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Legal contract: IP SIEF Agreement Contract for the 2010 Registration deadline IP substances

Note for information only

(not part of this legal contract):

*The Lead Registrant is preparing the Registration of the substance in close cooperation with the other members of the "Inorganic Phosphate (IP) Consortium". The IP Consortium Agreement, as valid at the date of signature of this contract, is annexed to this Agreement for information, but is not part of and is independent from this Agreement. In the context of this Consortium Agreement, the Lead Member has delegated to ReachCentrum, Avenue E. van Nieuwenhuyse 6, 1160 Brussels, Belgium, acting as **Secretariat** of this Consortium, the management of the dossier preparation and management, as well as representation and communications with the SIEF Participants*

Definition of the Parties to this Agreement contract

The **substances listed in Annex 2**, hereinafter referred to as "**the Substance(s)**", are those which the Inorganic Phosphates Consortium intends to Register under REACH in 2010, that is substances for which Joint Submission preparation is being managed by the IP Consortium for 2010 Registration deadline and for which the Lead Registrant is an IP Consortium Member.

The list in Annex 2 also specifies for each of these substances the company which is hereinafter referred to as the **Lead Registrant**.

This SIEF Agreement Contract, hereinafter the "**Agreement**", is entered into by and between:

- the **Lead Registrant acting in its own name and in the name and on behalf of all Members of the Inorganic Phosphates Consortium** in accordance with the Inorganic Phosphates Consortium Agreement,
- and the SIEF Participant which has electronically signed and accepted, for the substance, the present Agreement via the online tool LOAShop <http://loashop.reachcentrum.eu> (hereinafter referred to as "**Non-Lead Member**"):

hereinafter referred to as "**the Parties**".

The Agreement is entered into by the Non-Lead Member **only for the Substance or substances** for which they electronically sign and accept via the online tool LOAShop.

Preamble

Whereas the Parties to this Agreement have pre-registered the Substance, have agreed on the identity and the **sameness of the Substance, as attached in Annex 3***, and thus are participants of the same Substance Information Exchange Forum ("SIEF") as potential registrants for the Substance under the meaning of Article 29 of the European Community Regulation EC 1907/2006 ("REACH");

* NOTE: the sameness document is considered adequate to identify the Substance, but may be slightly modified or adjusted (eg. purity or impurity specifications) prior to Registration submission, as a function of comments from other SIEF participants or of further information coming available in the Registration Dossier preparation process. In this case, a revised sameness document will be circulated to the Non-Lead Member and will be considered as accepted by the Non-Lead Member if no objection is received **within 10 days**.

The indications included in Annexes 3 and 4 for substances other than the Substance covered by this Agreement, are not part of this Agreement Contract.

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 (hereinafter "**the Agency**");

Whereas the Lead Members, as defined in the Article 1 of this Agreement will prepare the Joint Registration Dossier to be submitted to the Agency through the Lead Registrant;

Whereas the Members of the Inorganic Phosphates Consortium are aware that they have co-operation and data sharing obligations with other SIEF participants;

Whereas the Non-Lead Member has the intention to register the Substance and he is willing to appoint the Lead Registrant as lead registrant in order 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:

The Agreement: this document, which constitutes a binding legal contract between the Non-Lead Member and the Lead Registrant, applicable to the Substance only, once the Non-Lead Registrant has electronically signed and accepted, for the Substance, the present Agreement via the online tool LOAShop operated by ReachCentrum at <http://loashop.reachcentrum.eu>.

Applicable registration deadline: For the Substance, this is fixed and agreed between the parties as: **1st December 2010**. The Lead Registrant may however decide to submit the Joint Registration earlier than this, at his own free choosing, for any reason or organization or otherwise.

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 party 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 expressed as % dry weight, that is excluding water, 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 paragraph 2 of Article 11 (1) of REACH, and if REACH Registration submission made by the Lead Registrant specifies that under GHS the Substance is "Non classified", also paragraph 4 of Article 11 (1) of REACH (that is, CSR including Guidance on Safe Use).

NOTE: For substances for which the Registration dossier submitted indicates Classification under GHS, data for paragraph 4 of Article 11 (1) of REACH (CSR including Guidance on Safe Use) will be prepared by the Lead Registrant and transmitted to the Non-Lead Member who will have the responsibility of submitting themselves this part of the Registration dossier for the substance.

Parties: being the signing 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 a member of 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 members of the Inorganic Phosphates Consortium ('Lead Members'). The Lead Registrant for each substance is specified in Annex 2.

- **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, and which has electronically signed and accepted, for the Substance, the present Agreement via the online tool LOAShop operated by ReachCentrum at <http://loashop.reachcentrum.eu>.

Inorganic Phosphates Consortium: the "IP" Consortium initially established in October 2008 for the purpose of REACH registration of a number of inorganic phosphates substances. The initial members of this Consortium were the following companies: BK Giulini GmbH, Chemische Fabrik Budenheim KG, FMC Foret S.A., Prayon SA, Thermphos International BV, CECA S.A. Since the Consortium's establishment a number of further companies have also become members: at the date of 31st December 2009 Fosfa AS, Gelita AG, Haldor Topsoe A/S, AB Lifosa, Uralchem Assist GmbH., Vion NV and Heubach GmbH. Further additional companies may also become members of the Consortium in the future, according to the conditions specified in the Consortium Agreement: this option is also open to the Non-Lead Members, in which case they will then become a Lead Member.

IP Consortium Agreement. The IP Consortium Agreement, as currently valid is attached to this Agreement (Annex 6), for information only. It is noted that the members of this Consortium may in the future modify this Consortium Agreement. The Lead Registrant will make available to the Non-Lead Member any modifications to this Consortium Agreement by maintaining an up-to-date copy on the Consortium web site.

LOAShop: website operated by ReachCentrum (Avenue E. van Nieuwenhuysse 6, B-1160 Brussels, Belgium) at <http://loashop.reachcentrum.eu> for online collection of information concerning Non-Lead Members (company details, invoicing references, bank account references, details of Affiliates and companies represented by ORs), for online signature of SEIF Agreement Contracts and for online purchase of Letters of Access

The Substance: the substance, which is one of the substances listed and specified in Annex 2 (sameness), for which the Non-Lead Member has electronically signed and accepted the present Agreement via the online tool LOAShop operated by ReachCentrum at <http://loashop.reachcentrum.eu> – this Agreement applies ONLY to this Substance and not to the other substances listed in Annexes 1 or 2.

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 of Information by any Party or a third party, 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 or with legally valid ownership or access 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 use of or 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.

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 of the Treaty on the Functioning of the European Union (TFEU) as well as any applicable national laws. The Parties explicitly agree to observe Cefic REACH Competition Law compliance guidance attached as Annex 5 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. Regular report of the preparation of the Joint Registration Dossier

1. The Lead Registrant undertakes to inform the Non-Lead Member on the development of the Joint Registration Dossier.
2. In particular, the Lead Registrant undertakes to inform the Non-Lead Member on the list of uses to be covered in that chemical safety report (CSR) without undue delay.
3. The Non-Lead Member undertakes to make all best efforts to check proactively and regularly all updated Information that is made available by the Lead Registrant on the development of the Joint Registration Dossier.
4. The Parties agree that such communication may be channelled via the use of emails circulated to either all signatories of this agreement or to all participants in the SIEF of the Substance, or by placing documents on IP Consortium's website, or by any other appropriate medium or method.
5. The Lead Registrant undertakes to inform the Non-Lead Member of proposed GHS classification for the Substance, both for the pure substance and for principal forms placed on the market of which the Lead Registrant is aware. **A proposal for this(these) GHS classification(s) is attached to this agreement (Annex 4).** The Lead Registrant will inform the Non-Lead Member of any modifications to this proposal, resulting from new information or other developments, without undue delay. The Non-Lead Member is considered to agree with the proposals in Annex 4 and with any modifications communicated to them unless they inform the Lead Registrant of their disagreement and submit a different proposal accompanied by technical and scientific justifications **within 10 days**. If the Non-Lead Member is aware of other forms of the substance placed non-confidentially and widely on the market which require a different GHS classification and labelling, he will inform the Lead Registrant of this and supply specifications of the form and a proposed GHS classification and labelling text, without undue delay and at the latest **within one month of signature of this Agreement**.

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, and subject to all necessary information being fully available in time, 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, **at least 2 months 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 by completing the information on LOAShop, with its name, address and other relevant data documenting such status of Affiliate **within one month of signature of this Agreement**.
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 by completing the information on LOAShop with the name, address and other relevant data of the represented legal entity **within one month of signature of this Agreement**.
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 data referred to in Article 11 (1) paragraph 2 (and paragraph 4 (subject to the conditions indicated above) of REACH that have been submitted in the joint submission, 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, that is both the initial payments and any later payments which may become due later as specified under the conditions of this Article, 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 and only for 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 written 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 provide the valid security token number and the name of the joint submission object in REACH-IT.

2. The Lead Registrant shall inform the Non-Lead Member of the submission of the Joint Registration Dossier to the Agency and provide documentation of the same.

3. The Lead Registrant shall further communicate without undue delay the confirmation that the joint registration has been successful and shall inform the Non-Lead Member of the reception of the relevant registration number that has been obtained from the Agency

4. For all of the above, the Lead Registrant will respect a delay of 10 working days unless this is rendered impossible for reasons beyond his control, in which case he will do it as rapidly as is possible.

2. Obligations of the Non-Lead Member

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

1. According to Article 11 (1) REACH, and subject to all necessary information being fully available in time, 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, **at least 2 months 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.

Article IX. Participation in and financial compensation for the Joint Registration Dossier

1. The Non-Lead Member shall compensate in a timely, fair, transparent and non-discriminatory way, as specified below, 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 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, cost for the joint dossier preparation, including costs related to the preparation of the Chemical Safety Report, Lead Members company time calculated as per the rules in Annex 1 to this Agreement and costs of external experts.

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 VI 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 ReachCentrum for emission of token and Letter of Access using LOAShop

3. Expenses referred to above shall be allocated equally, in a transparent, fair and non discriminatory way, to all Non-Lead Members having signed this agreement and paying fully the Joint Registration Compensation, 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. As specified in Annex 1, and subject to the timings specified in this Annex, the Lead Registrant or his representative (ReachCentrum), will send invoice(s) to the Non-Lead Members for the Joint Registration Compensation at appropriate dates. The Non-Lead Members will only receive the valid security token number after full payment of the invoice(s).

5. In case new studies have to be purchased or performed or other dossier preparation, administrative or other costs have to be engaged after fixing of the amount of or after payment of the Joint Registration Compensation, the resulting cost will be equally divided between all Non-Lead Members concerned.

6. If the final dossier cost share proves to be higher than estimated when invoices were issued as above for whatever reason, including management or testing costs which become necessary after Dossier submission, then the increase will be shared by all remaining Non-Lead Members.

7. SIEF participants will not have any right of access to the Joint Registration Dossier unless and until they have signed this agreement and have fully paid all invoice(s) due, and they will lose any rights if at a future date they do not pay within one month any additional invoices resulting from the clause above.

8. 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 Representatives 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. 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 completing the information on LOAShop, with its name, address and other relevant data documenting such status of Affiliate **within one month of signature of this Agreement**.

14. 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 completing the information on LOAShop with the name, address and other relevant data of the represented legal entity **within one month of signature of this Agreement**.

15. 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 or by the Lead Members or by their representatives or service providers or otherwise, 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 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 1 June 2022.

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 five (5) years after termination of the SIEF.

3. The Lead Registrant has the right to terminate its functions as lead registrant under the cumulative following 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 to 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 CEPANI shall be applicable. The place of any hearing shall be Brussels 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 Belgium.
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.

The Parties are validly bound by this Agreement when the Non-Lead Member has given its consent to this Agreement by the LOAShop electronic signature process

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.

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)

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.

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).

Calculation of value

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.

Klimisch category

The above value of the Study will then be adjusted according to its **Klimisch category evaluation**, by multiplying $K \times BC$, 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
 - à +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
 - à +15% to cover **management and administrative costs (choosing and briefing laboratory, managing contracts and payments)**
 - à 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);

<http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach/stpp-reach-consortium.aspx>

- § **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, September 2007”
- § 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 through the online signature process on LOAShop <http://loashop.reachcentrum.eu>

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 Only Representative of more than one company will be calculated per company, according to the number of companies represented (unless these are Affiliates as covered above);
- Only Representatives 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 on LOAShop, 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 on LOAShop <http://loashop.reachcentrum.eu> and must pay the LOAShop handling fee of 425 Euros (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 (consultants, Cefic ...), 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 over the last five years (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 Euros 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 $\frac{a}{(a+b+c+d+e)}$ 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 (eg. 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 $1/N_S^{\text{th}}$ of costs)

ii.b) for costs concerning several of the IP Consortium Substances (eg. 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 1000 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 Euros 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:

<http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach/stpp-reach-consortium.aspx>

- 10 000 Euros (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 Euros (per substance)

Lead Member staff time rate:

§ 800 Euros per day / 400 Euros 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.

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

The total amount payable ("initial payment") will be indicated online in the LOAShop system

<http://loashop.reachcentrum.eu>

In LOAShop, 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 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 2013 or 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 enters into the LOAShop full bank account details (including account number and BIC).

The LOAShop 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 2013 and 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 since last year. 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).

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 enters all required information into the LOAShop system, signs online this Agreement and requests to purchase LoA, an invoice will be sent by the Secretariat to the address and with the references indicated by the Non-Lead Member in LOAShop.

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 in LOAShop) 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 post 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 correct and up to date in LOAShop or for other reasons.

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

Annex 2: List of Substances and Lead Registrants

Full legal name and address of Lead Registrants

BK Giulini GmbH, company with limited liability under German law (Gesellschaft mit beschränkter Haftung), registered office Giulinistrasse 2, 67065 Ludwigshafen am Rhein, Germany

Chemische Fabrik Budenheim KG, limited partnership under German law (Kommanditgesellschaft), registered office Rheinstrasse 27, D-55257 Budenheim, Germany

FMC Foret S.A., company with limited liability under Spanish law (sociedad anonima), registered office Plaza Xavier Cugat, 2, Edificio C, planta 3ª, Parque de Oficinas Sant Cugat Nord 08174 Sant Cugat del Vallés (Barcelona), Spain

Prayon SA, company with limited liability under Belgian law (société anonyme), registered office Rue J. Wauters 144, B-4480 Engis, Belgium BCE 0405 747 040

Omnisal GmbH, company with limited liability under German law, affiliate of **Thermphos International**, Dessauer Straße 128, D-06886 Lutherstadt Wittenberg, Germany

Roullier : TIMAB Industries (Société par actions simplifiée), 55 boulevard Jules Verger, BP 10180, 35803 DINARD Cedex, France

List of Substances

NOTE: the Joint Registration Dossier will be submitted using the substance name and EINECS number in **bold and marked with *** below ONLY. The other names and EINECS numbers given below will be indicated in the Dossier as being covered because considered to be the same substance.

