



REACH

Developments and Progress

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Three basic messages:

- You will lose the EU market if you/your EU importers do not meet REACH obligations. Penalties (severe) for those that try to evade REACH.
- REACH is another step towards increasing, global control of chemicals. Anticipate and plan accordingly.
- Trade associations, like the IMnI, provide invaluable support, knowledge and skills to members in raising awareness of and assistance in meeting the needs of global regulatory control.



Overview

- REACH: a brief recap
- REACH update:
 - overview of pre-registration
 - Mn Consortium progress
- Future steps for registrants
- Enforcement
- Top tips & experiences to-date
- What's next?

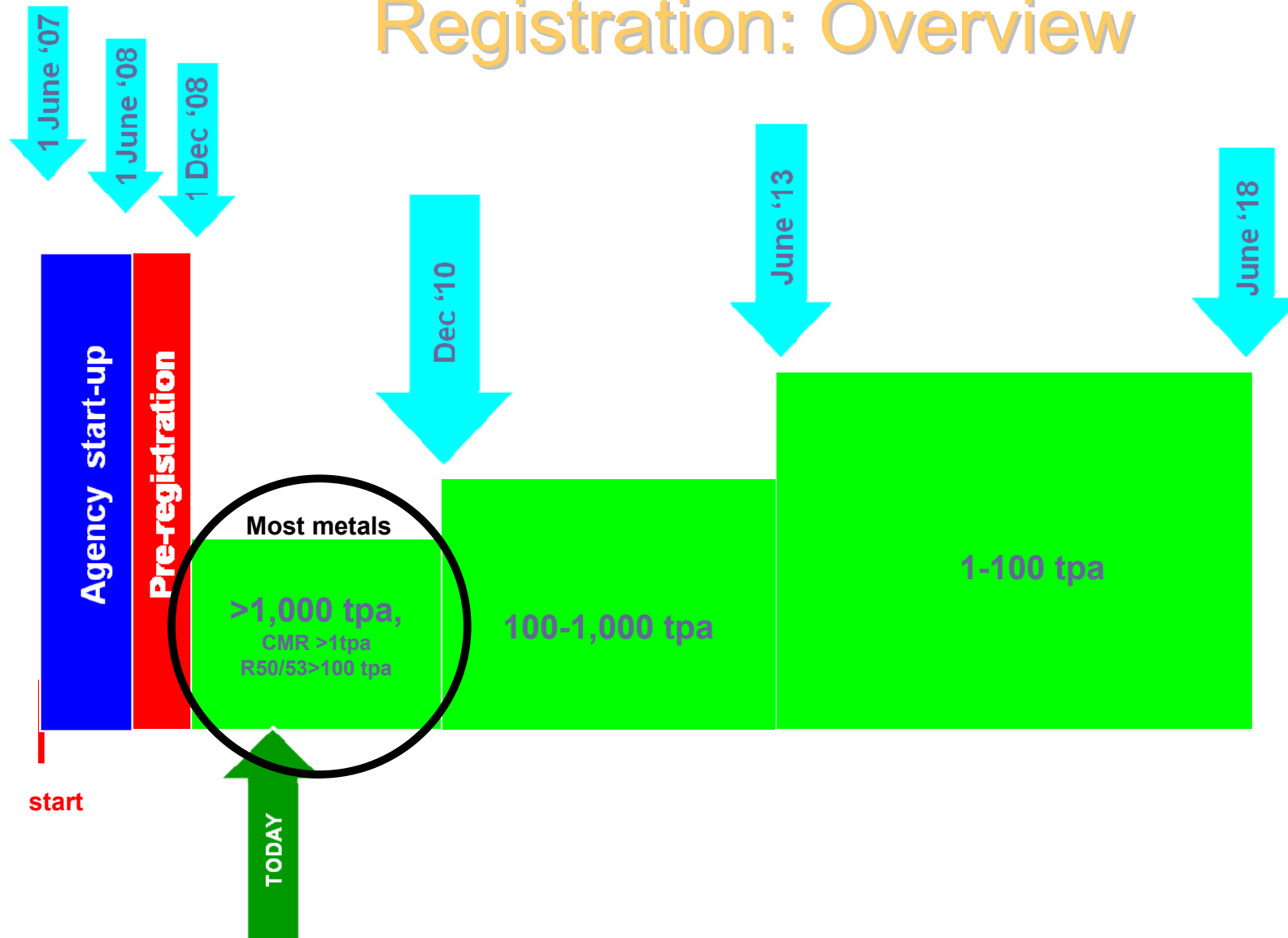


REACH – a permit to trade

- REACH is not only about chemicals!
....driven by substances, including metals
- EU Regulation effective from 1 June 07
- Chemicals Agency (ECHA) in Helsinki
- Affects each EU legal entity that manufactures or imports **any substance ≥ 1 tpa**
- Registration deadlines; **first is 2010 $\geq 1,000$ tpa**
- **No data no market** – a permit to trade!



