

# REACHLAW

**REACHLaw Webinar: Helsinki, May 5<sup>th</sup>**

**Intermediate REACH registration process  
- A fast lane to compliance -**

**Welcome !**

**(We will start when all confirmed attendees have signed in)**

# REACHLAW

**Sound check:**

**You should be able to hear us now**

**Please confirm using chat if sound is ok ?**

REACHLAW

**We are starting in a few minutes.....**

## Welcome by Jouni Honkavaara, Partner and CMO



**Mr Jouni Honkavaara**  
**Partner and CMO**

### **Contents today**

- 1. Introductions & purpose of this webinar**
- 2. Some Technical Advice for this webinar**
- 3. Intermediates: Basic REACH classifications and requirement**
- 4. Registration process: Master plan and our services**
- 5. Q & A**
- 6. Conclusions, how to proceed**

# Contents today

## 1. Introductions & purpose of this webinar

# Introductions

## Our Executive Team & skills

**Mr Lasse Kurkilahti**, Partner and Chairman of the Board, former CEO and President of Kemira Ltd, also former Chairman of Finnish Chemical Industry Association, MSc in Business Administration

**Mr Lasse Musakka**, Partner and CEO, MSc in Economics

**Mr Mathias Berner**, Partner and Sales Director, D.Sc. (Tech)

**Mr Riku Rinta-Jouppi**, Partner and Chief Legal Council, MA Law, MSc in Bioinformation Technology

**Mrs Ying Zhu**, Partner and COO, PhD in Bio Chemistry, MBA

**Mr Jouni Honkavaara**, Partner, CFO and CMO, MSc , MBA

**> 40 specialists in REACH/EU competition law, chemistry, toxicology and business**

## Key capabilities of REACHLaw:

Industry knowledge, Legal REACH knowledge, Chemistry,  
Close Cooperation with ECHA and Helsinki REACH Centre, Independence

# REACHLaw people in our studio in Helsinki

- **Dr. Ying Zhu**, Partner and COO, PhD in Bio Chemistry, MBA
- **Dr. Mathias Berner**, Partner and Sales Director, D.Sc. (Tech)
- **Mr Riku Rinta-Jouppi**, Partner and Chief Legal Council, MA Law, MSc in Bioinformation Technology
- **Mrs Jaana Montonen**: Senior Environmental Consultant RA, MSc in Environmental Science

# Our mission

## REACHLaw Ltd

exists exclusively to provide full set of REACH services and timely solutions to its clients

by

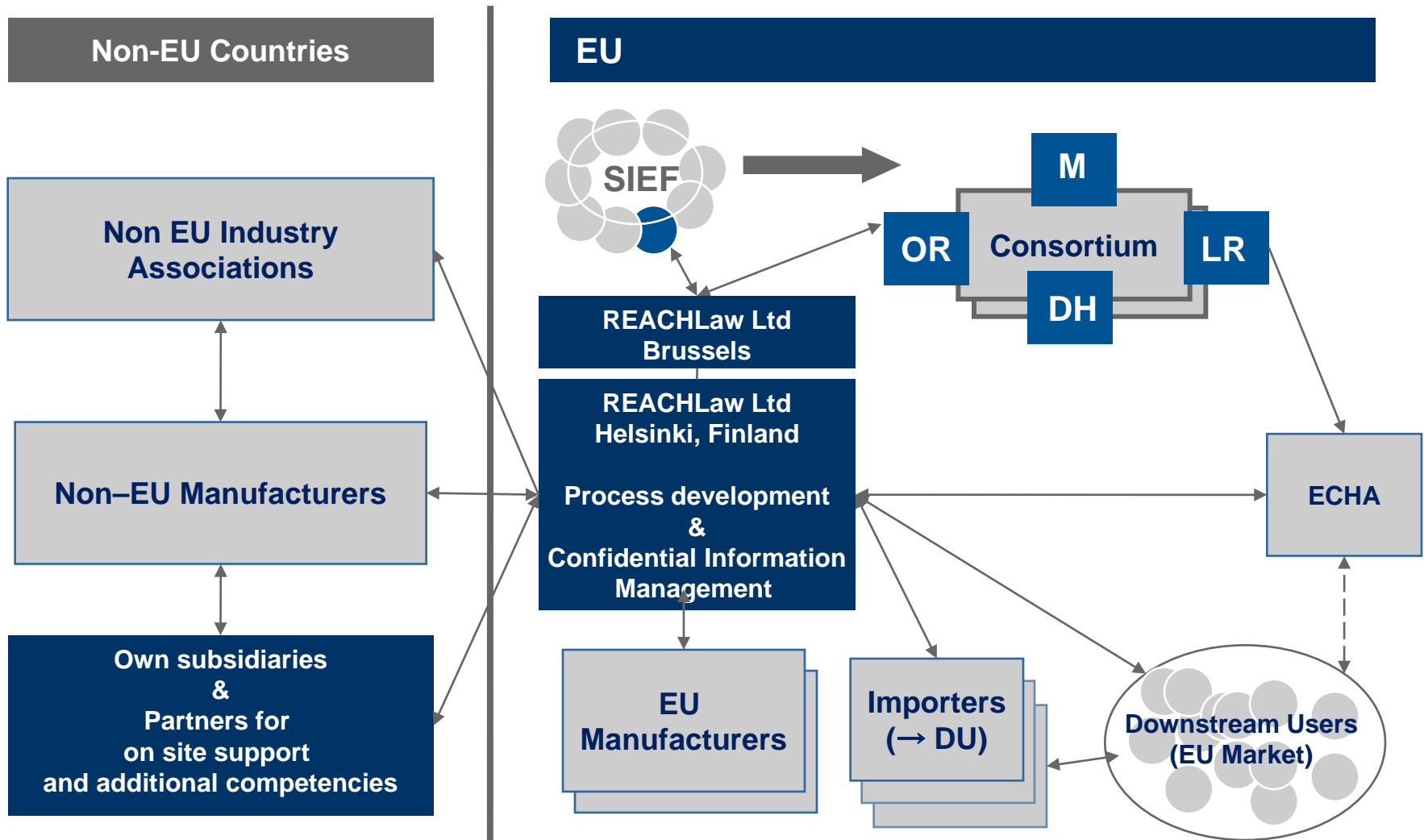
offering unique combination of expertise in REACH, legal, chemistry, environmental and business

