Hong Kong REACH Workshop
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Overview of REACH Today and Challenges of Non-EU Companies for REACH Implementation in 2009

REACHLAW

Agenda

1. Introductions
2. Current Status of REACH
3. Authorisation and Restriction Processes
4. Current Status of Enforcement
5. Second Level of Enforcement: Your Customers
6. Legal Rights and Remedies
7. Conclusions

Introductions

- Some of you may know me from my previous role as Programme Manager of Helsinki REACH Centre (HRC)

- Now I am working as Head of REACH Competence Centre at REACHLaw
  - We provide legal advisory services to HRC

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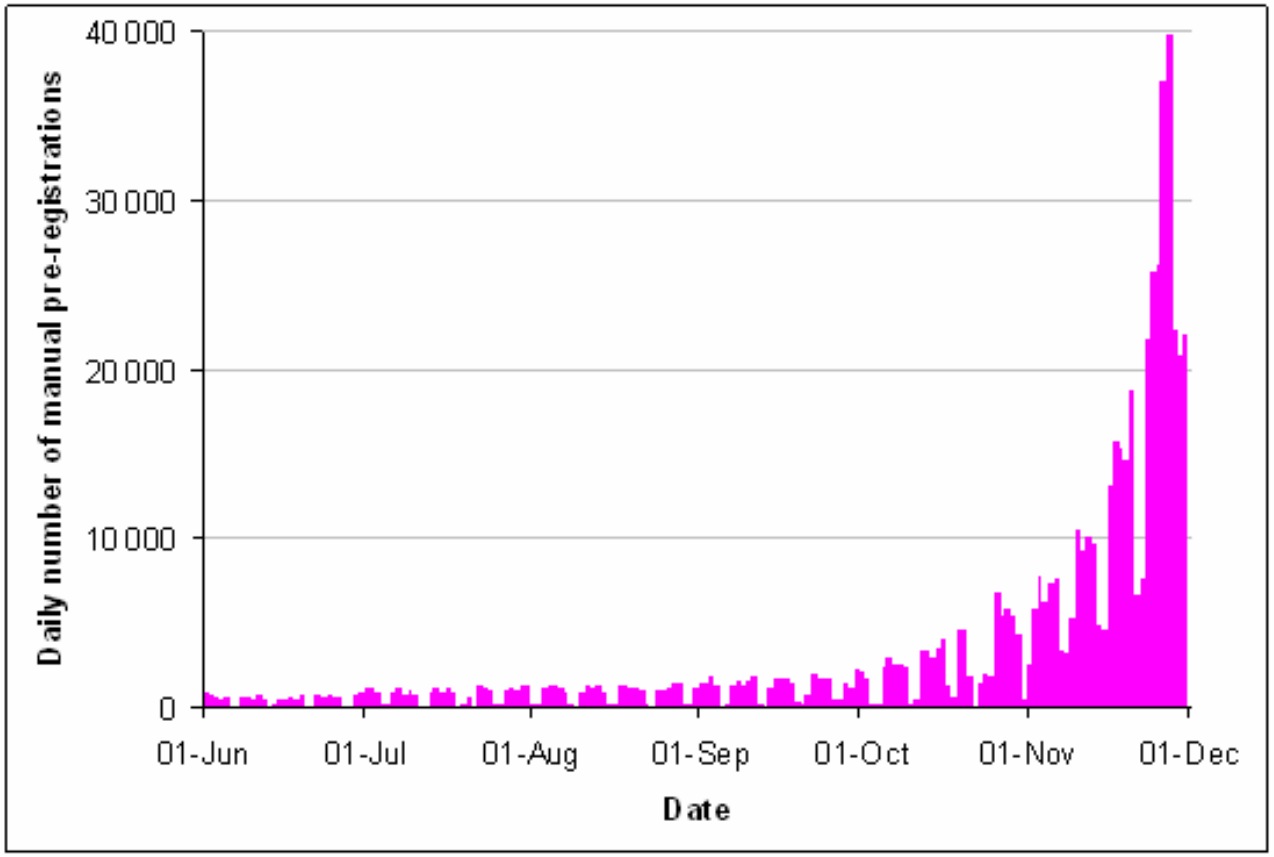
Pre-registration: so far so good



