

REACH Registration Strategies



EU REACH Workshop, Asia 2009
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Content

- **Choice on registration route
(for phase-in substance)**
- Strategy on cost control
- Strategy on CBI protection
- Strategy on marketing promotion
- Conclusion



SIEF Status of Phase-in Substance

- SIEFs with well-run Consortia
- SIEFs with notified Lead Registrant
- SIEFs without Consortia and LR (SIEF orphan)



Which SIEF your substance belongs to ?

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Registration Option 1

* Purchasing the Letter of Access

- Get the right to refer to registration dossier, only for REACH compliance
- No ownership transfer
- No obligation to registration activities involvement within consortia
- Normally lower compensation for data sharing

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Registration Option 2

* Join in the Consortia

- Get the ownership of new studies carried out by consortia
- Get the right to use studies for other Non-REACH regulation compliance, if appropriate
- Benefit from compensation through cost sharing, e.g. selling LoA;
- Pay membership fee
- Actively involved in consortia activities, e.g. meeting, email etc.

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Registration Option 3

* Opt out, submit separately

- Protect your confidential business information
- Fail in negotiation of cost sharing
- Disagree with the Lead Registrant on the selection of data

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Registration Option 4

* Push the SIEF progress by cooperating with a competently technical partner

- Pre-registrants networking and available data collection
- LR election or consortia formation
- Data gaps analysis and fill-in;
- IUCLID 5 dossier compilation ;
- Cost sharing principle establishment ;
- Create SIEF Agreement and promote joint-submission ;
-

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Registration Option 5

- * For some substance with deadline of 2013/2018, keep waiting and watching
- * Make decision after the first phase registration finished, on which time almost everything is clear.



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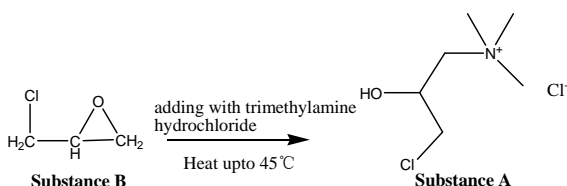
Asia
2009



Prepare your individual dossier now & pay attention to sameness criteria

*** The importance of sameness to successful co-registration:**

- The base of joint submission
- The prerequisite for data sharing
- The core element of dossier evaluation
- Case analysis :



If the concentration of B is over 0.1%, product A will never meet the Sameness criteria due to the outcome of different classification.

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Prepare your individual dossier now & pay attention to sameness criteria

*** Prepare substance identity information**

- UV, IR, NMR and MS, HPLC and GC ;

*** Collect information on uses and exposure/emission from your downstream users**



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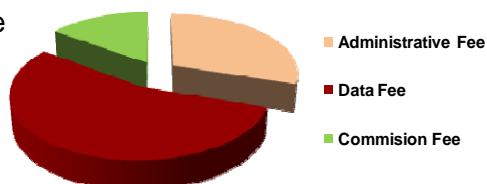


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Registration Fee

Registration fee is composed of:

- 1) **Administrative fee**, charged by ECHA (refer to the 340/2008/EC)
- 2) **Data Fee**, including data sharing cost, testing cost etc.
- 3) **Commission fee**, pay to the Only Representative or other third parties



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24 HOURS
SERVICE

Administrative Fee



* Standard Fee

Submission type Tonnage band	Joint submission	Opt out
1~10	1200	1600
10~100	3225	4300
100~1000	8625	11500
>1000	23250	31000

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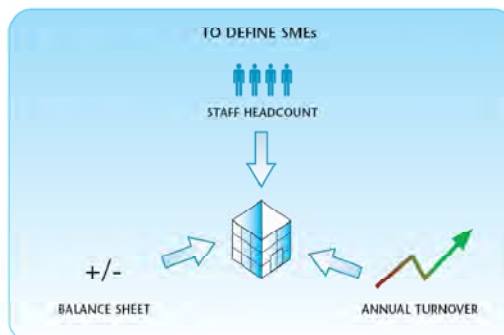


24 HOURS
SERVICE

Administrative Fee

* Reduced fee for SME

- Medium, 30% discount
- Small, 60% discount
- Micro, 90% discount



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SME Criteria



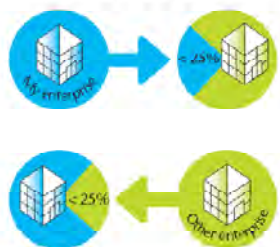
THE NEW THRESHOLDS (Art. 2)

Enterprise category	Headcount: Annual Work Unit (AWU)	Annual turnover	Annual balance sheet total
Medium-sized	< 250	≤ €50 million (in 1996 € 40 million)	≤ €43 million (in 1996 € 27 million)
Small	< 50	≤ €10 million (in 1996 € 7 million)	≤ €10 million (in 1996 € 5 million)
Micro	< 10	≤ €2 million (previously not defined)	≤ €2 million (previously not defined)

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AUTONOMOUS ENTERPRISES

My enterprise holds less than 25% (capital or voting rights) in another and/or another holds less than 25% in mine.