# REACHLaw Ltd today : global, world class REACH service provider

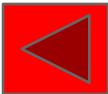


**Our customers: > 200 major manufacturers in 25 countries with around 2000 substances**

# Our Service Model



# Examples on our service packages

- REACH related services:
    - **Registration Service Package for Manufacturers**
      - Only Representative model for non-EU manufacturers
      - Service/outsourcing /Third party model\_for EU manufacturers and subsidiaries of non-EU manufacturers
      - Service Package for Late Arrivals
      - **Intermediate Registration Service Package**
    - **Services for Lead registrants & Consortia**
      - Pre-Consortium Study for Consortium formation
      - Lead Registrant Support Service Package
      - Consortium Support Service Package
    - **Services for Downstream users**
      - Downstream User Registration package
      - Exposure scenarios
-  Focus today

# Purpose of this webinar

- This webinar is mainly for
  - Major manufacturers of **intermediates**, who are
    - **worried about the slow progress**
    - who may/need to **take a leading or active role in the intermediate registration process**
    - **concerned about how the work should be organized and may need help**
- Note: We are not talking what REACH is
  - We want to give practical advice, describe activities needed now (**what, by whom, how) to get the work running**)
    - **Urgent issues**
    - Longer term issues

# Contents today

- Some Technical Advice for this webinar

# Some technical advice for this webinar

- Let's make this webinar interactive:
  1. You are able to send questions to us using chat, please do that ! We will answer your questions when they are coming or in Q & A (we have our people ready....)
  2. Questions you have been sending in advance will be answered in suitable sections of the presentation or during Q & A
  3. In case we feel a question very company or substance specific or if we think that answers would take too much time, we will ask you give your contact information.
  4. In case you want our webinar material or if you want us to contact you, please send email to [ilona.pitkanen@reachlaw.fi](mailto:ilona.pitkanen@reachlaw.fi)

AND IN ANY CASE PLEASE SEND US FEEDBACK, THANK YOU

# Contents today

- Intermediates: Basic REACH classifications and requirements

# Intermediates: Definition

- **Intermediate Guidance**
  - Substance manufactured for and consumed or used for
    - Chemical processing in order to be **transformed into another substance(s)**
    - **Not present in the final manufactured substance** (except possibly as an impurity)
- Substance can have the role of
  - "usual substance" (more data requirements) or
  - "intermediate" depending how it is used
  - Knowledge about the process is necessary to make correct interpretation

# Intermediates: Different types

1. Non-isolated intermediates
  2. On site isolated intermediates
  3. Transported isolated intermediates
- **Important:**
    - Different data requirements in these 3 groups
    - Sometimes hard to make interpretations
      - In case of uncertainty formal legal and use / process documentation to be recommended to be safe

# Intermediates: Different types

## 1. Non-isolated substance

- During the synthesis not **intentionally** removed (sampling allowed) from the equipment where the synthesis takes place
- Equipment:
  - Reaction vessel
  - Ancillary equipment
  - Any equipment used for batch or continuous flow
  - Exempted: **tanks and other vessels used for to be stored after the manufacture**

# Intermediates: Different types

## 2. On site isolated intermediates

- Case 1: Not meeting criteria of non-isolated intermediate
- Case 2: Synthesis happening on same site
  - Equipment:
    - Reaction vessel
    - Ancillary equipment
    - Any equipment used for batch or continuous flow
    - Exempted: **tanks and other vessels used for to be stored after the manufacture**

# Intermediates: Different types

## 3. Transported isolated intermediates

- Not meeting criteria of non-isolated intermediate
- Transported between or supplied to other sites

# Intermediates: Lifecycle

- Begins when removed from manufacturing process
- Ends when consumed in the synthesis process of another substance

# Intermediates: "Strictly controlled conditions"

- Both manufacture (not for non-EU manufacture) and uses (for on site and transported isolated intermediates)
- Data requirements can be reduced significantly if you are able to confirm/document this
- Key issue, see next two slides !

# Intermediates: Important

If the manufacturer confirms that the isolated intermediate is **manufactured and used under strictly controlled conditions**, the information requirements on the substance intrinsic properties (physicochemical, human health and environment properties) are reduced

**If strictly controlled conditions are not met, a full (standard) data package is required** depending on the tonnage level (*Articles 10 & 12*).

# Strictly controlled or not: data requirements

Type	Tonnage band	SCC	Data requirements
Transported isolated intermediates	>1000	Non SCC	Annex VI-X (standard requirements)
	>1000	SCC (manufacture&use)	Existing data + Annex VII
	<1000	SCC (manufacture&use)	Existing data
On-site isolated intermediates	>1000	Non SCC	Annex VI-X (standard requirements)
	>1000	SCC (manufacture)	Existing data
	<1000	SCC (manufacture)	Existing data
Non-isolated	Any	-	None

SCC = strictly controlled conditions reduced requirements do not apply for monomers