http://echa.europa.eu

Pre-registration results

- At the end of the pre-registration period:
  - 65,000 companies signed up in REACH-IT
  - 2,750,000 pre-registrations received
  - 146,000 different substances pre-registered
    - Complete EC inventory
    - 17,000 identified by CAS numbers
    - 9,500 identified by chemical names
    - 14,500 multi-constituent substances (*Reaction mass*)

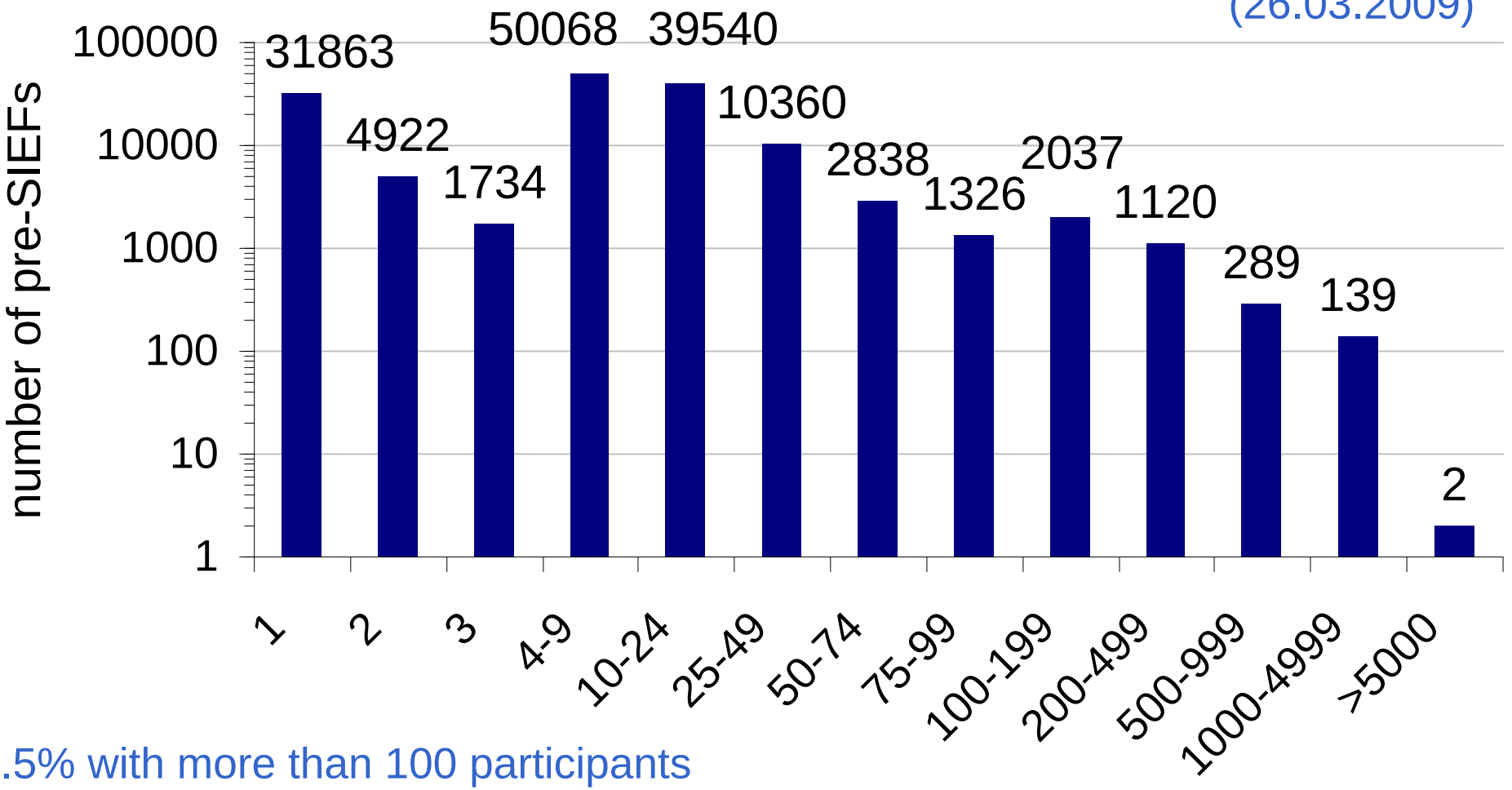
Pre-registration conclusions

- Volume about 15 x expected by ECHA
- Late pre-registrations: 3600
- Number of pre-registrations to be safe ?
- Non-EU pre-registrations ?
- Importers ?

- Our conclusion: Fewer ”real” registrants when the work really starts

Number of pre-SIEFs

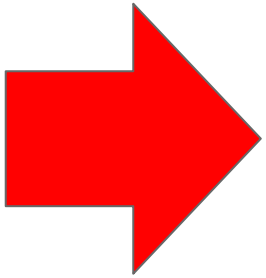
total = 146,333 pre-SIEFs
(26.03.2009)



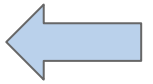
2.5% with more than 100 participants

Some statistics: pre-SIEFs

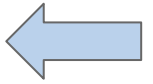
No of Participants	No of Pre-SIEFS in range	Percentage of pre-SIEF covered by consortia
1000-4999	138	?
500-999	287	?
200-499	1114	?
100-199	2006	?
75-99	1290	?
50-74	2733	?
25-49	9734	?
10-24	35439	?
1-9	94428	?
Grand Total	**147169**	**0**



Low cost?

