Inorganic Phosphates REACH Consortium

Substance Information Exchange Forum (SIEF) Agreement

This SIEF Agreement (hereinafter the “Agreement”) is entered into by and between:

Consortia Management GmbH, Herrnsheimer Hauptstrasse 1b, 67550 Worms, Germany, acting as Consortium Secretariat in the name and on behalf of the Lead Registrant [add Lead name & address] and the Inorganic Phosphates (IP) Consortium for the substance as defined below,

hereinafter referred to as "**Lead Registrant**"

and the SIEF participant, signatory of the present Agreement,

[add name & address]

hereinafter referred to as "**Non-Lead Member**",

both hereinafter referred to as “the Parties”.

Preamble

Whereas the Parties to this Agreement have pre-registered and have agreed on the identity and the sameness of the Substance, and thus are Participants of the same Substance Information Exchange Forum (“SIEF”) as potential registrants for that Substance under the meaning of Article 29 of the European Community Regulation EC 1907/2006 (“REACH”);

Whereas the REACH Regulation imposes on manufacturers and importers as well as on only representatives the obligation to register the Substance within the prescribed deadlines;

Whereas the REACH Regulation requires, subject to certain exceptions, multiple registrants of the same substance to share certain data and jointly submit through a Lead Registrant part of the information required for the registration relating to the Substance to the European Chemicals Agency (“Agency”);

Whereas the Lead Members defined in the Article 1 of this Agreement have prepared the Joint Registration Dossier to be submitted to the Agency through the Lead Registrant;

Whereas the Members of the Consortium are aware that they have cooperation and data sharing obligations with other SIEF participants;

Whereas the Non-Lead Member has the intention to register the Substance and is willing to appoint the Lead Registrant as lead registrant in order to have him to submit the Joint Registration Dossier;

Whereas the Agency represented in its REACH guidance that it is advisable for the SIEF participants to agree in writing certain SIEF operational rules concerning data sharing, rights on the developed information and sharing of costs;

Therefore, with a view to fulfilling their regulatory obligations under the REACH Regulation in respect to the Substance, the Parties hereto have decided to pursue the following objectives (hereinafter the “Purpose”):

1. to agree on the operating rules governing the exchanges of information between the SIEF potential registrants (Title I);

2. to agree on the rules regarding the rights to participate in the joint submission of data, to use the (robust) study summaries and to refer to the relevant full study reports in the Joint Registration Dossier developed by the Lead Members (Title II);

3. to consider Global Harmonised System (GHS) classification and labelling, for the Substance, as required under EU REGULATION (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures (hereinafter referred to as “GHS”)

under the terms and conditions set forth in this Agreement.

THE PARTIES HAVE AGREED UPON THE FOLLOWING:

Article I. Definitions

Terms written in capital letters are defined in the Preamble above, in this Article 1 or in other parts of this Agreement. To the extent not otherwise defined in this Agreement, any definition specified in REACH, in particular in Article 3, shall apply to this Agreement:

Affiliate: Any legal entity controlling, controlled by, or under common control with, either directly or indirectly, a Party or in case of an only representative, the affiliate of the non-EU manufacturer or in case of a third representative, the affiliate of the legal entity represented. For these purposes, “control” shall refer to: (i) the possession, directly or indirectly, of the power to direct the management or policies of a person, whether through the ownership of voting rights, by contract or otherwise; or (ii) the ownership, directly or indirectly, of 50 % or more of the voting rights or other ownership interest of a person.

Data Owner: Any entity holding rights to use Information on the Substance, either as SIEF participant or as non-SIEF participant.

Information: Studies, other scientific, statistical, or technical data, including but not limited to composition, characteristics, properties and processes and applications, and any information in any form made available by a Party or generated by the Parties jointly, pursuant to or in the course of this Agreement.

Joint Registration Dossier: The data that the Parties are required to submit jointly to the Agency in order to register the Substance, pursuant to Article 11 (1), paragraph 2 REACH.

CSR: The Chapters 3 to 8 of the chemical safety report (CSR) that the Parties are required to submit under Article 14 of the REACH Regulation, in the format specified in Annex I of the REACH Regulation that was prepared outside the Joint Registration Dossier to cover the uses of the Lead Members and that will be made available by the Lead Registrant to the Non- Lead Member.

Parties: Being the parties to this Agreement, having the quality of either:

- **Lead Member**: a SIEF participant who is subject to the registration requirements under REACH, who participates to the SIEF discussions in order to compile the Joint Registration Dossier and who is party to the Inorganic Phosphates Consortium.

- **Lead Registrant**: a SIEF participant who is subject to the registration requirements under REACH, which the Non-Lead Member agree hereto to appoint acting as Lead Registrant as defined under Article 11 (1) REACH. The Lead Registrant is a member of and duly represents and acts in the name and on behalf of the other parties to cooperation ('Lead Members').
- **Non-Lead Member**: a SIEF participant being neither a Lead Member nor a data holder (Article 28 (7) REACH) and that agrees to rely on the Joint Registration Dossier prepared and/or made available by the Lead Registrant, on his own behalf, for its Affiliates, and/or on behalf of the represented potential registrants in case he is a third-party representative.

