LEAD REACH Consortium: Funding Structure for Sharing of REACH-Related Costs

Disclaimer

1. INTRODUCTION

In order to fulfil their obligations under the European Union Regulation No 1907/2006 (the "REACH Regulation"), a collective of entities involved in the EU manufacture/import of Lead, Lead Oxides, Lead Stabilisers and other Lead Substances established the Lead REACH Consortium 1st January 2008.

The objective of the Consortium has been to allow its Members to collectively meet their obligations under the REACH Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals of Lead Substances.

The contractual relationship of the parties was and continues to be regulated by the Lead REACH Consortium Agreement (the "Agreement"). This Agreement also regulates the contractual relationship of the Consortium Members with other interested third parties such as Associate Members and/or other downstream users in accessing data and participating in joint projects with the Consortium.

The purpose of this document is to set out: 1) the different types of work performed by the Consortium in order to achieve REACH compliance in relation to Lead and Lead compounds for its Members; and 2) how and to what extent, the various interested parties have contributed (in a transparent and non-discriminatory manner) to the costs in achieving this objective as envisaged in Commission Implementing Regulation (EU) 2016/9.

2. WORK UNDERTAKEN BY THE CONSORTIUM

2.1 ADMINISTRATION, MANAGEMENT AND RESEARCH

Pursuant to the Agreement, the International Lead Association (the "ILA") has acted as the Consortium's Secretariat throughout the period and at the direction of the Consortium Members, has conducted the day-to-day affairs of the Consortium.

The Secretariat has, at the direction of the Consortium Members, also: 1) co-ordinated, inter alia, the preparation of research and other activities to be accomplished for REACH Compliance; 2) managed and maintained the Consortium's budgets in each calendar year (the "Budgets"); overseen the financial governance of the Consortium; and 3) overseen and supported the Steering Committee and General Assembly of the Consortium on technical issues and research which has been conducted on behalf of the Consortium.

The Secretariat has charged administrative costs which has included typical office costs, the employment of a REACH Manager and technical and other support staff. It has also charged for travel and subsistence and other costs incidental to it acting as the Consortium's Secretariat (i.e. accountancy, legal and other professional and technical retainers).

The Consortium has conducted and continues to conduct a full range of technical and scientific studies on Lead and Lead compounds as required for the purposes of REACH Compliance, which includes the cost of technical managers employed by the Secretariat

together with the cost of external consultants who have been retained for specific projects and studies.

The Secretariat, at the direction of the Consortium Members, has also overseen and advised upon Substance Specific Research which has been conducted for and specifically charged to those entities to which it has related.

2.2 DEVELOPMENT OF CORE DATA

2.2.1 VRAL REPORT DATA

Prior to the inception of the REACH Regulation, a significant amount of core data concerning Lead and Lead Compound Substances was generated through the EU Voluntary Risk Assessment on Lead ("VRAL") coordinated by the ILA. The VRAL report has been reviewed by EU Member States and the European Commission's Scientific Committee on Health and Environmental Risks ("SCHER") and therefore represents a significant and respected volume of work relevant to Lead REACH compliance.

As not all members of the Lead REACH Consortium were contributors to the VRAL studies, it was agreed, through the Lead REACH Consortium Agreement, that Members of the Consortium would make a contribution for access to this technical and scientific data to the extent that it was relevant for the purposes of REACH Registration. The Agreement contemplated that a competent analysis with regard to the usability of the studies would be made by the Steering Committee of the Consortium, who would determine the financial value of the VRAL report based upon relevance and usability.

2.2.2 DOSSIER PREPARATION

The Consortium Agreement contemplated that Annexes VII to XI REACH were to be considered by the Steering Committee of the Consortium and for it to define the end points that were still subject to testing. The Steering Committee considered all of the collated data (including the VRAL data) and decided what further data was required in order to prepare the IUCLID Files for the purposes of preparation of the technical dossier. The Steering Committee then formulated testing proposals for the additional tests pursuant to REACH Article 10 (a) (ix) together with any further testing work that the Consortium Members considered necessary for the purposes of REACH Registration.

For the purposes of REACH Compliance, in addition to the preparation of the technical dossiers (the IUCLID Files), the Consortium was required to prepare a Chemical Safety Report setting out the various uses of Lead and Lead Compounds and to prepare Chemical Safety Assessments (i.e. exposure scenarios) together with guidance on safe use of each Substance (collectively referred to as the "Core Data").

2.2.3 SUBSTANCE SPECIFIC RESEARCH

In addition to the Core Data prepared for the Consortium, Members have also been entitled to request that research (relevant to only those members) be conducted for specific Substances. As per the Agreement, Members have been entitled to form a

Substance Group through the Consortium and upon the condition that the Group would undertake to meet the costs arising from such research, the Consortium would undertake such work and behalf of that Substance Group.