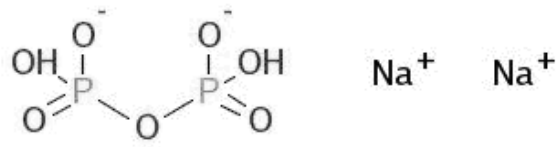
IP	Chemical name(s)	EINECS N°(s)	CAS N°(s)	Lead Registrant
2	Sodium dihydrogenorthophosphate *	231-449-2 *	7558-80-7, 13472-35-0, 10049-21-5	Thermphos International
	Monosodium phosphate			
3	Disodium hydrogenorthophosphate *	231-448-7 *	7558-79-4, 10028-24-7, 10039-32-4, 7782-85-6	Thermphos International
	Disodium phosphate			
4	Trisodium orthophosphate *	231-509-8 *	7601-54-9, 10101-89-0, 15819-50-8, 10361-89-4, 60593-58-0, 60593-59-1	Thermphos International
5	Disodium dihydrogenpyrophosphate *	231-835-0 *	7758-16-9	Thermphos International
	Sodium (acid) pyrophosphate			
6	Trisodium hydrogen diphosphate *	238-735-6 *	14691-80-6, 26573-04-6, 16457-94-6	Thermphos International
	Trisodium pyrophosphate			
7	Tetrasodium pyrophosphate *	231-767-1 *	7722-88-5, 13472-36-1	Thermphos International
8	Trisodium trimetaphosphate *	<i>2010 Registration as "Intermediate" only</i>		BK Giulini
	Sodium trimetaphosphate	232-088-3 *	7785-84-4	
10	Sodium metaphosphate *	233-343-1 *	10124-56-8	BK Giulini
12	Potassium dihydrogenorthophosphate *	231-913-4 *	7778-77-0	Prayon
	Monopotassium phosphate			
13	Dipotassium hydrogenorthophosphate *	231-834-5 *	7758-11-4	Prayon
	Dipotassium phosphate			
55	Potassium pentahydrogen bis(phosphate) *	238-961-5 *	14887-42-4	Prayon
15	Tetrapotassium pyrophosphate *	230-785-7 *	7320-34-5, 79102-70-8, 7790-67-2	BK Giulini
16	Pentapotassium triphosphate *	237-574-9 *	13845-36-8, 66904-52-7	BK Giulini
	Potassium tripolyphosphate			
21	Calcium bis(dihydrogenorthophosphate) *	231-837-1 *	7758-23-8, 10031-30-8	Chemische Fabrik Budenheim
	Monocalcium phosphate			
22	Calcium hydrogenorthophosphate *	231-826-1 *	7757-93-9, 7789-77-7	Chemische Fabrik Budenheim
	Dicalcium phosphate			
60	MCP-DCP Reaction Mass MDCP *	233-283-6 *	10103-46-5	Roullier
23	Tricalcium bis(orthophosphate) *	231-840-8 *	7758-87-4	Chemische Fabrik Budenheim
	Beta-tricalcium phosphate			
24	Bone Ash	270-423-5, 215-145-7, 235-330-6 *	68439-86-1, 1306-06-5, 12167-74-7	Chemische Fabrik Budenheim
	Hydroxylapatite			
	Tricalcium phosphate			
29	Pentacalcium hydroxide tris(orthophosphate) *			
29	Magnesium hydrogenorthophosphate *	231-823-5 *	7757-86-0, 7782-75-4	Chemische Fabrik Budenheim
	Dimagnesium phosphate			
39	Aluminium tris dihydrogenphosphate *	236-875-2 *	13530-50-2	Chemische Fabrik Budenheim
	Monobasic aluminium phosphate			
47	Disodium fluorophosphates *	233-433-0 * 231-552-2	10163-15-2, 7631-97-2	BK Giulini
48	Ortho phosphoric acid *	231-633-2 *	7664-38-2	FMC Foret
	Phosphoric acid			

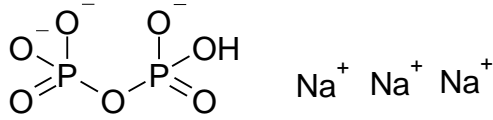
Annex 3: Substance Sameness specifications

IP2: Sodium dihydrogenorthophosphate	
Type of substance	mono-constituent
Origin	inorganic
Reference EC number (s)	231-449-2
Other EC numbers considered to be the same substance	
EC name	sodium dihydrogenorthophosphate
CAS number (s)	7558-80-7 (anhydrous), 13472-35-0, 10049-21-5
SMILES	OP(=O)(O)[O-].[Na+]
Molecular formula (or formulae)	H ₃ O ₄ P.Na or NaH ₂ PO ₄
EU food legislation number / INS n°	E339i
Structure image or diagram (indicative)	
Molecular weight (or range)	120 - 121
Granulometry range	Between 10% and ≥50% of particles have a diameter of <100 µm.
pH range for aqueous solution	4-5
Composition expressed as % dry weight, that is excluding water	
<p>The main impurities are conform to the following limits (in all cases,):</p> <ul style="list-style-type: none"> · Substance >90% purity · All impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties · All hazardous impurities are < 0.1% 	

IP3: Disodium hydrogenorthophosphate	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	231-448-7
Other EC numbers considered to be the same substance	N/A
EC name	disodium hydrogenorthophosphate
CAS number (s)	7558-79-4 (anhydrous), 10028-24-7, 10039-32-4, 7782-85-6
SMILES	OP(=O)([O-])[O-].[Na+].[Na+]
EU food legislation number / INS n°	E339ii
Molecular formula (or formulae)	H ₃ O ₄ P.2Na or Na ₂ HPO ₄
Structure image or diagram (indicative)	
Molecular weight (or range)	142 - 144
Granulometry range	Ca. 10% of particles have a diameter of <100 µm.
pH range for aqueous solution	
Composition expressed as % dry weight, that is excluding water	
<p>The main impurities are conform to the following limits (in all cases,):</p> <ul style="list-style-type: none"> · Substance >90% purity · All impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties · All hazardous impurities are < 0.1% 	

IP4: Trisodium orthophosphate	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	231-509-8
Other EC numbers considered to be the same substance	N/A
EC name	trisodium orthophosphate
CAS number (s)	7601-54-9 (anhydrous), 10101-89-0, 15819-50-8, 10361-89-4, 60593-58-0, 60593-59-1
SMILES	[O-]P(=O)([O-])[O-].[Na+].[Na+].[Na+]
EU food legislation number / INS n°	E339iii
Molecular formula (or formulae)	H ₃ O ₄ P.3Na or Na _(3+x) PO ₄ .H _x
Structure image or diagram (indicative)	
Molecular weight (or range)	164 - 167
Granulometry range	More than 10% of particles are < 100µm in diameter
pH range for aqueous solution	
Composition expressed as % dry weight, that is excluding water	
<p>The main impurities are conform to the following limits (in all cases,):</p> <ul style="list-style-type: none"> · Substance >90% purity · All impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties · All hazardous impurities are < 0.1% 	

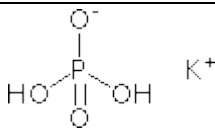
IP5: Disodium dihydrogenpyrophosphate	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	231-835-0
Other EC numbers considered to be the same substance	N/A
EC name	disodium dihydrogenpyrophosphate
CAS number (s)	7758-16-9
SMILES	OP(=O)([O-])OP(=O)(O)[O-].[Na+].[Na+]
EU food legislation number / INS n°	E450i
Molecular formula (or formulae)	H ₄ O ₇ P ₂ .2Na or Na ₂ H ₂ P ₂ O ₇
Structure image or diagram (indicative)	
Molecular weight (or range)	222 - 224
Granulometry range	Between 25% and ≥50% of particles have a diameter of <100 μm.
pH range for aqueous solution	
Composition expressed as % dry weight, that is excluding water	
<p>The main impurities are conform to the following limits (in all cases,):</p> <ul style="list-style-type: none"> · Substance >90% purity · All impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties · All hazardous impurities are < 0.1% 	

IP6: Trisodium hydrogen diphosphate	
Composition	mono-constituent
Origin	inorganic
Reference EC number (s)	238-735-6
Other EC numbers considered to be the same substance	
EC name	Trisodium hydrogen diphosphate Trisodium pyrophosphate
CAS number (s)	14691-80-6 (anhydrous), 26573-04-6, 16457-94-6
SMILES	OP(=O)([O-])OP(=O)([O-])[O-].[Na+].[Na+].[Na+]
EU food legislation number / INS n°	E450ii
Molecular formula (or formulae)	H ₄ O ₇ P ₂ .3Na
Structure image or diagram (indicative)	
Molecular weight (or range)	247
Granulometry range	≥50% of particles have a diameter of <100 μm. Therefore the registration dossier will take in to account the inhalation risk.
pH range for aqueous solution	
Impurities	
<p>The main impurities are conform to the following limits (in all cases, expressed as % dry weight, that is excluding water):</p> <ul style="list-style-type: none"> · Substance >90% purity · All impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties · All hazardous impurities are < 0.1% 	

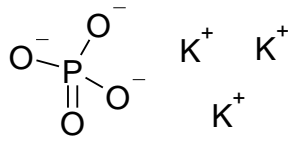
IP7: Tetrasodium pyrophosphate	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	231-767-1
Other EC numbers considered to be the same substance	
EC name	tetrasodium pyrophosphate
CAS number (s)	7722-88-5 (anhydrous), 13472-36-1
SMILES	[O-]P(=O)([O-])OP(=O)([O-])[O-].[Na+].[Na+].[Na+].[Na+]
EU food legislation number / INS n°	E450iii
Molecular formula (or formulae)	H ₄ O ₇ P ₂ .4Na or Na ₄ P ₂ O ₇
Structure image or diagram (indicative)	
Molecular weight (or range)	266 - 270
Granulometry range	Between 10% and ≥50% of particles have a diameter of <100 μm.
pH range for aqueous solution	
Composition expressed as % dry weight, that is excluding water	
<p>The main impurities are conform to the following limits (in all cases,):</p> <ul style="list-style-type: none"> · Substance >90% purity · All impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties · All hazardous impurities are < 0.1% 	

IP8: Trisodium trimetaphosphate	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	232-088-3
Other EC numbers considered to be the same substance	
EC name	trisodium trimetaphosphate
CAS number (s)	7785-84-4
SMILES	[O-]P1(=O)OP(=O)(OP(=O)(O1)[O-])[O-].[Na+].[Na+].[Na+]
Molecular formula (or formulae)	H ₃ O ₉ P ₃ .3Na or O ₉ P ₃ .3Na
Structure image or diagram (indicative)	
Molecular weight (or range)	306- 309
Granulometry range	More than 10 % of particles are < 100µm in diameter
pH range for aqueous solution	
Composition expressed as % dry weight, that is excluding water	
<p>The main impurities are conform to the following limits (in all cases,):</p> <ul style="list-style-type: none"> · Substance >90% purity · All impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties · All hazardous impurities are < 0.1% 	

IP10: Sodium metaphosphate	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	233-343-1
Other EC numbers considered to be the same substance	
EC name	sodium metaphosphate
CAS number (s)	10124-56-8
SMILES	[O-]P1(=O)OP(=O)(OP(=O)(OP(=O)(OP(=O)(OP(=O)(O1)[O-])[O-])[O-])[O-]
Molecular formula (or formulae)	H ₆ O ₁₈ P ₆ .6Na or O ₁₈ P ₆ .6Na
Structure image or diagram (indicative)	<p>The diagram shows a cyclic chain of six phosphorus (P) atoms. Each phosphorus atom is bonded to two oxygen (O) atoms, one double-bonded and one single-bonded. The single-bonded oxygen atoms are further bonded to other phosphorus atoms in the chain, forming a continuous ring. Six sodium ions (Na+) are shown, each associated with one of the single-bonded oxygen atoms in the chain, representing the sodium counterions.</p>
Molecular weight (or range)	612 – 618
Granulometry range	Between 10% and ≥50% of particles have a diameter of <100 μm.
pH range for aqueous solution	
Composition expressed as % dry weight, that is excluding water	
<p>The main impurities are conform to the following limits (in all cases,):</p> <ul style="list-style-type: none"> · Substance >80% purity · All impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties · No one impurity is >10% · All hazardous impurities are < 0.1% 	

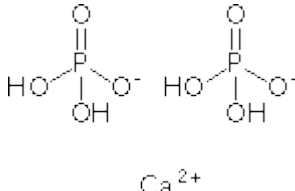
IP12: Potassium dihydrogenorthophosphate (MKP)	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	231-913-4
Other EC numbers considered to be the same substance	
EC name	potassium dihydrogenorthophosphate
CAS number (s)	7778-77-0
SMILES	OP(=O)(O)[O-].[K+]
EU food legislation number / INS n°	E340i
Molecular formula (or formulae)	H ₂ O ₄ P.K or H ₃ O ₄ P.K
Structure image or diagram (indicative)	
Molecular weight (or range)	136 - 137
Granulometry range	Between 10% and ≥35% of particles have a diameter of <100 µm.
pH range for aqueous solution	
Composition expressed as % dry weight, that is excluding water	
Purity	
Typical purity of substance	80 %
Lower content	> 70 %
Higher content	100 %
Impurities in the substance: The substance may contain the impurities indicated below, derived from the production process, each one present at the concentrations indicated below :	
Dipotassium hydrogenorthophosphate - # EINECS : 231-834-5	<15%
Potassium sulphate # EINECS : 231-915-5	<10%
Potassium chloride #EINECS : 231-211-8	<5%
Calcium hydrogenorthophosphate #EINECS : 231-826-1	<10%
Other inorganic phosphates or other inorganic substances related to the registered substance which do not significantly affect the toxicological and ecotoxicological properties of the registered substance	<10% in total
All other impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties	
Hazardous impurities	<1%

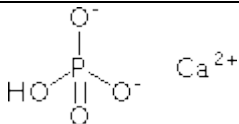
IP13: Dipotassium hydrogenorthophosphate (DKP)	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	231-834-5
Other EC numbers considered to be the same substance	
EC name	dipotassium hydrogenorthophosphate
CAS number (s)	7758-11-4 (anhydrous), 16788-56-1, 78436-04-1
SMILES	OP(=O)([O-])[O-].[K+].[K+]
EU food legislation number / INS n°	E340ii
Molecular formula (or formulae)	H ₃ O ₄ P.2K
Structure image or diagram (indicative)	
Molecular weight (or range)	175
Granulometry range	Ca. 100% of particles have a diameter of <100 µm.
pH range for aqueous solution	
Composition expressed as % dry weight, that is excluding water	
Purity	
Typical purity of substance	80 %
Lower content	> 70 %
Higher content	100 %
Impurities in the substance : The substance may contain the impurities indicated below, derived from the production process, each one present at the concentrations indicated below :	
Potassium dihydrogenorthophosphate # EINECS : 231-913-4	<15%
Other inorganic phosphates or other inorganic substances related to the registered substance which do not significantly affect the toxicological and ecotoxicological properties of the registered substance	<20% in total
All other impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties	
Hazardous impurities	<1%

