

REACH Consortium or SIEF: Choose Right Registration Strategy



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Questions

- What is a REACH consortium? How is it functioning?
- What is the role of Only Representative in consortium?
- Does consortium guarantee that the registration can be done before its deadline?
- What is the advantage of compensation?
- How is the cost shared between the members of consortium?
- What is a letter of access?
- How much does in t it approx cost to get a letter of access?
- Shall our clients join the consortium or buy a letter of access to finish registration?
- What advantages does joining consortium have over buying a letter of access?
- What should be done by OR if clients choose to join the consortium and buy a letter of access respectively?

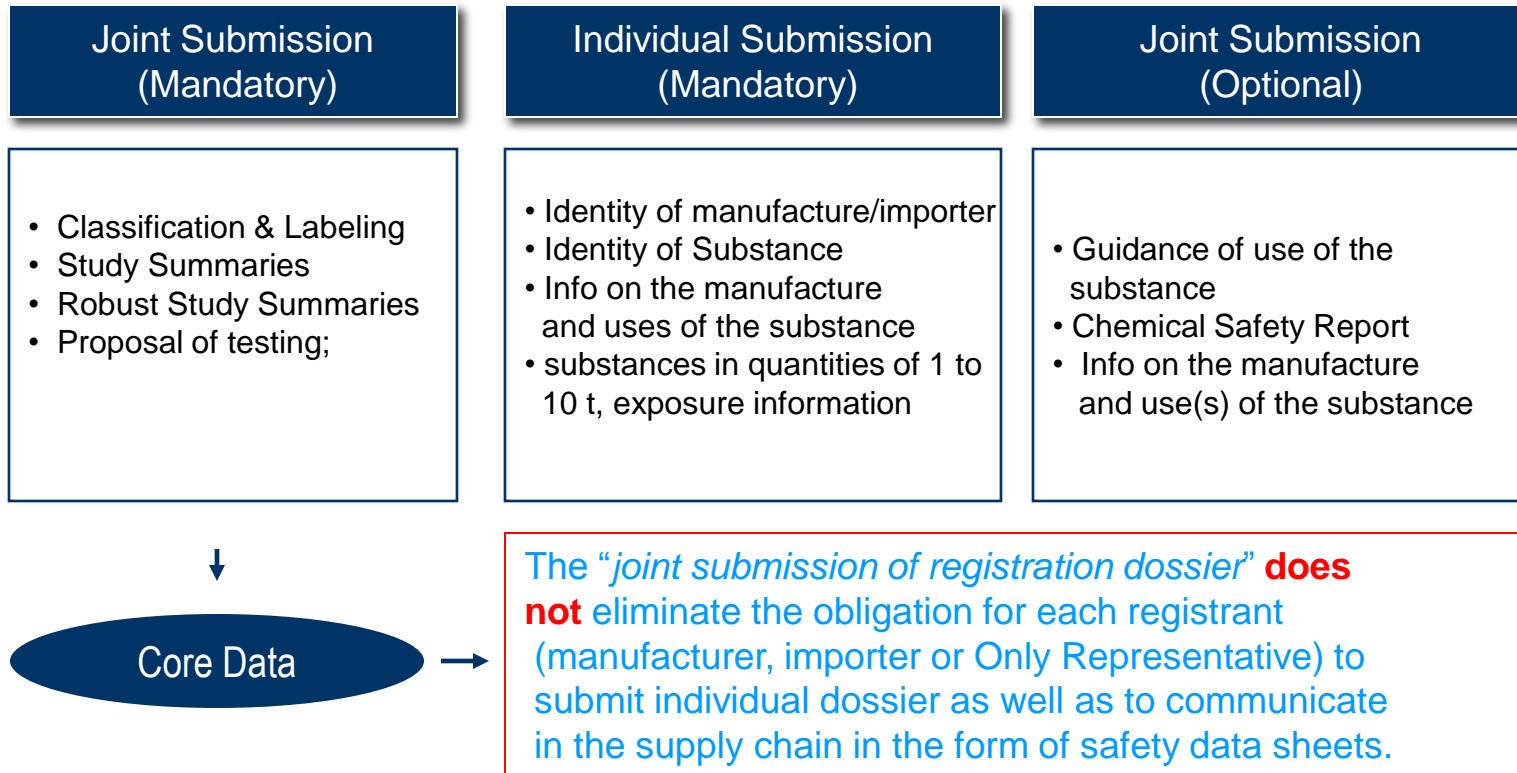
Catalog

- **Joint submission and data sharing in REACH**
- **Key elements in consortium**
- **Cost-sharing mechanism and cost estimation**
- **Help our clients make right decisions**
- **Other issues to consider as Only Representative**
- **Supportive evidence of several consortiums**

Joint Submission and Data Sharing in SIEF

- Registrants of the same SIEF must *make a joint submission* and *designate a lead registrant* who is obliged to submit, *on all registrants' behalf*, a part of the technical dossier.
- Refusal to sign up to a joint submission is only possible if:
 - a. it is disproportionately costly for the specific registrant;*
 - b. the registrant needs to prevent disclosure of commercially sensitive information;*
 - c. the registrant disagrees with the lead registrant on the selection of the information.*