2.2.4 REGISTRATION

In conjunction with the relevant Substance Lead Registrant, appointed by the members of the relevant Substance Information Exchange Forum (SIEF), the Secretariat has liaised with and supported Members in preparing company-specific aspects of pre-registration and registration. The Secretariat also assisted Members in the analysis of company-specific data (e.g. occupational exposure and environmental emissions) and in the preparation of the registration files in order to ensure that the files met with each Member's REACH Requirements.

The Secretariat also prepared registration dossiers, in a format specified by the Agency, that were distributed to Consortium Members to allow submission to the Agency as required for each Member's Registration.

2.2.5 EVALUTION, AUTHORISATION AND RESTRICTION

Following on from Registration, the work of the Consortium continues on behalf of the Members to deal with the Evaluation, Authorisation and Restrictions relating to Lead and Lead Compounds. It is anticipated that the Consortium will continue until, at least, all of these aspects of REACH compliance have been completed.

3. FUNDING CONSORTIUM COSTS

The Consortium's legal agreements and supporting documents for the purposes of cost sharing are listed in the Appendix and which are available on the Secretariat's website (https://ila-reach.org).

3.1 FULL MEMBERS

Each Member of the Consortium, in each financial year, has been and continues to be required to pay, upon written request from the Secretariat, its Pro-Rata Share of the costs of the Consortium, as defined and described in Schedule 8 of the Consortium Agreement. Pro-Rata Share means each Member's share of the aggregate amount of the total expenses and liabilities of the Consortium in each financial year (whether incurred at any time before or after such a Member became a party to the Agreement). For the purposes of transparency, the Secretariat is required to prepare the Budget (which clearly sets out all of the anticipated costs of the Consortium for the financial year ahead) and which Budget is approved by the General Assembly in respect to that financial year. Upon approval of the Budget, each Consortium Member is required to pay an amount equal to its Pro-Rata Share as determined in that Budget.

3.1.1 **CONSORTIUM COSTS RELATING TO REACH REGISTRATION**

From the creation of the Lead REACH Consortium in 2008 until 31st December 2010 (the "Registration Period") the Consortium's principal objective was in the researching and preparation of the Core Data which was deemed to be required for the purposes of REACH Registration of Members' Substances. This Registration process has always been considered the most significant cost in ensuring the Members' compliance with the REACH Regulation. Accordingly, the annual fee payable by each Consortium Member during the Registration Period comprised of Fixed Levy Fees, tonnage-based Levy Fees, and for non or partial-VRAL contributors, VRAL Levy Fees.

The Fixed Levy Fees, the Levy Fees and the VRAL Fees, represented a Consortium Member's Pro-Rata Share requirement (other than any additional fees which are set out in the Consortium Agreement) for the purposes of registration of relevant Substances.

The Levy Fee element of the annual contribution was based upon the tonnage of Lead Metal or Lead Content of Lead Compounds manufactured within or imported into the community during the previous financial year. The declarable metric tonnage also included the lead content of lead compounds or complex intermediates and in terms of a battery lead oxide, the quantity of lead in the lead oxide component of battery oxide.

Again, in order to equitably distribute the cost across the Membership, in a manner proportionate to each Member's annual quota of manufactured/important lead, different Levy Fees were imposed for: Lead manufacturers/importers; Lead oxide manufacturers/importers; and Lead stabiliser produces/importers.

The Levy Fees varied in each financial year during the Registration Period (but on a Pro-Rata basis) in order to ensure that the requirements of the Budget were met.

In terms of the VRAL Fee, during the Registration Period, Consortium Members who had not contributed to the costs incurred in preparing the VRAL Report or did contribute to such costs but such contribution was less than the VRAL Fee, were required to pay the VRAL Fee or the shortfall of such VRAL Fee. This Fee was set to the equivalent of 50% of the rate paid by the original VRAL Funders, in acknowledgement that only approximately half of the VRAL data was of direct relevance to REACH Registration. It was anticipated that the VRAL Fees, payable by Members for use of the VRAL data, would be redistributed among the original VRAL Funders on a pro-rata basis at the direction of the Secretariat.

In addition to the above, the Consortium recognised that certain Members needed to produce data for Substances which were specific to their needs and which the core Membership would not require. In order to ensure that this was equitably charged to those who required such data, the Consortium, through a Substance Group, prepared the required data for Registration and charged the costs relating to Substance Specific Research to the relevant Members as per the Agreements for Substance-Specific Funding and summarised in the Complex and Pure Substances Costs document.

