



How to Get the Most Out of REACH Pre-registration Webcast

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Topics Covered Today

- 1. Specific Pre-registration Questions**
- 2. Considerations When Making an Inventory**
- 3. Supply Chain and Structuring**
- 4. Consortia Issues**
- 5. SIEF Conditions**

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Specific Pre-registration Questions

- **Why is Pre-registration important?**

Not compulsory but **extends Registration deadlines for manufacture/use/importation** of *phase-in* substances. Deadlines based on tonnages and properties of substances (2010, 2013 and 2018).

- **What is the window for Pre-registration?**

Start on 1 June 2008 BUT:

'ending on 1 December 2008' - Regulation

'to 1 December 2008' - Registration Gdnc. (Jun'07)

'to 1 December (inclusive)' - Data Protection Gdnc. (Sep'07) and FAQ (Dec'07)

Specific Pre-registration Questions

- **Why not skip Pre-registration and Register a phase-in substance?**
 - **Obligation to Register (if not going to Pre-Register) applies from 1 June 2008.** No Registration = No market. National law penalties.
 - **Must file “inquiry” and suspend manufacturing/import/use activities (excluding stocks) (from 1 June) until complete and Registration dossier submitted so there is always a gap.**
 - (i) Prior to Registration, ask ECHA if a Registration has already been submitted for the same substance.
 - (ii) If previous and/or potential Registrant(s), the early Registrant is still part of the SIEF.
 - (iii) Organised data sharing and new tests as required (exposes gaps in your data?).

Specific Pre-registration Questions

- **Does it matter when you Pre-register?**
- **What are the implications of the timing of Pre-registration for downstream users?**
 - Batches manufactured prior to Pre-registration
 - Batches manufactured when Pre-registration has begun
- **Why would you consider being the SIEF Facilitator?**
 - Potential Lead Registrant
 - Smaller Manufacturer or Importer

Specific Pre-registration Questions

- **What information do you have access to as a:**
 - **Pre-Registrant**
Until 30 November 2008
Dedicated web-page on REACH-IT only seen by Potential Registrants (not DUs) of a substance and Potential Registrants of substance(s) which are candidates for read across. **Your identity and expected tonnage band etc. will be disclosed unless you have appointed a 3rd Party Representative - appoint now!**
 - **Downstream User**
From 1 December 2008 until no later than 1 January 2009
ECHA website will publish a list of all Pre-Registered substances and envisaged Registration deadlines (but not include the names of the Pre-Registrants). **What do you do if the substance you use is not on the list?**
- **What if you manufacture or import for the first time after the Pre-registration deadline has passed?**

Considerations When Making an Inventory

- **Mono-constituent & Multi-constituent substances:**
 - Mono-constituent substance: a substance, one main constituent is present to at least 80% (w/w), although certain deviations are permissible
 - Multi-constituent substance: a substance, more than one main constituent is present in a concentration 10% (w/w) and < 80% (w/w), although certain deviations are permissible
 - **Pre-Registering and Registering each constituent of a multi-constituent substance**

Considerations When Making an Inventory

- Annex IV Criteria: adding/deleting entries: the deadline was **10 January 2008**.
- Annex IV Criteria: evaluating current entries: existing entries will be reviewed to see if they meet the developed criteria. The following approach will be applied:
 1. The contractor will collect data according to the information requirements for inclusion in Annex IV from easily accessible data sources.
 2. The contractor will group substances in Annex IV, where possible, so that readacross principles can be used for substances in the same group. Certain groupings have been proposed.
 3. The burden of proof is directed at identifying evidence of human health or environmental effects according to the criteria.

Considerations When Making an Inventory

- **Article Considerations**

Guidance still pending but key issues apparently resolved:

- **Register all** not just what has to be released
- **0.1% applies to whole articles** (as shipped) not components or homogenous parts (complaints by at least 5 states on this) - some companies taking stricter approach
- **Indicative criteria** on container *v* article

- **Tonnage Calculations: the *moving targets***

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Supply Chain and Structuring

- 1. Who is doing what within the supply chain?**
- 2. Particular OR concerns**
- 3. How does a toll manufacturer fit in?**
- 4. Third party representatives**

Supply Chain and Structuring

1. Who is doing what within the supply chain?

- Compliance discussions with companies in different parts of the supply chain have raised practical issues
- Supply chain communications essential for effective registration planning
 - Clear for supply chains within the EU, i.e. DUs have to know if their EU supplier is going to register and keep the substance available for their use in the EU market
 - Outside the EU these supply chain communications are even more important

Supply Chain and Structuring

Case study:

- Facts: Non-EU substance Supplier A (SA) sells Substance #1 (S#1) direct to EU.