# Key issues in categorization

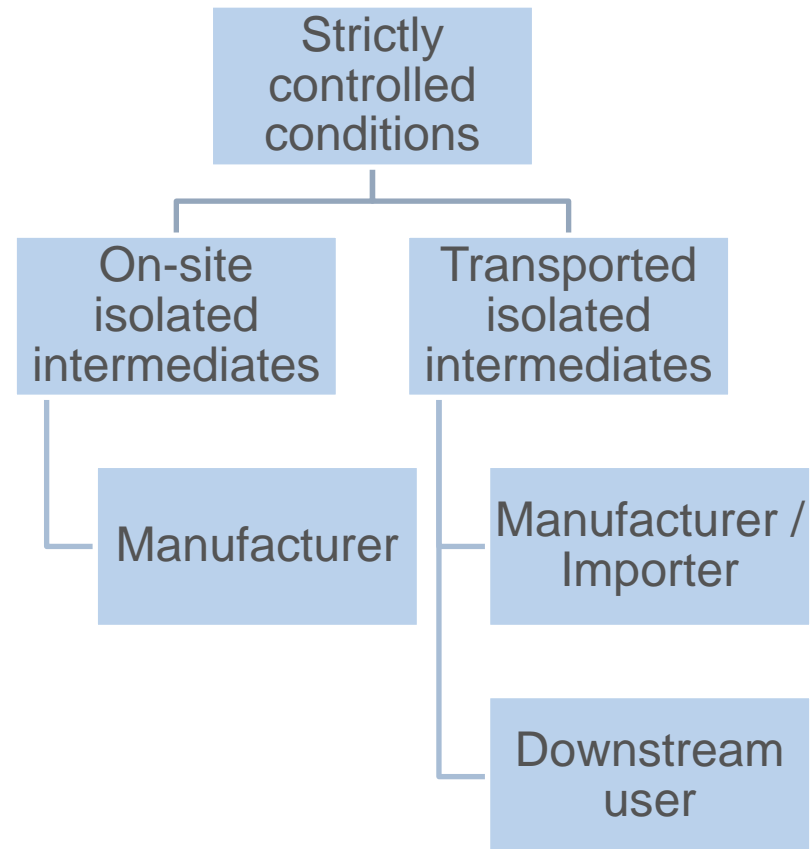
- "Strictly controlled" ?
- By Jaana Montonen, REACHLaw

# Strictly controlled conditions

- Key issue concerning the data requirements and registration
- Two possibilities:
  - 1) Limited set of data + confirmation on strictly controlled conditions
  - 2) Full registration dossier

# Strictly controlled conditions - What it means

- Combination of technical measures
  - Normal operating conditions
  - Non-routine operational circumstances
- Confirmation covering the whole life-cycle



# Strictly controlled conditions – Article 18(4)

- a) Substance rigorously contained by technical means during its whole lifecycle
- b) Technologies shall be used to minimise emission and exposure
- c) Properly trained and authorised personnel
- d) Special procedures during cleaning and maintenance
- e) Special procedures in case of accident and where waste is generated
- f) Substance-handling procedures are well documented and strictly supervised by the site operator

# Strictly controlled conditions - What is required?

- Assessment of use(s) documented within a company
  - Justification of the use as an intermediate
  - Operating conditions
  - Risk management measures (RMM)
  - Exposure considerations
  - Reference or derivation of threshold values

# Strictly controlled conditions - Downstream user tasks

- **Transported isolated intermediates**
  - Inform M/I that the substance is used under strictly controlled conditions
- Check if intermediate is covered by any restriction (Annex XVII *Restrictions...*, Article 67)

# Summary: Intermediates > 1000 t/y

- In case you HAVE BEEN able to meet and document ”strictly controlled conditions” data requirements are much lower
- => ”REACHLaw fast lane to compliance” with your intermediates
- Purpose: Quickly get rid of REACH work (in a few months) and save SIEF work and others costs
- In case you are NOT able to meet and document ”strictly controlled conditions” you must make a full registration process

# Contents today

- Registration process: Master plan and our services

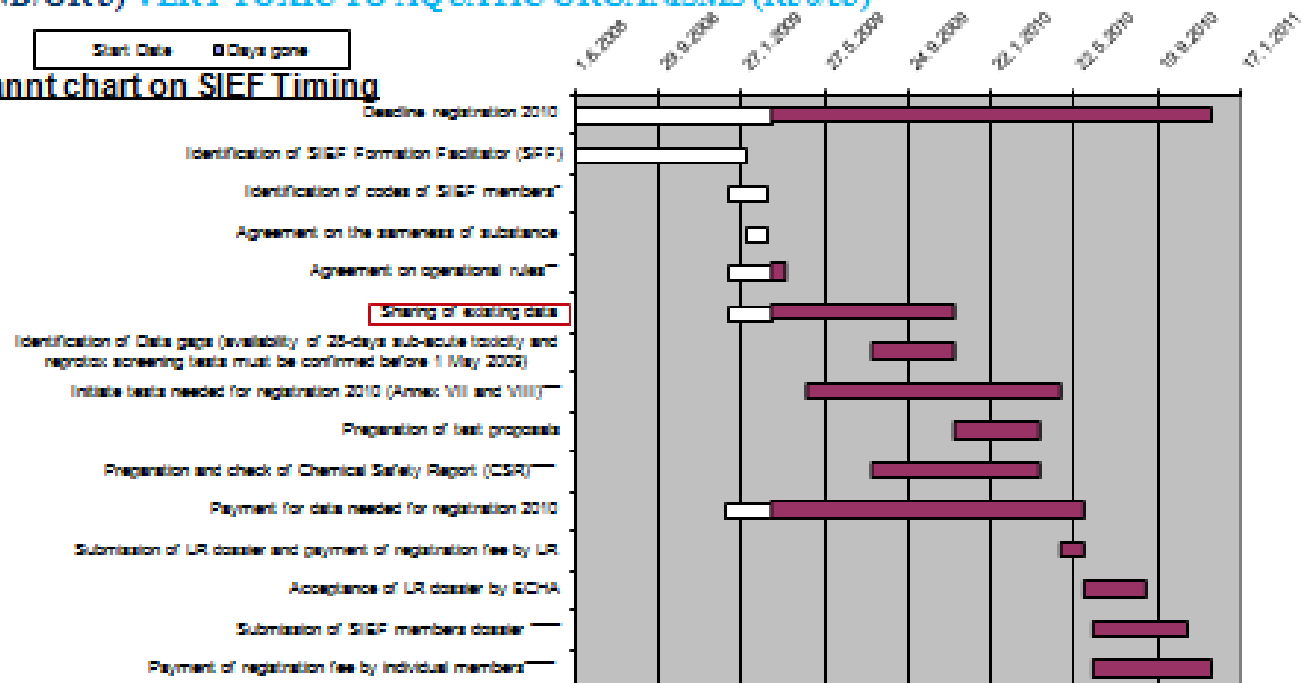
# From what to how: Development of master project plan