- In addition to the joint submission, REACH contains a *data-sharing obligation* under which registrants must share their information on data and to work together to analyze whether new tests are needed for the joint registration dossier.
- **Hint:**
 - a. Registration Dossier prepared by a consortium under a SIEF shall be submitted jointly on all registrants' behalf, not just consortium members' behalf*
 - b. Consortium is obliged to contact non-consortium members in the SIEF to encourage them to join the consortium or buy a letter of access to make sure non-consortium members can also participate in the joint submission.*

Joint Submission and Individual Submission



- Question:**
- a. Does consortium cover CSR and guidance of use?**
 - b. Does consortium cover all uses of members?**
 - c. What if individual use is not covered by joint registration dossier?**

Comparison between Consortia and SIEF

SIEF	Consortia
<ul style="list-style-type: none">• Mandatory• Lack of legal framework• Time-consuming communication• Hard to organize• Lack of detailed mechanism for cooperation	<ul style="list-style-type: none">• Voluntary• Pooling resources• Contractual agreement on liabilities and cost-sharing mechanism• Protection of CBI• Grouping similar substances lowers cost of the data through read-cross and QSAR

Hint: *Consortium, whilst not a mandatory requirement of REACH, are the most efficient means of achieving the required levels of co-operation to comply with the REACH objectives.*

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Types of membership of “Consortia”

Founding member

- Regular Members that have borne financial and active contribution on behalf of the consortium before its incorporation.
- Manufactures or importers or associations