SA also supplies S#1 to DU/formulators in same country who sell their preparation direct to EU and to other non -EU countries.

I.e., multiple supply chains to EU market, with all imports into the EU having S#1 in them in registrable quantities (i.e. over 1 tonne); different EU importers.

- Issue: Non-EU DUs are contacting and asking SA to take care of REACH compliance, but of course they also are getting questions, from their own non-EU DUs about what they will do for REACH compliance.

Supply Chain and Structuring

Need to think about registration of own exports, but also registration of S#1 in DU's exports to the EU.

“Probably will register” – no longer an option. Definitive responses from substance manufacturer now expected.

1. Own exports. SA must ensure direct exports of S#1 are properly registered, but relations with existing EU buyer/importer/distributor not great (invoice and quality issues), so ...

Explore either i) identification of another EU buyer/importer capable and willing for REACH registration, or ii) directly appointing an OR to handle the registration.

But: Starting to run out of time (pre-registration window opening in June) for new relationship; Other suppliers of S#1; SA's quantity would take importer into next tonnage band.

= Decision-taking on importer vs. OR registration still in process of resolution. But other factors to watch.

Supply Chain and Structuring

- 2. Regarding exports of S#1 by non-EU DU, separate supply chains to the EU face their own, separate REACH registration obligations regarding the various substances in their preparations, i.e., registration of SA's' S#1 but also for other key ingredients.**

To the extent SA identifies and reaches agreement with new EU importer, DU will have to work out with its EU importer(s) for registration of each input substance. But data must be transmitted down supply chain to DU's importer for eventual registration of S#1.

Supply Chain and Structuring

But, if SA appoints OR, OR can be appointed also for imports of S#1 from SA's non-EU DUs.

- Interesting especially if non-EU DU sells into EU through unrelated entity with whom it does not want to share proprietary information or otherwise trust with all REACH compliance obligations – good customer relations.

Supply Chain and Structuring

Implications:

- OR reduces DU's supply chain burden to register S #1
- Avoids passing data and potentially proprietary information to DU and downward to EU border for registration purposes
- But: Cumulation of OR's tonnage for registration of S#1 (i.e., add direct imports from SA and the imports of S#1 in the DUs' preparations, which potentially move tonnage into next registration band (more data, earlier). SA must find out quantity of its S#1 going to the EU in the DU's preparation and balance merits of having its OR cover all imports or, alternatively, assisting the DU with data but having DU's EU importer separately register its imports of S#1.

Supply Chain and Structuring

Overall messages:

- Supply chain communications absolutely essential if any efficiencies are to be found in compliance process.
- Simple enquiries not useful – need to actively discuss existing supply channels, quantities, registration options for each party relating to those specific channels, and finally decide jointly what is the optimum solution for supply chain. And only then -- start talking realistically about cost-sharing within the supply chain.
- Competitive pressures arising – if you are not REACH ready or cost-sharing ready, DUs may have other supply options and may need, for their own commercial viability, to secure new, more customer-friendly suppliers.

Supply Chain and Structuring

2. Particular OR Concerns

i. Cumulation of tonnages

- **OR might be appointed by one or several non-EU substance producers, formulators or producers of articles.**
- **Latest FAQ highlights that OR representing more than one non-EU producer must submit one registration dossier for same substance and covering the total volume that OR is responsible for, i.e., cumulating the total tonnage of that substance from all non-EU producers that have appointed him.**
- **(Parallels obligation of EU importer of substance exported by several different suppliers).**

Supply Chain and Structuring

- Note: cumulation of tonnages from different non-EU supply chains may advance registration deadline and increase the amount of test data required for registration beyond what would be required for the tonnage from any one of the non-EU producers.
- The OR (or importer) may thus have to pay for acquisition of data from within the SIEF and bear costs that no one of the non-EU producers would be bound to acquire or pay for regarding its registration alone. Who will pay additional costs?

