REACH Consortium or SIEF: Choose Right Registration Strategy

Yunbo Shi (yunbo.shi at cirs.ie), Managing Director
Chemical Inspection and Regulation Services, Ltd
March 17th, 2009
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 it approximate 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?
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

<table>
<thead>
<tr>
<th>Joint Submission (Mandatory)</th>
<th>Individual Submission (Mandatory)</th>
<th>Joint Submission (Optional)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Classification &amp; Labeling</td>
<td>• Identity of manufacture/importer</td>
<td>• Guidance of use of the</td>
</tr>
<tr>
<td>• Study Summaries</td>
<td>• Identity of Substance</td>
<td>substance</td>
</tr>
<tr>
<td>• Robust Study Summaries</td>
<td>• Info on the manufacture and uses</td>
<td>• Chemical Safety Report</td>
</tr>
<tr>
<td>• Proposal of testing;</td>
<td>of the substance</td>
<td>• Info on the manufacture</td>
</tr>
<tr>
<td></td>
<td>• substances in quantities of 1 to</td>
<td>and use(s) of the substance</td>
</tr>
<tr>
<td></td>
<td>10 t, exposure information</td>
<td></td>
</tr>
</tbody>
</table>

**Core Data**

The **“joint submission of registration dossier” does not** eliminate the obligation for each registrant (manufacturer, importer or Only Representative) to submit individual dossier as well as to communicate in the supply chain in the form of safety data sheets.

**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**
- Mandatory
- Lack of legal framework
- Time-consuming communication
- Hard to organize
- Lack of detailed mechanism for cooperation

**Consortia**
- Voluntary
- Pooling resources
- Contractual agreement on liabilities and cost-sharing mechanism
- Protection of CBI
- Grouping similar substances lowers cost of the date 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.*
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 OR
- Supportive evidence of several consortiums
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”

General Assembly

Steering/Management Committee

Sectariant
- Coordination
- Communication
- Meetings
- Daily Administration

Trustee

Working Group 1

Working Group 2

Working Group 3

All members;

Selected members;

• Regular members
• Sectariant
• External experts
• Consultants
• Advisors
• Organized based on substances and duties

• Neutral party appointed by the committee;
• Responsible for receiving, collecting, recording and aggregating any information, including confidential and proprietary information;
• eg. Generally, cost-sharing is tonnage based. Only trustee knows specific tonnage of individual members so that CBI is protected and the act is compliant with competition law.
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

Case I
Consortia Member

Individual Exposure Scenario or use to be covered?

Steering Committee

Y

N

Covered in joint submission of CSR

Hiring consultants to prepare individual ES with the cost borne by himself.

Case II
Downstream Users

Representing non-EU manufactures

Individual ES or use

To Be Covered?

Steering Committee

Y

N

Covered in joint submission of CSR

Hiring consortium to prepare ES with the cost borne by non-EU Manufactures

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.
Catalog

- Joint submission and data sharing in Reach
- Key elements in consortia
- **Cost-sharing mechanism and cost estimation**
- Help our clients make right decisions
- Other issues to consider as OR
- Supportive evidence of several consortiums
Cost-sharing Mechanism and Cost Estimation

Estimated Cost per member

<table>
<thead>
<tr>
<th>Fixed Cost</th>
<th>Entrance/Joining Fees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable Cost</td>
<td>Tonnage Based Annual Subscription Fees</td>
</tr>
<tr>
<td>Additional Cost of Data per member</td>
<td></td>
</tr>
</tbody>
</table>

- Approx 20,000 to 60,000 euros for 3 years in total
- Average 30,000 euros if joining now until 2010 per member
- Tonnage Based
- Related to # of members
- Compensated from LoAs

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) \(x(1+p)\) (Note: \(p\) is usually equal to 25%)

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

Sometimes both apply. Late fee is more common.
Catalog

- Joint submission and data sharing in Reach
- Key elements in consortia
- Cost-sharing mechanism and cost estimation
- Help our clients make right decisions
- Other issues to consider as OR
- Supportive evidence of several consortiums
Two Ways to Get Data for Non-consortia Members

Join the consortium?

Buy a letter of access?
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

1. More Substances To Be Registered Covered by Consortium
2. More SIEF Members And Consortium Members
3. Higher Tonnage, Data holder
4. Special Uses wishing To be covered

Join in the consortium

Otherwise

Buy a letter of access

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)
- Determine Intentions of Our Clients (Communication)
  - Join in consortia?
    - Yes
      - Sign Consortium Agreement
      - Fax Back to Sectariant
      - Pay Membership Fee
      - Appoint OR as Representatives
      - Communicate to DU/Consortia
      - Finish required payment
      - Submit individual dossier
    - No
      - 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.

**STEP 2** Determination of Intentions of Our Clients (Communication)
- Join in consortia? Up to Clients
  - Yes
    - Sign Consortium Agreement
    - Fax Back to Sectariant
    - Pay Membership Fee
    - Appoint OR as Representatives
    - Communicate to DU/Consortia
    - Finish required payment
    - Submit individual dossier
  - No
    - Follow the progress
    - Prepare own CSR if not covered
    - Buy license of access
    - Complete registration dossier
    - Finish required payment
    - Submit individual dossier

**STEP 3** Check to See if There is a Consortia or Not
- Join in consortia? Up to Clients
  - Yes
    - Sign Consortium Agreement
    - Fax Back to Sectariant
    - Pay Membership Fee
    - Appoint OR as Representatives
    - Communicate to DU/Consortia
    - Finish required payment
    - Submit individual dossier
  - No
    - Follow the progress
    - Prepare own CSR if not covered
    - Buy license of access
    - Complete registration dossier
    - Finish required payment
    - Submit individual dossier

Which Way To Go? Needs to Be Evaluated.
• Joint submission and data sharing in Reach
• Key elements in consortia
• Cost-sharing mechanism and cost estimation
• Help our clients make right decisions
• Other issues to consider as OR
• Supportive evidence of several consortiums
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 manufacturers 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

- 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/](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/yr
  - A 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](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 10,000 euros; >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.