Regular member

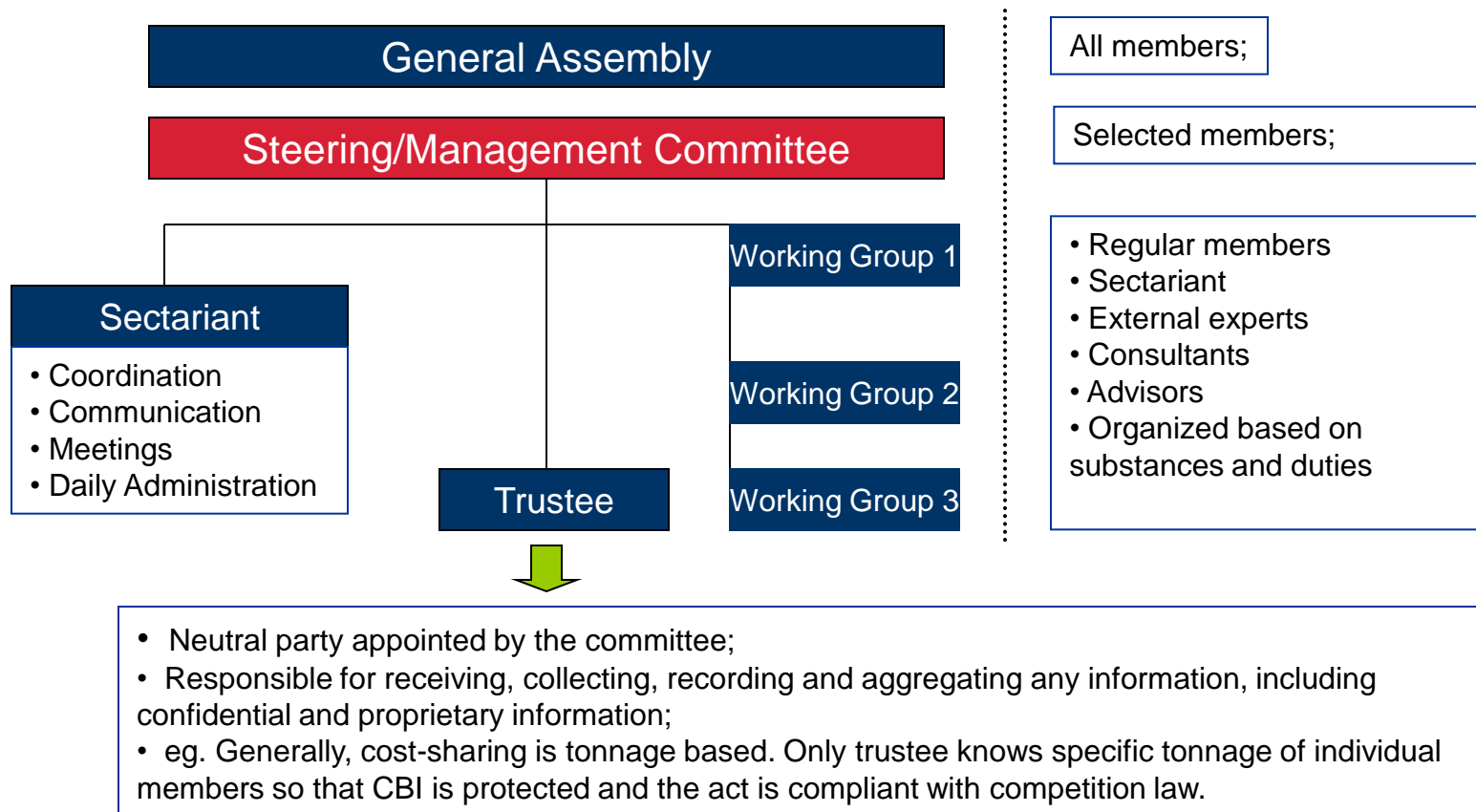
- Manufacturers, importers who are subject to a registration requirement according to REACH
- Only Representatives representing Out-EU manufactures

Associate member

- Downstream users who wish their use to be covered
- Data holders or so called Observers

Note: In many cases, Only Representative **cannot join** the consortium as a Regular member but they can be appointed by the Regular member to represent them at the consortium meetings.

Bodies of “Consortium”



Jobs Done by “Consortium”

- Development of **core data**

→ 14 out of 14 consortiums promise to finish the job on time or try every effort to finish the job before the deadline.

- Preparation of the **Chemical Safety Report and the guidance on safe use**

→ 12 out of 14 consortiums will submit them jointly with common uses of members covered, not necessarily all possible uses. 2 of them are subject to the decisions of the management committee.

- Submission of the joint registration dossier by the lead registrant.