Substance: [Name, CAS No. xxx, EC No. xxx]

Title I: SIEF OPERATING RULES

Article II. Confidentiality

1. The Parties shall:

a) Treat all Information as confidential and not disclose it to third parties unless regulatory disclosure requirements apply. Each Party shall advise immediately the other Parties in writing of any disclosure or misuse by any Party or a third party of Information, as well as of any request by competent authorities relating to the disclosure of that Information.

Disclosure of Information as required for legal and/or regulatory purposes including the REACH Regulation, shall only take place by the Parties in a form (for example short summaries where possible) reflecting the minimum information required to be disclosed. This restriction does not apply to the Party who has provided the Information.

b) Use the Information only for the Purpose or otherwise as permitted under or in accordance with this Agreement.

c) Disclose the Information to their employees, Affiliates, external experts and/or consultants and if the Non-Lead Member is an only representative or a third-party representative, the non-EU manufacturer(s) or the legal entity(ies) represented by any of them, only on a need to know basis and only to the extent absolutely necessary for the Purpose or otherwise as permitted under or in accordance with this Agreement. Each Party shall have in place policies and procedures to ensure the confidentiality of Information and require that its external experts and/or consultants also have such policies and procedures in place to ensure their compliance with these confidentiality obligations.

2. The obligations specified in Article II. 1 above shall not apply to Information for which the receiving Party can reasonably demonstrate that such Information:

a) was known to the receiving Party on a non-confidential basis prior to its disclosure pursuant to this Agreement;

b) is publicly known at the time of disclosure or thereafter becomes publicly known without breach of the terms of this Agreement on the part of the receiving Party;

c) becomes known to the receiving Party through disclosure by sources other than the disclosing Party, having a right to disclose such Information;

d) was independently developed by the receiving Party without access to the disclosing Party's Information, as evidenced by documentary records.

Specific items of Information shall not fall within any exception merely because they are combined with more general Information falling within any exception. Likewise, any combination of specific items of Information shall not fall within any exception merely because the specific items fall within any exception, but only if the combination itself, and its principles of operation, fall within any exception.

3. Only representatives and third-party representatives shall disclose their principals to the Consortium Secretariat. The Consortium Secretariat will not disclose this information.

Article III. Competition Law compliance

1. The Parties acknowledge that any activities carried out under this Agreement have to be carried out in full compliance with EU competition law, in particular but not limited to Articles 101 and 102 TFEU (Treaty on the Functioning of the European Union), as well as any applicable national laws. The Parties explicitly agree to observe Cefic REACH Competition Law compliance guidance attached as **Annex 2** to this Agreement.

2. Should it become apparent at any time that this Agreement, any provision of this Agreement, or any activity or decision of the Parties, can have a potentially restrictive effect on open and fair competition, in breach of any statutory provision, each Party to this Agreement shall take immediate steps to remedy that situation.

Article IV. Legal personality

This Agreement or the cooperation contemplated herein shall not constitute or be deemed to constitute a legal entity or partnership between the Parties.

Article V. Report on the Joint Registration Dossier

The Lead Registrant or the appointed Consortium Manager undertakes to inform the Non-Lead Members on the updates of the Joint Registration Dossier without undue delay.

TITLE II: DATA SHARING AND JOINT SUBMISSION OF THE DOSSIER

1. OBLIGATIONS OF THE LEAD REGISTRANT

Article VI. Participation in the joint submission of data by multiple registrants

1. According to Article 11 (1) REACH, the Parties hereto agree to have the Joint Registration Dossier for the Substance submitted by the Lead Registrant on behalf of the Non-Lead Member having fulfilled its obligations under Article IX to this Agreement, before end of the applicable registration deadline. Upon demand of the Agency, within the requested deadline

and to the extent necessary, the Lead Registrant agrees to complete the Joint Registration Dossier.

2. Notwithstanding anything to the contrary under this Agreement, the Parties remain individually responsible to comply with REACH, in particular, but not limited to, in relation to the individual submission of the information required under Article 11 (1) REACH.

3. The participation in the Joint Registration Dossier may deviate per requesting Non-Lead Member according to its tonnage band or possible opt-outs for certain endpoints.

4. If the Non-Lead Member requests the submission of the Joint Registration Dossier on behalf of an Affiliate, the Non-Lead Member shall notify the Lead Registrant with its name, address and other relevant data documenting such status of Affiliate before the registration due date. Upon receipt of such information, the Non-Lead Registrant shall be allowed to enable the participation to the Joint Submission also to such Affiliate.

5. If the Non-Lead Member is a third-party representative and requests the submission of the Joint Registration Dossier on behalf of a legal entity represented by him in the SIEF, the Non-Lead Member shall notify the Lead Registrant under confidentiality obligations with the name, address and other relevant data of the represented legal entity before the registration due date. Upon receipt of such information, the Non-Lead Registrant shall be allowed to enable the participation to the Joint Submission also to such legal entity.

6. The Lead Registrant shall open a joint submission object in REACH-IT.

7. The Lead Registrant shall pay the fee (in accordance to Article 11 (4) REACH) as invoiced by the Agency for the submission of the Joint Registration Dossier without undue delay.