Supply Chain and Structuring

- Individual non-EU producers must be attentive to potential other appointments of that OR for same substance and decide respective responsibilities should additional appointments take the OR over a tonnage threshold.
- If grouping of non-EU producers want to commonly appoint OR, need to agree on sharing of additional costs incurred by their cumulated tonnage.

Supply Chain and Structuring

ii. SME Implications

- Above cumulation complications arise for both large producers/exporters and SMEs but implications particularly serious for SMEs.
- EU SMEs granted clear benefits to reduce REACH burden: substantial reductions in fees and charges payable to ECHA.
- Reductions definitely accrue to EU SME producers, but unclear whether reductions will get passed on to non-EU SMEs.

Supply Chain and Structuring

Leaked December draft text of ECHA fees and charges has OR provision (Art 11) in 2 parts:

- 1 – the fee or charge to OR would be determined by reference to size of the exporter represented.
- 2 – if the OR represents more than one exporter, the fee or charge would be determined by reference to “total size” of all exporters represented by that OR. Effectively, the SME fee “reduction” in principle available to a non-EU SME might be lost.

Latest: OR provision (now Art 12) amended – 2nd paragraph deleted!

- SME fee reduction now determined by reference to size of non-EU producer “represented by that only representative in connection with that transaction”.
- If official, appears to re-establish SME reduction for non-EU SMEs even if OR represents multiple producers – but new text not clear and just appeared, so checking with the ECHA!

Supply Chain and Structuring

3. How does a toll manufacturer fit into compliance strategy?

Toll manufacture: “a person contracts with a manufacturer to manufacture or produce a new chemical substance, and (i) the manufacturer manufactures or produces the substance exclusively for that person, and (ii) that person specifies the identity of the substance, and controls the total amount produced and the basic technology for the plant process”. IPR normally also held by the person contracting for the manufacture.

US: Pre-Market Notification by the person contracting for manufacture of substance.

ECHA: “The trigger to consider whether an entity is required to register is, therefore, whether it undertakes a process that can be described as manufacturing according to the definition of Article 3 (8). In this regard, an entity that synthesises a substance on behalf of a third party is to be considered as manufacturer for the purposes of REACH and, consequently, is required to register. This situation does not change in the case the raw materials would be supplied by your client to the manufacturer.”

I.e., the toll manufacturer is responsible for registration under REACH.

Supply Chain and Structuring

4. Third party representatives

Art 4: Any manufacturer, importer, or DU may appoint third party representative for discussions with other manufacturers, importers or downstream users concerning: joint registration, data-sharing and cost-sharing for additional testing. Identity of manufacturer, importer or downstream user who appoints representative shall not “normally” be disclosed by the Agency.

TPR avoids disclosure of identity of the registrant vis -à-vis other registrants or data-holders in the SIEF.

Not to be confused with OR! No transfer of responsibility for registration or other REACH obligations

TPR must be indicated at time of pre-registration. Contact details indicated in pre-registration will be made available to all other intending registrants of same and read-across substances. Decide early if TPR is appropriate for which substances.

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Consortia – Basic Concepts

- SIEF Consortium
 - SIEF merely a list of contact details
- Consortium not mandatory, so why join one ?
 - Ensures interests sufficiently protected
 - Creates controlled structure for SIEF communications
 - Efficiencies
- When to form / join consortium : the earlier the better ?
- Main business concerns in complying with SIEF requirements
 - CBI
 - Competition law compliance
 - Data evaluation and cost sharing

SIEF Cooperation: Emerging Models

- Three different models already being used by different industry sectors
- Open consortium model
 - examples in metals sector, driven by international trade association
 - open to all SIEF participants for relevant substance (avoids competition concerns regarding entry conditions)
 - rationale:
 - maximise efficiencies by incorporating majority, if not all, SIEF participants under same cooperation framework
 - cooperation on sameness envisaged prior to pre-registration (ACT NOW, don't run out of time!)
 - Ensure mechanisms for cooperation realistic for large membership (quorum, voting, etc.).