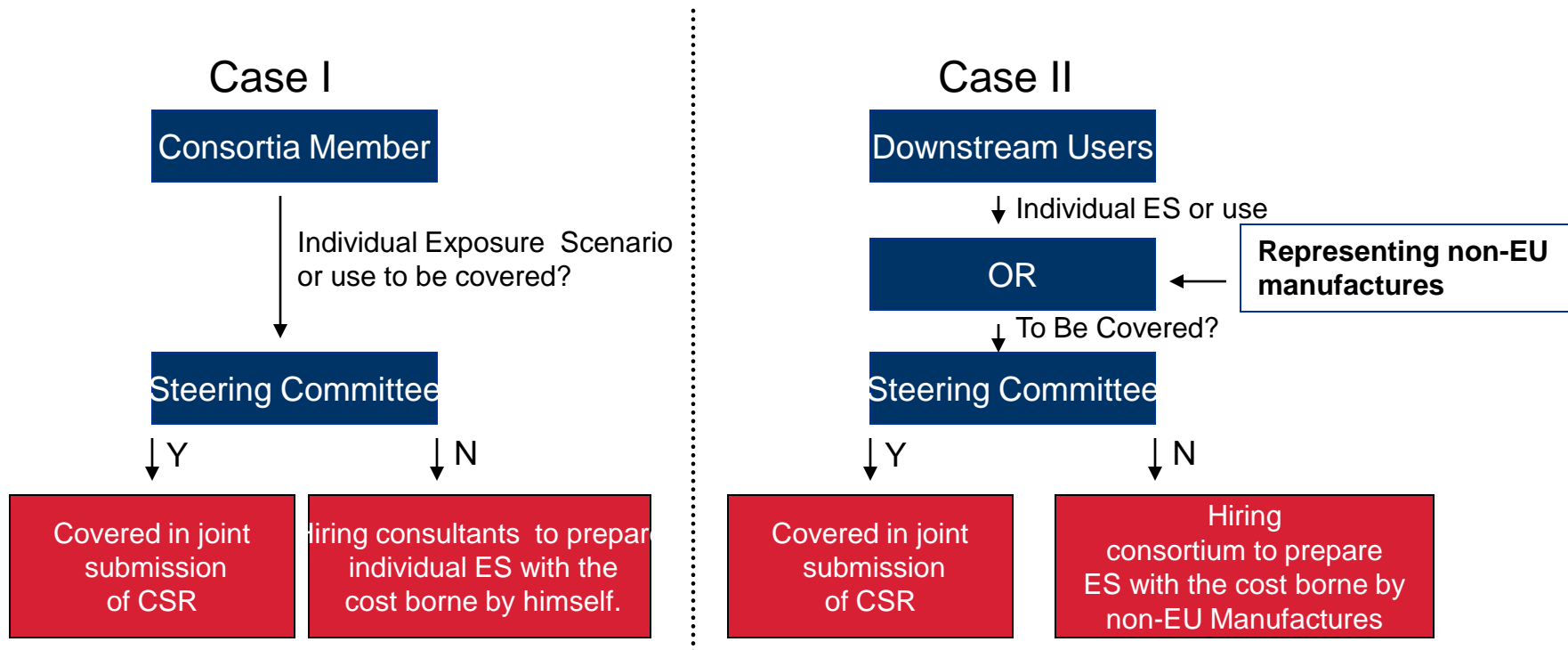
→ It is the same for all consortia.

- Cooperate in order to identify and share existing data, identify and fill data gaps for the purpose of joint submission.

→ Communication with SIEF members is required

- Indicate as to which of the information submitted jointly has been reviewed by an assessor

CSR or individual ES subject to the decision of the steering committee



Note:

- a. Most of the common uses of consortium members will be covered in CSR submitted jointly
- b. It is possible that uses of non-consortium members will not be covered in the joint registration dossier. Individual Chemical Safety Report has to be prepared.

Protection of CBI by Consortium

- Any **only representative** applying to become a Member of the Consortium **will be required to disclose to the Trustee** the identity and the number of their principals and evidence of their authority to act as the representative of each principal.
- Information such as tonnage band, substance registered regarding the only representatives' principals must be held confidential by the **Trustee** and must not, without the prior written consent of the only representative, be disclosed to any Member or other Third Party.

Rights on Data

- **Existing Studies:**

Retained by the Member who provides access to the respective studies and proof of their cost.

- **New Studies:**

Regular Members shall have **joint ownership** of new studies pro rata to their respective financial contributions.

- Granting a letter of access to the studies generated by the consortium to Third Parties for use within or outside the scope of REACH may be subject to a decision of the Steering Committee in each case

Letter of Access

- Enable third parties, especially non-consortium members in the SIEF to refer to the joint registration dossier prepared by the consortium.