8. The Lead Registrant shall make available the Technical Dossier in IUCLID format (i.e. data referred to in Article 11 (1) paragraph 2 REACH that have been submitted in the joint submission) and when applicable the CSR as defined according to Article I of this Agreement] to the Non-Lead Member, and/or Non-Lead Member's Affiliate notified under Article VI. 4 of this Agreement, provided the Non-Lead Member has fulfilled its obligations under Article IX of this Agreement.

Article VII. Grant of right to use the (robust) studies summaries in the Joint Registration Dossier and to refer to the full study reports

1. Subject to the payment of the Joint Registration Compensation as specified under Article IX of this Agreement, the Lead Registrant grants the Non-Lead Member the non-exclusive, non-transferable, and non-terminable right:

(a) to use the (robust) studies summaries and other Information used in the Joint Registration Dossier within the applicable tonnage band and for which no opt-out has been claimed by the Non-Lead Member;

(b) to refer to the full study reports on which basis the (robust) studies summaries have been developed; and

(c) to grant the rights referred to under (a) and (b) hereabove to the Non-Lead Member's Affiliates notified under Article VI. 4, with the right to sub-license such rights only to their only representatives.

2. Notwithstanding the foregoing, if the Non-Lead Member is a third-party representative, he is granted only with the rights specified under (a) and (b) hereabove, and only for the purpose to pass them to the legal entities represented by him in the SIEF and notified to the Lead Registrant under Article VI. 5.

3. The rights granted under this Article can be exercised only for the purpose of compliance with REACH in relation to the Substance. The Parties shall abstain from any other use, whether commercial or non-commercial. For the avoidance of doubt, any further use of the studies shall be subject to an additional agreement.

4. The Lead Registrant represents that he has been granted or shall be granted by the Data Owners, being the owner(s) and/or the subjects authorized to grant the rights to use the (robust) studies summaries and to refer to the full study reports, the rights specified under Article VII paragraph 1.

Article VIII. Information on the submission of the Joint Registration Dossier

1. Provided the Non-Lead Member has fulfilled its obligations under Article IX, the Lead Registrant shall inform immediately the Non-Lead Member of the creation of the joint submission object in REACH-IT and shall provide the valid security token number and the name of the joint submission.

2. The Lead Registrant shall further communicate that a registration number has been obtained from the Agency in respect of the submission of the Joint Registration Dossier without undue delay.

2. OBLIGATIONS OF THE NON-LEAD MEMBER

Article IX. Financial compensation for the Joint Registration Dossier

1. Before execution by the Lead Registrant of its obligations pursuant to Title II.1 of this Agreement, the Non-Lead Member shall compensate in a fair, transparent and non-discriminatory way the Lead Registrant with a “Joint Registration Compensation” for the development and submission of the Joint Registration Dossier and the rights granted under Article VII.

2. The Joint Registration Compensation, in accordance with the principles set out in **Annex 1**, will comprise following elements:

a) Administrative expenses reasonably incurred by the Lead Members and the Lead Registrant including but not limited to, secretarial services, management of confidential data, costs for the joint dossier preparation and costs of external experts. Costs for the preparation of the Chemical Safety Report which is made available by the Lead Registrant to the Non-Lead Member.

b) Expenses to acquire rights to use existing studies of an individual Lead Member and costs for studies jointly developed by the Lead Members according to Annexes VII to VIII of REACH.

c) Costs for rights to use studies from Data Owners, if the Lead Registrant is authorized by Data Owners to transfer to Non-Lead Member the rights specified under Article VII. paragraph 1.

d) Advantage Compensation Payment as specified in **Annex 1**.

e) Handling Cost: this is a fee specified in **Annex 1** charged by Consortia Management for emission of token and Letter of Access procedure.

3. Expenses referred to above shall be allocated equally, in a transparent, fair, and non-discriminatory way, to all SIEF participants with the intent to register the Substance, taking into account the following exceptions:

a) Where a Non-Lead Member registers the Substance in a tonnage band lower than the one covered by the Joint Registration Dossier, it shall only be requested to compensate for the development of those parts of the Registration Dossier that it is included in and for those studies to which it receives a right to refer and for general costs proportionally to these items.

b) Where the Non-Lead Member decides, based on Article 11 (3) REACH, to opt-out from the Joint Submission or some parts of the Joint Registration Dossier and submit the relevant information separately, it shall only be requested to compensate for the development of those parts of the Joint Registration Dossier that are submitted jointly and for those studies to which it receives a right to refer and for general costs proportionally to these items.

4. Based on the above, the Lead Registrant will send an invoice to the Non-Lead Members for their cost share after their request for joint submission (2010, 2013, 2018 and first time registrants). The Non-Lead Members will only receive the valid security token number within 7 days after payment of the invoice. Payment is due within 1(one) month after receipt of an invoice issued by the Lead Registrant.

5. When cost and income estimations related to the Joint Registration Dossier change, in particular in 2013 and 2018, additional payments or refunds respectively may be requested by the Lead Registrant and SIEF Members respectively. For refunds a threshold of € 500 per SIEF participant is applicable. Where a company wishes to recoup costs less than € 500, they will bear the administrative and accounting costs of retrieving such refunds.