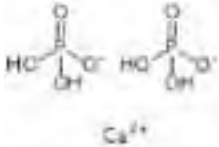
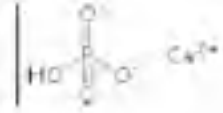
IP55: Potassium pentahydrogen bis(phosphate)	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	238-961-5
Other EC numbers considered to be the same substance	
EC name	potassium pentahydrogen bis(phosphate)
CAS number (s)	14887-42-4
SMILES	[O-]P(=O)([O-])[O-].[K+].[K+].[K+]
Molecular formula (or formulae)	H3O4P.1/2K / K3O4P
Structure image or diagram (indicative)	
Molecular weight (or range)	212
Granulometry range	
pH range for aqueous solution	
Composition expressed as % dry weight, that is excluding water	
<p>The main impurities are conform to the following limits (in all cases,):</p> <ul style="list-style-type: none"> · Substance >90% purity · All impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties · All hazardous impurities are < 0.1% 	

IP15: Tetrapotassium pyrophosphate	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	230-785-7
Other EC numbers considered to be the same substance	
EC name	tetrapotassium pyrophosphate
CAS number (s)	7320-34-5 (anhydrous) 79102-70-8 (monohydrate) 7790-67-2 (dehydrate)
SMILES	[O-]P(=O)([O-])OP(=O)([O-])[O-].[K+].[K+].[K+].[K+]
EU food legislation number / INS n°	E450v
Molecular formula (or formulae)	H ₄ O ₇ P ₂ .4K or O ₇ P ₂ .4K
Structure image or diagram (indicative)	
Molecular weight (or range)	330 - 334
Granulometry range	Between 10% and ≥70% of particles have a diameter of <100 μm.
pH range for aqueous solution	9.5-11.5
Composition expressed as % dry weight, that is excluding water	
<p>The main impurities are conform to the following limits (in all cases,):</p> <ul style="list-style-type: none"> · Substance >90% purity · All impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties · All hazardous impurities are < 0.1% 	

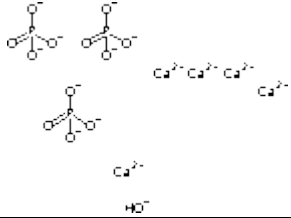
IP16: Pentapotassium triphosphate	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	237-574-9
Other EC numbers considered to be the same substance	
EC name	pentapotassium triphosphate
CAS number (s)	13845-36-8 (anhydrous) 66904-52-7 (dihydrate)
SMILES	[O-]P(=O)([O-])OP(=O)([O-])OP(=O)([O-])[O-].[K+].[K+].[K+].[K+].[K+]
EU food legislation number / INS n°	E451ii
Molecular formula (or formulae)	H ₅ O ₁₀ P ₃ .5K or O ₁₀ P ₃ .5K
Structure image or diagram (indicative)	
Molecular weight (or range)	448 – 453
Granulometry range	Between 1% and ≥60% of particles have a diameter of <100 μm.
pH range for aqueous solution	9.0 – 12.5
Composition expressed as % dry weight, that is excluding water	
<p>The main impurities are conform to the following limits (in all cases,):</p> <p>Substance >90% purity</p> <p>All impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties</p> <p>All hazardous impurities are < 0.1%</p>	

IP21: Calcium bis(dihydrogenorthophosphate) (MCP)	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	231-837-1
Other EC numbers considered to be the same substance	266-030-3
EC name	Calcium bis(dihydrogenorthophosphate)
Synonyms	Monocalcium Phosphate (MCP), Monobasic Calcium Phosphate, Triple Super Phosphate
CAS number (s)	7758-23-8 (anhydrous), 10031-30-8 (1-hydrate), 65996-95-4 (TSP)
SMILES	OP(=O)(O)[O-].OP(=O)(O)[O-].[Ca+2]
EU food legislation number / INS n°	E341i
Molecular formula (or formulae)	Ca(H ₂ PO ₄) ₂ or Ca ₂ H ₃ O ₄ P or CaH ₄ O ₈ P ₂
Structure image or diagram (indicative)	 <p>The diagram shows two phosphate groups, each consisting of a central phosphorus atom double-bonded to one oxygen and single-bonded to three others (one hydroxyl group and two negatively charged oxygens). These two phosphate groups are coordinated to a central calcium ion (Ca²⁺).</p>
Molecular weight (or range)	234 -236
Granulometry range	Ca. 100% of particles have a diameter of <100 µm.
pH range for aqueous solution	~ 3.9
Composition expressed as % dry weight, that is excluding water	
Typical purity of substance	80 %
Purity: lower content	70 %
Purity: higher content	100 %
Impurities in the substance: The substance may contain the impurities indicated below, derived from the production process, each one present at the concentrations indicated below :	
Calcium hydrogenorthophosphate # EINECS : 231-826-1	<10%
Calcium sulphate - # EINECS : 231-900-3	<10%
Mineral phosphate rock	<10%
Orthophosphoric acid - #EINECS : 231-633-2	<5%
Iron salts	<5%
Magnesium salts	<5%
Other inorganic phosphates or other inorganic substances related to the registered substance which do not significantly affect the toxicological and ecotoxicological properties of the registered substance	<10% in total
All other impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties	
Hazardous impurities	<1%

IP22: Calcium hydrogenorthophosphate	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	231-826-1
Other EC numbers considered to be the same substance	
EC name	calcium hydrogenorthophosphate
Synonyms	Dicalcium Phosphate
Dicalcium Orthophosphate	
Dibasic Calcium Phosphate	
CAS number (s)	7757-93-9 (anhydrous)
7789-77-9 (2-hydrate)	
SMILES	OP(=O)([O-])[O-].[Ca+2]
EU food legislation number / INS n°	E341ii
Molecular formula (or formulae)	CaHPO ₄ or Ca.H ₃ O ₄ P
Structure image or diagram (indicative)	
Molecular weight (or range)	136 - 138
Granulometry range	Up to 100% of particles have a diameter of <100 µm. Therefore the registration dossier will take into account the inhalation risk.
pH range for aqueous solution	~ 7
Composition expressed as % dry weight, that is excluding water	
Typical purity of substance	80 %
Purity: lower content	> 70 %
Purity: higher content	100 %
Impurities in the substance: The substance may contain the impurities indicated below, derived from the production process, each one present at the concentrations indicated below	
Calcium bis(dihydrogenorthophosphate) # EINECS : 231-837-1	<10%
Calcium sulphate - # EINECS : 231-900-3	<10%
Tricalcium bis(orthophosphate) #EINECS: 231-840-8	<5%
Mineral phosphate rock	<10%
Iron salts	<5%
Magnesium salts	<5%
Other inorganic phosphates or other inorganic substances related to the registered substance which do not significantly affect the toxicological and ecotoxicological properties of the registered substance	<10% in total
All other impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties	
Hazardous impurities	<1%

IP60: MDCP Calcium phosphate reaction mass	
Type of substance	Reaction mass of Calcium bis(dihydrogenorthophosphate) and Calcium hydrogenorthophosphate (multi-constituent)
Origin	Inorganic
Reference EC number (s)	233-283-6
Other EC numbers considered to be the same substance	None
EC name	Calcium phosphate
Synonyms	MDCP (Mono Di Calcium Phosphate)
MCP – DCP Reaction Mass	
CAS number (s)	10103-46-5
SMILES	
EU food legislation number / INS n°	Not applicable
Molecular formula (or formulae)	CaHPO ₄ ; Ca(H ₂ PO ₄) ₂
Structure image or diagram (indicative)	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p><small>Calcium bis(dihydrogenorthophosphate)</small></p>  </div> <div style="text-align: center;"> <p><small>Calcium hydrogenorthophosphate</small></p>  </div> </div>
Molecular weight (or range)	420 - 430
Granulometry range	>1.4mm : 5% max
	>0.2 mm: 5% max
	0 % of particles have a diameter of <100 µm
pH range for aqueous solution	3 to 5
Composition expressed as % dry weight, that is excluding water	
Purity	
Range of MCP content	40-75%
Range of DCP content	10-40%
Impurities in the substance : The substance may contain the following main impurities, derived from the production process	
Tricalcium phosphate (Hydroxylapatite) EC# 215-145-7	< 10%
Phosphoric acid EC# 231-633-2	< 5 %
All other impurities > 5% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties	
All hazardous impurities	< 0.1%

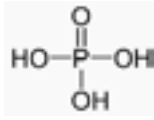
IP23: Tricalcium bis(orthophosphate)	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	231-840-8
Other EC numbers considered to be the same substance	
EC name	Tricalcium bis(orthophosphate)
Synonyms	Tricalcium Phosphate, Tricalcium Di(orthophosphate), β-Tricalcium Phosphate, Tribasic Calcium Phosphate
CAS number (s)	7758-87-4
SMILES	[O-]P(=O)([O-])[O-].[O-]P(=O)([O-])[O-].[Ca+2].[Ca+2].[Ca+2]
EU food legislation number / INS n°	E341iii (same as IP24)
Molecular formula (or formulae)	Ca ₃ (PO ₄) ₂ or Ca.2/3H ₃ O ₄ P or Ca ₃ O ₈ P ₂
Structure image or diagram (indicative)	<p>The diagram shows two phosphate groups (PO₄³⁻) and three calcium ions (Ca²⁺). Each phosphate group consists of a central phosphorus atom double-bonded to one oxygen and single-bonded to three negatively charged oxygen atoms. The three calcium ions are positioned around the phosphate groups, representing the overall neutral compound.</p>
Molecular weight (or range)	310
Granulometry range	Up to 100% of particles have a diameter of <100 μm. Therefore the registration dossier will take into account the inhalation risk.
pH range for aqueous solution	
Composition expressed as % dry weight, that is excluding water	
Purity	
Typical purity of substance	80 %
Lower content	> 70 %
Higher content	100 %
Impurities in the substance: The substance may contain the impurities indicated below, derived from the production process, each one present at the concentrations indicated below	
All impurities > 5% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties	
All hazardous impurities	< 1%

IP24: Pentacalcium hydroxide tris(orthophosphate)	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	235-330-6 *
Other EC numbers considered to be the same substance	215-145-7 270-423-5
EC names	Pentacalcium hydroxide tris(orthophosphate) *
Synonyms	Hydroxylapatite / Hydroxy Apatite Calcium Hydroxide Phosphate Pentacalcium Hydroxy Monophosphate Tricalcium Phosphate (frequently used commercial name) Bone ash
<i>NOTE: the Joint Registration Dossier will be submitted using the substance name and EINECS number marked with * above ONLY. The other names and EINECS numbers given above will be indicated in the Dossier as being covered because considered to be the same substance.</i>	
CAS number (s)	1306-06-5 (hydroxylapatite) 12167-74-7 (Calcium Hydroxide Phosphate)
SMILES	[OH-].[O-]P(=O)([O-])[O-].[O-]P(=O)([O-])[O-].[O-]P(=O)([O-])[O-].[Ca+2]
	.[Ca+2].[Ca+2].[Ca+2].[Ca+2]
EU food legislation number / INS n°	E341iii (same as IP23)
Molecular formula (or formulae)	Ca ₅ (PO ₄) ₃ OH or 10 CaO ₃ (P ₂ O ₅)H ₂ O or Ca ₅ HO ₁₃ P ₃ (hydroxylapatite)
Structure image or diagram (indicative)	
Molecular weight (or range)	502
Granulometry range	Up to 100% of particles have a diameter of <100 µm. Therefore the registration dossier will take into account the inhalation risk.
pH range for aqueous solution	
Composition expressed as % dry weight, that is excluding water	
Purity	
Typical purity of substance	80 %
Lower content	> 70 %
Higher content	100 %
Impurities in the substance : The substance may contain the following main impurities, derived from the production process	
Calcium hydrogenorthophosphate EC# 231-826-1	< 25%
All other impurities > 5% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties	
All hazardous impurities	< 0.1%

IP29: Magnesium hydrogenorthophosphate	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	231-823-5
Other EC numbers considered to be the same substance	
EC name	Magnesium hydrogenorthophosphate
Synonyms	Dimagnesium Phosphate
Dibasic Magnesium Phosphate	
CAS number (s)	7757-86-0 (anhydrous)
7782-75-4 (3-Hydrate)	
SMILES	OP(=O)([O-])[O-].[Mg+2]
EU food legislation number / INS n°	E343ii
Molecular formula (or formulae)	MgHPO ₄ or H ₃ O ₄ P.Mg
Structure image or diagram (indicative)	
Molecular weight (or range)	120
Granulometry range	Up to 100% of particles have a diameter of <100 µm. Therefore the registration dossier will take into account the inhalation risk.
pH range for aqueous solution	
Composition expressed as % dry weight, that is excluding water	
Purity	
Typical purity of substance	80 %
Lower content	> 70 %
Higher content	100 %
Impurities in the substance: The substance may contain the impurities indicated below, derived from the production process, each one present at the concentrations indicated below	
Magnesium bis(dihydrogenorthophosphate) # EINECS : 236-004-6	<15%
Magnesium oxide - #EINECS : 215-171-9	<10%
Orthophosphoric acid - #EINECS : 231-633-2	<5%
Other inorganic phosphates or other inorganic substances related to the registered substance which do not significantly affect the toxicological and ecotoxicological properties of the registered substance	<10% in total
All other impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties	
Hazardous impurities	<1%

IP39: Aluminium tris dihydrogenphosphate	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	236-875-2
Other EC numbers considered to be the same substance	
EC name	aluminium tris dihydrogenphosphate
CAS number (s)	13530-50-2
SMILES	OP(=O)([O-])[O-].[Al+3]
Molecular formula (or formulae)	Al.3H ₃ O ₄ P
Structure image or diagram (indicative)	
Molecular weight (or range)	318
Granulometry range	Up to 85% of particles have a diameter of <100 µm. Therefore the registration dossier will take into account the inhalation risk.
Form	Solid
pH range for aqueous solution	2.1 – 2.2 (50% solution)
Composition expressed as % dry weight, that is excluding water	
Purity	
Typical purity of substance	80 %
Lower content	> 75 %
Higher content	100 %
Impurities in the substance : The substance may contain the following main impurities, derived from the production process	
Aluminium orthophosphate EC# 232-056-9	< 20%
All other impurities > 5% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties	
All hazardous impurities	< 1%

IP47: Disodium fluorophosphate	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	233-433-0 *
Other EC numbers considered to be the same substance	231-552-2
<i>NOTE: the Joint Registration Dossier will be submitted using the EINECS number marked with * above ONLY. The other EINECS number given above will be indicated in the Dossier as being covered because considered to be the same substance.</i>	
EC name	Disodium fluorophosphate
CAS number (s)	10163-15-2, 7631-97-2
SMILES	[O-]P(=O)([O-])F.[Na+].[Na+]
Molecular formula (or formulae)	FH ₂ O ₃ P.2Na or FO ₃ P.2Na
Structure image or diagram (indicative)	
Molecular weight (or range)	142 – 144
Granulometry range	> 80% of particles have a diameter of <100 µm.
pH range for aqueous solution	
Composition expressed as % dry weight, that is excluding water	
The main impurities are conform to the following limits (in all cases,):	
Substance >90% purity	
All impurities > 1% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties	
All hazardous impurities are < 0.1%	