Registration: Overview



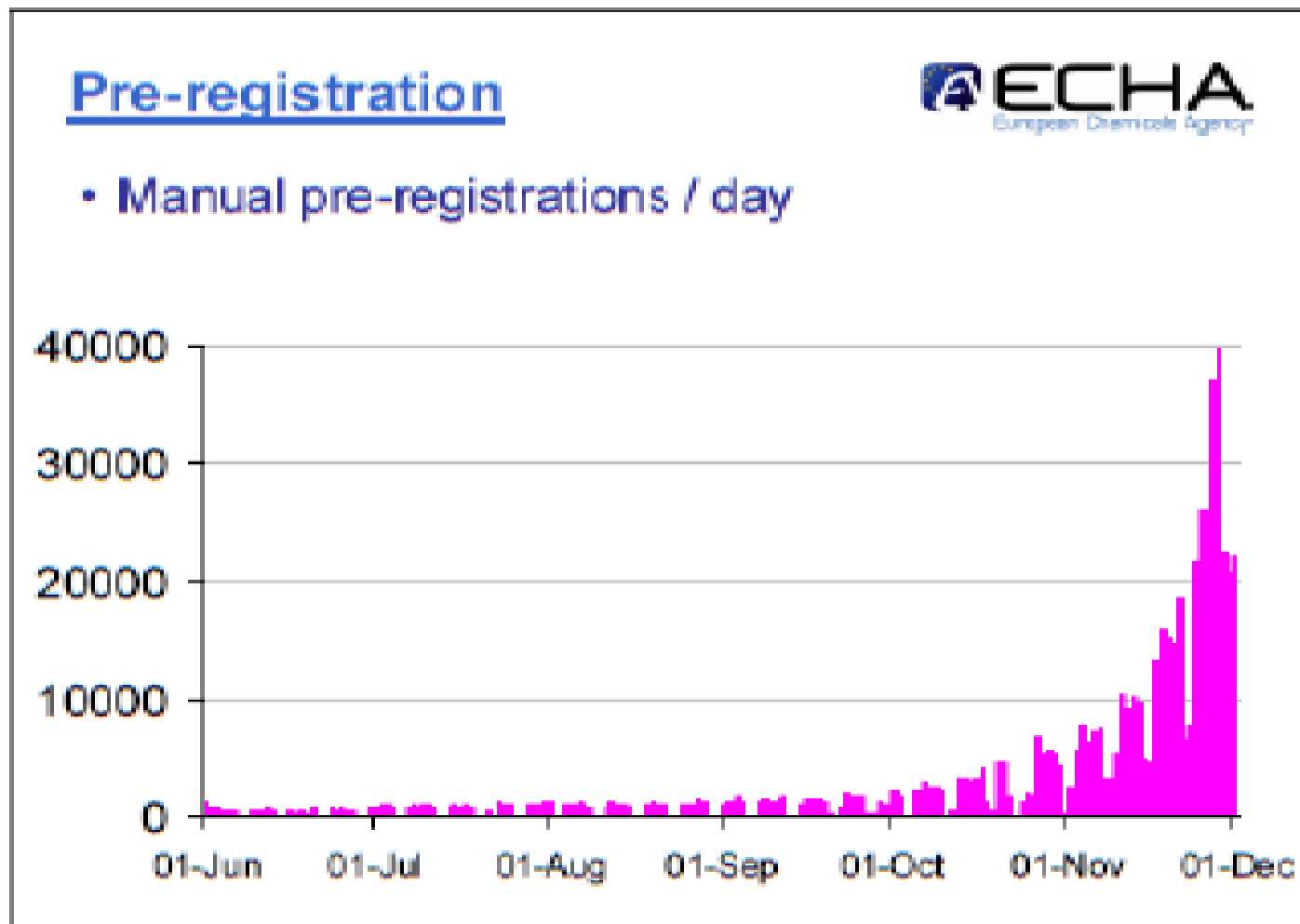


REACH: pre-registration results

- Pre-registration ended 1 Dec 2008
- Total 2.7m pre-registrations vs 200,000 expected by EU authorities
- 65,000 companies; 146,000 substances
- **Mn-based substances:**
 - **5,660 pre-registrations, including**
 - **3,350 for Mn alone**
- Many, many precautionary pre-registrations



Pre-registration: June-Dec 2008





Current situation

- Without pre-registration an EU manufacturer or importer must cease trading until a **registration** is submitted to ECHA
- SIEFs are forming – but very slowly
- REACH is a low or lower priority for many businesses due to current trading conditions
- Challenges for $\geq 1,000$ tpa without consortium
- The IMnI is working to assist its REACH Consortium members with their obligations



REACH Mn Consortium

- Started in 2007; driven by IMnI, 11 active players as founding members
- Operational from 1 Jan 2008
- Now 41 members, large and small players, covering a broad industry profile
- First-class support from IMnI team as Trustee
- Technical programme underway: extensive data search completed, testing started
- Co-ordination with other metal consortia



REACH Mn Consortium

	2007				2008				2009				2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Consortium set-up programme		█	█	█												
Existing data gathering					█	█	█	█								
Data from members					█	█	█	█	█							
Data gap analysis							█	█	█	█						
Test strategy (pre-SIEF)							█	█	█	█						
Upload existing data onto IUCLID V							█	█	█	█	█					
Master specifications defined							█	█								
Decision and provision of samples							█	█	█							
Pre-SIEF substance sameness									█							
SIEF data call										█	█					
Data review / new data gathering									█	█	█	█	█	█		
Exposure scenario and identified uses							█	█	█	█	█	█				
Agreement of test strategy							█	█	█	█						
Testing programme annexes 7 & 8											█	█	█	█		
Proposal and agreement on C&L													█	█	█	█
Human health RA										█	█	█	█	█		
Environmental RA										█	█	█	█	█		