6. In case new studies (incl. studies from the REACH Evaluation process) have to be purchased or performed or other dossier preparation, administrative or other cost have to be engaged after conclusion of this Agreement, the resulting cost will be equally divided between all SIEF participants who are required to incorporate the results of these new studies into their registration dossier, unless they claim to opt out in accordance with Article 11 (3) REACH. The Non-Lead Member will be granted on these new studies the same rights as referred to under Article VII. 1 (a) and (b) of this Agreement.

7. If the SIEF comprises various Affiliates of the Non-Lead Member, only one of these Affiliates within the SIEF shall be subject to the obligation to compensate the Joint Registration Dossier. Such single Joint Registration Compensation will be calculated on base of the highest tonnage band of all these Affiliates. Accordingly, the Affiliates of the compensating Non-Lead Member, or the Affiliates of the non-EU established companies represented by an only representative being a Non-Lead Member, shall also have the right to refer to the Joint Registration Dossier under the same conditions without additional payment. In that case, the Non-Lead Member that has paid the compensation is responsible for compliance of its Affiliates or their only representative with the rights and obligations pursuant to this Agreement, including the confidentiality obligations under Title I, Article II of this Agreement.

8. If an only representative represents more than one non-EU entity within the SIEF, such only representative shall compensate the Lead Registrant on account of each non-EU entity it represents by the payment of a separate Joint Registration Compensation per Non-EU entity [and its Affiliates].

9. If a third-party representative represents more than one entity within the SIEF, such third party representative shall compensate the Lead Registrant on account of each entity it represents by the payment of a separate Joint Registration Compensation per entity [and its Affiliates].

10. All payments due hereunder shall be net payments, i.e. free of any bank or transfer charges or similar charges and without deduction of any taxes, levies or other dues payable If payer is required to withhold any tax or to make any other deduction from any such payments, then the said payments shall be increased to the extent necessary to ensure that, after making of the required deduction or withholding, payee receives and retains (free from any liability in respect of any such deduction or withholding) a net sum equal to the sum which it would have received and so retained had no such deduction or withholding been made or required to be made (gross-up amount). If upon application of the beneficiary any withholding tax can be reduced, or refunded, or an exemption from withholding tax is granted, payer shall file on behalf of payee for such reduction, refund, or exemption. Payee shall render any assistance to payer to obtain such withholding tax reduction, refund, or exemption. Payer shall be entitled to any refund of withholding taxes.

11. Indirect taxes, including but not limited to Value Added Tax (VAT), Goods and Service Tax (GST), service tax, business tax, as applicable pursuant to the relevant tax law, shall be borne by payer. However, payer is entitled to withhold any payment of indirect taxes unless payee has provided payer with a sufficient invoice for purposes of indirect taxation.

12. If the Non-Lead Member requests the submission of the Joint Registration Dossier on behalf of an Affiliate, the Non-Lead Member shall notify the Lead Registrant by disclosing its name, address and other relevant data documenting such status of Affiliate within one month of signature of this Agreement.

13. If the Non-Lead Member is a third-party representative and requests the submission of the Joint Registration Dossier on behalf of a legal entity represented by him in the SIEF, the Non-Lead Member shall notify the Lead Registrant under confidentiality obligations by disclosing the name, address and other relevant data of the represented legal entity within one month of signature of this Agreement.

14. The participation in the Joint Registration Dossier may deviate per requesting Non-Lead Member according to its tonnage band or possible opt-outs for certain endpoints.

3. OWNERSHIP OF INFORMATION

Article X. Ownership of Information

1. This Agreement does not grant any ownership rights or change existing ownership rights to any of the Information provided under this Agreement to the Non-Lead Member, on whatever form and whenever, by the Lead Registrant, including without limitation, the Joint Registration Dossier.

2. Such Information shall consist in any and all data and/or studies:

a) Individually developed by one of the Lead Members;

b) Collectively developed by the Lead Members for which they have acquired valid title or right to use; and

c) Acquired from Data Owner(s) for which the Lead Members, or the Lead Registrant as the case may be, have been granted valid rights.

3. Neither this Agreement nor any disclosure of Information shall vest any present or future rights in any patents, trade secrets or property rights and no license is granted.

TITLE III: FINAL PROVISIONS

Article XI. Limitation of liability in the SIEF

1. The Parties shall undertake their Purpose related activities specified hereunder in good faith and according to all applicable laws and regulations, and they shall use all reasonable endeavours to ensure the best possible results based on the evidence, methods and techniques known at the time.

2. Each Party having submitted a study which has been used in the Joint Registration Dossier represents to the others (i) that it is the rightful owner of or subject authorised to grant the right to use the study(ies) and free to grant rights therein, (ii) that, to the knowledge of this Party, these studies do not infringe on the rights, in particular, but without limitation, intellectual property rights, of any third party and (iii) that this Party has not received a claim or notice of any alleged infringement.

3. It is the individual responsibility of each Party to critically assess the Information that is generated or that is made available. Each Party assumes the full responsibility for its own use of the Information so developed or received. No warranty for acceptance by the Agency of the Joint Registration Dossier or any data it contains is given.

4. None of the Parties, including the Lead Registrant, shall be held liable for any direct, indirect, or consequential loss or damage incurred by any Party in connection with the activities contemplated in this Agreement, unless caused by gross negligence or wilful misconduct. In particular, the Lead Members, including the Lead Registrant, shall not be held responsible and liable for delays in the completion and submission of the Joint Registration Dossier, unless caused by gross negligence or wilful misconduct.

