



US Clients
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Consortium participation

Inside track to Letters of Access

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Short-comings of the SIEF

- **Too large** – many are well in excess of 500
- **Too diverse** – response rates are seldom more than 15%
- **Too unwieldy** – SIEF agreements can't be established in time to organise work
- **Too late** - Many important (2010) SIEFs are still not up and running

Most progress being made in Consortia

Joining a Consortium

- Need to know that one exists (e.g. industry knowledge or publication – Chemwatch)
- Membership rules vary but often there is a choice to either join as the principal or via a consultant/ Only Representative
- Key factors to consider are:
 - ❖ Strategic significance of the substance
 - ❖ Alignment of registration time-scales
 - ❖ Relationship between SIEF and Consortium
 - ❖ Data-gap analysis (where known) and cost sharing plans
 - ❖ Regulatory uncertainties

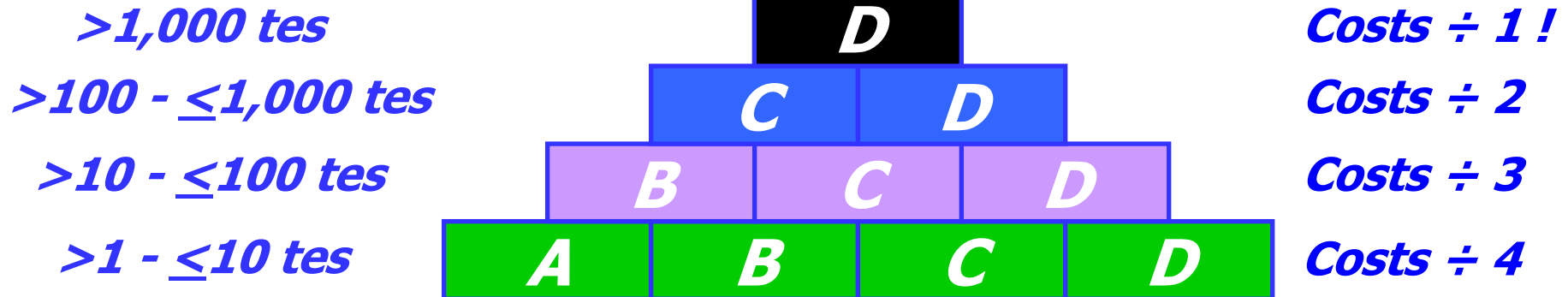
More factors to consider

- Where a consortium exists and you choose not to be a member – must rely on communication
- The challenge is always that you don't know what you don't know
- The data-gap analysis is a key factor in working out how much needs to be spent and when.
- Should insist on knowing as early as possible how costs are going to be shared:
 - ❖ Fixed price per tonnage band or variable approach
 - ❖ Available data and who owns it
 - ❖ Risk premium and how its assessed

The Brick-Wall Principle still holds.....

- *Company A* >1 - ≤10 tes
- *Company B* >10 - ≤100 tes
- *Company C* >100 - ≤1,000 tes
- *Company D* >1,000 tes

Test Requirements



- *Potential for further cost differentiation above 1000tes*
- *Need to decide on group level or legal entity*
- *Non-testing costs shared equally between all members*

Cost-sharing approaches are emerging...

REACH Registration Letter of Access fees (estimate) Substance EC.

Data inputs				
	Tonnage band			
	1-10	10-100	100-1,000	>1,000
No. of Registrants in tonnage band	30	10	5	2
Total value of studies in tonnage band (Euros)	30,000	150,000	500,000	1,000,000
Total Registration dossier value (Euros)	160,000			

Key principles

Dossier: The Registration dossier fee is split equally among Registrants. As extent of Registration dossier increases with tonnage, the fee increases for tonnage bands in proportion to the total value of studies in it and lower tonnage bands.

Studies: The study fee is split equally between all Registrants requiring a LOA.

Data calculations: Registration dossier Letter of Access fee

	Tonnage band				Comment
	1-10	10-100	100-1,000	>1,000	
Total value of studies in tonnage band (Euros)	30,000	150,000	500,000	1,000,000	Input value
Total value of studies in all required tonnage bands (Euros)	30,000	180,000	680,000	1,680,000	Cumulative total of study values in this and lower tonnage bands
Effective number of "shares"	1	6	23	56	1-10 t equals 1 share. Other tonnage bands are rounded to nearest full share
No. of Registrants of tonnage band	30	10	5	2	Input value
Total No. of shares in of all Registrants in tonnage band	30	60	115	112	No. shares * No. Registrants
Total number of shares of all Registrants over all tonnage bands	317				Sum of all tonnage bands
Total Registration dossier value (Euros)	160,000				Input value
Registration dossier fee per share (Euros)	505				Total Registration dossier value / total number of shares over all tonnage bands
Fee per Registrant for Registration dossier (Euros)	505	3,028	11,609	28,265	Fee per share * Effective number of share of tonnage band

Most follow similar themes...

Data calculations: Study Letter of Access fee					
	Tonnage band				Comment
	1-10	10-100	100-1,000	>1,000	
Total value of studies in tonnage band (Euros)	30,000	150,000	500,000	1,000,000	Input value
Total value of studies over all tonnage bands (Euros)	1,680,000				Sum of total value of studies of each tonnage band
No. of Registrants in tonnage band	30	10	5	2	Input value
No. of Registrants requiring tonnage band studies	47	17	7	2	Cumulative total of number of Registrants in this and lower tonnage bands
Fee per Registrant for studies in tonnage band (Euros)	638	8,824	71,429	500,000	Total value of studies in tonnage band / No. Registrants requiring tonnage band studies
Fee per Registrant for studies of all required tonnage bands (Euros)	638	9,462	80,890	580,890	Cumulative total of Registrant fees in this and lower tonnage bands
Total Registrant fees for studies (Euros)	1,680,000				Calculation integrity check (red shading indicates error)

Data output: Registrant fees for Letters of Access				
	Tonnage band			
	1-10	10-100	100-1,000	>1,000
Fee per Registrant for Registration dossier (Euros)	505	3,028	11,609	28,265
Fee per Registrant for studies of all required tonnage bands (Euros)	638	9,462	80,890	580,890
Total fees for Registration dossier and studies (Euros)	€ 1,143	€ 12,490	€ 92,499	€ 609,155

Conclusions on consortium participation

- Participation is voluntary but the dynamics of the situation may dictate the course of action
- Unless there are specific circumstances, participation at lower tonnage bands may not be cost-effective
- Later access will cost more, but percentages may be tolerable
- Consortium participation may provide you with market information and contacts that prove valuable
- Prioritisation and resource management is key