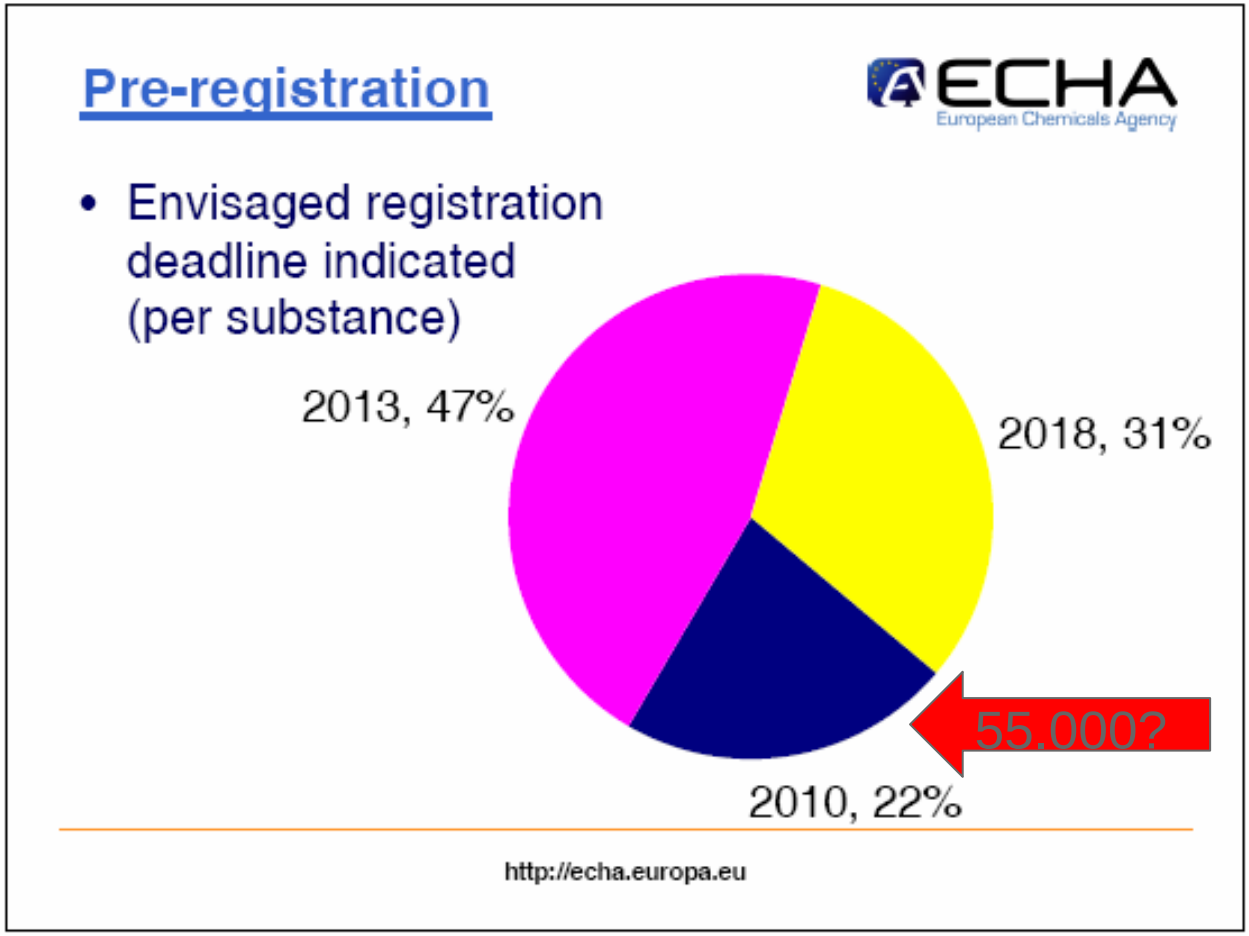


High cost?



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

Which substances will be affected 2009-2010 (=deadlines for registration)



Registration statistics: 1 June 2008 – 21 April 2009

	Submissions	Accepted for processing	Passing the TCC	Complete dossiers
Inquiry	1302	925	n/a	384
PPORD notification	596	403	292	282
Intermediates (on site)	83 (69 non phase-in)	51	28	27 (24 non phase-in)
Intermediates (transported)	232 (219 non phase-in)	126	91	90 (86 non phase-in)
Registration	319 (226 non phase-in)	97	43	41 (26 non phase-in)
Total	2552	1602	454	824

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Purpose of SIEF and consortia, roles

- SIEF, approx. no. 146000
  - Legally binding
  - Facilitator
  - Lead registrant
  - Major tasks: Agree on data sharing and CLP
- Consortia, approx. no. 500
  - ”Voluntary”
  - Major work will be done here ??
- **Risks for conflicts of interest: SIEF elects SFF, LR, decides on cost sharing and C&L**

Current status:Types of SIEF's (according to our experiences from 2000 Pre-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"	No existing examples	Major work done by SIEF	No one	Role in SIEF depending on existing data

CEFIC tried to help

Deadline is within 2 weeks after the sending of the letter but no later than 1st of March 2009 if the earliest registration deadline in the SIEF is 30 November 2010.
Assignment of SIEF codes is not static and may change over time
No assignment of code will mean default code 4 (please note that these codes can be changed at any time by contacting the SFF).

SIEF Code	Position	My position (please indicate the appropriate cell)
1 Leading	This is a substance of high strategic importance for my company and I have available resource to (co) lead and drive registration to completion	☐
2 Involved	My company is registering and may be actively involved. My company will receive a SIEF progress report, an invoice* and an invitation to comment	☐
3 Passive	My company has the intention to register this substance. My company will receive a SIEF progress report and an invoice*	☐
4 Dormant	My company has no intention to register nor to spend money. My company will receive no communications and no invoice (besides mandatory data sharing).	☐

* Invoice will include the data needed for the corresponding registration and any additional management compensation according to cost sharing system agreed in the entire SIEF.