## REACHLAW

SIEF TIMING: 1) FOR SUBSTANCES PRODUCED 1000 TONNES OR MORE PER YEAR,  
 2) FOR THOSE CLASSIFIED AS MUTAGENIC AND REPROTOXIC SUBSTANCES (CMR)  
 AND/OR 3) VERY TOXIC TO AQUATIC ORGANISMS (R50/53)

Start Date    Days gone

Gantt chart on SIEF Timing



# Master plan – key topics

- Step 1: Categorization of intermediates-finding the critical ones
- Step 2: Alone or in consortium: Check of SIEF/Consortium status
- Step 3: Tests and testing proposals
- Step 4: Dossiers needed
- Step 5: Cost modeling
  
- **Note: All these steps are described in our "Intermediate Registration Service Package" service description**

# Master plan – examples on key topics

- Step 1: Categorization of intermediates: finding the critical ones

# Categorization: Simplified example

Substance/Intermediate	Type	Tonnage band	Deadline	Data available	Downstream users	SIEF status	Existing Consortium	Potential role	Critical Actions
S1	Transported	>1000	2010	-	30	Not moving	None	LR	Check of SIEF status (IM/subst) as lead registrant, SC check (prod+Dus)
S2	Transported	>1000	2010	++	Internal	Not moving	None	LR	Check of SIEF status (IM/subst) as lead registrant, Strictly Controlled check (prod+Dus)
S3	On site isolated	>1000	2010	+	N/A	Not moving	None	LR	Check of SIEF status (IM/subst) as lead registrant, Strictly Controlled check (prod)
S4	Transported	>1000	2010	+++	4	Active	RC	involved	Follow up of consortium and SIEF, Strictly Controlled check (prod+Dus)
S5	Transported	>1000	2010	+	9	Active	RC	passive	Follow up of consortium and SIEF, Strictly Controlled check (prod+Dus)
S6	On site isolated	>1000	2010	+	2	Active	RC	passive	Follow up of consortium and SIEF, Strictly Controlled check (prod+Dus)
S7	Transported	100-1000	2013	N/A	7	?	?	passive	Follow up of consortium and SIEF
S8	On site isolated	100-1000	2013	N/A	3	?	?	passive	Follow up of consortium and SIEF
S9	On site isolated	100-1000	2013	N/A	7	?	?	passive	Follow up of consortium and SIEF
S10	On site isolated	100-1000	2013	N/A	1	?	?	passive	Follow up of consortium and SIEF

# Master plan – examples on key topics

- **Step 2: Alone or in consortium: Check of SIEF/Consortium status:**

# Some statistics : pre-registrations

- Total number of pre-registrations
  - 2,750,000 pre-registrations
  - 65,000 companies signed up in REACH-IT
  - 146,000 different substances pre-registered
- Volume about 15 x expected by ECHA
  
- Number of pre-registrations to be safe ?
- Non-EU pre-registrations ?
- Importers ?
  
- **Our conclusion: Less "real" registrants when the work really starts**

# Background: Some ECHA statistics

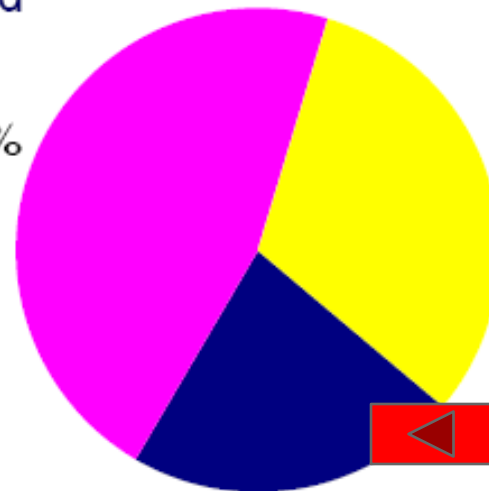
## Pre-registration



- Envisaged registration deadline indicated (per substance)

