



Agreement for Substance-Specific Funding for Pure Substances

BACKGROUND:

- (A) Companies participating in the Lead REACH Consortium are subject to different fees depending on the substances in which they have an interest. As well as contributing to core Consortium costs via Fixed Fees and Levy Fees, the Consortium Agreement requires that Members pay a pro-rata share of any Substance-Specific costs, subject to a two thirds majority approval from companies declaring an intent to use the Consortium information to fulfil their REACH obligations.
- (B) Consortium members must use this form to declare their intent to use Consortium information to fulfil their REACH obligations for pure substances, and to commit to fund a pro-rata share of the substance-specific costs as set out in Appendix 1.

IT IS NOW AGREED:

1. The definitions in the Lead REACH Consortium Agreement shall have the same meaning in this Agreement unless context otherwise admits.
2. In consideration of the Consortium undertaking to carry out the Substance Specific research as contemplated by this Agreement each Company agrees to be bound by this Agreement and to pay the fees for such Substance Specific research as they approve on the basis set out herein.
3. In stating "yes" in any of the boxes in Column 2 below the Company is agreeing to be bound to pay the pro-rata costs of any Substance Specific Research that is conducted by the Consortium (through the Secretariat of the Consortium) for that Substance (as listed in Column 1 in the table below) opposite which the Company has stated "yes" in Column 2. The Substance Specific costs set out herein shall include the pro-rata cost of the Substance Specific Research for the preparation of a core IUCLID file on lead ion toxicity (as more particularly described in the Consortium Agreement) and in respect of the IUCLID research the Company agrees to pay the fee of €3,265 for such research in addition to the Substance Specific Research costs indicated in Appendix 1 below.

4. The estimated costs of such Substance Specific Research for each Substance is as set out in Appendix 1 but in committing to any such research the Company understands that it shall be liable to pay its full pro-rata share relating to that Substance and such payment shall be paid without withholding, set-off or counterclaim within 30 days of receiving an invoice for the same from the Secretariat. Column 3 of the table below attempts to set out the maximum figure which may be payable as a pro-rata share by a party in respect of Substance Specific Research carried out for any Substance but as with Appendix 1 these figures are only a guideline and are not intended to contractually cap the sums payable hereunder. For the avoidance of doubt a pro rata share shall mean a split based on the number of Companies seeking to utilise any Substance Specific Research per Substance.
5. The Company shall be entitled to receive all invoices, receipts and records which may reasonably be required to verify the fees but the Secretariat's decision as to the fees payable by the Company shall be final and binding upon the Company.
6. The Company warrants that it has full power and authority to enter into this Agreement.
7. For the avoidance of doubt all information supplied to the Company hereunder shall be deemed Confidential Information and the obligations of the Company set out in the Reach Consortium Agreement regarding Confidential Information shall extend to this Agreement.
8. This Agreement shall be governed by the Laws of England and Wales and the parties agree to submit to the exclusive jurisdiction of the English Courts.

This form must be completed and returned along with other membership papers.

A summary of the substance-specific work undertaken on pure substances and the historic derivation of the costs per substance, per member company is given in Appendix 1.

Please complete the following page and return this form to:

**Pb REACH Consortium
c/o International Lead Association
120 New Cavendish Street
London W1W 6XX
United Kingdom**

Tel: +44 (0)20 7833 8090

Email: reach@ila-lead.org

Substance name	Is this a substance for which you intend to use Lead REACH Consortium data to meet your REACH obligations?* (answer "yes" or "no")	Substance-specific cost per legal entity (Euros)
Lead Metal		580
Lead Oxide		} 116**
Lead Tetroxide		
Dibasic Lead Phthalate		} 5,000**
Neutral Lead Stearate		
Dibasic Lead Stearate		
Dibasic Lead Phosphite		
Basic Lead Sulphite		
Basic Lead Sulphate		
Tribasic Lead Sulphate		
Tetrabasic Lead Sulphate		
Lead Dichloride		10,050

* You must declare all the substances for which you intend to use Pb REACH Consortium information to fulfil your REACH obligations. This includes substances you manufacture in the European Community or import into the European Community. These obligations may include, for example, the obligation to communicate information down the supply chain.

** Substances belong to the same substance Group. Only one fee payable irrespective of the number of substances in this Group for which you intend to use REACH Consortium data to meet your REACH obligations.

Company name _____ (“the Company”)

Company representative (PRINT) _____

Signature: _____

Dated: _____

Appendix 1

Request for substance-specific funding for the preparation of registration files for “pure” substances (mono-constituents)

General REACH coordination activities for pure substances as well as the preparation of the chemical safety reports is being funded through the Consortium’s core budget. Each member’s contribution to core Consortium costs is being raised via the Consortium’s annual Fixed Fee and Levy Fee.