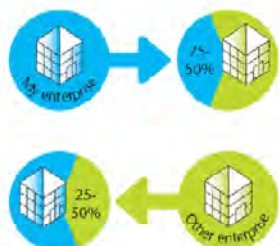
LINKED ENTERPRISES

My enterprise holds more than 50% of the shareholders' or members' voting rights in another and/or another holds more than 50% in mine.



PARTNER ENTERPRISES

My enterprise holds at least 25%, but no more than 50% in another and/or another holds at least 25%, but no more than 50% in mine.



- Further requests, please contact with RUIO tech!

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Administrative Fee



* Reduced fee for intermediate under strictly control condition

- Charged as standard fee for 1-10 t/a, irrespective of tonnage bands
- 1,200 EUR for joint-submission;
- 1,800 EUR for opt-out

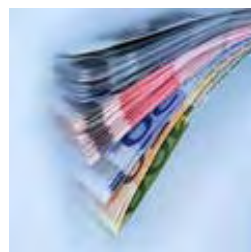


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Commission Fee



- * Fixed cost
- * Vary between different service provider



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Data Fee

- * Data fee is always influenced by:
 - Data access type, joining consortia or purchasing LoA
 - Time of join data sharing, late members fee
 - Substance properties, intermediate or general substance
 - Potential registrants numbers
 - Others

Find the way mostly fitting to your substance, select the cost-effective way in data sharing!

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Registrant Category and CBI Protection

* Potential risks from registration by importers:

- Information disclosure on product formulation

* Potential risks from registration by assigning EU importers as OR:

- Information disclosure on product formulation
- Information disclosure on other EU customers
- Information disclosure on some specific uses

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Registrant Category and CBI Protection

* Potential risks from registration by assigning third party as OR :

- With irresponsible OR, information may be disclosed accidentally
- Information may be used outside REACH regulation, if your OR also provide trade service

Recommendation:

1) Choose a competent and highly responsible organization as your Only Representative and sign comprehensive Non Disclosure Agreement.

2) Register by your EU daughter company under REACH.

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Submission Type and CBI Protection

- * Opt out, if CBI disclosure will occur within joint submission
- * Making your own chemical safety report when the use information is confidential



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Supply Chain Communication and CBI Protection

- * The product is exported indirectly, and the Non-EU exporter doesn't intend to disclose the information on EU importers to registrant, especially when the registrant is non-EU manufacturer's daughter company/



Recommendation: :

1) Non-EU manufacturer change your OR to third party organization and sign NDA.

2) Non-EU exporter change your supplier

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Supply Chain Communication and CBI Protection

- * Registrant intend not to disclose the information on product composition, when deliver the Safety Data Sheet to DU

Recommendation:

Jus list the information on the C&L of confidential components, and hide the component identity.

Supply Chain Communication and CBI Protection

- * Worry about the misuse of registration number listed on the SDS by other companies

Recommendation: Encrypt the critical parts of registration number

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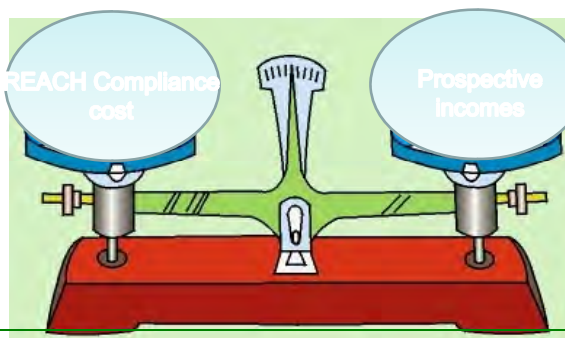
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Business Opportunities behind REACH Compliance

- Balancing reputation improvement, environment protection and investment in REACH compliance before making the final decision.



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Non-EU manufactures with 2013/2018 registration deadline

- **The benefits from earlier registration :**
 - (1) Safeguard the EU exportation
 - (2) Compete with the pressure from early registrants
 - (3) Maybe lower the registration cost
 - (4) More EU business opportunities

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*RUJO Tech will help
 you promote business
 after REACH
 compliance!*

REACH Compliant Suppliers Inventory

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Conclusion



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THANK YOU!