2013, 47%

2018, 31%

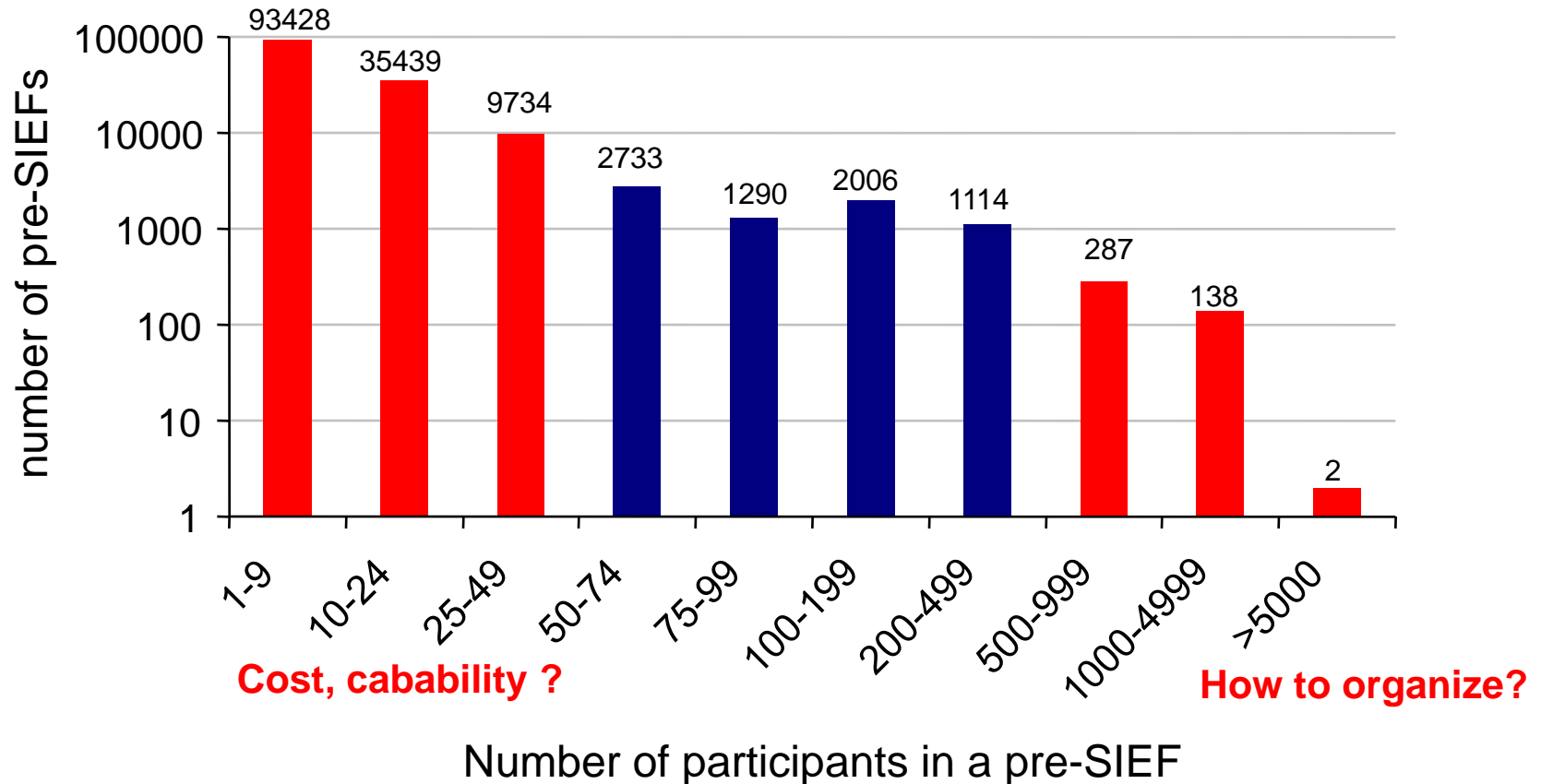


2010, 22%

**Critical group  
(around 30.000 substances)**

<http://echa.europa.eu>

# SIEFs, major problems



If > 1000 ton and no existing consortia -> major difficulty in registering on time ?

# SIEFs, current status

- We have made pre-registrations for a large number of substances
- Less than 20 % of pre-SIEFs are running... at some level
- Why so low level of activities ?
- Reason to be worried ??

# "Typical SIEFs"

Type of SIEF	Activities/status	Characteristics	Dominating players	Key issues
1. "Dormant"	No progress, major type so far	No leading manufacturer	No one so far	Leading must show up, others can just wait
2. "Mess"	Playground for commercial service providers	No real leading manufacturer having industrial interest	No one so far	Leading must show up,
3. "Nominal"	Low activity in SIEF, leading has taken to role	Major work done in existing consortia	Large USA/EU based manufacturers	Cost sharing issues, membership in consortium
4. "Fighting"	Discussions dominated by one manufacturer	Major work done by the leading company (no consortium)	One large manufacturer	Cost sharing mechanism
5. "Real"	Some - No existing examples	Major work done by SIEF	No one	Role in SIEF depending on existing data

## In SIEF / Consortium or alone: Basic rule

- In case you are not meeting "Strictly Controlled Conditions" :
  - => normal registration and all needed annexes like for any substance >1000 t/y,
  - => In SIEF/Consortia
- In case you are able to meet and document "Strictly Controlled Conditions" or < 1000 t/y
  - => Choice: Alone or in SIEF / Consortia

# Note: intermediate registration alone or in sub-SIEF / Consortia

- 1. Open questions on the process and interpretations (ECHA)
- 2. In the following slides we are referring to sub-SIEF / OPT out, this mechanism is not yet defined clearly by ECHA
- 3. When referring to being lead registrant, we mean being a Lead Registrant in "intermediate sub-SIEF / Consortia " with intermediate requirements

# Alone: When and how ?

- When:
  - You are able to meet SC conditions and you have (all) necessary data (Annex VII)
  - SIEF is not moving, taking LR position not possible (LR must submit the complete dossier)
  - Or the other potential registrants have higher data requirements
    - substance manufacturers or
    - intermediate manufacturers not meeting SC conditions
- How (Still open with ECHA !)
  - Opt out ?

# In SIEF / Consortium: When and how

- When:
  - Several potential intermediate registrants, which are able to cooperate in "intermediate SIEF / Consortium"
    - > 1000 t / y and deadline 2010
    - and willing to share costs
    - and able to meet SC conditions
- How (Still open with ECHA !)
  - "Intermediate Sub-SIEF" to share costs
  - SIEF is organised or you may take leading role in organizing SIEF

# When should you take the leading role ?

- You are a major manufacturer
- You have strong industrial interest
- No existing consortia
- SIEF not proceeding
- Registration deadline 2010
- (Knowledge, resources)
- (Able to start consortium discussions)

# **How to get the work started if you feel you need to take the leading position**

1. Thru "intermediate" SIEF (to become elected to LR)
2. Forming an "intermediate" consortium and after that become LR

# Thru SIEF – attendees need to agree

REACHLaw responsibilities: REACHLaw will prepare together with the customer documents and proposals to other potential registrants needed for

- a) Definition of the form of co-operation between the parties and possible internal rules to be accepted by other SIEF members
- b) Organization of the exchange of data
- c) Scope of the co-operation: whether the co-operation should be limited to the SIEF obligations (data sharing and classification and labeling) or whether it should be extended to cover other objectives
- d) Who could perform the necessary technical work.

REACHLaw will also be responsible for

- e) Keeping written records of the agreements made in a SIEF (e.g.: who is the Lead Registrant, who will opt out, etc).
- f) Act as a contact point for communication within the SIEF and with other SIEFs for “read across” purposes.
- g) Request confidential treatment of data (Art 10(a)(xi), if required
- h) Identifying the other registrants in his registration dossier which may contain “mandatory joint submission” as well as “voluntary joint submission”
- i) Take care of ECHA communication including joint submission and keeping the dossier up-to-date.
- j) In case the customer wants REACHLaw also to be responsible for technical work, please see other Registration Service Components in this Service description.

