EUROMETAUX
EUROPEAN ASSOCIATION OF METALS

REACH
Duties and workload of Lead Registrant

June 2009

Introduction

Through the Lead Registrant, REACH Registrants are required to jointly submit information on the hazardous properties of the substance, its Classification and Labelling and can, if they agree, also jointly submit the Chemical Safety Report and/or the guidance on safe use.

It is important to note that the "joint submission of data" does not eliminate the obligation for each Registrant to submit its own information in its individual dossier. See Table 1 for details of the information that can be submitted jointly and/or individually.

This document explains the duties and workload of the Lead Registrant under REACH.

Who is the Lead Registrant?

The Lead Registrant is referred to in Art. 11.1 and 19.1 of the REACH Regulation as: "*one Registrant acting with the agreement of the other assenting Registrant(s) and who shall submit the joint dossier*".

The ECHA guidance on data-sharing[1] and the ECHA SIEF key principles[2] outline that:

- Only one Lead Registrant can be appointed per substance even if several tonnage bands co-exist and whether the substance is used as an intermediate or not. All potential Registrants should be part of the discussions irrespective of their tonnage band or use.

- The Lead Registrant should logically be one of the Registrants required to submit its Registration dossier by the earliest deadline. This is, however, not an obligation, as the Member Registrants can appoint a leader with a lower tonnage band, in this situation the Lead Registrant would still have to submit a Registration dossier in accordance with deadline and information requirements of the highest applicable tonnage band, although he would only pay the fee corresponding to his own tonnage.

How to appoint a Lead Registrant?

- If only one potential Registrant volunteers, the SIEF members still have to formally agree with the appointment of the designated lead registrant.

- If two or more potential Registrants volunteer, they can seek an agreement between them as to who will be the Lead Registrant and propose it to the SIEF members. If the volunteers cannot agree, then it is up to the other potential Registrants to elect the Lead Registrant.

  N.B.: For those substances where a consortium exists, the rules and procedures for the proposal of the Lead Registrant may be set in the consortium agreement, although the rules within the SIEF will have to be agreed by all the (active) members.

- If no potential Registrant volunteers, a mechanism by default is proposed in the ECHA Guidance[1]. The Lead Registrant will be the EU Manufacturer or Importer with the highest volume of production or import of the substance[3].

---

[1] http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.pdf

[2] http://echa.europa.eu/doc/reachit/sief_key_principles.pdf

[3] it should be noted that in case of difficulties to reach consensus within the SIEF, the enforcement of this mechanism is not guaranteed.

N.B.: In all cases, it is recommended to document clearly who is appointed as Lead Registrant and to make clear who is acting on behalf of whom.

It is recommended by ECHA to appoint the Lead Registrant as early as possible and that the Lead Registrant, once elected, confirms his nomination to ECHA via lead-Registrant@echa.europa.eu

What are the tasks of the Lead Registrant?

If the Lead Registrant is in a SIEF without the support of a consortium

- The key tasks of the Lead Registrant, outlined in 8.3.2 of the guidance document on data-sharing, are to:
  - Submit the information, required in line with Art. 11(1) and 19(1), on behalf of the joint submission members in his Registration file: i.e.
    - information specified in Art. 10 (a) (iv), (vii);and
    - request of confidential treatment of data Art. 10 (IX), if required
  - Optionally, the Lead Registrant may also submit the information outlined in Art. 10(a)(v) and Art. 10(b) (i.e. the CSA/CSR).
  - Provide future updates of the joint submission dossier

- Optional tasks that can be undertaken by the Lead Registrant:
  - Substance sameness check (for new Registrants)
  - Data sharing:
    - Propose internal rules for the form of cooperation and decision making process within the SIEF, including communication;
    - Agree on the entity in charge of the performance of the necessary technical work;
    - Prepare an inventory of available data;
    - Carry out the validation and valuation of the data;
    - Facilitate an agreement on cost sharing formulas with regard to the joint submission process;
    - Designate/propose a trustee in charge of cost sharing issues related to the sharing or obtaining of data, and responsible for collecting and maintaining the confidentiality of the technical data that could contain confidential business information
    - Identify the information to be included in the Registration dossier;
  - Facilitate agreement on Classification and Labeling
  - Communication with the other relevant SIEFs and with ECHA
  - Run the SIEF after Registration (at least until 2018!). Incorporate new comers and follow up with ECHA, etc.

