APPENDIX 10
Of the Precious Metals and Rhenium Consortium Agreement

Lead Registrant Duties, Responsibilities and Declaration of Commitment

1. Background

As per Article 11 of the REACH regulation, **registrants are required to jointly submit information** on the hazardous properties of the substance (studies and proposals for testing) and its classification and labelling, and can, if they agree, also jointly submit the CSR and/or the guidance on safe use (cf. Table 1). This joint submission is done by a designated Lead Registrant (LR), on behalf of the other registrants[1].

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

[1] It is important to note that the "joint submission of data" does not eliminate the obligation for each registrant to submit as well an individual dossier. Although the information that needs to be submitted jointly is submitted by one LR on behalf of the others, additional information needs to be submitted by all registrants individually. The content of the individual file will be determined by the optional parts that are jointly submitted (cf. Table 1).

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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 with 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?

Although there are **no specific rules** in REACH, the LR is described as 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).

The ECHA guidance on data-sharing[2] and ECHA SIEF key principles[3] outline that:

- **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. It means that all the potential registrants should be part of the discussions irrespective of their tonnage band.

- The LR will be logically **one of the Registrants who plan to submit their registration at the earliest registration deadline**. The latter is not an obligation as the joint submission registrants have the possibility to appoint a leader with a lower tonnage band. However, the LR would have to submit a registration file in accordance with the **highest applicable tonnage band**, although he will still **pay the fee corresponding to his own tonnage.**

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 specify 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[4]) by decision of the

[2] http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.pdf
[3] http://echa.europa.eu/doc/reachit/sief_key_principles.pdf

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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.

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 **propose it to be supported by the other potential registrants**; and if this fails; 2) the other registrants need to proceed to a vote in order to elect the most appropriate LR.
- **If no potential registrant volunteers** to become LR, within the PM & RE Consortium a mechanism will be sought to identify a LR and in the event of failure the default mechanism as proposed above will be applied.

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 &

[4] If for any reason, the LR withdraws or behaves improperly, the concerned Sub-Assembly has the right to replace him.

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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 (as described in section 5 above) 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.

7. Declaration of commitment of the LR

After a LR has been elected by the Consortium and no objection has been received from the SIEF, each LR will be invited to complete and sign the following template, for each PM & Re Consortium substance or intermediate it will endorse the LR role for.

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Declaration of Commitment

Text in orange: keep the applicable option only
Text in blue: complete with relevant information
Text in green: to be completed by PM & Re Consortium Secretariat

Notice: This document is confidential to the PM & Re Consortium and shall not be distributed or used outside the membership of the PM & Re Consortium unless so requested by European Competent Authorities in REACH.

I/We, the undersigned FULL NAME OF THE SIGNATORY am/are duly representing, and acting on behalf of FULL NAME OF THE COMPANY MEMBER OF THE PM & Re CONSORTIUM as well as on behalf of FULL NAME OF THE LEGAL ENTITY ACTING AS LEAD REGISTRANT IN REACH-IT (may be different from Consortium Member one, e.g.: an Affiliate company), hereby commit to the role of Lead Registrant for EC NAME AND NUMBER OF SUBSTANCE OR INTERMEDIATE which Registration Dossier will be submitted to the ECHA through the REACH-IT before the APPLICABLE DEADLINE. The Dossier submitted will include all information requirements that apply to the registration of a Substance/Intermediate in the 1-10/10-100/100-1000/>1000 t/a tonnage band.

I/We undertake to respect all applicable terms and conditions related to the role and responsibility of a Lead Registrant as set out in the PM & Re Consortium Agreement, as well as to comply with the REACH Regulation (including Confidentiality and EU Competition Law).

With the support of the PM & Re Consortium Secretariat and with the collaboration of the legal entities jointly registering this Substance/Intermediate with FULL NAME OF THE COMPANY MEMBER OF THE PM & Re CONSORTIUM, I/We engage to implement all necessary means and human, material and/or financial resources, that are required to achieve a successful registration of the above Substance/Intermediate.

INFORMATION ON THE SIGNATORY OF THIS DECLARATION OF COMMITMENT	
Name:	
Position:	
Professional address:	
Professional phone number(s):	
Professional fax number(s):	
Professional e-mail address:	

I/We, acting as Signatory on behalf of FULL NAME OF THE COMPANY MEMBER OF THE PM & Re CONSORTIUM and of FULL NAME OF THE LEGAL ENTITY ACTING AS LEAD REGISTRANT IN REACH-IT (may be different from Consortium Member one, e.g.: an Affiliate company), execute this Declaration of Commitment as of the date first mentioned above my signature:

Place: _____

Date: _____

Signature: _____

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