# Thru Consortium - The role of consortia

- When several leading manufacturers are ready to take the responsibility and when it is necessary to agree about
  - Scope
  - How
  - Organisation
  - Costs
  - .....
- Simply: Agreed, formalized cooperation based on agreement

# Thru consortium -Practical example: Pre-consortium study

- Purpose: To check if it will be possible to create a consortium for the work needed
- How to prepare ?
- Ready made documents necessary:
  - Potential members
  - Contacting letters
  - Pre-consortium agreement,
  - Scope definition
  - **Cost model**
  - Consortium agreements
  - Meetings with agendas, scheduling....
  - **Very difficult for single manufacturer: Trustee in most cases necessary for confidential information**

# Steps in practise (simplified) – REACHlaw input

Step	Name	Purpose	REACHLaw provides	Customer's responsibilities/provides	Scheduling
Step 1	Initial Planning	Initial selection of pot. Members	Analysis of attendees in case they are unknown	Pre-SIEF Listing	week/date:
Step 2	Initial Contacting	Initial contact with selected	Letter, Pre-Consortium agreement, "key issues" paper	Accepts material	week/date:
Step 3	Report of Initial reactions	Short list of pot. Members	Report and proposal of attendees	Accepts attendees	week/date:
Step 4	1st meeting	First meeting	Facilitation, agenda, materials	As an attendee	week/date:
Step 5	Definition phase	Scope, costs, resources, organisation etc	As a result. Acceptable conditions and scope	Own conditions	week/date:
Step 6	2nd meeting	Check of draft agreement	Facilitation, draft agreement, conditions	As an attendee	week/date:
Step 7	Signing phase	Final members	support, information, last negotiations	As an attendee	week/date:

# Master plan – examples on key topics

- Step 3: Tests and testing proposals: By Jaana Montonen, REACHLaw

# TESTING REQUIREMENTS FOR INTERMEDIATES

- **Non-isolated intermediates**
- **On-site isolated intermediates**
- **Transported isolated intermediates**

# Starting point

Tonnage bands	Annex VI	Annex VII	Annex VIII	Annex IX	Annex X	Annex XI
1 – 10 t/y	x	x (+ Annex III)				x
10 – 100 t/y	x	x	x			x
100 – 1000 t/y	x	x	x	x		x
≥1000 t/y	x	x	x	x	x	x

If substance is not hazardous, only data for physicochemical properties required (**Annex III**)

- When there is an information gap which cannot be filled by any non-testing method, registrant has to take action
  - **Annexes VII** or **VIII** : generate new information
  - **Annexes IX** or **X** : prepare a testing proposal

# NON-ISOLATED INTERMEDIATES

For the use of a substance as a **non-isolate intermediate**, there are **no obligations** under REACH (Article 2(1)(c))

# ON-SITE ISOLATED INTERMEDIATES

(IF MANUFACTURED AND/OR USED **UNDER STRICTLY CONTROLLED CONDITIONS**)

TESTING REQUIREMENTS



**REDUCED TO:**

- **ALREADY AVAILABLE DATA** ON SUBSTANCE'S PHYSICOCHEMICAL, HUMAN HEALTH AND ENVIRONMENT PROPERTIES, WHICH

**REGISTRANT HOLD HIMSELF OR HAS OBTAINED FROM OTHER SOURCES**

# ON SITE ISOLATED INTERMEDIATES

(IF STRICTLY CONTROLLED **CONDITIONS ARE NOT MET AND IN CASE OF MONOMERS**  
**USED AS ON-SITE ISOLATED INTERMEDIATES FOR POLYMERISATION**)

**STANDARD TESTING REQUIREMENTS** FOR PHYSICOCHEMICAL,  
TOXICOLOGICAL AND ECOTOXICOLOGICAL PROPERTIES



**ACCORDING TO ANNEXES VI-X,** FOR THE DATA DEPENDING ON  
THE TONNAGE LEVEL (*Articles 10 &12*)

# TRANSPORTED ISOLATED INTERMEDIATES

(IF MANUFACTURED AND/OR USED UNDER STRICTLY CONTROLLED CONDITIONS AND ANNUAL QUANTITY OF SUBSTANCE IS **LESS THAN 1000 TONNES**)

TESTING REQUIREMENTS

```
graph TD; A[TESTING REQUIREMENTS] --> B[REDUCED TO:  
ALREADY AVAILABLE DATA ON SUBSTANCE'S PHYSICO-CHEMICAL,  
HUMAN HEALTH AND ENVIRONMENT PROPERTIES,  
WHICH  
REGISTRANT HOLD HIMSELF OR HAS OBTAINED  
FROM OTHER SOURCES];
```

**REDUCED TO:**

**ALREADY AVAILABLE DATA** ON SUBSTANCE'S PHYSICO-CHEMICAL, HUMAN HEALTH AND ENVIRONMENT PROPERTIES,  
WHICH

**REGISTRANT HOLD HIMSELF OR HAS OBTAINED  
FROM OTHER SOURCES**

# TRANSPORTED ISOLATED INTERMEDIATES

(IF MANUFACTURED AND/OR USED **UNDER STRICTLY CONTROLLED** CONDITIONS AND ANNUAL QUANTITY OF SUBSTANCE IS **1000 TONNES OR MORE**)

TESTING REQUIREMENTS

```
graph TD; A[TESTING REQUIREMENTS] --> B[INFORMATION FOR THE PHYSICOCHEMICAL, TOXICOLOGICAL AND ECOTOXICOLOGICAL PROPERTIES FROM:]; B --> C["- ANY AVAILABLE EXISTING DATA (Chapter 3 of title II of REACH)"]; B --> D["- TESTINGS SPECIFIED IN ANNEX VII (Article 18(3))"];
```

INFORMATION FOR THE PHYSICOCHEMICAL, TOXICOLOGICAL AND ECOTOXICOLOGICAL PROPERTIES FROM:

- ANY AVAILABLE EXISTING DATA (Chapter 3 of title II of REACH)
- TESTINGS **SPECIFIED IN ANNEX VII** (Article 18(3))

# TRANSPORTED ISOLATED INTERMEDIATES

(UPDATE IF THE TRANSPORTED INTERMEDIATE **PASSES THE 1000 T/YEAR**)

**AS A MINIMUM** TESTING REQUIREMENTS ACCORDING TO  
**ANNEX VII** (Article 18(3))

# TRANSPORTED ISOLATED INTERMEDIATES

(IF STRICTLY CONTROLLED CONDITIONS **ARE NOT MET** AND **IN CASE OF MONOMERS** USED AS TRANSPORTED ISOLATED INTERMEDIATE FOR POLYMERISATION)

**STANDARD TESTING REQUIREMENTS** FOR PHYSICOCHEMICAL, TOXICOLOGICAL AND ECOTOXICOLOGICAL PROPERTIES



ACCORDING TO ANNEXES VI-X, FOR THE DATA DEPENDING ON THE TONNAGE LEVEL (*Articles 10 & 12*)

# SUBSTANCE TESTING DATA REQUIREMENTS INCLUDED IN **ANNEX VII FOR PHYSICOCHEMICAL PROPERTIES:**

(Methods can be mostly found by <http://ecb.jrc.ec.europa.eu/testingmethods/annex5/>)

- State of the substance at 20 celsius and 101.3 kPa
- Melting/freezing point
- Boiling point
- Relative density
- Vapour pressure
- Surface tension
- Water solubility
- Partition coefficient n-octanol/water
- Flash-point
- Flammability
- Explosive properties
- Self-ignition temperature
- Oxidising properties
- Granulometry

# TESTING DATA REQUIREMENTS IN ANNEX VII FOR TOXICOLOGICAL INFORMATION :

(Methods can be mostly found by <http://ecb.jrc.ec.europa.eu/testingmethods/annex5/>)

## Sensitization & irritation

- Skin irritation or skin corrosion: *in vitro*
- Eye irritation: *in vitro*
- Skin sensitisation: *in vivo*

## Mutagenicity

- *In vitro* gene mutation study in bacteria

## Acute toxicity

- By oral route

# TESTING DATA REQUIREMENTS ACCORDING TO **ANNEX VII** FOR ECOTOXICOLOGICAL INFORMATION :

(Methods can be mostly found by <http://ecb.jrc.ec.europa.eu/testingmethods/annex5/>)

## Aquatic toxicity

- Short-term toxicity testing on invertebrates (preferred species *Daphnia*)
- Growth inhibition study aquatic plants (algae preferred)

## Degradation

- Biotic degradation
- Ready biodegradability

# OTHER TESTING DATA REQUIREMENTS FOR PHYSICOCHEMICAL, TOXICOLOGICAL AND ECOTOXICOLOGICAL INFORMATION IN **ANNEX VII**

OTHER AVAILABLE AND RELEVANT INFORMATION OF THE SUBSTANCE

```
graph TD; A[OTHER AVAILABLE AND RELEVANT INFORMATION OF THE SUBSTANCE] --> B[CLASSIFICATION BY (Q)SARs, READ-ACROSS OR GROUPING  
- IF THE SUBSTANCE WILL BE PUT ON THE MARKET]; A --> C[ASSIST IN IDENTIFYING THE PRESENCE OR ABSENCE OF  
HAZARDOUS PROPERTIES OF THE SUBSTANCE]; B --> C;
```

CLASSIFICATION BY (Q)SARs, READ-ACROSS OR GROUPING

- IF THE SUBSTANCE WILL BE PUT ON THE MARKET

ASSIST IN IDENTIFYING THE PRESENCE OR ABSENCE OF  
HAZARDOUS PROPERTIES OF THE SUBSTANCE

## Summary: Data requirements in different groups (volume > 1 t/y)

Type of intermediate	Phys-Chem	Tox	Ecotox	Others
Non isolated intermediates	No REACH obligations	No REACH obligations	No REACH obligations	No REACH obligations
On site isolated intermediates Case a) SC	a) existing data,	a) existing data,	a) existing data	a) existing data
b) Non SC	b) Standard req. Annex VI-X <i>(Articles 10&amp;12)</i>	b) Standard req. Annex VI-X <i>(Articles 10&amp;12)</i>	b) Standard req. Annex VI-X <i>(Articles 10&amp;12)</i>	b) Standard req. Annex VI-X <i>(Articles 10&amp;12)</i>
Transported isolated intermediates Case a) SC	a) Existing data (<1000 t/y) + Annex VII (>1000 t/y)	a) Existing data (<1000 t/y) + Annex VII (>1000 t/y)	a) Existing data (<1000 t/y) + Annex VII (>1000 t/y)	a) Existing data (<1000 t/y) + Annex VII (>1000 t/y)
b) Non SC	b) Standard req.	b) Standard req.	b) Standard req.	b) Standard req.
SC = strictly controlled conditions				

# Master plan – examples on key topics

- Step 4: Dossiers – by Jaana Montonen, REACHLaw

# Isolated intermediates – preparation of registration dossier

- Identification of required information
  - Is the substance an isolated intermediate?
  - Is the substance manufactured and used under strictly controlled conditions?
  - Is the substance transported?
  - Tonnage per year?