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Why so slow progress – major reason ?

- **Big ones not taking the lead, especially non-EU manufacturers**
- Pre-registration, basic challenges
  - Major tasks
    - Substance identification (chemistry)
    - Knowledge about & interpretation of REACH regulation (legal)
    - Volume calculation
    - REACH-IT
- Registration, completely new challenges
    - **Pre-SIEF , SIEF and consortia formation: Who should take the leading position, what it means, how to cooperate in SIEF / Consortia, cost sharing etc (legal & business)**
    - Later: Evaluation of data, new research (toxicological & eco-toxicological tasks)

Pre-SIEFs have started, but….

- Based on our experience on around 2.000 substances
- About 20 % have Pre-SIEFs ”really” running April 2009 … with differing quality
- Why so low level of activities ?
- **Reason to be worried ??**

Next Step: (pre)SIEF status

- What is the status of the pre-SIEF?
  - Is it progressing?
- Based on the pre-SIEF listing, are there other major manufacturers?
- Who is the SIEF Formation Facilitator?
- ECHA will not assist in this process!

IF THE MAJOR MANUFACTURERS WILL NOT TAKE THE LEAD, REGISTRATION DEADLINE WILL BE MISSED

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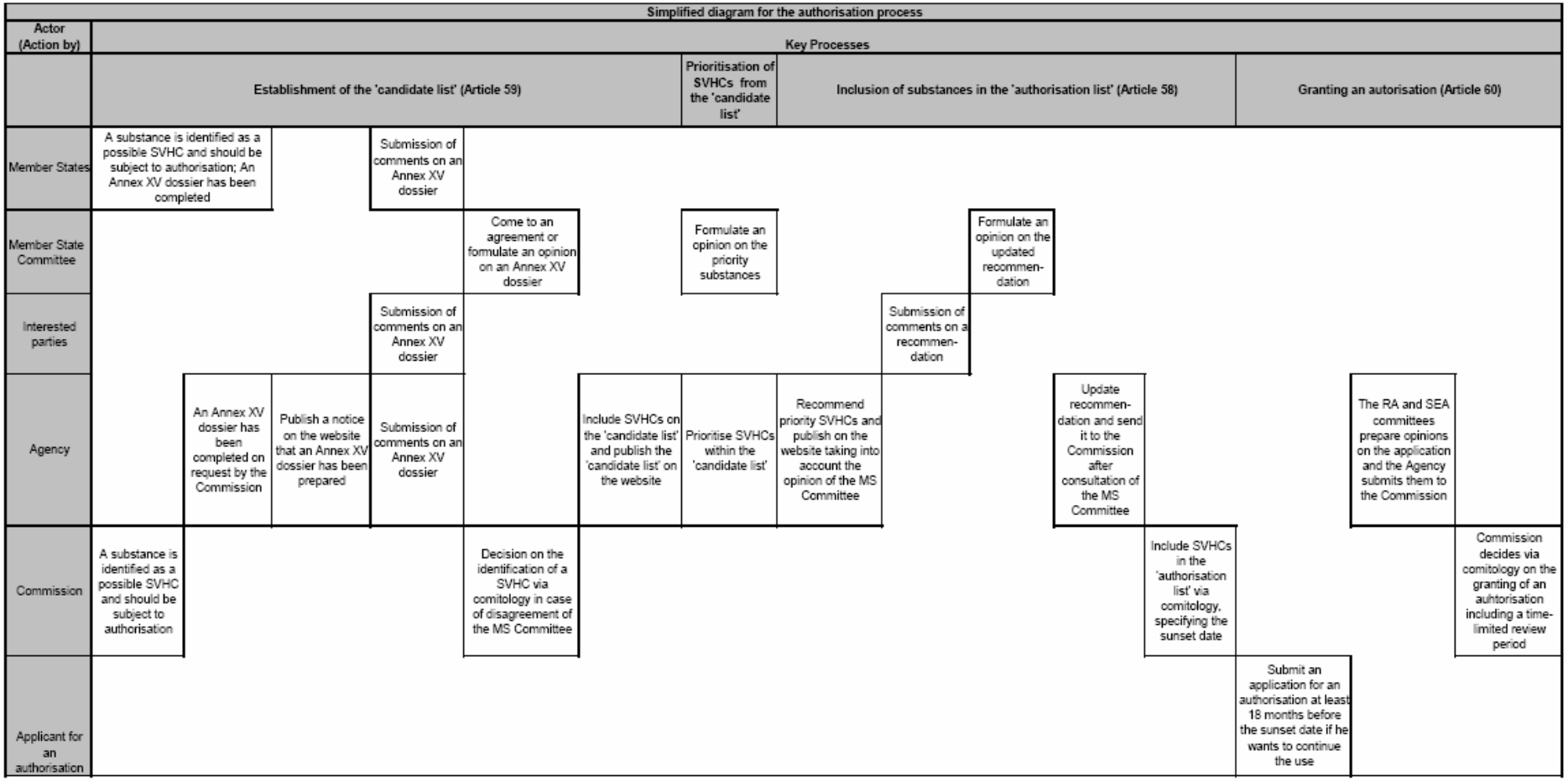
Authorisation process