In addition to the above fees, in circumstances where a Consortium Member required further Substance Specific Data and had only paid fees for Core Data regarding lead metal,

the Substance Specific Fees relevant to the compound(s) were payable. Similarly, where a Consortium Member, having paid Fees for a lead compound subsequently needed to register lead metal, it has been required to pay both the difference in the Fixed Fee between lead compounds and lead metal for that year, plus the Substance Specific fee for lead metal.

3.2 COSTS TO NEW MEMBERS

In the event that any new Members applied to join the Consortium during the Registration Period, the Agreement stipulated that, at the time of admission to the Consortium, the new Member was required to pay its Pro-Rata Share of all of the costs incurred by the then Members (upon the same equitable principles that was applied to the existing Membership) with the exclusion of costs incurred in the financial year in which the new Member joined the Consortium. The new Member was, therefore, required to pay its Pro-Rata Share of the Fixed Levy Fee, Levy Fee and the VRAL Fee that had been charged to other Members up to the previous financial year before the new Member joined the Consortium.

In addition to the above, the new Consortium Member was also required to pay its Pro-Rata Share for the financial year, in which it joined, upon the same basis as existing Members.

All monies received from any new Members would then be treated as a pro-rated refund to the other Consortium Members.

From 1st January 2011, any new Members have been expected to pay the Fixed Levy fee from formation of the Consortium up to the year of joining together with the fees levied to other Members for that membership year. This was considered to be an equitable contribution by a new Member for the work that was performed by the Consortium regarding REACH registration for which the new Member would take benefit.

In the event that a new Member has required access to Substance Specific Data, it has been required to pay these charges on the same basis as existing Members (as outlined above) and which fees are in addition to the Fixed Fee Levy that is chargeable to a new Member.

3.3 WITHDRAWAL BY A CONSORTIUM MEMBER

A Member may withdraw from the Consortium only at the end of a calendar year provided that it has served the Consortium with at least six months' notice of such withdrawal (ending no sooner than the calendar year end) and provided that circumstances have arisen, respecting that Consortium Member, which has led to discontinuation of the registration requirement or in the event of some other serious reason which would make continued membership of the Consortium untenable. In the event of a legitimate withdrawal, the Member continues to be liable for its Pro-Rata Share of costs up to the point of withdrawal from the Consortium at the end of that calendar year. From the date of withdrawal, that Member shall not be entitled to any refund of fees paid to the Consortium other than in circumstances where that entity was an original VRAL Funder in which case, that entity would continue to be entitled to receive its Pro-Rata share of the VRAL fees.

3.4 REGISTRATION FEES

Each Member has been required to register with the European Chemicals Agency in advance of the REACH Registration deadline relating to the Substance tonnage bands and a registration fee has been payable to the Agency. Agency fees are set out in Regulation (EC) No 340/2008 (as amended); reduced registration fees have applied to small and medium-sized businesses and further reductions have been available for Members of the joint submission. As this item is only relevant to and payable by individual Member entities directly to the Agency, it is not relevant for further discussion in this document.

3.5 LETTERS OF ACCESS

Registrants, who are not and will not become either Members or Associate Members of the Consortium, may apply to the Consortium for partial or full reference to Core Data and other information available from the Consortium through a requested Letter of Access (the "LoA"). The Steering Committee of the Consortium may grant entities an LoA to such information as that entity requires, solely for the purpose of registration of that sole entity, pursuant to REACH. The LoA only allows the applicant the right to refer to the dossier as a co-registrant as required by REACH Article 10 (a) and does not allow that entity any proprietary right in the data nor allow it to use the data/studies.

The fees chargeable for such an entity to use the data is decided upon by the Steering Committee but is based upon similar principles from how Consortium Members are charged. The Levy is therefore, based upon an entity's EU tonnage production/import level for each separate Substance for which the entity requires data.

As an LoA, however, only entitles an entity to access the data rather than the full benefits of Membership of the Consortium, the fees charged are intended to reflect that position by being set at a level lower than Pro-Rata Share of each Member.

3.6 ASSOCIATE MEMBERS

Although the burden of preparation for the relevant technical data and registration falls upon the Lead manufacturers and importers, the Consortium envisages certain circumstances where it may be appropriate for Downstream Users of Substances to contribute to the work of the Consortium. The Agreement provides that third parties may be admitted as Associate Members if they can contribute to the objectives of the Consortium and they shall pay such subscription fees as the Steering Committee may decide from time to time. Associate members may attend General Assembly meetings and Steering Committee meetings (including without limit expert/technical group meetings) but shall have no voting rights and shall also be subject to the same confidentiality undertakings as all other Members.

As it is more likely that Associate Members will join the Consortium for the purposes of contributing data rather than relying upon data collated by the Consortium, it is unlikely that any Associate Member will be required to pay subscription fees but the Consortium does however, reserve the right to charge for contributions to cost sharing if it is deemed that the

Associate Member will derive some benefit. Any fees so charge will be decided upon a case-by-case basis.