# Isolated intermediates – IUCLID 5 Dossier templates

- In case of stand alone registration or by lead registrant in case of joint registration
  - REACH registration on-site isolated intermediates > **1 tonne**
  - REACH registration transported isolated intermediates **1–1000 tonnes**
  - REACH registration transported isolated intermediates > **1000 tonnes**
- Members of a joint submission (not the lead registrant)
  - REACH registration member of a joint submission – intermediates

# Isolated intermediates – joint submission of data by multiple registrants

- First Lead registrant: the joint information
  - Classification
  - Any available existing information
  - Annex VII if at or above 1000 tpa
- Subsequently each registrant: separately specific information
  - Identity of Manufacturer
  - Identity of Intermediate
  - Brief description of use
  - Details of RMM

# Master plan – examples on key topics

- Step 5: Cost modelling

# Principal model for cost estimate for a specific manufacturer (simplified)

Some major cost factors

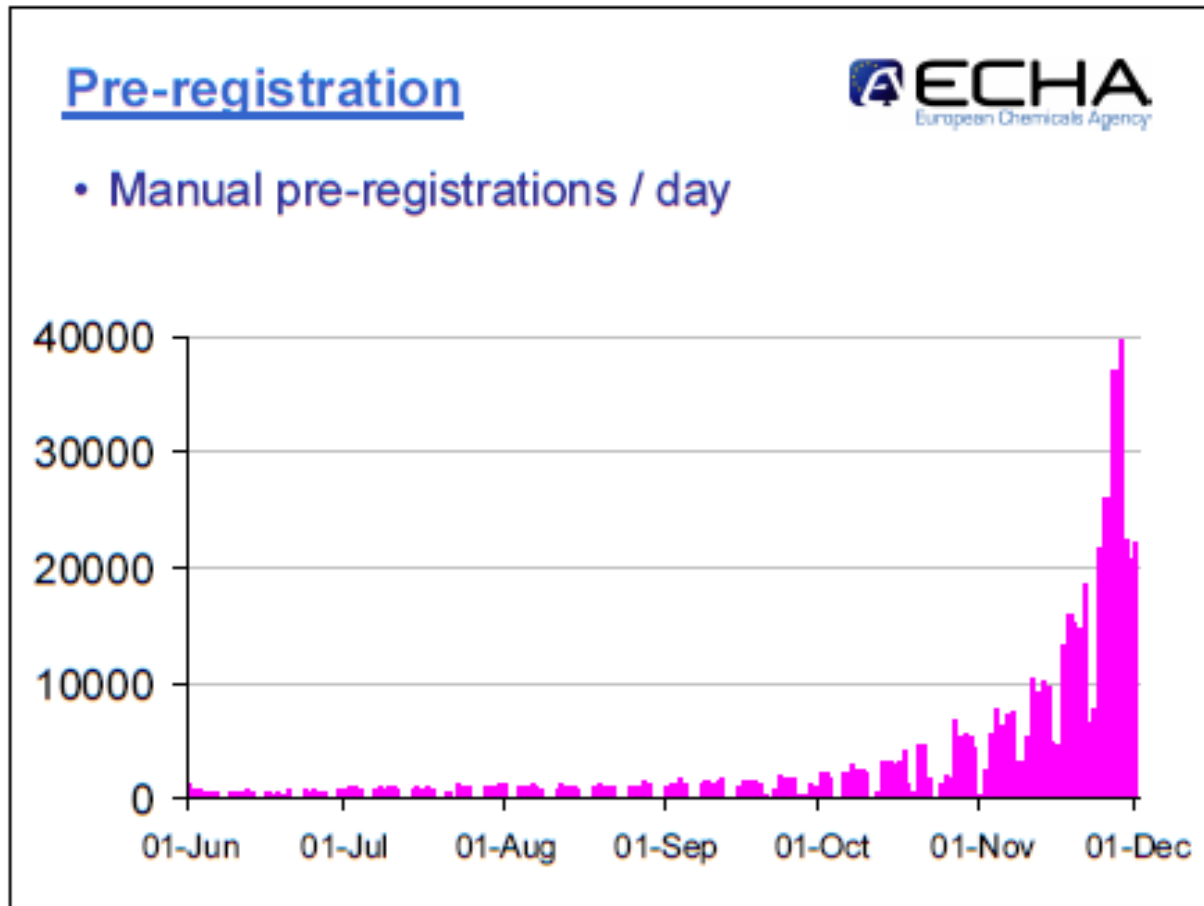
1. The exported volume (= data requirement)
2. Your individual data gap (= your missing data, compensation cost to others))
3. The total data gap (=cost for new research)
4. Number of potential registrants sharing the cost
5. Cost sharing mechanism
6. Consortia costs
7. Echa fees
8. External service fees

Data requirement (=studies)	You	Other potential Registrants	Total Info gap
> 10	X 0 0	X 0 X	X 0 X
>100	X 0 0	0 X 0	X X
>1000	0 0 0	0 0 X	0 0 x

# Summary of our offering

- **Case 1: In case you want "fast lane" compliance**  
=> Intermediate Registration Service Package covering all work needed , first step is checking "Strictly controlled conditions"
- **Case 2: You are a leading company and want to check if cost sharing and Consortium is possible**  
=> Pre-consortium Study + Lead Registrant Service Package
- **Case 3: You want support in registration work**  
=> Basic Registration Service Package

Let us not repeat pre-registration problem...50 % in the last two weeks .... NOT possible now...



**If you want to have materials, teleconference or a face-to-face meeting, please let us know !**

Thank You, we hope our webinar was useful for you !

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# Meet us in ... some upcoming events

## EUROPE:

- Helsinki, ECHA Stakeholder Day, 27.5.2009
- Helsinki, Chemicals Forum , 28-29.5.2009
- Brussels, REACHLaw seminar, 2-4.6.2009
- Helsinki, FECC Annual Conference, 22-24.6.2009
- Amsterdam, REACH Europe, 24-25.6.2009

## ASIA:

- Tokyo , REACH seminar, (Mid June)
- Singapore, REACH Europe Singapore, 17-18.8.2009
- Hongkong , REACH seminar (Mid August)
- Shanghai, REACH ASIA,15-16.9.2009

# So far we have been covering.....

- Step 1: Categorization of intermediates
- Step 2: Alone or in consortium: Check of SIEF/Consortium status
- Step 3: Tests and testing proposals
- Step 4: Dossiers needed
- Step 5: Cost modeling

**Your turn !!!**

**Questions, please use chat box**

REACHLAW

**REACHLaw Webinar: Helsinki, May 5<sup>th</sup>**

**Thank You**