IP48 (Ortho) phosphoric acid	
Type of substance	mono-constituent
Origin	Inorganic
Reference EC number (s)	231-633-2
Other EC numbers considered to be the same substance	/
EC name	Orthophosphoric acid
Other names	Phosphoric acid
CAS number (s)	7664-38-2
SMILES	OP(O)(O)=O
Molecular formula	H ₃ PO ₄
Structural formula	
Molecular weight (or range)	97.9952 g/mol
Physical form	The Dossier will address both solid phosphoric acid (colourless crystal) and liquid (solution in water)
Composition expressed as % dry weight, that is excluding water	
Purity	
Typical purity of substance	≥ 85%
Lower content	≥ 80%
Higher content	c. 100%
Impurities in the substance	
All impurities > 1% are inorganic substances, which do not significantly affect the substance's toxicological and ecotoxicological properties	
The main impurities are conform to the following limits	
Iron expressed as Fe ₂ O ₃ (%) :	0 - 6 % (proposed analysis method Fe: ICP)
Aluminium expressed as Al ₂ O ₃ (%) :	0 – 8 % (proposed analysis method Al: ICP)
Magnesium expressed as MgO and/or MgF ₂ and/or MgSiF ₆ (%) :	0 – 3 % (proposed analysis method Mg: ICP)
Calcium expressed as CaO and/or CaF ₂ (%) :	0-2 % (proposed analysis method Ca: ICP or ISO 3707/ 1976)
Sulphate SO ₄ ²⁻ (%) expressed as H ₂ SO ₄ :	0-7,5% (proposed analysis method NFT 20-469/1984 or ISO 2997/1974)
Flouride F ⁻ (%) expressed as Na ₂ SiF ₆ , MgF ₂ and/or CaF ₂ and/or MgSiF ₆ (%) :	0 – 3 % (proposed analysis method Selective electrode, ISO 3360/1976)
Phosphorous acid as H ₃ PO ₃ :	0 – 3% (proposed analysis method Iodine titration)
All other impurities must be lower than 0,1% for each chemical element (proposed analysis method ICP)	

Annex 4: Proposed GHS Classification

IP n°		GHS Classification
2	Sodium dihydrogenorthophosphate	No classification
3	Disodium hydrogenorthophosphate	No classification
4	Trisodium phosphate	GHS07: Warning 3.2/2 3.3/2 3.8/3 H 315, H 319, H 335 P 261 P 280 P 302+352 P 305+351+338 P 337+313 P 332+313
5	Sodium pyrophosphate	GHS07: Warning 3.3/2 H319 P264 P280 P305 + P351 + P338 P337 + P313
6	Trisodium pyrophosphate	No Classification
7	Tetrasodium pyrophosphate	GHS07: Warning 3.1 Cat 4 H302 P264 P270 P301+312 P330 Classification pending for eye irritation –studies underway
8	Sodium trimetaphosphate	No classification
10	Sodium metaphosphate	No classification
12	Potassium dihydrogenorthophosphate	No classification
13	Dipotassium hydrogenorthophosphate	No classification
55	Phosphoric acid, potassium salt (2:1)	GHS05 Danger 3.3/1B 2.16/1 H314 H290 P234 P260 P280 P301+330+331 P305+351+338-303+361+353
15	Tetrapotassium pyrophosphate	GHS07: Warning 3.3 Cat 2 H 319 P280, P305 + P351 + P338 P 337 + P313

IP n°		GHS Classification
16	Potassium tripolyphosphate	<p>Pure substance (powder): No Classification</p> <p>Solution pH 9.9: No classification</p> <p>Solution pH 11.0 - 11.4: <i>GHS05 Warning</i> 3.2/2, 3.3/2, 2.16/1 H 315, H 319, H 290</p> <p>Solution pH >=11.5 : <i>GHS05 Danger</i> 3.2/1c, 3.3/1, 2.16/1 H 314, H 290</p>
21	Calcium bis (dihydrogenorthophosphate) = MCP	<p>GHS05: Danger 3.3/1 H318 P280</p>
22	Calcium hydrogenorthophosphate = DCP	No Classification
23	Tricalcium bis(orthophosphate)	No classification
60	MDCP (MCP-DCP Reaction Mass)	Classification pending for eye irritation –studies underway
24	Pentacalcium hydroxide tris(orthophosphate)	No classification
29	Magnesium hydrogenorthophosphate	No classification
39	Monobasic aluminium phosphate	<p>GHS05: Danger 3.3/1 H318 P280</p>
47	Disodium fluorophosphate	<p>GHS07: Warning 3.1.O/4 H302 P 301+312 P330</p>
48	Phosphoric acid	Classification and Labelling already defined by REACH Regulation Annex VI.

Annex 5: Cefic guidance on competition compliance

Cefic REACH competition law compliance guidance

Could competition law apply to REACH activities? YES.

It is expressly stated in the REACH Regulation (hereinafter "REACH") that *"this Regulation should be without prejudice to the full application of the Community competition rules."* (Recital 48). Therefore, rules of competition law adopted at Community level (hereinafter "EC competition law"), but also at the national level, do apply to REACH and all related activities.

REACH is not a competition law free zone

This guidance on EC competition law is intended to help anyone involved in REACH activities, including consortia formation, to assess the compatibility of their activities with EC competition law. Companies involved in REACH should always ensure that their activities comply with EC competition law irrespective of the form of co-operation they choose.

Important Note: *Readers of this guidance should not presume that they know all there is to know about EC competition law just by reading this document. This guidance is designed to allow companies involved in REACH to make a preliminary assessment of their conduct under EC competition law. It does not intend to substitute the applicable EC competition law provisions, as these have been interpreted by the European Courts, the European Commission and the national competition authorities. It only gives general guidance and thus does not and cannot cover all the different competition scenarios that may arise from REACH. Seek legal advice if needed.*

Brief introduction to EC competition law

EC competition law is not intended to prohibit legitimate activities of companies. Its objective is to protect competition in the market as a means of enhancing consumer welfare. Therefore, agreements between companies or decisions by associations or concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market are prohibited - Article 81 (1) of the EC Treaty.

Three basic points should be borne in mind:

- 1 regardless of the good intentions of companies and groups of companies, if the effect of activities is found to affect competition and markets unduly, this activity will be illegal;
- 2 Article 81 (1) can be violated by agreements (regardless of their form, whether express or implied, for example: a decision by a consortium, actions minuted as a follow-up of a meeting, exchanges of e-mails.....) as well as by concerted practices;
- 3 to violate Article 81 (1) it is not required that there is an actual effect on the market; the object to impede competition is sufficient to infringe the law.

EC competition law also prohibits the abuse of a dominant position (Article 82 of the EC Treaty). This may be conduct of one single company, or of a group of companies.

A competition investigation may be initiated either by a competition authority itself; or following a complaint by a third party, or following a leniency application to a competition authority of a party to the unlawful agreement that would like to cease its unlawful activity.

Companies engaged in conduct in breach of Article 81 or Article 82 may not only find that their agreements will be void and unenforceable, but are exposed to significant fines and, under certain Member States legislation, criminal sanctions. Furthermore, an infringement of EC competition law may expose the infringer to significant civil damage claims.

For more information on EC competition law, Articles 81 & 82 of the EC Treaty (see backcover), and the web site of the Commission Directorate General Competition or the web sites of the national competition authorities of the EU Member States (http://ec.europa.eu/comm/competition/index_en.html).

Management of activities DO & DON'T

✓ DO	✗ DON'T
REACH ACTIVITIES AND EC COMPETITION LAW	
DO pay attention to EC competition law as this may apply to REACH related activities	DO NOT presume that because you are strictly applying REACH, EC competition law will not apply
COMPETITION COMPLIANCE	
DO comply with EC competition law when acting under REACH DO always refer to EC competition law compliance, adopt a system, and strictly adhere to it DO avoid any misunderstanding by competition authorities about what you are doing	DO NOT misuse REACH activities to engage in anticompetitive conduct such as cartel activities DO NOT ignore, and thus DO know the most important EC competition law rules, as ignorance is not an excuse with competition authorities
ORGANISATION OF ACTIVITIES	
DO have an effective organisation (e.g. by signing appropriate agreements including rules for defining items such as membership, data sharing, cost sharing, adoption of an EC competition law compliance set of rules)	DO NOT work in a disorganised way. If you have rules or sign an agreement apply these in full and ensure they are followed
TYPE OF ACTIVITIES	
DO always apply EC competition law compliance to any type of REACH related activities : not only formal meetings, but also activities such as conference calls, use of IT systems, exchange of correspondence, e-mails, informal meetings	DO NOT engage in prohibited activities during social gatherings incidental to your lawful activities or otherwise; EC competition law rules will equally apply to these
WORKING UNDER REACH	
DO limit your activities to what is strictly required under REACH	DO NOT go beyond activities which are strictly required under REACH
OVERSIGHT AND SUPERVISION	
DO refer to this guidance when conducting activities and distribute it regularly to REACH participants, in particular to newcomers DO have an agenda and minutes which accurately reflect the discussions and matters; limit your discussions to the agenda topics and consult with legal counsel when necessary DO use an independent third party or trustee if necessary (e.g. to exchange individual tonnages from companies when determining the cost sharing of each participant)	DO NOT apply EC competition law compliance guidance infrequently but instead, apply it in your day-to-day activities in order for it to become routine good practice DO NOT deviate from agenda DO NOT draft agenda and/or minutes which do not reflect discussions or activities DO NOT organise the exchange of sensitive information via a company representative who will simply sign a secrecy agreement
RECORD KEEPING	
DO keep a written record of your REACH activities DO ensure retention of the agenda, minutes and other important documents	DO NOT believe that written communications are discouraged. On the contrary, if you are involved in an inquiry conducted by a competition authority your defence may rely heavily on accurate records prepared in the ordinary course of REACH activities which have far more credibility than after-the-fact oral explanations
NECESSARY VIGILANCE	
DO protest against any inappropriate activity or discussion (whether it occurs during meetings, conference calls, social events, or when working via electronic means – for example using a dedicated intranet). Ask for these to be stopped; dissociate yourself from these and have your position clearly expressed in writing, ideally in the minutes or in any case as soon as possible after the respective meeting or activity If a third party or trustee is used to facilitate the meeting, he/she should stay in the room, stop the inappropriate activity and record the incident	DO NOT pursue activities in breach of EC competition law
LEGAL ADVICE	
DO recognise and acknowledge that an issue or question may be complex and needs to be handled in a proper way	DO NOT presume that you know all about competition law rules just by reading this document. It is neither exhaustive nor a substitute for legal advice
DO ask for guidance at an early stage	DO NOT wait to seek appropriate legal advice and DO NOT ignore important questions as these will not be resolved by themselves
DO always remember that if you are uncertain DO NOT act. Ask and wait for the answer, before acting	

REACH DO & DON'T

Working in SIEF

Substance Information Exchange Forums (hereinafter “SIEFs”) are provided for in REACH. The aims of the SIEFs are to: (a) facilitate data sharing for the purpose of registration, between potential registrants, thereby avoiding duplication of studies; and (b) agree classification and labelling (for more details, see Article 29 of REACH and related Guidance on Data Sharing available on the ECHA web site http://ec.europa.eu/echa/reach_en.html).

- ✓ **DO** ensure, that the issue of sameness and identity check are handled by applying objective and transparent criteria when discussing the SIEF’s formation
- ✓ **DO** ensure that, before any discussion on the issue of sameness starts with other undertakings, each undertaking individually identifies its own substance(s) and documents its reasons for this approach.
- ✓ **DO** ensure that any deviation from this approach, following discussions with other undertakings, is clearly and objectively justified and documented.
- ✓ **DO** ensure that the final decision on sameness is clearly and objectively justified and those reasons documented.
- ✗ **DON'T** misuse this process to unduly exclude certain competitors.

Consortium membership/participation

Formation of a consortium is one way for companies to organise their co-operation under SIEFs. There are several possible forms of cooperation that companies can choose, consortia being just one of these that is often referred to. A consortium does not need to be a 1:1 image of a SIEF and may only involve some of the participants of a particular SIEF. It may also cover some of the activities to be conducted under REACH, or alternatively, it may cover more than one SIEF. However, it is generally advisable to open membership of consortia to undertakings that are registrants or potential registrants of the substance(s) to which the consortium relates:

- (i) manufacturers and importers;
- (ii) producers and importers of articles from which the relevant substance(s) are intended to be released;
- (iii) only representatives of (i) and (ii). In addition, the members of a consortium may consider inviting the following groups to participate in the consortium (this does not necessarily mean that such groups should ultimately be invited):
- (iv) downstream users;
- (v) data holders;
- (vi) other third parties that may have an interest in being involved in a given consortium.

When preparing membership/participation conditions, it is important to have written rules (including a well documented “decision making” process) which are:

- clear and transparent, avoid ambiguity; and
- based on objective criteria, applied in a non-discriminatory way, with a straightforward admission mechanism.

In addition, distinctions between different types of membership/participation may be made when relevant (e.g. full member, associate member, observer or expert).

✓ **DO** ensure that any distinctions between or within categories of members/participants as regards their rights are based on objective criteria. Nonetheless, there are limits to such distinctions, for example :

- ✗ **DON'T** base distinctions only on size/level of turnover. Note, however, that distinctions may be based on objective criteria, for example, between categories of consortium members that have greater obligations under REACH because they fall into higher tonnage bands;
- ✗ **DON'T** base distinctions purely on membership of a particular trade association, sector group or other body, as these are separate entities.

✓ **DO** ensure as a general rule that, where the membership of a consortium is limited, the rules of the consortium do not result in the total exclusion of access by non-members to data produced in the context of REACH. Such exclusion may, however, be justified in certain

circumstances to be interpreted in the light of REACH and related obligations on data sharing and EC competition law.

✓ **DO** ensure that the final decision on membership is clearly and objectively justified and the reasons for this decision are documented, in particular in cases where membership is refused.

✓ **DO** ensure, as a general rule, that membership rules are sufficiently flexible to allow new members to join at a later date.

✓ **DO** base resolution of membership disputes, where possible, on arbitration by an impartial body which applies objective criteria.

Costs

✓ **DO** ensure that costs are carefully calculated using a coherent and objectively justified methodology that is well documented.

✓ **DO** ensure that costs are only recovered for necessary data.

✓ **DO** ensure that costs are divided according to a transparent methodology that is well documented and that is applied in a non-discriminatory way, taking into account all relevant objective factors such as the level of access and right of use.

✓ **DO** ensure that any sensitive information supplied for the purposes of cost calculations - such as production volumes - are not directly or indirectly exchanged between participants but are channelled through an independent third party or trustee (See also below).

Data sharing

✓ **DO** ensure that differences in levels of access or ownership rights are objectively justified.

✓ **DO** ensure that differences in levels of access or ownership rights are reflected in divisions of costs and undertakings are not required to pay for access to information that they do not require for registration.

✓ **DO** respond promptly to data requests made legitimately under the REACH data sharing rules (which may not necessarily imply “immediate communication” of the relevant data, since – among others – a process of negotiation may occur).

✓ **DO** ensure that, when choosing between alternative sources of data, choice is based on objective criteria related to the quality of the data, taking into account in particular its reliability, relevance and adequacy. The processes followed in order to define and apply these criteria must be carefully documented.

Discussions on business related issues

✗ **DON'T** discuss business related issues that ought to be decided individually by each company. This applies for example to:

- changes in sales, supply, purchasing and marketing strategy resulting from REACH, including company business plans;
- possible de-selection of substance or use. This is to be defined on an individual basis only and there should not be any “collective de-selection”.