SIEF Cooperation: Emerging Models

- Closed consortium model
 - limited to founding members, either driven by companies themselves or small trade association
 - restricting further membership not necessarily anti-competitive provided comply with REACH requirements
 - provide data to SIEF members outside closed consortium;
 - participate in SIEF initiatives such as classification and labelling and election of lead registrant; and
 - share costs of consortium studies fairly.
 - rationale:
 - deal with only competitors with which have trusted relationship; and
 - management of small consortium administratively more realistic (resources and time).

Under some versions of this model:

 - create new missing data prior to entry into SIEF to avoid Regulation 'lead participant' requirements; and
 - enter SIEF as seller of complete data package only.

SIEF Cooperation: Emerging Models

- **Data licensing**
 - example in the oil sector, driven by trade associations
 - not a consortium
 - trade association (not its members) creates complete data package, enters SIEF as a data holder and then licences data package to SIEF participants
 - rationale:
 - create new missing data prior to entry into SIEF to avoid Regulation 'lead participant' requirements;
 - enter SIEF in data holder capacity only; and
 - opportunity for SIEF participants to licence all data needs from one source without time and costs of establishing or joining a consortium.
 - disadvantage: still need to establish a cooperation framework for joint submission of data for registration

Data Valuation and Costs Sharing

- Evaluation and cost sharing baseline principles:
 - Proof of historic value of data
 - Fair, transparent and non-discriminatory method
 - ‘Equal shares’ default mechanism
- Cost Evaluation:
 - ‘Historic value’ or current value (‘replacement value’) ?
 - Total study costs: Risk premium? Additional administrative and management costs?

Costs Sharing

- Sharing formulae:
 - ‘Set off’ compensation for holder of studies similar to ‘key study’ chosen for submission?
 - Proportionate to production or sales volume of each purchaser?
 - Costs mechanism flexibility for later purchasers of data?
 - Same charge for SIEF participants inside or outside consortium.

SIEF Issues

- Do you have to participate?

All Pre-Registrants must Participate even if don't Register later (only data sharing).
Even if you have an exempt active substances in a PPP or biocide you will have to participate in the SIEF.

Third Party Data Holders who submitted data (DUs and others) may participate - join early

- Types of SIEF Member

Pre-Registrants (whether or not they Register)

Registrants (who did not Pre-Register)

PPP and biocide data holders for exempt actives

Third Party Data Holders (DUs and others)

ORs

3rd PRs

- Can NGOs join the SIEF and obtain my data?

SIEF Issues

- How much is this going to cost me?



QUESTIONS?

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Step toe Integrated REACH Services

Legal

- Overall coordination of and participation in REACH compliance strategy
- Responding to *ad hoc* strategic/legal regulatory questions
- Preparation and negotiation as appropriate of Confidentiality, Data and Cost Sharing and Lead Registrant Agreements within the relevant SIEF(s)
- Preparation and negotiation of Consortia Agreements and Letters of Access
- Participation in relevant Consortia's steering and legal affairs activities
- Participation in SIEF meetings raising coordination/legal issues (technical and other SIEF activities will be covered by Steptoe technical representatives)
- Acting as Only Representative
- Acting as 3rd Party Representative

Steptoe Integrated REACH Services

Technical

- **Preparation of Pre-Registration: Compilation of REACH Substance Portfolio or review the Portfolio, as needed (assessment, *inter alia*, of substances exempt, substances to be pre-registered, registered, authorized, etc)**
- **Preparation of Registration Dossier**
- **Review of the adequacy of Pre-Registration and Registration activities**
- **Preparation of CSR and SDS**
- **SIEF participation as a Third Party Representative (technical group and general representation when legal support is not necessary)**
- **Participation in relevant consortia's technical affairs activities**
- **Development of strategy for sourcing of data to fill data gaps (if any), including:**
 - **Literature search and review**
 - **Data valuation**
 - **Recommend study protocols, provision of cost estimates, sourcing CRO's and studies (e.g. acquisition from other SIEF members, further testing, etc.)**