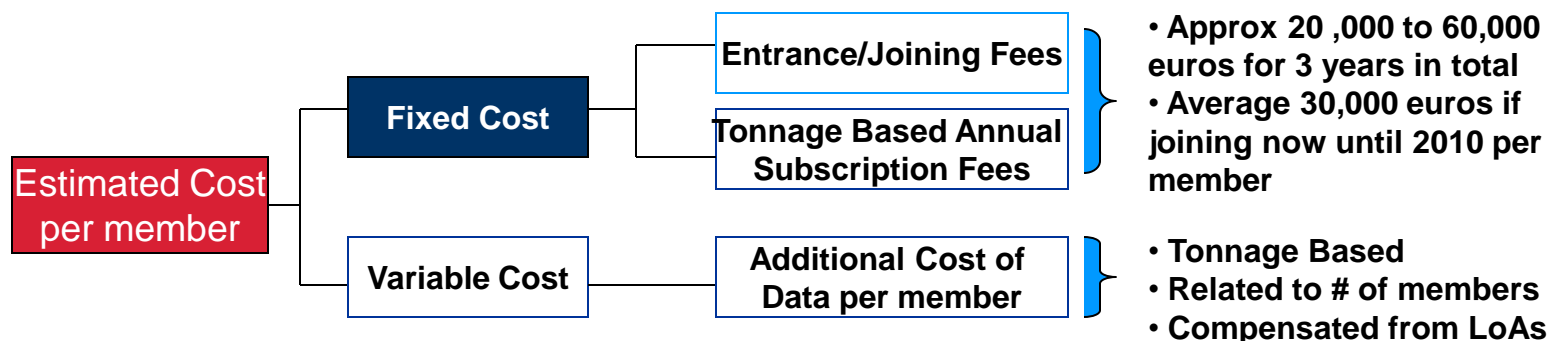
However:

- Reference might be limited to core data only, excluding CSR and guidance on their use.(such as AI ,etc)
- Reference is restricted only for the registration purpose only.
- Reference is not transferable to any other entity or person.
- *The entity who receives a letter of access* is not authorised to receive any copies of the Dossier nor is authorised to inspect or view the Dossier or any related specific document in whole or in part.
- Letter of Access shall in no event be construed as granting any property rights whatsoever in the Dossier.
- *The above limitations are exactly why letter of access should be cheaper.*

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Cost-sharing Mechanism and Cost Estimation



Examples:

Styrene Consortia:

31 consortia members, total cost approx 3 million euros;
Estimated cost per member 100,000 Euros ;
The actual cost is lower due to the revenues of LoAs;

Ethyl Benzene Consortia:

14 consortia members, total cost approx 600,000 euros;
Estimated cost per member 42,857 Euros per member ;
The actual cost is lower due to the revenues of LoAs;

Estimated Cost for full registration dossier of one substance is around 30,000 ~150,000 euros;
LoAs are cheaper: 5,000 ~ 50,000 euros

Even though we don't know the specific number, we can still make right decisions!!

