

Lead REACH Consortium Letter of Access Summary

The Pb REACH Consortium (Consortium) offers non-Consortium members the opportunity to purchase Letters of Access (LOA). The LOA allows companies access to certain data generated by the Consortium, for the purpose of the company complying with its own REACH Registration obligations.

This document briefly summarises the product being offered and the accompanying fee structure. This document is NOT intended to be a full explanation of the contractual conditions under which an LOA may be purchased.

What is a Letter of Access?

Although Companies can apply for membership of the Consortium, the LOA allows applicants access to certain data generated by the Consortium for the purposes of that Company complying with its own REACH obligations. The LOA is intended to be a more convenient way of accessing data without the need to become a full member of the Consortium; it is intended to be a cheaper option than full membership, particularly for lower tonnage bands.

What will a Company receive upon purchasing an LOA?

The LOA legal agreement entitles a non-Consortium member to receive:

- A Letter of Access document signed on behalf of the Pb REACH Consortium confirming that the
 company has the right to refer to the Lead Registrant dossier for the sole purpose of making a
 REACH Registration for a Consortium substance and for the purposes of meeting its
 downstream user (DU) communications obligations for identified uses;
- A 'token' which must be used to confirm membership of the 'Joint Submission' in REACH-IT, an essential step prior to submitting a registration dossier as a member of a Joint Submission;
- Where applicable, access to the Chemical Safety Report (Part B) for a Consortium substance (a
 CSR is not required for all substances in all tonnage bands);
- Classification & Labelling information;
- Where applicable, a list of identified uses (not required for all substances in all tonnage bands).

What are the costs?

The fees structures set out below have been adopted to reflect how Consortium membership fees are calculated. Please note that as with Consortium membership, all fees are payable per legal entity and no discount is offered for multiple legal entities which are part of the same corporate group.

Tonnages stated in this document refer to quantities of a substance for which a company intends to use Pb REACH Consortium information to fulfil its REACH obligations. They apply to substances manufactured in the European Union and/or European Economic Area and/or imported into the European Union and/or European Economic Area. These obligations may also include, for example, the obligation to communicate information down the supply chain, e.g. in the case of recyclers recovering substances which they need not register due to exemption under REACH Article 2(7)(d).

The fees are listed in the table below; more detailed explanation is provided on Pages 3-4.

| Dossier type | Fee | | |
|---|---|--|--|
| Full substances dossiers (pure substances) | | | |
| >10,000 tpy (metal) or > 1,000tpy (compounds) | Same as Consortium membership | | |
| 1,000-10,000 tpy (metal) | €34,190 | | |
| 10-1,000tpy (metal or compounds) | €4,800 per substance | | |
| 1-10 tpy (metal or compounds) | €1,200 per substance | | |
| Intermediates dossiers (pure substances) | | | |
| Any tonnage | €1,000 per substance | | |
| Intermediates dossiers (complex substances) | | | |
| > 1,000tpy transported | Fixed fee of €5,000 (payable once only) plus a contribution to substance- specific funding | | |
| <1,000tpy transported | €3,000 per substance | | |
| >1,000tpy on-site | €3,000 per substance | | |

LOA fees for "full" substance dossiers

The fees in this section do not apply to the registration of substances as intermediates under strictly controlled conditions.

A. >10,000 tpy (metal) or > 1,000tpy (compounds)

Companies manufacturing or importing (M/I) >10,000 tpy lead metal or 1,000 tpy of any lead compound (calculated as the average tonnage manufactured or imported over the preceding three years) are considered to be significant players in the EU marketplace and are therefore **encouraged to join the Consortium** on the same terms as other members. However, if such a company does not wish to join, then they may purchase an LOA for the same cost as Consortium membership. Further information on Consortium membership, including fees, is available on the Consortium's website.

B. 1,000-10,000 tpy (metal)

For M/I in the range 1,000-10,000 tpy, the total cost is €34,190. This sum consists of:

- a contribution both to core Consortium costs, and
- a contribution to the cost of the Voluntary Risk Assessment on Lead, and
- a contribution to substance-specific work for lead metal of €290 (i.e. 50% of the cost calculated per Consortium member in December 2009).

C. 10-1,000tpy (metal or compounds)

For manufacture or import in the range 10-1,000tpy a **fixed fee of €4,800** <u>per substance</u> will apply for lead metal and its compounds, recognising that a Chemical Safety Assessment has been conducted and the resulting exposure scenarios will be made available.

D. 1-10 tpy (metal or compounds)

For manufacture or import in the range 1-10tpy a **fixed fee of €1,200** <u>per substance</u> will apply for lead metal and its compounds, recognising that no Chemical Safety Assessment is required.

LOA Fees for Intermediates Dossiers

Intermediates – "pure" substances (mono-constituents)

In the interests of minimising administrative burden, a **single fixed fee of €1,000 per substance** is payable for an LOA for any "pure" substance meeting the criteria for strictly controlled conditions, irrespective of tonnage band or whether the intermediate is transported or retained on-site.

Intermediates - "complex" substances (UVCBs)

For "complex" intermediates resulting from the production and processing of lead (to be registered as UVCBs) a different fee structure to that of pure substance intermediates applies, recognising that additional Consortium resources are required to deal with these complicated materials.

For transported, isolated intermediates > 1,000tpy and that are handled under strictly controlled conditions, LOA fees consist of a **single core fixed fee of €5,000** (payable once only) **plus a contribution to substance-specific funding** at a rate of 50% of the cost calculated per Consortium member in December 2009. These figures are listed in Appendix 2.

For complex intermediates below the 1,000tpy threshold and also for those exceeding 1,000tpy but remaining on-site (i.e. for which only "available data" are required) a **single fixed fee of €3,000 per substance** applies, i.e. there is no substance-specific component.