First List of Substances Prioritised by ECHA for Authorisation

- 5-tert-butyl-2,4,6-trinitro-m-xylene (**musk xylene**)
- Alkanes,C10-13,chloro (short chain chlorinated paraffins; **SCCPs**)
- Hexabromocyclododecane (**HBCDD**) and all major diastereoisomers identified
- 4,4'-Diamino diphenyl methane (**MDA**)
- Bis (2-ethylhexyl) phthalate (**DEHP**)
- Benzyl butyl phthalate (**BBP**) and
- Dibutyl phthalate (**DBP**)

Consultations: Opportunity to Inform ECHA about Your Use and RMMs

- ECHA has a good understanding of the intrinsic properties and the resulting hazard posed by these substances
- **However, ECHA has very limited information on specific uses of the substances**
- By providing ECHA evidence during the consultation that a certain use is adequately controlled by
  - Either there being sufficient controls established by other legislation or
  - Because risks are otherwise adequately controlled (eg. Intermediate use only)
- **Based on this new evidence uses can be exempted from the uses requiring authorisation**

ECHA Fees For Authorisation

ANNEX VI

Fees for applications for an authorisation under Article 62 of Regulation (EC) No 1907/2006

Table 1

Standard fees

Base fee	EUR 50 000
Additional fee per substance	EUR 10 000
Additional fee per use	EUR 10 000
Additional fee per applicant	Additional applicant is not an SME: EUR 37 500
	Additional applicant is a medium enterprise: EUR 30 000
	Additional applicant is a small enterprise: EUR 18 750
	Additional applicant is a micro enterprise: EUR 5 625

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Tasks of the Enforcement Forum

4. The Forum shall undertake the following tasks:

(a) spreading good practice and highlighting problems at Community level;

(b) proposing, coordinating and evaluating harmonised enforcement projects and joint inspections;

(c) coordinating exchange of inspectors;

(d) identifying enforcement strategies, as well as best practice in enforcement;

(e) developing working methods and tools of use to local inspectors;

(f) developing an electronic information exchange procedure;

(g) liaising with industry, taking particular account of the specific needs of SMEs, and other stakeholders, including relevant international organisations, as necessary;

(h) examining proposals for restrictions with a view to advising on enforceability.