Draft CSR/CSA										█	█	█	█	█		
Final CSR/CSA												█	█	█		
Draft dossier/s												█	█	█		
Test proposals /annexes 9 & 10														█	█	█
Agreement on Dossier														█	█	█
Submission of 2010 registration dossier/s																█



Mn Consortium: completed activities

- ✓ Literature search and data gap analysis
- ✓ IUCLID 5 entry of existing data
- ✓ Contract test laboratories commissioned
- ✓ Master specifications and samples available
- ✓ Expert reports written:
 - genetic toxicity
 - reproductive toxicity
 - toxicokinetic (peer review due end of June)
- ✓ Aquatic toxicity testing for PNEC derivation



Next steps: potential registrants

- Remember, pre-registration only buys time
...REGISTRATION is vital
- First deadline is just next year (30 Nov)
- YOU must register. Start now to plan:
 - resources
 - skills (IUCLID 5)
 - registration information
 - budget costs (registration / joint submission)
- Enforcement has already started



Enforcement: some obligations

- EU manufacturer/importer must pre-/register substance/s at ≥ 1 tpa
- A nominated REACH Only Representatives must pre-/register substance/s at ≥ 1 tpa
- Obligation to communicate down/up the supply chain any new information on the substance
- You must retain all information required to demonstrate REACH compliance for 10 years
- Obligation to submit compliance evidence to Member States/ECHA if requested



Top tips and experiences

- Keep going, REACH will not disappear!
- Maintain REACH at a high level in your organisation
- Assemble good records of your REACH compliance actions
- Introduce procedures to communicate, update and retain substance information
- Plan / budget for any 2010 registration needs
 - your registration to ECHA
 - joint submission costs



What's next?

- GHS – globally harmonised system (worldwide)
- CLP – classification/labelling/packaging (EU)
- ChAMP – Chemical Assessment and Management Program (USA)
- Others?



Three basis conclusions

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Thank you!

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