How to apply for an LOA?

Companies intending to purchase an LOA must carefully read the separate document "Instructions on Applying for a Letter of Access" before completing the relevant forms. Latest versions of the documents can be downloaded from the Pb REACH Consortium's website or obtained directly from the Secretariat (reach@ila-lead.org).

What happens after an LOA has been purchased?

The LOA application process is only complete once the International Lead Association is in receipt of full and correctly completed LOA agreement and the appropriate fees. Applicants will then receive:

- A letter confirming that the company has the right to refer to the Lead Registrant dossier.
- The 'Token' that enables the company to confirm membership of the "Joint Submission" in REACH-IT;
- A read-only copy (HTML or PDF) of the Lead Registration dossier;
- A part-filled IUCLID dataset for co-registrants;
- Where applicable, access to the Chemical Safety Report for a Consortium substance (a CSR is not required for all substances in all tonnage bands).

LOA holders must confirm membership of the joint submission in REACH-IT **before** submitting their coregistration dossier. Companies are responsible for compliance with their own registration deadline.

Appendix 1

Additional Information

LOA fee principles

It is important to understand that the properties of lead and its compounds have been studied extensively over many years and as a result there are a huge number of relevant studies available, each one of which has had to be reviewed (in excess of 1,000 studies). Furthermore, highly complex methodologies have been employed in the assessment of lead, and these have largely been funded by the industry. The lead industry has also funded an EU Voluntary Risk Assessment on Lead and its compounds (VRAL) which has been reviewed by EU Member States and the European Commission's Scientific Committee on Health and Environmental Risks (SCHER).

The VRAL exercise was fully funded by industry at a cost of €3 million and the reports provide the basis for the joint registration materials for all full substance dossiers. The Consortium's budget for the period 2008-2010 was set at a further €3 million and, in addition, the total cost of substance-specific work was up to €800,000 (pure substances and complex intermediates).

The LOA fees have been set on the principle that they should be less than the current minimum Consortium membership fees for all but the highest tonnage bands. This in part reflects the fact that LOA purchasers will not receive the full range of benefits available to Consortium members. Some of the benefits that Consortium members receive compared with those purchasing LOAs include:

- Secretariat support in preparing company-specific aspects of registration (LoA holders receive
 access to the dossier without additional support from the Consortium);
- Involvement in the preparation of (updates to) registration files, thus ensuring they meet each member's REACH requirements (LoA holders simply buy the file with no right to influence the content);
- Analysis of company-specific data (for example occupational exposure, environmental emissions);
- Ownership of data generated or purchased by the Consortium (LoA holders are only entitled to refer).

Fees for companies manufacturing or importing significant tonnages, i.e. significant players in the market are set at a level which encourages such companies to join the Consortium and hence make a

full contribution to the work of the Pb REACH Consortium. However, in all cases Consortium membership remains open to any company preferring to join, irrespective of tonnage.

Consortium fee structure

The Lead REACH Consortium fee structure includes the following components:

- Core Consortium Fees: Fixed Fee (minimum fee) and Levy Fee (tonnage-based fee payable in addition to the Fixed Fee);
- VRAL Fee (payable by companies that that did not fund the voluntary risk assessment on lead);
- Substance-Specific Fees (fees related to work on individual substances of relevance to a company).

The Consortium also reserves the right to charge a "late entry fee", at a rate of 3% above the London Interbank Offered Rate (LIBOR), where a company joins the Consortium after 1 July 2008.

Core Consortium fees fund work relevant to the preparation and maintenance of core dossiers for all Consortium substances (both full substances and intermediates). Data from the VRAL also contributes to these core dossiers. Hence for the purpose of determining LOA fees, these costs are treated together.

For Consortium members, substance-specific (SS) costs such as research and the preparation of IUCLID files are shared equally between all members in each substance group.

Current Consortium fees

New members must pay fees backdated to 2008. In addition, members must contribute to the cost of relevant substance-specific work. For 2016, the Fixed Fee for 2016 is set at €6,000 for lead metal and €4,500 for lead compounds.

Further information on Consortium membership can be downloaded the Consortium's website, or obtained by contacting the Secretariat (reach@ila-lead.org).

Appendix 2

Substance-specific fees for complex intermediates

The table below lists the substance-specific component of the LOA fee for complex intermediates that are transported, isolated, manufactured/imported > 1,000tpy and handled under strictly controlled conditions. The substance-specific fees are payable per substance and are in addition to the €5,000 core fixed fee for such intermediates.

| Substance name | EC Number | Substance-specific fee (€) |
|---|--------------|----------------------------|
| Lead, Bullion | 308-011-5 | 725 |
| Matte, lead | 282-356-9 | 1208 |
| Speiss, Lead | 282-366-3 | 3500 |
| Slags, Lead smelting | 273-825-9 | 2071 |
| Flue dust, lead refining | 273-809-1 | 552 |
| Lead dross | 273-796-2 | 805 |
| Lead, dross, copper rich | 273-925-2 | 1812 |
| Lead dross antimony rich | 273-791-5 | 1611 |
| zinc, desilverising skims | 273-802-3 | 1312 |
| lead antimonial dross | 273-795-7 | 1312 |
| lead dross, bismuth rich | 273-792-0 | 1750 |
| waste, battery reprocessing | 305-445-7 | 1050 |
| residues, lead smelting waste water treatment | 305-424-2 | Not applicable |
| Slimes + sludges, battery scrap antimony + lead -rich | 310-061-8 | 2625 |
| Lead alloy, base, Pb,Sn, dross | 273-701-4 | 1500 |
| Slags, lead reverbatory smelting | 273-800-2 | 3500 |

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