



1. Background

As per Article 11 of the REACH regulation, registrants are required to submit parts of the registration jointly. This joint submission is done by a designated Lead Registrant (LR), on behalf of the other registrants.

This document presents the duties and liabilities of the LR in order to assist those legal entities wishing to act as LR to identify the potential workload and responsibilities that may be associated to this role under REACH.

2. SIEF Formation Facilitator versus Lead Registrant

It should be clarified that the SIEF Formation Facilitator (SFF) role is not formally recognised under REACH; therefore pre-registrants have no obligation to use a SFF to form a SIEF. This is not the case of LR, which is a legal requirement under REACH.

Whereas the legal entity having volunteered to act as SFF may or not, volunteer or act as LR, the SFF will not automatically become the LR. The SFF and the LR have two different roles under REACH, although parts of these roles may, in some cases, overlap.

3. Who is the Lead Registrant?

The LR is the one registrant acting with the agreement of the other assenting registrant(s) and who submits parts of the registration on behalf of one or more of these assenting registrants (cf. Articles 11 and 19 of the REACH regulation).

When submitting the joint registration, the LR shall identify the other registrants by specifying: their name, address, telephone number, fax number and e-mail address, and parts of the registration which apply to other registrants (by using the number(s) of the endpoints given of each correspondent Annex (VI to X)).

It is important to note that the joint submission does not remove the obligation for each one of the other registrants to submit as well an individual dossier, which will contain legal entity-specific information.

In order to ensure a cross-link with the registration submitted by the LR, when submitting its individual registration, any other registrant shall identify the LR submitting on his behalf, by specifying his contact details, and indicate the parts of the registration which are submitted by the LR.

4. How to appoint a Lead Registrant?

Article 4.7.1 of the PM & Re Consortium Agreement foresees that each relevant Work Group proposes a Consortium LR who is then officially designated (and replaced) by decision of the concerned Sub-Assembly. Once this Consortium LR is appointed, the Consortium Secretariat submits the proposal to the SIEF, in order to check if there is any objection to the proposal. If there is none, the Consortium LR becomes the LR.

Only one LR can be appointed per substance even if several tonnage bands co-exist and whether the substance is used as an intermediate or not. All other registrants of the same substance, whether members of the Consortium or not, must agree on the proposed LR and on the content of the parts of the registration that will be submitted by the latter.



The proposed LR should:

- Ideally be one of the main manufacturers or importers of the substance on the EU and have, as such, a good technical knowledge on the substance, and a confirmed interest in marketing the substance on the EU
- Have a clear understanding of REACH requirements and enough resources to be actively involved in REACH preparatory work, registration submission through REACH IT (could be time-consuming), and communication obligations (with ECHA and the other registrants),
- Be subject to the earliest registration deadline applicable to the SIEF, or must otherwise be prepared to adopt such a deadline.

However, a legal entity not fulfilling the above criteria can also volunteer and be appointed as LR, as long as the registration is submitted on time for the first applicable registration deadline in the SIEF. After the joint and the individual submissions, each registrant, including the LR, pays a registration fee that will correspond to its individual tonnage band.

When requesting legal entities to volunteer to act as LR, several situations can occur:

- **No legal entity volunteers** - A default mechanism is proposed: the LR will be the EU manufacturer or importer with the highest capacity of manufacture or import of the concerned substance.
- **Only one legal entity volunteers** - This volunteer needs to obtain the other registrants' support.
- **Two or more legal entities volunteer** - 1) the volunteers should come to an agreement on who is better placed to endorse the LR role, and if this fails; 2) the other registrants need to proceed to a vote in order to elect the most appropriate LR.

In any case, the procedure through which the LR was proposed and designated in the Consortium and then in the SIEF shall be documented for transparency.

5. What are the tasks of the Lead Registrant?

For a joint registration to be successful substance sameness must have been confirmed and the applicable information requirements must have been fulfilled by having conducted tests or by submitting test derogation/waiving proposals, or testing proposals for Annexes IX and X, as applicable.

In the PM & Re Consortium, the compilation of the IUCLID 5 files has usually been added to the responsibilities of the consultants having been commissioned with each metal-specific project of the Consortium. The workload involved in the preparation of the joint registration is therefore minimal for the LR, who will only need to provide the consultants, with the support of the Secretariat & Trustee, with the contact details and the parts of the registration which apply to the other registrants (as explained in section 3 above).

Article 4.7.2 of the PM & Re Consortium Agreement already details the contribution made by the Secretariat & Trustee to the workload and duties associated to the LR. This support should be considered in the context of the following tasks incumbent on the LR:

- (a) Submit the registration to the Agency on behalf of the Members, including their respective Affiliates which have to register the concerned Substance or Isolated Intermediate, in the format specified by the Agency, containing the Core Data and Chemical Safety Report as approved by the other registrants, on the date determined by the Management Committee;



- (b) Not modify the “joint part” of the registration without the prior approval of the other registrants.
- (c) Together with the Trustee:
 - Ensure that the complete and valid identity of the Members and Affiliates taking part to the joint submission of the registration is notified to the Agency in the registration;
 - Ensure that confidential information in the registration is marked or identified as such and shall submit to the Agency any requested justification for non-disclosure of information in the registration as per Article 10(a)(xi) of the REACH regulation.
- (d) Submit a copy of the full registration as submitted to the Agency to the Trustee;
- (e) Submit to the other Members who have contributed to the registration:
 - A copy of all the non-confidential information in the registration as submitted to the Agency;
 - A copy of those parts of the registration as submitted to the Agency, that each contributing Member is entitled to, based on the Substance and tonnage bands declaration that the Member has provided to the Trustee at the time of signature of this Agreement, or otherwise updated to the Trustee (and consequently has paid for according to the cost-sharing formula set out in Appendix 9);
- (f) Forward to the Members concerned, through the Secretariat, any communication received from the Agency (e.g. data requests, registration update requirements, etc.).

In addition, the LR shall ideally act as the official contact point after registration. Following the first contact, it will be up to the Consortium Secretariat to launch any necessary exchange or decision-making, in order to respond to the request.

6. What are the liabilities of the Lead Registrant?

As per Article 4.7.1 of the PM & Re Consortium Agreement, the Consortium LR shall be subject to the same rights and obligations as the other Members, in particular regarding confidentiality obligations. Article 8.3.5 of the PM & Re Consortium Agreement foresees that the Consortium LR shall not be liable to third parties to an extent more than liability of the Members, except:

- (a) in respect of liability attributable to its wilful misconduct, fraud, and gross negligence as Consortium LR; and
- (b) in respect of liability attributable to its role of Consortium LR according to which the Consortium LR shall be liable to the Members with whom it is preparing and submitting a registration to the Agency.

The above liability shall be made clear to the SIEF when a proposed LR is put forward for election.