3.7 LICENCE TO USE

In certain circumstances, entities may request the use of the Lead REACH Data collected by the Consortium for: 1) the entities' fulfilment of their REACH or CLP associated Regulations obligations for the defined purpose Substance only; and/or 2) Read-across purposes and for purposes other than REACH (i.e. use of data outside of the EU). The Consortium has prepared a License to Use Agreement to allow entities to use the Consortium data for these strict purposes.

External companies, including holders of Letters of Access, are required to contact the Secretariat to discuss their case, and to initiate the process for a Licence to Use ("LtU"). Interested companies are required to provide a letter to the Secretariat outlining their intentions and request for use of the Consortium data.

For Consortium Members, who already have ownership of the data, the procedure and some general principles are laid out in the Consortium Agreement. In summary, a Consortium Member may use the existing studies and any new studies for purposes other than REACH, and for compliance with laws and regulations in other non-EU jurisdictions, provided prior authorisation has been obtained from the Steering Group, and provided such studies will not appear in the public domain. The Consortium Member will still require an LtU to cover any such use, and there may be additional fees and costs chargeable to the Consortium Member in the event that the entity's tonnages of non EU import/production of lead substance(s) exceeds that Member's EU tonnages for the import/production of lead substance(s).

Non-consortium members, and holders of LoAs, (whether EU or non-EU) will be required to purchase an LtU under the standard arrangements as outlined in the License to Use Agreement.

LtU fees were set recognising that the LtU holder is granted the right to use the Lead REACH Consortium's data for the purpose of registering another substance (or using the data for the same substance in a non-EU jurisdiction), rather than simply allowing the entity(s) to refer to a Consortium joint REACH registration dossier. It was also recognised that significantly fewer LtUs than LoAs would be sold and in order to recover the costs of setting up and administrating the License to Use Agreement, LtU fees were set higher than the corresponding LoA fees.

The LtU can either be applied for by a single entity or by a Consortium representing the interests of a number of entities either on its own account or through an intermediary.

In the case of a single entity, the Consortium charges a fee for the use of the data relating to each Substance to which the entity wishes to apply the data. The fee charged will also be based upon the entity's annual tonnage manufacture/import of each relevant Substance in the jurisdiction.

In the case of a Consortium wishing to use the Lead REACH data for the purposes of its members, a fee will be charged based upon the declared tonnage of the largest manufacturer/importer of Lead into the jurisdiction in that Consortium. A further premium is chargeable to the Consortium based upon the (banded) number of members that Consortium holds from time to time.

4. TRANSPARENCY OF CONSORTIUM COSTS

For the purposes of ensuring transparency of the Consortium costs, the Consortium Agreement requires the Secretariat to maintain the Consortium's accounts in accordance with the UK generally accepted accounting principles (GAAP). Accordingly, the Secretariat is required to accurately and fairly reflect the cost sharing accounts relating to Consortium Members and to reflect all the transactions conducted through the Consortium together with all its assets and liabilities. The Consortium Members may have reasonable access (other than market sensitive data which may not be shared with Consortium members – for competition law purposes) to these accounts. Furthermore, the Secretariat is also required to generate annual financial statements and budgets setting out the financial affairs and requirements of the Consortium. Invoices generated by the Consortium are audited by an independent third party on an annual basis to ensure accuracy and fairness of the Consortium accounts. The typical cost for the annual audit is included within the Consortium's admin/management budget.

5. REIMBURSEMENT OF SURPLUS FUNDS UPON DISSOLUTION

The Lead REACH Consortium shall continue in effect until such time as the General Assembly considers that the Consortium has met all of the REACH compliance obligations of its Members.

The Consortium Agreement stipulates that the Consortium may be terminated by a two thirds majority of the General Assembly and states that after payment of all expenses and liabilities relating to REACH compliance, the General Assembly may direct that the balance of funds shall be returned to the Consortium Members in such equitable manner (based upon their Pro-Rata Share) as may be directed by the General Assembly.

APPENDIX: References

Agreements

Lead REACH Consortium Agreement

Agreement for Substance-Specific Funding for Pure Substances

Agreement for Substance-specific funding for complex substances (intermediates)

LOA agreement (EU entity)

LOA agreement (OR)

LTU agreement (EU REACH; single entity use)

LTU agreement (EU REACH; Consortium use)

LTU agreement (Non-EU use; single entity)

LTU agreement (Non-EU use; single entity (existing member of the Lead REACH Consortium))

LTU agreement (Non-EU use; Consortium use)

Supporting documents

Lead REACH Consortium Fee structure, which details the different components of Consortium membership fees

Complex and Pure Substances Costs, summarising Substance Specific Fees

Basis of Participation