Article XII. Term and termination

1. This Agreement shall be in force until the end of the Joint Submission activities.

2. This Article and the provisions relating to the protection of confidentiality (Article II), ownership of Information (Article X), dispute resolution and applicable law (Article XV) and limitation of the liability (Article XI) shall survive the termination of this Agreement. With regard to the studies, the obligations specified in Article II of this Agreement shall survive for a period of twelve (12) years following the initial submission to the Agency. With regard to all other Information, the obligations specified in Article II shall survive for a period of 5 years after termination of the SIEF.

3. The Lead Registrant has the right to terminate its functions as lead registrant under the cumulative conditions that:
- it has been validly replaced in its functions within the SIEF;
- its assignee has accepted to be bound by the obligations of the Lead Registrant under this Agreement; and
- the Non-Lead Member has been notified about such replacement.

4. The Non-Lead Member has the right to terminate the present Agreement subject a prior written notice to the Lead Registrant at the latest nine months before the relevant registration deadline. No reimbursement shall be due.

Article XIII. Legal entity change

The consent of the other Party shall not be required in case a Party assigns, transfers or delegates its rights and obligations under this Agreement to any of its Affiliates or to a legal successor in ownership by sale, division, merger or consolidation of all or substantially the whole of the business relevant to the Substance referred to in this Agreement, subject to acceptance by the assignee of the terms of this Agreement, to be notified to the other Party without undue delay.

Article XIV. Administration and reporting of costs

1. All financial settlements, billings, and reports rendered under this Agreement shall reflect properly the facts which may be relied upon as being complete and accurate in any further recording and reporting made by a Party for any purpose.

2. In accordance with generally accepted accounting procedures, documentation will be maintained and preserved including but not limited to written or electronic records, records on expenses, books of account, correspondence, memoranda, and receipts.

3. The Lead Registrant will provide copies of documentation to justify accounts and other financial matters to any Non-Lead Member who reasonably requests this.

Article XV. Dispute resolution and applicable law

1. The Parties shall first attempt to settle amicably any dispute arising out of this Agreement. Any dispute shall be resolved by arbitration, ousting jurisdiction by ordinary courts, by a panel of three arbitrators. Each party to the dispute will nominate one arbitrator. These two arbitrators will then designate a third arbitrator who will also act as chairman. The arbitration decision shall be binding on the parties. The arbitration rules of the ICC (International Chamber of Commerce) shall be applicable. The place of any hearing shall be Frankfurt and the language of the arbitration shall be English. Each Party may at any time request from any competent judicial authority any interim or conservatory measure.

2. This Agreement shall be governed by the laws of Germany.

3. If at any time any provision of this Agreement is or becomes invalid or illegal in any respect, this shall have no effect on the validity of the remaining contractual provisions. The invalid provisions are to be replaced, backdated to the time of their becoming ineffective, by provisions which come closest to achieving their objective.

Inorganic Phosphates REACH Consortium

The Parties are validly bound by this Agreement when the Non-Lead Member has given its consent to this Agreement.

The Parties agree that signatures transmitted electronically via portable document format (PDF) attachment shall be binding as if they were original signatures.

The Non-Lead Member declares herewith agreement with the conditions as specified above.

COMPANY name (Non-Lead Member)	COMPANY name (client, in case Non-Lead Member acts as OR or TPR)
UUID (Non-Lead Member)	
Name of authorized representative (Non-Lead Member)	Name of authorized representative (client)
Job title of authorized representative (Non-Lead Member)	Job title of authorized representative (client)
Signature of authorized representative (Non-Lead Member)	Signature of authorized representative (client)
Date	Date

Annex 1

Rules of calculation of the Joint Registration Compensation

for the REACH Registration dossier for the Substance

Valuation of information

The following rules will generally apply for the valuation of Information, studies, and reports.

These are initially evaluated with respect to their scientific value. In a second step, their financial value is calculated as described below.

The object of the valuation is to ensure that adequate compensation is paid to the report owner for the provision of preliminary services and that the recipients' requirement for a high-quality report is satisfied.

Scientific evaluation

The quality of the reports is determined by the Technical Committee, or experts commissioned by the latter, in accordance with the Klimisch et al.[1] method by classifying the report into one of the following categories: (1) reliable without restriction, (2) reliable with restrictions, (3) not reliable, (4) not assignable.

The allocation to the four categories must be accompanied by appropriate substantiation in accordance with the requirements described in the chapter "Documentation of reliability categories in data sheets (IUCLID)" of the Klimisch et al. publication.

The quality of the robust summaries and IUCLID datasets is determined by the IP Consortium, or experts commissioned by the latter.

If the documents (IUCLID data set and/or robust summary) submitted by a party supplying a report are not in conformity with the state of the art or missing, the IP consortium or experts commissioned by the latter, should develop a robust summary and an IUCLID update.

Also, studies, for which no standard protocol exists, e.g., exposure studies, must be documented by an IUCLID data set and a robust summary, and are also to be evaluated under the Klimisch et al. method.