Exchange of information

Even if most of the information to be exchanged under REACH is unlikely to be problematic under EC competition law (because this information is mostly of a scientific or technical nature and does not enable competitors to align their market behaviour), certain information exchanged (such as volume information) can raise EC competition law issues. As a consequence:

✓ **DO** limit your exchanges of information to what is strictly necessary under REACH.

✗ **DON'T** exchange non-public sensitive information such as (non exhaustive list):

- Individual company prices, price changes, terms of sale, industry pricing policies, price levels, price differentials, price mark-ups, credit terms etc;
- Costs of production or distribution etc;
- Individual company figures on sources of supply, costs, production, inventories, sales, etc;
- Information as to future plans of individual companies concerning technology, investments, design, production, capacity, distribution or marketing of particular products including proposed territories or customers;
- Matters relating to individual suppliers or customers, particularly in respect

of any action that might have the effect of excluding them from the markets.

X DON'T exchange technical information if this exchange is not necessary under REACH, especially if this exchange of technical information may provide competitors with the ability to align their market behaviour.

✓ **DO** reduce the frequency of exchanges.

✓ **DO** exchange tonnage bands instead of individual more specific volume information. If not feasible, and specific volume information or other sensitive data needs to be communicated, use precautionary measures, e.g. organise such exchange via an independent third party or trustee (See below).

Use of an independent third party or trustee

If under particular circumstances, participants to a SIEF or consortium need to use sensitive individual figures (e.g. for the exchange of information or cost allocation) it is recommended to do so via an independent third party or trustee.

Who could be an independent third party?

A legal or natural person not directly or indirectly linked to a manufacturer/importer or their representatives. This independent third party may be for example an accountant, an auditor, a consultant, a law firm, a laboratory, a European/international organization, a neutral company, etc. The independent third party will not necessarily represent any participants but can be hired by them, for example to support certain activities. It is advisable that the independent third party signs a confidentiality agreement that will ensure that the independent third party undertakes not to disclose the information it receives.

The following activities can be facilitated by an independent third party for EC competition law purposes:

- ***Produce aggregated anonymous figures*** When participants need to refer to the aggregate of sensitive individual figures, the independent third party will request them to provide their individual input. The input will be collated and aggregated into a composite return that does not give the possibility of deducing individual figures (e.g. by ensuring that there will be a minimum of three participants). In addition, no joint discussion shall take place between this independent third party and the participants on the anonymous or aggregated figures. Questions should be addressed on an individual basis between each participant and the independent third party, who should not reveal any other data during such discussion.
- ***Calculation of cost allocation based on individual figures for cost sharing*** Where participants decide that all or part of their cost sharing should be based on their actual and individual figures (e.g. sales or production volumes), the independent third party will send a questionnaire to each of the individual participants to collect the relevant confidential individual information. It will then send to each participant an invoice corresponding to its particular amount only.
- ***Companies need to send sensitive individual information to the authorities, without circulating it to the other actors*** The independent third party would produce a non-confidential version of the same document for the remaining participants or the public that shall not contain sensitive information.

Meetings checklist

- Circulate the agenda in advance
- Stick to the agenda for the meeting discussions
- Have an accurate participation list (to be signed by each participant) and minutes
- Distribute this leaflet at the beginning of the first meeting (and to newcomers) and always refer to it and to EC competition law compliance at the beginning of each meeting
- Have detailed minutes
- Limit social contacts outside of meetings, and continue to abide by these guidelines at such social events, if any.

EC competition law compliance tips for companies involved in the REACH process

- Widely voice in your own organisation the need for having EC competition law compliance for REACH activities as well and adopt a robust system that you apply effectively;
- Include EC competition law compliance in your REACH management process, and include REACH related aspects in your competition law compliance system;
- Make sure that the participants in the REACH process have received adequate EC competition law compliance training;
- Strictly limit the participation of marketing and business people in SIEFs and consortia.

Appendix - articles 81 & 82 of the EC treaty

Article 81

1. The following shall be prohibited as incompatible with the common market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market, and in particular those which:

- (a) directly or indirectly fix purchase or selling prices or any other trading conditions;
- (b) limit or control production, markets, technical development, or investment;
- (c) share markets or sources of supply;
- (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

2. Any agreements or decisions prohibited pursuant this Article shall be automatically void.

3. The provisions of paragraph 1 may, however, be declared inapplicable in the case of:

- any agreement or category of agreements between undertakings;
- any decision or category of decisions by associations of undertakings;
- any concerted practice or category of concerted practices;

which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not:

- (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;
- (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

Article 82

Any abuse by one of more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market insofar as it may affect trade between Member States. Such abuse may, in particular, consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- (b) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

Annex 6: Inorganic Phosphates (IP) Consortium Agreement

(as valid at the time of signature of this SIEF Agreement Contract)

Consortium Agreement for the REACH Registration of Inorganic phosphates

pursuant to requirements of the European REACH Regulation

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Inorganic phosphates Consortium Agreement

This Agreement is signed between the following Members:

Note: conform to §I below (“Definitions”), one “Member” may cover a number of legal entities which are separate REACH Registrants (each paying its own Registration Fee), if and only if each of these legal entities is an “Affiliate” (see Definitions) of this Member, and in this case this Member is treated as a single unit in all aspects of this Agreement: one vote, one share in cost sharing, etc ... Affiliates of Members as at the date of Entry into Force are listed indicatively in [Annex 4](#).

Members

At the date of Entry into Force of this Agreement, six Initial Members

- 1) **BK Giulini GmbH**, a company with limited liability under German law (Gesellschaft mit beschränkter Haftung), whose registered office is at Giulinistrasse 2, 67065 Ludwigshafen am Rhein, Germany,

- and 2) **Chemische Fabrik Budenheim KG** a limited partnership under German law (Kommanditgesellschaft) whose registered office is at Rheinstrasse 27, D-55257 Budenheim, Germany,

- and 3) **FMC Foret S.A.**, a company with limited liability under Spanish law (sociedad anonima) whose registered office is at Plaza Xavier Cugat, 2, Edificio C, planta 3ª, Parque de Oficinas Sant Cugat Nord 08174 Sant Cugat del Vallés (Barcelona), Spain,

- and 4) **Prayon SA**, a company with limited liability under Belgian law (société anonyme) whose registered office is at Rue J. Wauters 144, B-4480 Engis, Belgium BCE 0405 747 040,

- and 5) **Thermphos International BV**, a private company with limited liability under Netherlands law (Besloten Vennootschap) whose registered office is at Europaweg Zuid, Haven 9890, 4389 PD Ritthem, The Netherlands,

- and 6) **CECA S.A.**, a company with limited liability under French Law (société anonyme) whose registered office is at 89, boulevard National, 92257 La Garenne-Colombes cedex, France

Preamble

Whereas the Members are (as defined in REACH) manufacturers and/or importers and/or only representatives with registered offices in the European Economic Area, or non-EU manufacturers represented by an only representative established in the European Economic Area, of one or more of the Substances listed in Annex 1 with registered head offices or affiliates in the European Union.

Whereas the Substances have phase-in status according to Article 3 (20) of REACH.

Whereas REACH imposes on EU manufacturers and importers an obligation to register the Substances as such, in preparations or in articles within the prescribed deadlines.

Whereas REACH requires, subject to certain exceptions, multiple registrants of the same Substance to share certain data and jointly submit part of the registration relating to the substance.

Whereas considering the effort required by the regulatory obligations the Members wish to increase the efficiency of generation of Information, to avoid to duplicate work and to reduce associated costs as well as to file a harmonised set of data for each of the Substances to the European Chemicals Agency.

Therefore, with a view to fulfilling their regulatory obligations for the Consortium Substances, the Members form by the present a Consortium (see Definitions) in respect of anti-trust and competition legislation, open to any other interested operators subject to the criteria defined hereunder, in order to achieve the Purpose (defined in § II), and in particular to:

- share Information, review the available data, identify data gaps, propose additional testing, and, subject to an agreement on a case-by-case basis, perform testing where necessary,
- compile and submit harmonised sets of data for Registration and Registration Dossiers,
- manage Registration and access to these REACH Registration Dossiers and to relevant data before and after the Date of Registration, in particular with relation to: other potential REACH Registrants of the Substances, potential REACH Registrants of other substances with potential read-across to/from the Substances, any other party wishing to access or use this dossier for REACH or for any other regulatory purposes,
- carry out other joint activities necessary for the REACH Registration of the Substances or relevant to or related to the Purpose.

NOTE: Pre-Registration remains the responsibility of each Member and is NOT carried out by or otherwise coordinated or managed by the Consortium

Copyright

This Agreement text is based on the model text developed by Cefic for its member companies and Sector Groups, and on the text developed by the Initial Members of the STPP Consortium, modified by the Members and by experts commissioned by these Members. This text is thus copyright and property of Cefic and of the Members, and no part of it may be copied or used for other purposes without written authorisation from both Cefic and from the Secretariat.

The signature of this Agreement by those Initial Members which are also the Initial Members of the STPP Consortium (see Definitions), constitutes explicit acceptance by each of them of the use of this text for this Agreement, and also of the use of accounting and consortium management tools developed for the STPP Consortium, in both cases without payment of compensation in any form, corresponding to the difficulty in evaluating the value of this knowledge and to the fact that the five of the beneficiary companies are the same.

The Members have agreed the following:

I) Definitions

The following terms and expressions shall have the meaning assigned to them below:

Administration Fee: see Annex 9;

Advantage Compensation Payment: see Annex 9;

Affiliates: any legal entity controlling, controlled by, or under common control with a Member, and which is (as defined in REACH) : a manufacturer and/or importer and/or only representative with registered offices in the European Economic Area, or a non-EU manufacturer provided that he is represented by an only representative established in the European Economic Area. 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. The indicative list of Affiliates as at the date of Entry into Force of this Agreement and conditions for updating this list are included in Annex 4;

Agency: the European Chemical Agency;

Agreement: this contract between the Members;

Annex: refers to an Annex of this Agreement;

Confidential Information: see §.IV;

Concerned Substance / Concerned Member : see § III.6

Consortium: the Members acting together within this Agreement as specified in § VI.1;

Consortium Entry Fee: see Annex 9;

Core Data: the data that Members gather, develop in common and agree to submit to the Agency pursuant to Article 11 paragraph 1 of the REACH Regulation, including the following data:

- § Classification and labelling of the Consortium Substances pursuant to section 4 of Annex VI of REACH;
- § Study summaries of the information derived from the application of Annexes VII to XI of REACH;
- § Robust Study summaries of the information derived from the application of Annexes VII to XI, if required in Annex I of REACH;
- § Proposals for testing where listed in Annexes IX and X of REACH;
- § Chemical Safety Report (including chemical safety assessment) as required under Article 14 of REACH, in the format specified in Annex I of REACH;
- § Guidance on safe use of the Consortium Substances as specified in section 5 of Annex VI of REACH.

it is noted that information on manufacturing processes, Substance impurities (see Annex 1.2) and confidential uses (see Annex 2.2) will be submitted separately in each company's specific Registration information;

Date of Leaving: see § III.3 and §III.4;

Date of Registration: date on which a Registration Number is received from the Agency by the Lead Company, following submission of the Registration Dossier;

Deadline for registration: the date by which (one of or a group of) Consortium Substances must be registered at the latest, as specified in Article 23 of the REACH Regulation, as applicable for the

Tonnage Band indicated in Annex 1 (or the highest of these Tonnage Bands for a Group of Substance, as defined below). Note, this Deadline is modified if the relevant Tonnage Band(s) are modified as specified in Annex 1;

Directly Concerned Substance / Directly Concerned Member : see § III.6

Dossier Contribution Cost: see Annex 9;

Entry into Force: date on which this Agreement has been signed by all of the signatories listed in § XV. If the signatories sign on different dates, this means the date of signature of the last of the signatories;

General Costs of the Consortium: all costs concerning the management and administration of the Consortium: secretariat, accounting, establishment, meeting costs ...

Identified Uses: of the Consortium Substances are those listed in Annex 2.1 of this Agreement, as referred to in Article 3, sub 26 of the REACH Regulation;

Indirectly Concerned Substance / Indirectly Concerned Member : see § III.6

Information: Studies, other scientific, statistical, commercial or technical data, including but not limited to Core Data and other data concerning composition, characteristics, properties and processes and uses, and any Information in any form made available to the Members by a Member (including its employees, Affiliates or agents) or by any third party, or generated by the Members individually or jointly. The term Information comprises relevant information that has been exchanged or generated pursuant to or in the course of this Agreement, or prior to the Entry into Force of this Agreement;

Existing Information: Information which was NOT generated by the activities covered by this Agreement, that is

- Information which existed prior to the Entry into Force and was not generated in the joint activities of the Initial Members during the phase of establishing this Agreement (late 2007, early 2008);
- Information which was generated by third parties, independently of this Agreement, before or after the Entry into Force;
- in particular, the Studies listed in Annex 5;

Governing Committee: see § VI.3;

Group of Substances: several (more than one) Consortium Substances which for which Registered is prepared together, either in a single Registration Dossier or in separate Registration Dossiers which are prepared through the same work plan and are based on mainly the same content.

Joint Submission: as defined in Article 11 of the REACH Regulation.

Key study: a study considered as the “key study” as defined in the Agency “Guidance for the Implementation of Reach, Guidance on Data Sharing, September 2007”.

Lead Company: for a Substance or Group of Substances, the Member who is responsible for submitting the Core Data to the Agency on behalf of the Members and their Affiliates pursuant to Article 11 (1) of REACH;

Letter of Access: as per models in Annex 10A and Annex 10B.

Member(s): the Initial Members (see below) as well as any (as defined in REACH) manufacturers and/or importers and/or only representatives with registered offices in the European Economic Area or non-EU manufacturer represented by an only representative established in the European Economic Area, of one or more of the Consortium Substances, which become signatories to this Agreement in future as specified in § III of this Agreement;

Membership: being a Member as defined above;

Initial Members: the Manufacturers / Importers / Only Representatives, as defined in REACH, of the Consortium Substances which are signatories of this Agreement (that is, all the signatories in § XV except the Secretariat) at the date of Entry into Force;

Voting Member: (representative of a) Member who is part of a given Committee or Task Force and is entitled to vote and not excluded from voting on a given issue;

Pre-Registration: see NOTE under Preamble;

Pro Rata Share: see Annex 9;

Purpose: as defined above under Preamble and in § II;

REACH: the REACH Regulation N° 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396 of 30.12.2006), and also all subsequent regulations, decisions, guidelines and rules defining the implementation of this Regulation;

Registration: REACH Registration of a substance, as defined in Article 10 of the REACH Regulation;

Registration Dossier: all Information, Studies, summaries of Studies, data, documents collected and collated for the REACH Registration of (one of or a group of) Consortium Substances and submitted to or held available to the Agency, and in particular including the Core Data (see above);

Secretariat: see § VI.7;

Study: reports, tests or evaluations in written or electronic form, including full study reports, summaries and robust study summaries as defined by REACH, relating to properties, exposure assessment, environmental or biological behaviour and/or impacts, and/or risk characterisation of the Consortium Substances and which are of relevance for Registration;

STPP Consortium: the Consortium for the REACH Registration of Sodium Tripolyphosphate (STPP), established by signature in May of an agreement between the five companies who are also the Initial Members of this Inorganic Phosphates Consortium

Substance: the Consortium Substances, for the purpose of this Agreement, are listed in Annex 1;

Task Force: a working group made up of the Members, as defined in § VI.2;

Technical Committee: see § VI. 5;

Tonnage Band: as defined in REACH, article 12 – see Annex 1;

and otherwise **any definitions specified in REACH**, in particular in Article 3 of the REACH Regulation, shall apply to this Agreement.