Extra Cost for Late-entrants into Consortia

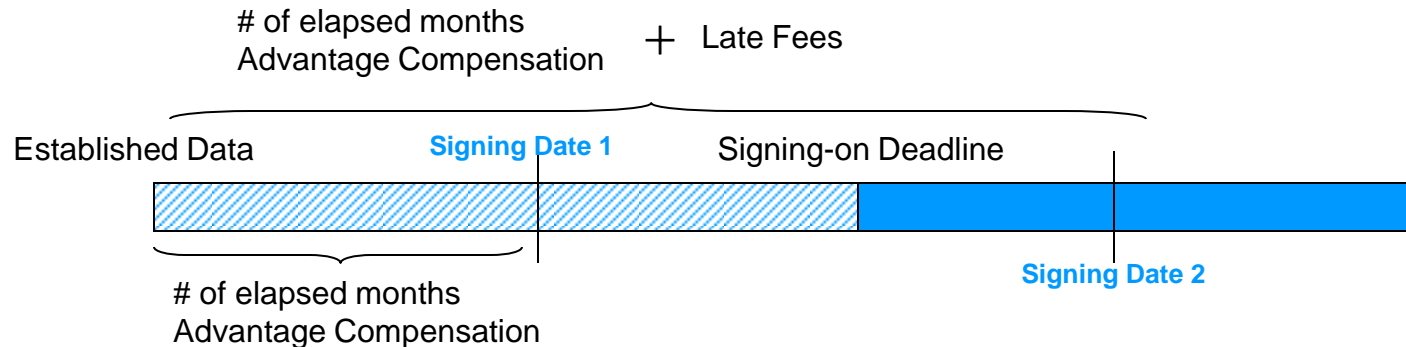
Late Fees

Joining fee+ annual subscription fees (accumulated number since the foundation of the consortia) $\times(1+p)$ (Note: p is usually equal to 25%.)

Advantage Compensation

(Joining fee or annual subscription fee) $\times (1 + a/12)^{\wedge}$ (# of elapsed months since the establishment of the consortia) (Note: Interest rate a is usually set to be 5%)

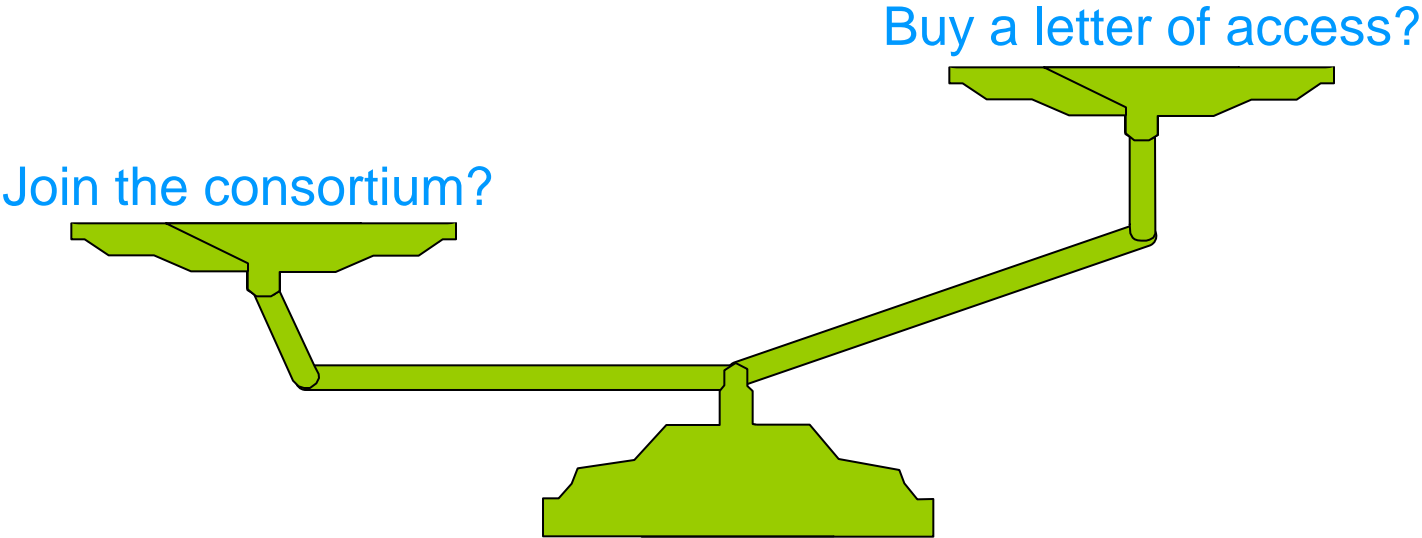
Sometimes both apply. Late fee is more common.