In addition to general coordination activities and the preparation of a chemical safety report, REACH requires the preparation of IUCLID files for each substance. Furthermore, in some cases specific testing on some substances has been deemed necessary, for example in order to derive the appropriate classification for a substance or group of substances. According to the Pb REACH Consortium Agreement, these are deemed to be “substance-specific” costs, meaning that the costs are to be charged per substance (or substance group) for which a Consortium Member intends to use the data for the purposes of meeting their REACH obligations. The Consortium Agreement currently defines the following substance-specific groups: lead metal, lead oxides, lead stabilisers.

This document sets out the basis upon which substance-specific fees were calculated for pure substances.

Substance-specific costs

The preparation of substance-specific IUCLID files for joint registration purposes can be broken down into two distinct parts. Firstly, a core IUCLID database on lead ion toxicity had to be generated which was then used as the basis for all substance-specific files. Secondly, information specific to individual substances had to be added to the substance-specific files, and in some cases parts of the core lead ion toxicity database had to be modified in order to satisfy the requirements of specific substance files.

Costs for preparing the core lead ion toxicity IUCLID database:

IUCLID - core lead ion toxicity	Cost (€)
Environment sections (high quality data only). Consultants: ARCHE	100,000
Human health sections (high quality data only). Consultants: ILZRO, Gradient	175,000
IUCLID file hosting system & support: Consultants: CWN Design, EBRC	18,870
TOTAL	293,870

Costs per substance for preparing the substance-specific components of the IUCLID databases were:

IUCLID – individual substances	Cost per substance (€)
Phys chem properties data. Consultant: EBRC	1,500
Other substance-specific data (including amending core toxicity data for individual substances). Consultants: ARCHE, EBRC, ILZRO	1,000
TOTAL	2,500

Previously, in addition to the preparation of IUCLID files, the following substance-specific costs have already been incurred:

Research	Cost (€)
Metal transformation/dissolution (T/D) testing. Consultants: CIMM	30,000
Lead distearate transformation/dissolution testing Consultants: CIMM	12,500
Trilead dioxide phosphonate transformation/dissolution testing. Consultants: CIMM	12,500
Lead dichloride	On request

Fee Calculation

Since the core lead ion toxicity IUCLID database is used for all substance-specific IUCLID files without amendment for substance-specific factors, this cost is split equally between all Consortium members. Based on a membership of 90 companies, the cost per company is **€3,265**.

The costs of preparing the substance-specific components of the IUCLID files and of the transformation/dissolution testing are split between those members that have REACH obligations for the relevant substances (or substance groups). Regarding transformation/dissolution testing on two lead stabilisers, this work was conducted at the request of members of the European Lead Stabiliser Association as representative testing for eight Consortium stabiliser compounds and should hence be funded by members of this “lead stabiliser” substance group. However, the composition of this substance group has been distorted due to the fact that a large number of battery manufacturers are required to register two lead stabiliser compounds present in battery oxides (i.e. tribasic lead sulphate and tetrabasic lead sulphate). Hence a separate “lead sulphates” substance-specific group will be created in order to share the costs of work on these two compounds. The lead sulphates group share of the transformation/dissolution testing costs equates to two fifths of the trilead dioxide phosphonate test costs of €12,500 since data on this substance will be applied to the REACH dossiers for the five inorganic lead stabilisers covered by the Consortium.

The costs per substance, excluding each company's contribution to the core lead ion toxicity database were as follows:

Substance	Number of Consortium members paying fees	Cost per substance group (excl core IUCLID) (€)	Cost per company <u>in addition to one-off core IUCLID fee of €3,265</u> (€)
Lead Metal	56	2,500 IUCLID + 30,000 T/D = 32,500	580
Lead Oxide	43	5,000 IUCLID	116
Lead Tetroxide			
Dibasic Lead Phthalate*	7	6x2,500 IUCLID + 20,000 T/D = 35,000	5,000
Neutral Lead Stearate*			
Dibasic Lead Stearate*			
Dibasic Lead Phosphite			
Basic Lead Sulphite			
Basic Lead Sulphate			
Tribasic Lead Sulphate			
Tetrabasic Lead Sulphate			
Lead Chloride	2	2,500 (IUCLID) + 17,600 (EBRC) = 20,100	10,050

* Organic lead stabilisers

**Substance-specific costs for lead chloride have yet to be determined. However in addition to the cost of €2,500 for the preparation of the substance-specific part of the IUCLID file it is anticipated that some phys chem and acute toxicity testing will be required.

For the avoidance of doubt, where substances have been aggregated into substance groups, the indicated fee is payable once only, irrespective of the number of substances within that group for which a member intends to make use of data.