Calculation of value

For data, studies and reports, which are not supported by any standard test protocols or for which a market price is not applicable, the party supplying should provide a document justifying the costs, including the expenses and/or the time required (overview of the process steps, working days, costs per working day), including: development of study concept, exploratory studies, carrying out of the study, analyses, expenses for further contractors, administrative costs (see below).

The basic cost "BC" of the Study or report

is assessed as follows:

- in general, for standard tests and Studies, by referring to the present-day cost of such a study, by reference to a list of typical study costs.
- for non-standard tests and Studies and reports, or where it can be demonstrated that a specific non-standard cost is applicable, either the real price of the work (updated by inflation) or a justified estimate of current day costs, will be used, as indicated above.

[1] H.-J. Klimisch, M. Andreae, and U. Tillmann, A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data, Regulatory Toxicology and Pharmacology 25, 1-5 (1997).

Klimisch category

The above value of the Study will then be adjusted according to its **Klimisch category evaluation**, by multiplying K x BC, where:

K = 100% for Klimisch category 1

K = 80% for Klimisch category 2

K = 25% for Klimisch category 3

K = 25% for Klimisch category 4

Administrative and risk costs

In general, the following fixed surcharges will be added to the cost:

→ +30% to cover **risk** inherent in carrying out new Studies: the decision to conduct a Study involves the risk that the Study results could adversely affect or prevent future substance marketing; hence, the company contributing a report was exposed to the risk that the investments made in the Study are of minor or no benefit; the other parties are not exposed to this risk since they already know the Study result; and

→ +15% to cover **management and administrative costs (choosing and briefing laboratory, managing contracts and payments)**

→ these two % are applied independently, and not additively, to the study cost (in general, total of +45%)

In particular cases, where it can be justified (specific risks, proof of real costs), different figures may be applied.

Authorised uses

% of value depending on **authorised uses**. The value calculated above will be multiplied by the following factor:

70%, corresponding to authorisation to access (use directly or by read-across) for REACH Registration for **more than one** of the IP Consortium Substances, and for no other uses, for all companies purchasing access rights to the Registration Dossiers, for Studies made available to the IP Consortium (that is, this does not cover authorisation for access for use under regulations other than REACH and does not cover use for REACH Registration of substances other than the IP Consortium Substances);

50%, corresponding to authorisation to access for REACH Registration for **only one** of the IP Consortium Substances, under the same conditions as above.

For Information for which the owner has already been credited 50% of the value under the STPP Consortium agreement (corresponding to use for Reach Registration of STPP only), the owner will receive a **further 20% only** to "extend" the access to **one or more** of the IP Consortium Substances.

Calculation if several studies are available

covering the same endpoint:

- In general, calculation of cost shares due by the different SIEF participants will be carried out by referring to the indications and examples in the Agency document "Guidance for the Implementation of REACH, Guidance on Data Sharing 2.0, April 2012".
- In all cases, payment will only be considered due by the IP Consortium to a data owner for Information which is necessary for the REACH Registration Dossiers for one or more of the IP Consortium Substances. That is, if Studies or Information (including

expert reports, internal industry documentation or reports, read-across Information...) are already available, adequate for Registration of the IP Consortium Substances, and to which the IP Consortium has access for use in the Registration Dossiers (existing studies, studies developed by the IP Consortium, publicly available Information, Information for which the IP Consortium has already paid for access rights from a third party…), then the IP Consortium will **not pay to access further Studies or Information**, unless specifically required to ensure the validity of the Registration Dossiers:

- Where several Existing Studies are available for the same endpoint for a given IP Consortium Substance then the Key Study for each endpoint will be identified and the Pro Rata Share due by each Non-Lead Member calculated, according to the examples in the Agency Guidance document referred above, as follows: only the value of the Key Study will be taken into account in calculating the Pro Rata Share.
- Non-Lead Member owning other Information concerning the relevant endpoint may subtract from their Pro Rata Share the calculated value of this information or the value of the Key Study (whichever figure is the lowest).

Joint Registration Compensation

General financial rules

The fees and amounts below are contributions fixed as defined, intended to cover the approximate relevant costs in a simple, fair, and reasonable manner, and not to correspond to the exact amounts.

All figures indicated are exclusive of VAT and of any other taxes which may be due.

In all cases, no rights of access to the Registration Dossiers or to any other Information can be claimed by a Non-Lead Member purchasing access rights, until:

- all payments due have been effectively made and received;
- the Non-Lead Member has given its consent to this Agreement and to the conditions of access. In all cases, the payments indicated cover access, as specified, to the Registration Dossiers and/or Information as these stand only, and with no guarantee of their validity or acceptance by the Agency.

In all cases, the payments indicated below are due per company manufacturing, importing, or representing the Substance:

- one company's payment will cover its Affiliates;
- payment by an OR of more than one company will be calculated per company, according to the number of companies represented (unless these are Affiliates as covered above);
- ORs will therefore be required to specify and justify the number of companies manufacturing the Substance (other than Affiliates) effectively being represented, by listing these companies under confidentiality, and if requested by the Lead Registrant, by further depositing justification documents with a lawyer or other recognised party under confidentiality.