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Two Ways to Get Data for Non-consortia Members

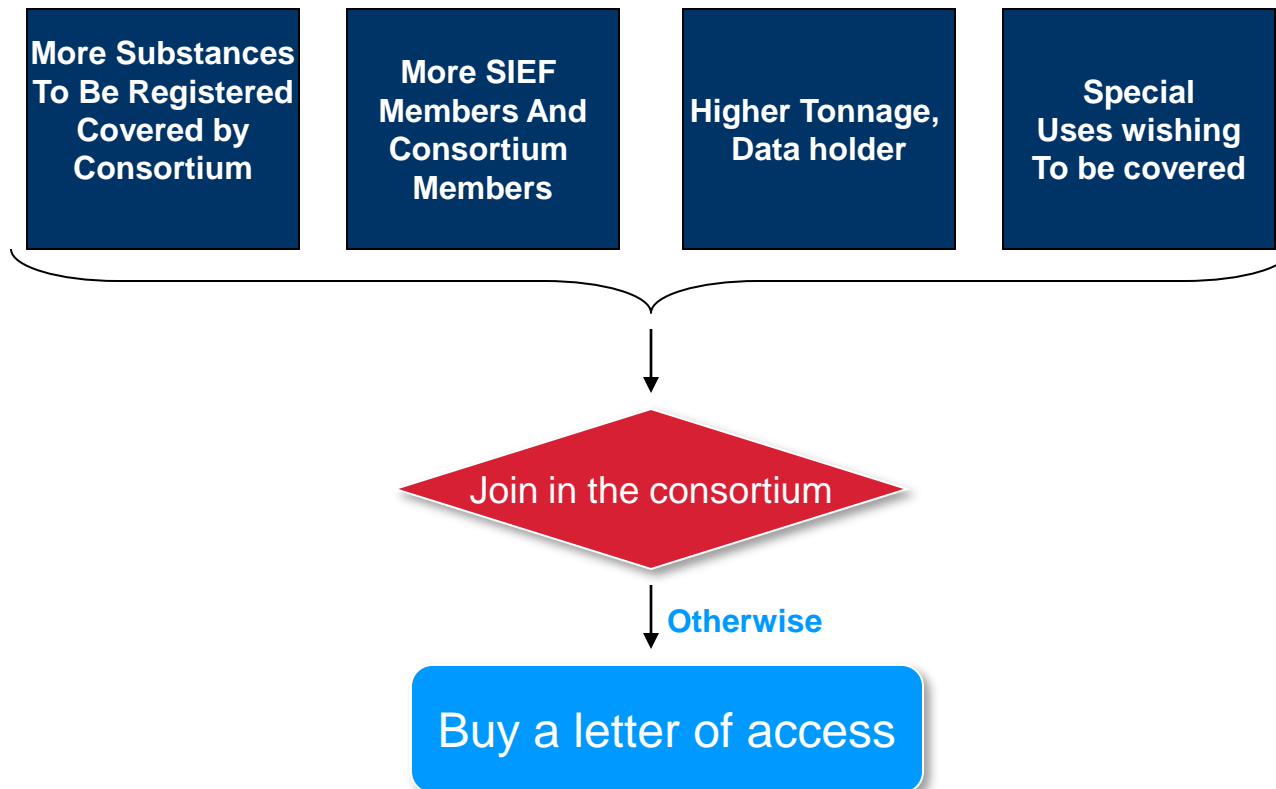


Five factors to consider before joining REACH consortium

- *The number of similar substances covered by a consortium*

The bigger this number is, the cheaper it will cost to get the registration dossiers for all intended substances as a consortia member than buying letter of access for each substance individually.
- *The number of active SIEF members and consortium members*
 - a. More active SIEF members indicate larger revenues from letter of access..
 - b. More consortia members indicate smaller cost of share on data for each member.
- *The higher tonnage it is, the more data will be required.*
- *Data holder with valid studies that could be used for REACH registration*
- *Uncommon use wishing to be covered (non-CBI) in CSR*

Five factors to consider to join the consortia



Generally, LoA is cheaper. But there are situations where joining the consortium is more cost efficient.

