider

- ❑ Mandatory sharing of animal testing
- ❑ Sharing of other tests upon request
- ❑ Minimise costs in industry
- ❑ The word 'consortium' is not mentioned in REACH
- ❑ Guidelines are explicitly mentioned in REACH

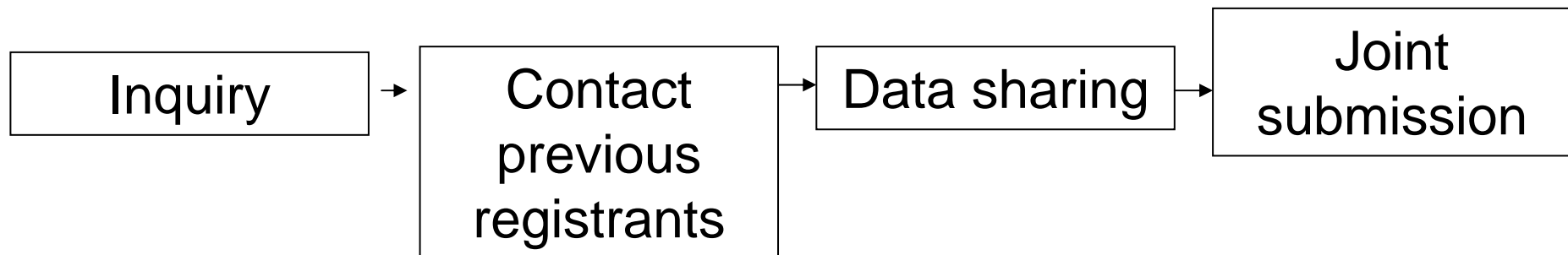
➡ *RIP 3.4: Guidelines developed by CEFIC, AISE, Eurometaux and FECC*

Two different mechanisms for phase-in and non-phase-in substances:

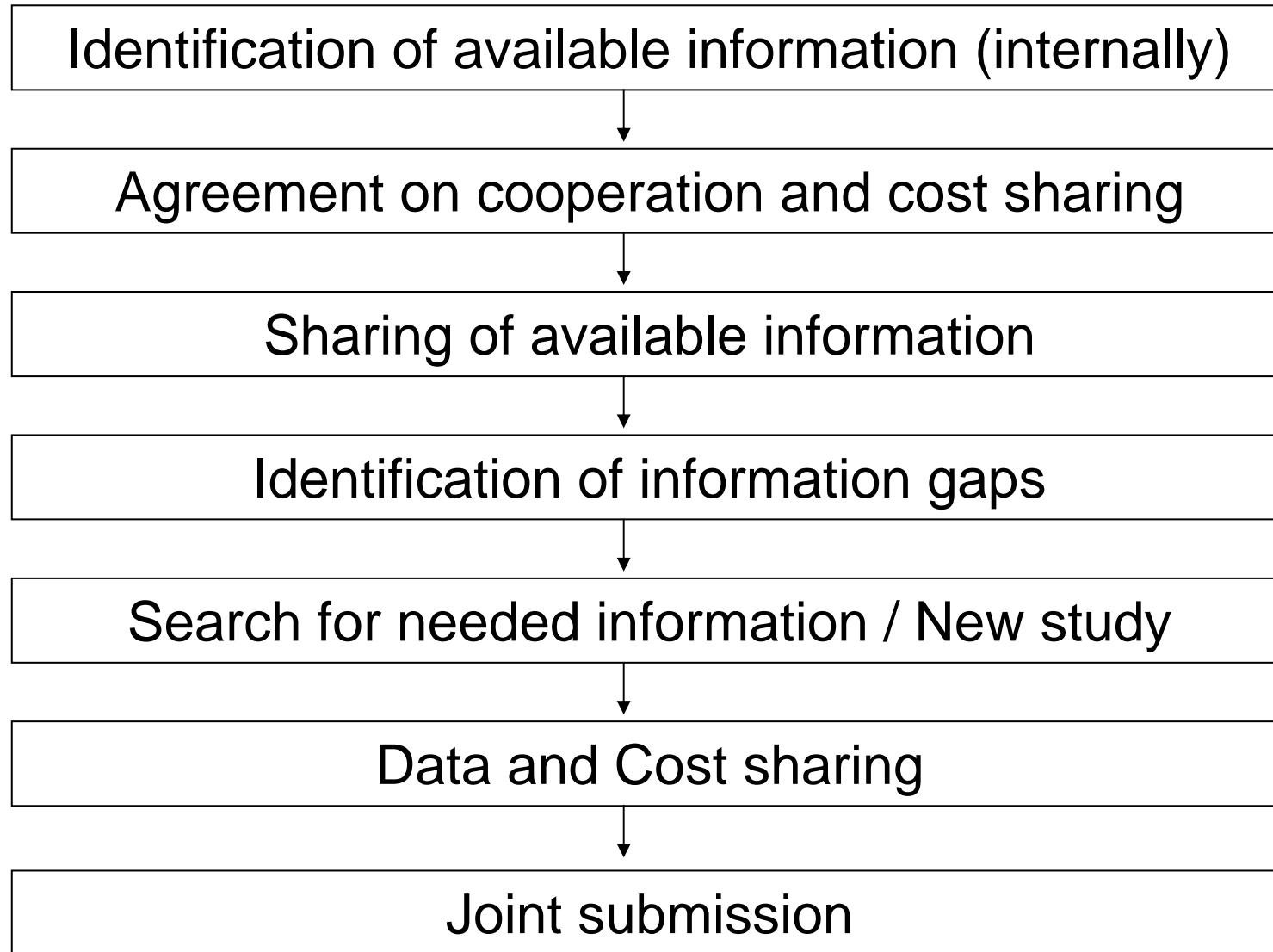
Phase-in:



Non-phase-in:



Phase-in:



Guidelines on cost sharing: affordable for SMEs!

*REACH says that SIEF participants shall make every effort to share costs in a **fair, transparent and non-discriminatory** way (article 30)*

- According to **volume** (applicable to all tonnage bands)
 - Principles also apply to **new studies**
 - Freedom of choice: **Historic vs replacement**
 - Mark-up factors **supported** by documentation
-

Guidelines on cost sharing: affordable for SMEs!

- Possibility of **reduction** factors
- **Risk premium** only in some circumstances
- Only payment for data needed for registration
- Only **one study per endpoint** will be compensated
- **Payment** at moment of registration
- Value for risk premium and administrative costs

 ***Recommendation: be aware of the guidelines for discussions on cost sharing***

- ❑ One Substance One Submission

 - ❑ Opt-out:
 - Disproportionately costly
 - Confidential information at stake
 - Disagreement with lead registrant

 - ❑ Implications:
 - Higher registration fees
 - Dossier evaluation
-
-

- ❑ The **Lead Registrant** ‘opens’ the joint submission
- ❑ Other members of the joint submission submit registration dossier referring to lead registrant submission for data
- ❑ Each company receives a **submission number** and a **reference number** (official registration number):

Type submission-unique number-check code- joint submission participant

Example format: 01-2114085-66-0000
 01-.....-.....-0001



JOINT SUBMISSION

<i>Joint submission</i>	<i>Separate submission</i>	<i>Optional</i>
Classification&Labelling	Identity of registrant	Guidance on safe use
Study summaries (Annexes VII to XI)	Identity of substance	Chemical Safety Report (if required)
Robust study summaries	Info on manufacture and use(s) of substance	
Proposals for testing	Exposure information if 1-10 t/y	
<i>Optional</i>		
Indication as to which info has been reviewed	Indication as to which info has been reviewed	

Thank you very much for your attention

Questions?

www.fecc.org
