



REACH Mn CONSORTIUM What's In It For My Company?

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MAIN POINTS

- IMnI Board decides to create a REACH Mn Consortium
- REACH requirements
- Why a REACH Mn Consortium?
- Current status of Mn REACH Consortium
- Lifetime
- Estimated costs
- REACH Workshop: Paris, October 10

REACH requirements

- Industry must demonstrate safety via registration of chemicals (including metals/metal compounds)
- Dossier to include tonnage-related data on effects on humans & environment; exposure data; risk assessment; guidance on safe use; classification; etc
- Tonnage-related timetable.....

REACH requirements

Tonnage band	1-10	10-100	100-1000	>1000	CMR 1&2
Technical info?	Yes	Yes	Yes	Yes	Yes
Data ex Annex	VII	VII & VIII	VII, VIII & IX	VII, VIII, IX & X	VII, VIII, IX & X
CSR	No	Yes	Yes	Yes	Yes
Time after EIF	11y	11y	6y	3.5y December 2010	3.5y

CSR = Chemical safety report

EIF = Entry into force (1 June 2007)

CMR = Carcinogen, mutagen or reproductive toxicant

Why a REACH Mn Consortium?

- Several Mn substances to register
- Single consortium facilitates “intelligent testing” and read-across for all substances (mandatory SIEFs* are for single substances)
- Avoids inconsistencies in data submitted to the Agency
- Share costs (administration & studies) and workload
- Reduced registration fees if in consortium
 - * Substance Information Exchange Forum (next slide)



Consortium Benefits

CONSORTIUM

- Consortium can be formed NOW & e.g. agree on C&L ahead of SIEF
- Private: consortium is voluntary and industry's responsibility
- Consortium allows a common strategy for assessment & registration of all Mn substances
- Independent selection of lead registrants
- Voluntary data sharing on a substance
- Trust (know the members)
- Data from 3rd parties can be anticipated

SIEF

- SIEF = virtual room, no structure, starting in January 2009
- A SIEF is mandatory
- No influence, no flexibility
- 1 SIEF per substance
- Lead registrant could be appointed by the Agency
- Sharing data may be imposed against compensation
- 3rd parties may submit data to the SIEF



Current status of Mn Consortium

- 11 companies have agreed to participate in forming the consortium
- Other companies have expressed interest
- Draft Consortium Agreement currently under consideration by company lawyers; to be adopted Q3 2007
- Steering Committee and Technical Working Group established; 1st meetings held today
- **Membership of Mn Consortium remains open to new participants**

Lifetime of the Consortium

- For substances ≥ 1000 tonnes per annum per manufacturer/importer, the deadline for registration is December 2010 – this would be the end of the main phase of the consortium
- At this time some tests (vertebrate animal studies) may still need to be conducted
- REACH foresees a potential need for updating of CSRs if/when new information becomes available
- A smaller “core group” could be formed after 2010 to manage these aspects, as/if necessary
- Lower tonnages have longer deadlines (June 2013 for substances ≥ 100 tpa; June 2018 for ≥ 1 tpa)

Estimated costs (2007-2010)

- Total costs comprise two main expenses:
 - Consortium set-up and project management
 - Data/information acquisition and assessment
- Consortium set-up and management:
 - An overall budget of **€ 2,000,000** has been estimated. This includes allowances for legal and technical/scientific consultants, administration, dossier preparation, etc

Estimated costs (2007-2010)

- **Data/information acquisition and assessment:**
 - For 1000 tpa substances with **no data**, costs to acquire the required data are estimated to be **up to € 2,000,000 per substance**;
 - For the registration of the **10-12 Mn substances** currently under consideration, total costs of **€ 5-10 million** have been estimated.
- **Total cost estimates** are, therefore **7.000.000 € to 12.000.000 €** for the period **June 2007/December 2010**
- An initial budget will be proposed to the Steering Committee this afternoon
- Cost estimates are unlikely to change significantly if further substances are included in the portfolio



REACH Workshop, October 10

- REACH has introduced new and mandatory requirements that are difficult to understand, complicated to deliver and which put enormous pressure on industry
- In order to help its members, and others with interests in the registration of Mn and its compounds, to understand REACH and its implications, IMnI will organise a one-day workshop in Paris on October 10
- Further information and invitations will be issued in the coming weeks – **but please put a marker in your calendar now:**

October 10, Paris



Thank you Ladies & Gentlemen!

Any Questions?