Calculation of Joint Registration Compensation (LoA cost)

To obtain access to the Registration Dossier(s) developed by the IP Consortium, the Non-Lead Member party must pay the **Joint Registration Compensation** (in effect, the cost of Letter of Access) consisting of the total of the following **two amounts** as defined below**:**

- **the Advantage Compensation Payment,**
- **and the Dossier Costs Contribution (Pro Rata Share),**

both calculated for each of the IP Consortium substance dossier(s) to which the Member wishes to have access.

This payment does NOT enable the Non-Lead Member to become a member of the IP Consortium, for which there is a separate Entry Fee.

The Non-Lead Member must also register and must pay a handling fee (per LoA and per substance).

Advantage Compensation Payment:

This is a one-off payment of a fixed amount required for any Non-Lead Member wishing to use one or more of the REACH Registration Dossiers developed by the IP Consortium for their own REACH Registration of the IP Consortium Substances and is additional to and independent of the Pro Rata Share, Dossier Contribution Costs and (for companies wishing to join the IP Consortium only) IP Consortium Entry Fee.

The Advantage Compensation Payment covers the goodwill, experience and know-how resulting from the work together of the initial Inorganic Phosphates (IP) Consortium Member companies, and with competent third parties (e.g. consultants), in joint research and collaboration concerning inorganic phosphates through the Cefic Sector Group PAPA (previously EFPA) over the last 30 years, including work studying, achieving and updating authorisation as food additives, and cooperating in communications and information exchange and joint research concerning the IP Consortium Substances.

The Advantage Compensation Payment and IP Consortium Entry Fee are not payable by companies who have been members of PAPA in the past, who have as such contributed financially to PAPA's activities during 2003-2007, and who have participated in the preparation of the IP Consortium over the period end 2007- 2008.

The Advantage Compensation Payment is fixed at € 5,000 per IP Consortium Substance up to a maximum of € 20,000 for 4 or more Substances, that is Substances for which the New Member is Directly or Indirectly Concerned as defined in the IP Consortium Agreement.

Pro Rata Share

That is, shared participation in all expenses incurred in producing, managing, and submitting the Registration Dossiers, including IP Consortium administration costs, and including costs of existing and new Information obtained or developed by the IP Consortium for the Purpose. These costs are detailed below.

Participation is as per the cost sharing mechanism specified below which ensures an equal share of these costs between Lead Members and Non-Lead Members.

All references to "Members" below are taken to mean the combined number of Lead Members and Non-Lead Members which effectively purchase right of access to the Substance REACH Registration Dossier by both entering into this Agreement and paying fully all invoices due.

Cost sharing: one company = one share per Substance

All dossier costs are shared as follows:

(i) for General Costs of the dossier preparation (including IP Consortium administration, operation, establishment, …) and for other costs necessary for Registration of all of the Substances

- cost share based on number of IP Consortium Substances: if company A is Directly Concerned by a Substances, company B is Directly Concerned by b, C is Directly Concerned by c, etc, … then company A will have to pay a /(a+b+c+d+e)th share.

(ii) for costs necessary for the Registration of one or several (not all) of the IP Consortium Substances

ii.a) one IP Consortium Substance only (e.g. a study of this Substance, which is not necessary for read across for other IP Consortium Substances)

- each company Directly or Indirectly Concerned by the Substance (that is, wishing to refer to the Registration Dossier for Registration of the Substance) pays an equal share (N_S Members concerned by a Substance, each company pays $1/N_S^{th}$ of costs).

ii.b) for costs concerning several of the IP Consortium Substances (e.g. a study of more than one IP Consortium Substance, or a study enabling read across to other IP Consortium Substances)

- cost share based on number of products: if company A is Directly or Indirectly Concerned by a' Substances, company B by b', and company E by e', then company A will have to pay a'/(a'+b'+e')th share.

For companies in tonnage bands lower than 1,000 tonnes

In this case, for both (i) and (ii) above, the total dossier cost (including Advantage Compensation Payment) is reduced proportionally to:

→ the number of endpoints required for a given tonnage band, for the general and administrative costs

→ the costs of the studies for which access is purchased or carried out for the endpoints required for a given tonnage band

Costs included in Pro Rata Share costs

The following will be accounted in the calculation of the Pro Rata Shared costs, by the Secretariat, applying where appropriate the rules on Member costs fixed below:

- Administrative expenses incurred for the management of the IP Consortium, including the Secretariat, legal and accounting costs, coordination and other administrative costs, management of confidential data or external experts, etc.;
- Value of or rights of access to (evaluated as indicated above) Existing Information owned by Members and purchased from other parties and required for registration;
- Costs for new Information developed where required for registration;
- Costs for a Lead-Member accomplishing tasks assigned to it by the IP Consortium and costs engaged by Lead-Members for management and administration of the dossier preparation as indicated below;
- All other costs engaged by IP Consortium Agreement in order to achieve registration.

Rules for Lead-Member company costs

The following rules will be used for evaluating and reimbursing costs engaged by IP Consortium Member companies in preparing, establishing, and managing the IP Consortium and in contributing to achieving registration. These amounts will be counted as IP Consortium costs (included in the Pro Rata Share costs as above).

In order to avoid excessively detailed accounting, the following "fixed" costs are taken as the minimum basis for calculating Member input and work.

For participation in a physical meeting:

- two days' staff time, per Lead Member present, as at rate below, including preparation and travel time,
- travel costs on the basis of an average cost of € 500 per Lead Member present, including travel costs and booking costs.