If the Lead Registrant is a member of a consortium*:*

The consortium's secretariat may assist the Lead Registrant with a considerable part of the organisational and preparatory work, although the extent of this is determined by the consortium members and may differ from consortium to consortium. Based on several examples within the non-ferrous industry, the key tasks of the Lead Registrant may be reduced to:

- Submitting the information, required in line with Art. 11(1) and 19(1), on behalf of the joint submission members in his Registration file: i.e.
  - the information specified in Art. 10 (a) (iv), (vii);and
  - request of confidential treatment of data Art. 10 (IX), if required
- Optionally, the Lead Registrant may also submit the information outlined in Art. 10(a) (v) and Art. 10(b) (i.e. the CSA).
- Providing future updates of the joint submission dossier.
- Being the contact point for formal communication with ECHA.
- Being the official contact point for data sharing after Registration

Even if the consortium elects one of its members as candidate LR, the person will still need to be confirmed as LR by the majority of the SIEF members. Similarly, the majority of SIEF members will have to agree on the definition of mandatory and optional tasks to be carried out by the Lead Registrant, even if already agreed upon in the consortium.
Therefore, it is advisable to document the agreed tasks and duties of the Lead Registrant and the different categories of SIEF members.

What are the liabilities of the Lead Registrant?

As a general rule, private parties are free to organise their relationships or contractual liabilities by contractual, but National laws will govern the liability of all SIEF participants.

Since the Lead Registrant assumes specific tasks which could seriously impact the compliance of other Registrants and could lead to liability claims (e.g. failure to register on time, quality of the dossier…), it is recommended to clarify liability in the agreements between SIEFs members and the Lead Registrant.

Where a consortium exists, the liability of the Lead Registrant may be set out in a specific liability clause in the consortium agreement. As an example, the clause within the nickel consortium is:

> *To the greatest extent possible under the laws of the relevant jurisdiction, the Lead Registrant shall not be liable for, and the Regular Members shall indemnify the Lead Registrant against and hold harmless from, all liabilities and claims (including reasonable attorneys fees and expenses in defending against such liabilities and claims) against the Lead Registrant in connection with the matters contemplated by this consortium agreement other than liabilities attributable to the gross negligence or willful misconduct of the Lead Registrant or breach of confidentiality provisions contained in Article 6.4.2 above by the Lead Registrant.*

Conclusion

The workload of a Lead Registrant depends on whether a consortium exists or not. Therefore, before a company volunteers as Lead Registrant, this should be taken into account the following aspects:

"Ideal Profile" of the "Lead Registrant"

- Producer or importer of the substance registering in the 1st Registration deadline
- Good technical knowledge on the substance
- Good knowledge of REACH
- Deep involvement in REACH preparatory work
- Enough resources available to:
  - Be deeply involved in the preparation of the Registration dossier
  - Upload the common Registration dossier on REACH-IT (could be time consuming!)
- Facilitate communication between ECHA and the other Registrants

Table 1 Overview of the data to be submitted jointly and/ or separately

Joint submission	Separate submission	Joint or separate submission: free decision
10(a IV) **Classification and Labelling** of the substance as specified in section 4 of Annex VI	10 (a I) **Identify of manufacturer or importer of the substance** as specified in section 1 of Annex VI	10 (a V) Guidance of safe use of the substance as specified in section 5 of Annex VI
10 (a VI) **Study summaries** of the information derived from the application of Annexes VII to XI	10 (a II) **Identity of substance** as specified in section 2 of Annex VI	10 (b) **Chemical Safety Report** when required under Article 14, in the format specified in Annex I. the relevant sections of this report may included, if the registration considers appropriates, the relevant use and exposure categories
10 (a VII) **Robust study summaries** of the information derived from the application of Annexes VII to XI, if required under Annex I	10 (a III) **Info on the manufacture and use(s) of the substance** as specified in section 3 of Annex VI; this information shall represent all the registrant's identified	
	use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories	
10 (a IX) **Proposals for testing** where listed in Annexes IX and X	10 (a X) **for substances in quantities of 1 to 10 tonnes, exposure information** as specified in section 6 of Annex VI	
Optional: 10 (a VIII) Indication as to which of the information submitted under Article 10(a), (iv), (vi), (vii) has been **reviewed by an assessor** chosen by the manufacturer or importer and having appropriate experience	Optional: 10 (a VIII) Indication as to which of the information submitted under Article 10(a) (iii) has been **reviewed by an assessor** chosen by the manufacturer or importer and having appropriate experience	Optional: 10 (a VIII) Indication as to which of the information submitted under Article 10(b) has been **reviewed by an assessor** chosen by the manufacturer or importer and having appropriate experience

The author reserves the right not to be held responsible for the topicality, correctness, completeness or quality of the information provided. Liability claims regarding damage caused by the use of any information provided, including any kind of information that is incomplete or incorrect, will therefore be rejected.