II) The purpose

II. 1) REACH Registration preparation

The Members of the Consortium undertake to cooperate and share human and financial resources in order to comply with the requirements of REACH for the Consortium Substances and in particular to pursue jointly the following objectives:

- (1a) define and agree the identity and the sameness of the Consortium Substances and their regulatory status
- (1b) define Groups of Substances (see Definitions)
- (1c) develop Core Data for the Consortium Substances fulfilling the REACH requirements applicable for the highest Tonnage Band(s) for a Substance (or Group of Substances) as defined in Annex 1, including where appropriate the following actions:
 - § Gather and assess available data on the Consortium Substances held by the Consortium Members or by third parties as well as data in the public domain (literature etc.);

- § Identify data gaps between the available data and the requirements in Annexes VI to XI of REACH;
 - § Where this is necessary (in view of data gaps for the Consortium Substances), appropriate and feasible, define and agree for which other substances the available Information might be relevant for Registration of the Consortium Substances, gather and assess available data and develop read-across;
 - § Assess opportunities for exposure-based waivers;
 - § Subject to obligations under Art. 30 of REACH Regulation carry out testing to close the data gaps identified in relation to Annexes VI to VIII of REACH taking into account Annex XI;
 - § Develop testing proposals as required according to Annexes IX and X of REACH taking into account Annex XI;
 - § Acquire where necessary Information, and appropriate access rights to this Information, from third parties;
 - § Prepare Study summaries and robust Study summaries, where appropriate;
 - § Develop for the Consortium Substances uniform classification, and where necessary uniform labelling, conform to applicable legislation;
 - § Coordinate the compilation and the submission of the Registration Dossiers for the Consortium Substances by the Lead Companies;
 - § Gather information on use and exposure categories of the Consortium Substances, conditions of use and exposure to humans and environment for the Identified Uses of the Consortium Substances;
 - § Perform a risk assessment according to scientific principles and regulatory guidelines with the intention to show a safe production and use of the Consortium Substances for the Identified Uses;
 - § Initiate testing where a higher tier risk assessment is needed to demonstrate safe manufacturing, transport, handling and use of the Consortium Substances in for the Identified Uses.
- (2) prepare Registration Dossiers for the Consortium Substances, and prepare all data and information necessary for these purposes
 - (3) Mandate the Lead Companies to carry out Joint Submissions on behalf of all the Consortium Members and of their Affiliates.
 - (4) Coordinate the submission to the Agency of the Core Data by the Lead Companies at least three months before the Deadline for Registration as defined in Definitions.
 - (5a) Continue the cooperation between Members relating to Registration of the Consortium Substances and consequences of this Registration, after Registration, and in particular during the dossier evaluation according to Title VI of the REACH Regulation, including supervising the performance of the testing proposals as authorised by the Agency.
 - (5b) Address legal and technical issues in relation to this Agreement and to the Purpose.
 - (6) Prepare and manage Information relevant to the Registration of the Consortium Substances, relevant to participation in Substance Information Exchange Forums (SIEF) for the Consortium Substances, and relevant to answering enquiries from participants in SIEFs for the Consortium Substances and for other substances ; including concerning possibilities to apply read-across approaches and (Q)SAR models both to and from other substances, and in particular:
 - § Coordinate relations between the Members and other companies in the Consortium Substances SIEFs concerning all issues relating to Registration of the Consortium Substances, or concerning the use of Information developed or collected through this Agreement and/or contained in the Consortium Substances Registration Dossiers developed through this Agreement;
 - § Coordinate relations between the Members and companies, in SIEFs for other substances, who wish to use Information developed or collected through this Agreement and/or contained

in the Consortium Substances Registration Dossiers developed through this Agreement, for read-across for REACH Registration of other substances or for any other purposes;

- § Coordinate relations between the Members and other companies holding information useful for the Purpose;
- § Look for and develop opportunities to obtain compensation for the Information collected and developed through this Agreement in exchange for use of this Information by third parties for Registration of the Consortium Substances, of other substances (read-across) or for other purposes.

- (7) Exercise the rights to Information and Studies in accordance with sections IV and V of this Agreement.
- (8) Manage and defend the rights of access, for use in REACH, other regulations or for any other purpose, to the Consortium Substances Registration Dossiers and to other Information developed through this Agreement, including defining, collecting and distributing payments for the purchase of these access rights.
- (9) Where this appears as preferable, for reasons of cost, reliability, efficiency or otherwise, to negotiate access for the Consortium Members to Studies, Information and/or complete Registration Dossiers developed by other organisations (company, consortium, other ...) for Consortium Substances, rather than the Consortium developing these itself, or to work jointly with other organisations to develop Information and Registration Dossiers

II. 2) Management of access to the REACH Registration Dossiers

See § V.2

III) Membership

III. 1) Admission of new Members to the Consortium

1. All conditions to access the Consortium, and in particular all financial conditions, shall in all cases be fair and transparent. Membership shall be open to any applicant who fulfils the Membership criteria defined in this Agreement (in particular the Definition of Members in § I) and is committed, in writing, to pay the financial contribution as defined by this Agreement.

The financial conditions of Membership of the Consortium are defined in Annex 9

2. Application for Membership shall be sent in writing and to the Secretariat which shall then submit such application to the next meeting of the Governing Committee, which shall be called within a reasonable delay and generally if practical within approximately two months. The Parties agree that the acceptance of a new Member is subject to the decision of the Governing Committee (as specified in § VI.10), it being understood that such consent cannot be unreasonably denied.

The Membership application shall specify and justify for which Consortium Substances for which the applicant is Directly and Indirectly Concerned.

In any case, the acceptance of a new Member cannot be denied should the applicant fulfil the following objective requirements:

- a) at the time of requesting Membership, **be Directly Concerned by** (see § III.6) at least one of the Consortium Substances, or be an "Only Representative" of such a company
- b) and have committed in writing to fulfil all the conditions of this Agreement, and in particular the financial conditions indicated in Annex 9

It is here noted that, by Article 7 of the REACH Regulation and according to Tonnage Bands, and except where exempted, under "importer of the Consortium Substances", are included importers

of products or formulations containing one or more of the Consortium Substances, where the substance “is intended to be released under normal or reasonably foreseeable conditions of use”.

Note: access to the Registration Dossiers, data and information developed under this Agreement is possible, without becoming a Member of the Consortium, according to the conditions specified in § V.3

3. Any decision refusing Membership shall clearly state the reasons why the Membership is not granted. The applicant whose application was turned down has the right to submit its observations in writing to the Governing Committee, which shall have to review the observations and reply in writing within a reasonable delay and generally if practical within approximately two months of receiving the observations. If there is disagreement and an amicable solution cannot be found, then the applicant shall be invited to submit the issue to arbitration as provided in § XIV.
4. A new Member shall commit in writing to the terms and conditions as set out in this Agreement and shall then receive an Access Letter for Directly Concerned Substances (and for Indirectly Concerned Substances for which appropriate financial payment or commitment is made) according to the model in Annex 10 A to this Agreement. As from receipt by the Secretariat of all payments due as defined in this Agreement (and in particular in Annex 9), the new Member shall have the same rights and obligations as any existing Member.
5. Membership explicitly implies and necessitates acceptance, by the Member, to make available for the Purpose all relevant Information concerning all Consortium Substances in its ownership and of which it has information, as specified in § V.1 of this Agreement, unless such information is subject to confidentiality which cannot be waived by such Member.

III. 2) Transfer of membership

1. A Member shall be entitled to transfer Membership including all its rights and obligations under the Agreement to a third party subject to:
 - § requesting the transfer in writing to the Secretariat, specifying clearly the identity of the new Member,
 - § the new Member must meet the Membership criteria defined in this Agreement,
 - § decision of the Governing Committee (as specified in § VI.10)
 - § written acceptance by the new Member of the conditions for Membership defined in this Agreement.

The decision procedures and deadlines are as specified in III.1

2. The consent of the Governing Committee shall not be required in the case of a transfer of Membership in the context of restructuring of legal persons affiliated to or within a Member composed of a group of companies, or in the case of the transfer of ownership of a Member to a new legal entity (take-over, merger, or similar).
3. The transfer by a Member of a part of its rights or obligations, including financial claims, to a third party shall not be permitted, unless decided by the Governing Committee.

III. 3) Termination of Membership

1. At any time, a Member can terminate its Membership in the Consortium if circumstances making the continued Membership in the consortium disproportionate or unjustified have durably occurred provided that the Member fulfils all of its financial obligations to the Consortium and to the other Members. In this case, the Member must provide three months prior written notice to the Secretariat.

2. At any time, a Member can terminate its Membership in the Consortium without justification, provided that it has fulfilled all of its financial obligations as specified in Annex 9. In this case, the Member must provide one year prior written notice to the Secretariat
3. The Date of Leaving is the date of expiry of the written notice period specified above, which runs from the reception of the notification by the Member to the Secretariat of the termination of Membership.

III. 4) Exclusion

1. Any Member, that
 - § does not meet durably the Membership conditions of this Agreement,
 - § fails to make payments due within the delay specified in Annex 9 and fails to correct this situation within 15 days of receiving a written reminder from the Secretariat,
 - § or commits a serious material breach of this Agreement that has not been repaired within 30 calendar days after formal notice has been sent by the Secretariat by registered mail to the Member concerned,
 - § or does not durably comply with the provisions of this Agreement such that this non-compliance has affected the effectiveness of the Consortium in achieving the Purpose, or has affected the functionality and reliability of the Information collection process, and/or has caused damages to the other Members,may be excluded from the Consortium, as follows, without prejudice to any other rights the Members may have against the defaulting Member.
2. The defaulting Member may be excluded by decision of the Governing Committee (as specified in § VI.10) and on the basis of an objective and documented justification in compliance with Articles 81 and 82 of the EC Treaty. The defaulting Member shall have the right to present its defence beforehand. The decision of the Governing Committee shall be immediately notified to the defaulting Member by registered mail.
3. The non-defaulting Members will share any damages suffered by the Consortium as a result of the defaulting Member, according to the cost sharing rules indicated in Annex 9, and the Consortium (as specified in § VI.8) shall coordinate any legal recourse against the defaulting Member on behalf of the non defaulting Members.
4. The Date of Leaving will be the date of receipt by the Member of the registered mail specified above.

III. 5) Common provisions on termination and exclusion

1. Subject to the conditions specified hereafter, termination or exclusion of a Member (both as above) are without prejudice to the rights and obligations of the Member that is terminating its Membership or is excluded (hereafter **Member leaving**) which have accrued up to the date of effective termination or exclusion provided that the Member leaving meets all payment obligations for the period of Membership and payment obligations due after ceasing to be a Member as specified in this Agreement. The Member leaving shall have no further rights to any results arising out of this Agreement in respect of which it has not fulfilled its financial contribution or to any compensation from new Members that have subsequently joined the Consortium for information and Studies developed before cessation of its Membership.
2. The other Members shall continue to be entitled to make use of the Information made available by the Member leaving on the conditions specified in this Agreement and provided that the Member leaving has been duly compensated under the conditions defined in this Agreement. Any recoverable damages suffered by the remaining Members as a result of the defaulting Member's actions shall be off set against any compensation payable to the Member leaving.

3. The Member leaving shall have no claims for reimbursement of any financial contribution to the Consortium.
4. The Member leaving shall remain liable for the activities undertaken under this Agreement for the period of its Membership, and for ongoing activities at the time of leaving as specified in Annex 9.
5. In the event of termination or exclusion, the rights and obligations resulting from this Agreement cease to exist, to the exception of, as defined in this Agreement, confidentiality commitment and data ownership, liability as defined in § XIII.2, settlement of disputes, and any outstanding financial obligations. In particular, the confidentiality conditions specified in § VI remain applicable to the Member leaving.
6. In particular, leaving the Consortium does not negate or remove the entitlement of the Member leaving to continue to use for itself and for its Affiliates only, under the conditions defined in this Agreement, those parts of the Registration Dossiers and other Information which were developed by the Consortium during the period in which the leaving Member complied with its financial obligations as defined in this Agreement and/or for which the leaving Member contributed financially under this Agreement.
7. A Member having left the Consortium cannot sell or transfer in any way to third parties, other than its Affiliates, without approval from the Consortium, any Information developed by the Consortium, the Registration Dossiers developed by the Consortium, nor any rights of access to these.

III. 6) Members Directly and Indirectly Concerned for Substances

The following definitions apply:

- **Directly Concerned Member** (for a Consortium Substance) : a Member which is at the time a manufacturer or importer into the EU of the Substance or is susceptible to become so in the future, and which has committed to contribute to the cost of Information and the Registration Dossier developed for the Substance by the Consortium;
- **Directly Concerned Substance** (for a Consortium Member) : a Substance for which the Member is a Directly Concerned Member as above;
- **Indirectly Concerned Member**: (for a Consortium Substance) : a Member which is NOT a Directly Concerned Member for the Substance but has committed to contribute to the cost of Information developed for the Substance by the Consortium because of interest in this Information for the purposes of read-across for Reach Registration or for other regulatory purposes for other Consortium Substances or for other substances not covered by the Consortium;
- **Indirectly Concerned Substance** (for a Consortium Member) : conversely as above;

A list of Directly and Indirectly Concerned Members for each Consortium Substance is maintained by the Secretariat, and can be consulted at any time by any Member. This list is updated by the Secretariat whenever a Member transmits information demonstrating that their status has changed for any Substance. The list is also updated automatically by the Secretariat whenever the Consortium's activities or decisions implicitly result in a Member becoming or ceasing to be Indirectly Concerned by a Substance (conclusions concerning read-across, decisions to carry out joint studies ...) and whenever a Member wishes to use Information for a Substance (Indirectly Concerned). When a Member ceases to be Directly Concerned by a Consortium Substance (or Substances), or ceases to be Indirectly Concerned by a Substance (or Substances), the implications for the financial and legal obligations of the Member are as for a Member Leaving, in particular as described in § III.5 (rights to Information, financial obligations, etc, applied to the studies, costs and information relevant to the Substance(s) concerned and applied to the calculation of the Pro Rata Share) and § IV Confidentiality.

Any questions or disagreements regarding the status of Members as Directly or Indirectly Concerned or not for any Substance shall be decided by the Governing Committee as specified in § VI.

As an illustrative example: a Member may inform the Secretariat that they cease to be Directly Concerned by a Substance (subject to the financial and legal obligations as indicated above), if the Member decides to join another consortium to develop the Registration Dossier for the Substance, or decides to purchase the Registration Dossier developed or being developed by another consortium, or if the Substance is deemed to be not subject to REACH Registration requirements, or if the Member no longer wishes to Register the Substance. If the Consortium itself decides to not pursue completion of a Registration Dossier for a Substance or Substances, preferring instead to refer Members to another consortium working on this Substance(s), then these Substance(s) will be removed from the list of Consortium Substances (Annex I) and cost shares etc. will be recalculated as described in § III.5.