For participation in a telephone meeting:

- one-day staff time per Lead Member participating as at rate below, including preparation.

For the Lead Registrant only, for time taken leading technical and administrative work in cooperation with the Secretariat, finalising and submitting the dossier:

- € 10,000 (per substance)
- Additionally, if the Substance is classified under GHS, for preparing CSR and Exposure Scenarios as a function of uses and applications: € 5,000 (per substance)

Lead Member staff time rate:

€ 800 per day / € 400 per half day, including secretarial and overheads.

The amounts and numbers of staff days indicated above are per Lead Member per meeting at which the Lead Member effectively participates, irrespective of how many persons are in fact present per Lead Member.

Payments and Access

Initial LoA cost estimate and reimbursements

The Lead Registrant will estimate the Joint Registration Compensation for >1,000 tonnes Registration, as above, on the basis of the number of Lead Members intending to register the substance for this tonnage band in 2010 plus one (that is, assume one Non-Lead Member LoA purchaser), as at end July 2010. The costs will be updated after the 2013 registration deadline.

To obtain right of access the Non-Lead Member must pay this amount, plus the LoA handling fee.

The Advantage Compensation Payment will be calculated at € 5,000/substance for the initial LoA purchase payment and will be partially reimbursed after Registration for companies exceeding the € 20,000/company ceiling fixed by the financial conditions (companies registering more than four IP substances).

Obviously, this leads to a “conservative” estimate of dossier cost **per registrant**, in that it is likely that more than one non-Member will purchase LoA, and therefore that the actual dossier cost share in this case will finally be lower (cost divided by higher number of registrants). Therefore, the dossier cost share will be recalculated after the 2010, 2013 and 2018 submission deadlines, and reimbursements - if due - will be made to all registrants having purchased a LoA.

Reimbursements will be made by bank transfer **within 3 months** of each of the three registration deadlines, subject to the conditions indicated below.

The following provisions (reserves) will be added to dossier cost before calculating the reimbursements:

- Estimated cost for submitted Testing Proposals
- 5% of dossier cost as a provision for possible future management costs arising after submission (dealing with questions from ECHA, dossier updates...)

These provisions will be added to the reimbursement calculations in 2018 if and only if it is by then clear that the relevant expenditure will be partly or fully not required.

No reimbursements will be made where the amount due to a given company is < € 500.

Reimbursements will only be made if the Non-Lead Member provides full bank account details (including account number and BIC).

The LoA Handling Fee and the Advantage Compensation Payment are not subject to cost share allocation, and so are not concerned by the reimbursements.

Different initial payments will be calculated similarly (taking into account LoAs already purchased for previous deadlines and taking into account the endpoints required for the different tonnage bands) ahead of the 2018 Registration deadlines, and reimbursements made after these deadlines, as indicated above.

Additional costs

The basic dossier cost above does NOT include the possible cost of taking into account any further studies which may be communicated after fixing this cost, nor any modifications of the dossier which could result from such information, nor any administrative costs of updating the dossier if this becomes necessary in the future. It does not include the costs of any submitted Testing Proposal, nor of any other additional testing ECHA may require after examination of the dossier. All such additional costs must be shared between all registrants (where concerned according to tonnage bands) and will be additional to those indicated here.

Also are not included ECHA registration fees and the cost of preparing and submitting the Non-Lead Member's company specific information and registration, which remain the individual responsibility of the Non-Lead Member.

The above conditions are in application of the IP Consortium Agreement financial conditions already communicated to the SIEF in the last years. This Agreement specifies in full the conditions for cost sharing, administrative costs and for valuation and accounting of existing studies and new information, based on standard prices and cost share principles and on the REACH Guidance Document (data sharing) and the Regulation (EU) 2016/9 on Joint Submission of Data and Data Sharing.

The Access Rights are accorded for use for REACH Registration of the Substance only, and for use for no other purposes and for no other substances.

Invoicing and token transmission

Within 10 days after the Non-Lead Member has provided all required, signs this Agreement and requests to purchase a LoA, an invoice will be sent by the Secretariat to the address and with the references indicated by the Non-Lead Member.

Within 20 days of the Non-Lead Member making complete payment of the amount invoiced, provided that the payment is made according to the instructions and including the references indicated on the invoice, the Secretariat will:

- Send to the Non-Lead Member by email (email specified by the Non-Lead Member) the name of the Substance Joint Submission Object in REACH-IT and an up to date “Token” to confirm membership in the relevant Joint Submission.
- Send to the Non-Lead Member by email a Letter of Access (signed by the Consortium Secretariat on behalf of the Lead Registrant and the other Consortium Members).

If the Token is not used by the Non-Lead Member before the end of its validity, then the Non-Lead Member can request an updated Token. One such request can be made at no cost.

The Lead Registrant, Secretariat and Lead Members take no responsibility for delays resulting from bank transfers getting lost due to inadequate references supplied by the Non-Lead Member, errors in transfer or other causes beyond their control, to emails or other communications not reaching the Non-Lead Member if their coordinates are not provided correctly and up to date or for other reasons.

The above process may be modified as a function of ECHA formalities.

Annex 2

Cefic guidance on competition compliance

Cefic REACH
guidance DO & DON'T