Proposed Procedure of Registration

STEP 1

Selection of Substances of Highest Priority (deadline 2010)

STEP 2

Determination of Intentions of Our Clients (Communication)

STEP 3

Check to See if There is a Consortia or Not

Yes

Join in consortia?
Up to Clients

Yes

No

- Sign Consortium Agreement
- Fax Back to Sectariant
- Pay Membership Fee
- Appoint OR as Representatives
- Communicate to DU/Consortia
- Finish required payment
- Submit individual dossier

A registration contract between OR and non-EU manufactures need to be drafted.

- Follow the progress
- Prepare own CSR if not covered
- Buy license of access
- Complete registration dossier
- Finish required payment
- Submit individual dossier

A registration contract between OR and non-EU manufactures need to be drafted.

No

①

Hire Consultants

②

Wait in SIEF

③

Do Own Test

④

Organize consortia

⑤

Cease Manufacture

Which Way To Go????
Needs to Be Evaluated.

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Other Issues to Consider as OR

- *Financial settlement mechanism*
- *Communication in the supply chain and confidentiality*
- *What if individual CSR/ES is needed for clients?*
- *How to finish the registration if there is no data or lead registrant/consortium?*

Hydrocarbon Solvents Consortium

- Founded in June 2008, >14 largest producers
- Hydrocarbon Solvents such as pentane, cyclohexane, 72 substances in total
- Fixed Cost
 - joining fee =10000 Euros
 - membership fee=approx 10,000 per year
 - 20,000 Euros for 2009, 30,000 Euros for 2010 in total
- Cost of data gathering and preparation of dossier for one substance is borne by members benefiting from this substance in proportion to their respective share which is tonnage based.
- Letter of access for manufactures or importers of only a few solvents is cheaper. Joining the consortium is a better decision for large manufacturers or importers of many solvents covered by this consortium.

Styrene and Ethyl Benzene Consortium

- 31 members for styrene; 14 members for ethyl benzene consortium
- Styrene and Ethyl Benzene Only
- Fixed Cost:
Styrene Euro 20,000, and Euro 30,000 for ethyl benzene (one time charge)
For late entrants: $(1+20\%)*$ paid by regular members
24,000 for Styrene for 2009, 36,000 for ethyl benzene
- Variable Cost:
The data cost for styrene was estimated at Euro 3 Million, and for ethylbenzene at Euro 600,000, expected to be lower than that.
- Cost of letter of access:
LoAs for third parties for studies can be issued at the same cost as for members plus 15% administration cost.

Antimony Consortium

- <http://www.iaoiia.org/>
- Founded by iaonia, 34 members (note: Hunan Chenzhou Antimony Co., Ltd.)
- 13 antimony compounds
- Fixed Cost: (late fee applied, tonnage based)
for <100t, 18833 euros for 2009, 28586 euros for 2010
for 100t~999t, 35883 euros for 2009, 54258 euros for 2010
- Variable Cost
Additional cost of data gathering and preparation of dossier is borne by members in proportion to their respective share which is tonnage based.
- A letter of access is only considered for the less than 10T category

Fe Consortium

- <http://www.iron-consortium.org/>
- 17 members
- For iron and its oxides, 9 substances in total
- Fixed Cost:
 - 25,000 euros for 300,000t/yr
 - 15,000 euros for <300,000t/yr
 - 7,500 euros for <5,000t/yrA late joining premium equal to 25% of the normal contribution applies.
- Variable Cost
 - Costs are shared pro-rata between Regular Members in accordance with the annual tonnage.
- A letter of access might be the most coefficient solution to small and medium producers

Co Consortium

- <http://www.thecdi.com/reach-consortium>
- Founded by CDI
- Co and its compounds (mainly coordination compounds, 27 substances in total)
- Fixed Cost: (Does not change with the number of consortia members)
Sign-on fees:
<100t 2000 euros; <1000t 10,000euros; >1000 t 20,000 euros;
- Variable Cost
Annual Subscription fees associated with the number of substances registered and corresponding tonnages.
- For manufactures and importer of many cobalt substances with higher bandage, membership is encouraged. Otherwise, letter of access is better.