It is noted that even if companies are not directly involved with a particular substance, they will nonetheless be kept up to date on the activities, studies, information collected and Registration Dossier preparation for the Substance, except where this concerns confidential information, in particular in order to facilitate possible sharing of information, read-across, joint organisation of activities, etc within the Consortium.

IV) Confidentiality

1. Subject to the conditions below the Members, unless compelled by law or a legally empowered authority, or unless legal disclosure requirements apply, undertake to keep confidential, as specified below, any information other than as specified hereafter, which is:
 - § directly or indirectly belonging or relating to other Members,
 - § disclosed by another Member pursuant to or in the course of this Agreement,
 - § or jointly developed, obtained from a third party or otherwise resulting from this Agreement.Such information, except as specified in § IV.7 and § IV.8, is termed “**Confidential information**”.
2. Each Member shall advise immediately the other Members in writing of any disclosure or misuse by any Member or a third party of Confidential Information, as well as of any request by competent authorities relating to the disclosure of such information.
3. Disclosure of results in Studies as required for legal and/or regulatory purposes including the REACH Regulation, shall only take place by the Members in a form (for example short summaries where possible) reflecting the minimum information required to be disclosed.
4. The above restrictions do not apply to the Member who has provided or who owns the Confidential Information.
5. Members may use Confidential Information only for the Purpose, and only for Substances for which they are Directly or Indirectly Concerned, or otherwise as permitted under or in accordance with this Agreement, or as authorised by the owner of the information.
6. Members will disseminate Confidential Information to their employees, Affiliates or external experts and/or consultants 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 Member shall have in place policies and procedures to ensure the confidentiality of information, computer files and documents, 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.
7. The obligations specified above shall not apply to Information for which the receiving Member can reasonably demonstrate that such information:
 - a) was known to the receiving Member 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;

- c) becomes non-confidential through disclosure by sources other than the disclosing Member, having a right to disclose such Information,
 - d) was independently developed by the receiving Member without access to the disclosing Member's Information, as evidenced by documentary records,
 - e) becomes subject to disclosure to governmental agencies or other authorities which then render the Information non confidential.
8. Specific items of information shall not fall within any exception merely because they are combined with other 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.
 9. Affiliates and external experts and/or consultants (if bound by a confidentiality agreement) of any Regular Member are not regarded as third parties for the purpose of this § IV. Each Member assumes full responsibility for compliance by its employees, Affiliates or external experts and/or consultants with the requirements of this Agreement in the respect of any Information received by this party, unless the party in question is also a signatory of this Agreement.
 10. In the event of non-compliance with the obligations set out in this § IV the Members whose Information is disclosed shall have the remedies available under the applicable law notwithstanding the stipulations contained in this Agreement.
 11. The duration of the above confidentiality obligations is defined in § XIII.

V) Ownership of data

V. 1) Obligation to make available data

1. Within 6 weeks of a new Member joining the Consortium, it shall make available to the Secretariat a list of all Information it owns, has access to and/or has knowledge of, which is relevant to the Purpose for any of the Consortium Substances (even if the Member is not Directly or Indirectly Concerned by the Substance), including Information concerning the uses and conditions of use of the Consortium Substances for which the Member is Directly Concerned within the categories of Identified Uses (Annex 2). The obligation to list the Information applies even if the Information itself is confidential, unless the simple listing of the knowledge would be contradictory to confidentiality conditions which the Member cannot waive. This list can take the form of indicating only Information which is additional or new to that already listed by the Secretariat, or for which the new Member has ownership or access rights additional to the rights already available to the Consortium. The Secretariat shall make the necessary arrangements for the review of this Information by the Technical Committee.

It is noted that the Initial Members of the Consortium have already fulfilled this obligation prior to the Entry into Force of this Agreement, see Annex 5 ("Existing Studies").

2. All Members agree to make available to the Secretariat, to the other Members and to third parties purchasing access to all or to part of the REACH Registration Dossiers developed within this Agreement, according to the conditions defined in this Agreement, and in particular in Annex 8 (Study valuation), Annex 9 (Financial Rules) and Annexes 10A and 10B (Model letters of access):
 - § all Existing Information and any new Information for which they are Directly or Indirectly Concerned relevant for the Registration of the Consortium Substances, for which they have or come to have ownership or right of access entitling them to do so, and which are relevant for the Purpose,
3. All Members agree to inform the Secretariat and the Lead Company of any contact or communication from third parties wishing to access any of the Registration Dossiers developed under this Agreement, or Information therein or developed by the Consortium, or otherwise

wishing to share Information, join or cooperate with the Consortium, or develop other relations with the Consortium

V. 2) Ownership rights and uses of Information

The following clauses are subservient to any requirements specified by REACH, by its official Guidance documents, by the Agency, and to any other applicable European or international regulations or laws:

1. Members will be entitled to use and refer to the Registration Dossiers developed within this Agreement **for the Substances for which they are Directly or Indirectly Concerned**, except as specified hereafter, **for purposes of REACH Registration of the Consortium Substances only**.

Members will however be entitled to use, for their own use and the use of their Affiliates, Information newly developed by activities carried out within this Agreement, to which they contributed financially as Directly or Indirectly Concerned Members, **for all regulatory or other purposes**.

Unless specifically agreed otherwise with the owner, Members will be entitled to use Existing Information collected within this Agreement (owned by a Member or a third party) concerning substances for which they are Directly or Indirectly Concerned for purposes of REACH Registration of the Consortium Substances only.

2. The above does NOT affect the copyright and ownership of Studies and data developed outside this Agreement by Members, owned by Members or by third parties.

Members wishing to use such Information, must ensure that they have the necessary authorisation from the data owners, unless this authorisation for the relevant use is obtained and covered by an agreement between the data owners and the Consortium.

Any intellectual property or ownership rights to any Existing Information independently developed by a Member or any third party and made available to the Members in accordance with this Agreement shall remain unaffected by this Agreement. The (other) Members shall have for an indefinite period of time the non-transferable right to use the Information for the Purpose, including the right to refer to the full Study report, provided that they share in its cost in accordance with the cost allocation method defined in this Agreement.

The Study made available by a Member or a third party to other Members may not be sub-licensed or otherwise made available to third parties without prior written approval of the Member who provided the Study.

The Member who provided a Study to other Members may extend, by agreement in writing, at a cost or free of charge, their right to use or refer to the Study for other purposes.

Existing Studies which are owned by several Members or by one or several Members and one or several third parties can only be made available to the other Members with the prior written approval of all owners unless otherwise agreed in writing among the owners of the Study.

3. Conditions concerning third parties wishing to use the REACH Registration Dossiers developed within this Agreement, or a part of this dossier, and/or any other Information developed within this Agreement are defined in § V.3.
4. The Members mandate the Governing Committee (as per definition of powers in § VI.8) to manage on their behalf all such authorisations, and the Secretariat to collect and to redistribute appropriately all payments relating to these authorisations.
5. Any Information generated or developed within this Agreement shall be owned jointly by the Directly and Indirectly Concerned Members provided that the individual Members have contributed to the costs thereof in accordance with the cost allocation method defined in this Agreement. Each of the joint owners shall obtain a copy of the full Study reports. The Information referred to in the first sentence may be used by the Members who have contributed to the costs

thereof for the Purpose and also for fulfilling their own other regulatory and legal requirements (under REACH and other regulations, European, national or other regulations, for the Consortium Substances and for other substances), but such Information shall not, for the period defined for duration of confidentiality under § XIII, be sold, licensed or otherwise made available to third parties by any Member unless as decided by the Governing Committee (as specified in § VI.10)

6. Affiliates of a Member shall have the same rights on Information under the same conditions as the Member to which they are affiliated.
7. Neither this Agreement nor any disclosure of Information shall be deemed by implication or otherwise to vest in one Member any present or future rights in any patents, trade secrets or property rights in data belonging to another Member and no licence is granted except as explicitly stated in this Agreement.

The conditions of access to Information are further specified in Annex 8.

V. 3) Third party access to Information

Third parties may be granted rights to use or refer to the parts or totality of the Registration Dossiers, or to any other Information generated by or owned by the Consortium Members jointly, including any Information for which the use granted by its owner to the Consortium Members jointly enabled such transfer of rights, subject to the financial conditions defined in Annex 9.

In particular, any potential REACH Registrant of one or more of the Consortium Substances, including the applicants for Membership whose application was refused, may request a right to use or to refer to the parts or all of the Registration Dossiers to the extent the Members of the Consortium are entitled to do so.

Where granted, such right will be non-exclusive and non-transferable.

Access will not be granted to data not owned by the Members, unless this has been agreed with the original owner.

Subject to the terms of this Agreement, the Governing Committee shall take a decision (as specified in § VI.10) whether or not to grant such rights to a third party, for which Consortium Substances the rights are granted, and determine the amount of compensation payable in accordance with Annex 9. This decision will be taken without undue delay.

The terms and conditions of access will be set out in each case specifying the Substances concerned and the exact scope in accordance with the model Letter of Access attached in Annex 10B.

VI) VI. Organisation

VI. 1) Legal personality

This Agreement and the cooperation contemplated herein shall not constitute or be deemed to constitute a legal entity between the Members nor make a Member the agent or representative of another Member unless expressly stated otherwise.

In its external relations, the Consortium will not act under its own name but as a community of all its Members. The Members hold the rights and obligations of the Consortium jointly.

VI. 2) Organisation

The bodies of the Consortium will be the Governing Committee and the Technical Committee.

The Consortium shall be governed by the Governing Committee.

In order to fulfil the Purpose, the Governing Committee shall be empowered to set up and define the composition, mandate, duration and rules of any necessary Task Forces. In particular, Task Forces may be established to address issues concerning only one or some Consortium Substances or Group or Groups of Substances, in which case such Task Forces will only include Directly and Indirectly Concerned Members.

A Secretariat may be appointed, for as long as is decided, as defined below.

Voting and quorum rules for the different committees are specified in § VI.10

VI. 3) Governing Committee

The Members of the Consortium shall meet in the Governing Committee in order to take decisions on the overall organisation of the Consortium. The Governing Committee shall have all powers necessary to ensure that the Purpose is achieved and to take decisions on all issues resulting from this Agreement.

The Governing Committee shall consist of one representative per Member.

The Governing Committee shall jointly elect a Governing Committee Chairperson, for a period of two years renewable, preferably from one of the Lead Companies.

Meetings of the Governing Committee shall be convened at least once every six months up until completion of REACH Registration of the Consortium Substances, and then at least once every three years or whenever is necessary, to review, on the basis of the technical and financial progress reports of the Secretariat, the progress and developments of the Consortium's work and budget, and more generally all Consortium activities and management issues, or other questions relating to the Purpose.

Meetings of the Governing Committee will also be convened if requested by the majority of the Members, whenever the agreed deadlines or estimated budget are overrun and/or when extraordinary circumstances occur.

The tasks of the Governing Committee include amongst others the following:

- § Appointment or ending the appointment of a Secretariat as specified below in § VI.7;
- § Directing the Technical Committee;
- § Establishing defining and directing Task Forces as required and appropriate;
- § Decisions on funding, scope and matters of policy;
- § Deciding if for some Substance(s) these should be removed from the Consortium list of Substance (Annex 1) or if access to a Registration Dossier developed by another organisation should be purchased or Information and/or Registration Dossier(s) developed jointly with another organisation
- § All decisions concerning the financial contributions of Members, including new Members and Members leaving the Consortium or excluded;
- § Decisions on the working and finance plan, including outline test plans and strategies for purchasing access to third party Information to fill data gaps;
- § Management of financial resources of the Consortium, including deciding budgets, examining and approving accounts, collecting funds and overseeing accountancy and budgets;
- § Deciding, conform to Annex 9, which costs engaged by Members, the Secretariat and other parties are included in the budget subject to the cost sharing;
- § Coordination and supervision of activities of the Lead Company;
- § Mediation in cases of disagreement or disparities within the Technical Committee;
- § Modification of any provision as well as the Annexes of this Agreement;
- § Adaptation of this Agreement in light of legislative and technical adaptation of the REACH requirements (in particular the establishment of the SIEF) or Entry into Force of the Globally Harmonised System;

- § Decision regarding admission, withdrawal and exclusion of Members;
- § Decisions regarding access rights to Information and to the Registration Dossiers, including deciding contract and other conditions and fixing payments in accordance with Annex 9 ;
- § Competition law compliance ;
- § Defining rules and modalities concerning communication between all parties involved.

VI. 4) Not applicable

VI. 5) Technical Committee

The Technical Committee shall consist of one representative per Member, unless one or more Members do not wish to be represented on this Committee.

The Technical Committee shall jointly elect a Technical Committee Chairperson who shall be responsible for the organisation of meetings and who shall report to the Governing Committee. If not, this role will be ensured by the Governing Committee Chairperson. Meetings of the Technical Committee shall be convened by its Chairperson when necessary to review the progress according to the work schedule and the engagement of costs.

The tasks of the Technical Committee include as necessary and appropriate, amongst others, the following, in all cases subject to respecting the general objectives fixed by the Governing Committee and subject to respecting the budgets decided by the Governing Committee:

- § Defining and overseeing the work of the Secretariat;
- § Defining and overseeing the technical work;
- § Defining Groups of Substances
- § Appointment of external consultants to perform technical and scientific tasks;
- § Delegating and directing sub-tasks;
- § Determining the value of Information;
- § Estimate financial resources required to comply with REACH requirements;
- § Proposing work plans and outline test plans to the Governing Committee, ensuring execution and quality of results of approved work and test plans;
- § Decisions to implement or reject testing proposals;
- § Within the outlines and strategies decided by the Governing Committee, decisions on data collection concerning the Consortium Substances, evaluating the Consortium Substances related Information to be shared, as well as completion of data gaps in compliance with the legal requirements laid down by REACH regarding data sharing, including decisions on purchase of access to third party Information where necessary;
- § Overlooking the progress and the budget management, reporting deviations to the Governing Committee;
- § Supervising preparation of the Registration Dossiers, including the determination of data gaps, waivers and surrogate data;
- § Approval of the Registration Dossiers and Core Data to be submitted jointly to the Agency (cf. in particular Article 11 of the REACH Regulation) and determination of the Information which shall be subject to a request for confidentiality according to Article 119 of the REACH Regulation;
- § Supervising preparation of the Chemical Safety Report (CSR), if required;
- § Collecting classification and labelling data from all Members and preparing harmonised classification and labelling in accordance with the Global Harmonised System of classification and labelling of chemicals (GHS);

VI. 6) Not applicable

VI. 7) The Secretariat

A Secretariat may be appointed by the Governing Committee, which can also terminate the appointment of the Secretariat. A Secretariat may be appointed as from the Entry into Force by designation in § XV of this Agreement and its signature by the Secretariat.

The conditions of the appointment of the Secretariat are specified in a Consortium Management Service Agreement with the Secretariat which is either signed by the Secretariat and all Member companies or signed by the Secretariat and the Governing Committee Chairperson after approval by the Governing Committee (as specified in § VI.10).

The Secretariat is accountable to the Governing Committee.

The Secretariat must be fully independent from all Members (that is: not under legal or financial control of any Member, no significant part of its capital or control held by any company holding significant capital or legal control in a Member ...).