Work Programme 2008-2010

B	**REACH Enforcement issues**		
B 1	Strategies for REACH enforcement	Article 2(1) (a),(d)	Very high
B 2	Clarification of borderlines between ECHA, CA and MS enforcing authorities	Article 2(1) (d)	High
B 3	Access to information needed for enforcement	Article 2(1) (a),(d),(f)	Very high
B 4	Electronic information exchange system	Article 2(1)(f)	Very high
B 5	Guidance document on enforcement	Article 2(1) (d), (e)	Very high
B 6	Training programme for inspectors, including exchange of inspectors and joint inspections	Article 2(1) (b),(c), (e)	High
B 7	Co-operations with the customs authorities	Article 2(1) (g)	High
B 8	Coordinated projects	Article 2(1) (b) (e), (g)	Very high
B 9	Sanctions for non compliance – overview		High
B 10	Advice on enforceability on REACH annex XVII	Article 2(1) (h)	Very high
B 11	REACH and related legislation		Medium
B 12	Information exchange / cooperation with other enforcement networks in the EU	Article 2(1) (g)	High
B 13	Dialogues with international stakeholders	Article 2.(1) (g)	Medium

Current Status: Enforcement Projects

- First Coordinated Enforcement Project started in April 2009: REACH ENFORCE-1
  - >20 MSCAs participating
  - Focus on checking
    1. **Are substances pre-registered?**
    2. **Are correct safety data sheets available?**

Current Status: Customs Authorities (UK)

- **HM Revenue and Customs** (HMRC) will provide assistance to the enforcement authorities by detaining goods at the point of import, either when **requested** to do so or in the event that HMRC **suspect** that goods may be imported which are in breach of a listed REACH provision
- HMRC will be allowed to assist criminal investigations by the enforcers
- HMRC will participate in the enforcement of the relevant REACH provisions on importation

Current Status: SVHCs

- 6 MSCAs have expressed dissenting views on application of 0,1% threshold for Arts 7(2) and 33
- So, in practise, if you export articles containing SVHCs to **Austria, Belgium, Denmark, France, Germany or Sweden** the MSCAs in these countries enforce a stricter interpretation of the regulation than other MSCAs (0,1% of components/homogeneous parts rather than articles)

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Second Level of Enforcement: Your Customers

- Your EU customers
  - Want to be sure that they are working according to REACH, otherwise they are subject to enforcement
  - They will require
    1. **Inclusion of REACH clauses in supply contracts**
    2. **Commitment to registration of substances in products supplied**
    3. **Up to date safety data sheets**

Second Level of Enforcement: Your Customer's Options

6.9 What are the options for an importer of a preparation when he is unable to obtain the relevant information from his supplier on the components of the preparation?

The REACH registration obligations apply to substances on their own and in preparations. Thus, to fulfil his duties as a registrant an EU-based importer of preparations has to have information on the composition of the preparations he imports into the EU. This obligation already existed under the previous legislation as regards substances to be classified as dangerous. Under REACH, an importer needs to know at least the identity and percentage content of all substances in the preparations he imports that could exceed the amount of one tonne/ year.

If the non Community formulator is not willing or not able to provide the required information, the importer has the following options:

- establish the composition of the preparation by analytical means,
- contact the non-community formulator and propose to him that he appoints an Only Representative in accordance with Article 8 of the REACH Regulation,
- find an alternative supplier who is prepared to provide all required information for the preparation,
- if sufficient information on the identity of the substance is available, pre-register but cease the import of the preparation when the relevant registration deadline according to Article 23 of the REACH Regulation arrives. Note, however, that if a pre-registration is not made an immediate registration of the substances would be required, unless the substance is imported for the first time by that importer in accordance with Article 28(6) of the REACH Regulation.

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Legal Rights and Remedies

- Right to a hearing
  - Right to know
  - Right to participate
- Right to an appeal
  - Against MSCA decisions
  - Against ECHA decisions
- Right to judicial remedy
  - National Courts
  - ECJ

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Conclusions

- To stay on the EU market for the long term:
  - Make sure your customer the authorities get the REACH information they require from you or your OR
  - Make sure your OR understands and can handle the need to comply with all legal obligations of importers under REACH, not just pre-registration
  - Take part in REACH seminars also in the future

Thank you for your attention!