If, at any time, no Secretariat is appointed, or if the Secretariat is not operational, then its tasks and its role as indicated throughout this Agreement will be assumed by the Governing Committee Chairperson, who may subcontract part or all of these tasks under the conditions specified below.

The Secretariat may subcontract part of its tasks to other persons or organisations, subject to prior approval of the Governing Committee (as specified in § VI.10) specifying the identification of the subcontractor and the nature and conditions of the tasks subcontracted, including the legal liabilities of the subcontractor, and subject to the subcontractor being also independent from all Consortium Members.

The legal liabilities of the Secretariat are as specified in § XII.

The Secretariat conducts all normal business of the Consortium, subject to the decisions of the Governing Committee and Technical Committee, and is responsible for daily management and external representation of the Consortium and shall in this regard deal particularly with the following:

- § Proposing the working and finance plan;
- § Organising and convening meetings, distribution of agenda and making minutes, archiving, and distribution of minutes and other information;
- § Keeping archives for a minimum period of twelve years and notifying the Members before any archive will be disposed of;
- § Ensuring compliance with competition laws;
- § Handling where necessary for the Purpose of confidential data (production volumes, markets, confidential uses, etc.)
- § Supervision of external consultants and experts;
- § Follow up the legislative and technical development of REACH and inform the Technical Committee and Governing Committee about relevant new developments;
- § Follow up of progress in the technical activities of the Consortium and reporting on the technical and financial aspects to the Technical Committee and to the Governing Committee;
- § Provision of technical and administrative support for the Technical Committee and for other Consortium activities;
- § Providing guidance for, coordination of and carrying out of guidance for data collection concerning the Consortium Substances, and proposing purchase of rights of access to Information where necessary for the Purpose;
- § Performing sub-tasks as agreed by the Technical Committee;
- § Processing of purchase orders and contracts for Studies in line with the approved test plans and for other work for Consortium activities;

- § Preparing Governing Committee decisions on rights of access of third parties to the Registration Dossiers and other Information, including proposing conditions and appropriate levels of payments in accordance with Annex 9;
- § Maintaining a list of decided Groups of Substances, Lead Companies for each Consortium Substance, status of Registration, Directly and Indirectly Concerned Members for each Consortium Substance, highest Tonnage Bands
- § Keeping track on ownership, access rights, costs and values of Information (developed within this Agreement, owned by Members or third parties and used for the Purpose), keeping records of compensation due for access rights and other payments due, keeping records of the costs, value and ownership rights of Information generated;
- § Keeping an up-dated list of third parties having access rights to Information and to the Dossiers developed by the Consortium;
- § Handling financial matters including preparing budgets, collecting payments due and making payments, invoicing, managing collected funds, preparing accounts;
- § Calculating cost shares and other payments due by and to Members, compensation and payments due by and to third parties;
- § Keeping an up-dated list of Members, Affiliates and their representatives;
- § Communicating to organisations, associations and potential new Members.

VI. 8) Delegations of powers and representation to third parties

The Governing Committee Chairperson is empowered to represent the Members and to sign all documents, contracts and agreements which are in compliance with valid decisions of the Governing Committee, except the following acts for which the Lead Company is empowered to represent the Members Directly Concerned by the relevant Consortium Substance(s) and to sign:

- all acts directly concerning the REACH Registration of the Consortium Substances, including joint submission of the relevant Information, and including dealing with any regulatory consequences of Registration of the Consortium Substances (SIEF, ECHA questions ...);
- Letters of Access or other documents concerning transfer of access rights to the REACH Registration Dossiers for the Consortium Substances, Information contained within this or developed or obtained within this Agreement.

The Governing Committee may empower the Technical Committee Chairperson to sign all documents, contracts and agreements on behalf of the Consortium Members which have been approved by the Technical Committee and which are covered by the powers and tasks of the Technical Committee.

The Governing Committee may empower the Secretariat to sign all documents on behalf of the Consortium Members, in place of the Governing Committee Chairperson and of the Lead Company, subject to the following conditions:

- In this case, the Secretariat shall represent the Members for all acts necessary to achieve the Purpose and shall fully and timely comply, on behalf of Members, with the relevant provisions of REACH in this respect;
- the Secretariat may represent the Members in the SIEF if this is possible under the SIEF operating rules and information tools to be established by the Agency. If this representation is not entrusted to the Secretariat, then the Lead Company may be designated to represent the other Members in the SIEF.

Only the Members who are required to submit a Study or data, according to their Tonnage Band for given Consortium Substance(s), shall be listed as parties to the relevant agreements and actions, and be liable for the expenses incurred.

Any legal suits shall be brought or defended by the Governing Committee Chairperson or a Member or the Secretariat, after authorisation by the Governing Committee as specified in § VI.10. A status report on such litigation shall be presented to the Governing Committee annually.

VI. 9) Working language

The working language of all Committees, Task Forces and other activities under this Agreement shall be English.

VI. 10) Rules on voting, quorum and meeting organisation

Unless specified otherwise in this Agreement, the following rules apply to meetings and to the decision making of the Governing Committee, Technical Committee and any Task Forces.

1. General rules concerning meetings

Meetings may take place in person, by telephone, video or webcam conferences or similar.

Each Member shall name to the Secretariat the person who is its representative in the Committees and Task Forces. The Member may name a substitute or a different representative before the start of a meeting. These persons must be salaried staff or legal representatives of the Member or of its Affiliates.

The Member's representative may be accompanied by other salaried staff or legal representatives of the Member or its Affiliates, unless another Member present objects to this. Only the Member's representative is entitled to vote.

The external experts indicated in Annex 6 are allowed to participate in meetings without having voting rights. Other third parties may participate at Technical Committee meetings without having voting rights, unless one or more Members object.

Notice of each Governing Committee meeting and the agenda shall be transmitted to each Member at least 21 days in advance; 10 days for the Technical Committee and Task Forces.

No decision can be taken on an item which does not appear on the circulated agenda unless all Voting Members are present and agree at the meeting and/or have agreed prior to the meeting (by email or in writing) to discuss this item.

A written consultation of all Voting Members of a Committee or Task Force can take place by email when a decision cannot be deferred until the following meeting and is not sufficiently important to justify convening a meeting, or when the organisation of a meeting is not feasible because of availability of Voting Members. Except in urgent cases, which must be explicitly indicated, replies must be given, within 21 days for the Governing Committee or 10 days for the Technical Committee and Task Forces. The absence of the reply after a written reminder and within this period shall signify acceptance. Any decision taken by written consultation shall be submitted for confirmation at the subsequent Committee meeting.

2. Voting rules: majorities

A Voting Member which is unable to have a representative (as defined above in § VI.1) present at a meeting may give their proxy vote only to the representative of another Voting Member. One Voting Member, however, may not vote by proxy for more than one other Voting Member (in addition to their own vote). The written proxy shall be presented to the Secretariat before the meeting or at the start of the meeting.

Decisions of the **Governing Committee** shall be taken as follows:

- § Unanimous decision of Voting Members (present or represented) is required for:
- modification of this Agreement or its Annexes (except as specified below);
 - admission of a new Member, transfer of Membership or Membership rights;
 - exclusion of a Member (the Member under discussion does not vote);
 - changes to the list of Consortium Substances in Annex 1
 - replacement of a Lead Company (the actual Lead Company does not vote, but all other Members vote even if not Directly or Indirectly Concerned);
 - decisions concerning legal actions brought by/against the Consortium;
 - dissolution of the Consortium and termination of this Agreement at any time before 12 years after the Date of Registration.
- § Any modification of the Advantage Compensation Payment (amount, mechanism) can be made only by the unanimous decision of those Initial Members which are still Members at the time of the decision.
- § 2/3 majority of Voting Members (present or represented) is required for:
- fixing the annual budget;
 - appointment, termination or modification of the Secretariat, delegation of the Secretariat's tasks;
 - authorisation and conditions of subcontracting by the Secretariat;
 - establishment of, appointment or modification of Task Forces;
 - modification of annexes 10 A and 10 B (terms of Letters of Access);
 - decisions regarding purchase of access to Registration Dossier(s) developed by other organisations or joint work with other organisations for the development of Registration Dossier(s)
 - authorisation of sale, rights of access, etc., to the Registration Dossiers and Information developed within this Agreement, and payment conditions.
- § Simple majority of Voting Members (present or represented) for:
- financial and budget decisions, except as specified above;
 - modification, according to the procedures indicated in these Annexes, of Annex 2 (Identified Uses), Annex 4 (affiliates), Annex 6 (experts);
 - validation of changes to the highest Tonnage Band indication for a Substance (as specified in Annex 1)
 - validation of changes to the list of Directly and Indirectly Concerned Members maintained by the Secretariat, as specified in § III.6
 - dissolution of the Consortium and termination of this Agreement after the date indicated above;
 - decision to appeal against any decision by the Agency, or by Member States, relating to the Purpose;
 - all other questions and decisions not specified above.

Decisions of the **Technical Committee and Task Forces** shall be by unanimous vote of Members present or represented at each meeting.

A Member shall be excluded from voting (and not be counted in the "Voting Members" above) in the event of a vote on:

- the exclusion of that Member ;
- on matters in which it has no vested interest, including a vote on testing proposals which it is not required to provide for Registration and of which it does not intend to participate in funding.

In particular, for questions concerning only certain Consortium Substances, only Directly or Indirectly Concerned Members are entitled to vote. Except where specifically defined otherwise elsewhere in this Agreement (eg. change of Lead Company, see § VII), for questions concerning the content of the Registration Dossier (selection of Key Studies, definition of Identified Uses, exposure scenarios ...) and concerning the calendar of Registration (dossier preparation timing, Registration, ...) only Members who are Directly Concerned are entitled to vote.

3. Voting rules: quorum

All decisions will only be valid if the following a quorum of Voting Members is present or represented:

- for Governing Committee decisions requiring a unanimous vote: 100% of Voting Members,
- for other Governing Committee decisions: 80% of Voting Members
- for Technical Committee and Task Force decisions: 2/3 of Voting Members of the relevant committee

If a Governing Committee meeting is unable to take decisions because the quorum is not achieved, then the Governing Committee Chairperson will call a second Governing Committee meeting and this time for the same decisions a quorum of only a majority of the Voting Members will be necessary, or a written consultation will be carried out to take the decision, in both cases according to the modalities (notice, agenda) defined above.

If a Technical Committee meeting is unable to take decisions because the quorum is not achieved, then decisions may be referred by its Chairperson to the Governing Committee, to a second Technical Committee meeting (with unchanged quorum rules) or to a written consultation.

For any modification of the Advantage Compensation Payment (amount, mechanism), a decision can only be taken by a vote of all of Initial Members which are still Members at the time.

VII) Lead Company

At the date of Entry into Force and unless replaced as specified in § VI, the Lead Company for each of the Consortium Substances is specified in Annex 1.

This Article and all other conditions concerning the Lead Company specified in this Agreement apply to the Lead Company for each of the Consortium Substances, as regards the REACH Registration of those Substances only.

The Lead Company may resign from its responsibility upon written notice to the Governing Committee with a notice period of six months. Such resignation, however, is only admissible if not endangering the Purpose of the Consortium. The Lead Company shall as far as is reasonably feasible fully and timely comply, on behalf of Members of the Consortium, with the relevant provisions of REACH.

The Lead Company, with the assistance of the Secretariat and other Members, shall where appropriate prepare and submit to the Agency, on behalf of the Directly Concerned Members and in the format specified by the Agency, the Registration Dossiers, Core Data, Chemical safety Report and Guidance on safe use as necessary for Registration of the Consortium Substances, at least two months before the Deadline for Registration defined in Definitions.

The Lead Company shall pay its fee as invoiced by the Agency after submission of the Core Data without undue delay. The Lead Company shall further communicate the Registration number as obtained by the Agency after payment of the fee to the other Members without undue delay.

The Lead Company undertakes to inform the Directly Concerned Members regularly on the developments of the Registration process. In addition, the Lead Company shall forward in writing to the Secretariat, within 10 calendar days, any communication received either from the Agency or a Member State or any other authority regarding the joint submission or Registration Dossiers.

The Lead Company shall if required and approved by the Governing Committee, appeal any adverse decisions of the Agency or the Member States relating to the joint submission or Registration Dossiers.

It is noted that each Member must nonetheless themselves carry out the Registration submission and other tasks which, by REACH or otherwise, are their own obligation, in particular submit any relevant confidential or specific company information (including as specified in Annexes 1 and 2), submit necessary information concerning Registration Fee payment and ensure payment of their own REACH Agency Fees and other dues.

Voting rules for changing a Lead Company are as defined in VI.10.2.

VIII) Individual obligations

1. The Members undertake to make all reasonable efforts to ensure the appropriate and timely completion of the Purpose. In particular, each Member shall:

- § Observe and comply with the provisions in this Agreement;
- § As specified and subject to the conditions in § V.1.1, make available to the Secretariat all available Information relevant for the Purpose;
- § Inform the Secretariat and the Lead Company of any relevant contacts with third parties as specified in § V.1.3;
- § Critically assess the Information submitted to or generated under this Agreement;
- § Allocate human and financial resources as appropriate, and participate in the work of, the Governing and Technical Committees and any Task Forces;
- § Fund the agreed work plans and other agreed actions for all Substances for which they are Directly or Indirectly Concerned;
- § Inform the Secretariat of any significant change with respect to legal status or organisation of the Member or of its Affiliates;
- § Inform the Secretariat of any change in their Tonnage Band for any Consortium Substance, or in any modification of the list of Substances for which they are Directly or Indirectly Concerned
- § Keep the Secretariat continuously informed of a responsible contact person for the duration of this Agreement.

2. Each Member is responsible for observing its rights and obligations pursuant to REACH, in as much as these rights and obligations are not observed by the application of this Agreement. This applies, in particular, to information which is to be submitted to the Agency within the Registration Dossier in due time by each Member as well as any Information communicated by the Members to customers, suppliers and other third parties, such as Safety Data Sheets.

IX) Competition law compliance

The Members 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 81 and 82 EC Treaty as well as any applicable national laws.

The Members explicitly agree to observe Cefic rules and policies regarding competition law and anti-trust, as available from Cefic (the European Chemical Industry Council, avenue E. van Nieuwenhuysse 4, B1160 Bruxelles, Belgium).

In order to ensure compliance with anti-trust and competition law, data which is not publicly available regarding quantities, manufacturing processes, impurities and uses other than the Identified Uses (Annex 2) will be transmitted, if required, in confidentiality to the Secretariat and will be kept by the Secretariat confidential from other Members and other companies potentially concerned, and will be transmitted in confidentiality only to the Agency as required for REACH purposes, or if necessary for technical studies to relevant contracted experts under confidentiality agreements. If no Secretariat is appointed and such confidential and commercial data needs to be collected, then this must be done through an independent organisation designated by the Governing Committee.

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

X) Definition of costs and cost allocation

X. 1) Valuation of Studies

The value of Existing Information shall be determined on the basis of an evaluation of the scientific quality and relevance to the Purpose, in accordance with **Annex 8**.

X. 2) Cost sharing principles

All costs of Consortium establishment and management, and all costs engaged for the Purpose, in particular in establishing and submitting the Registration Dossiers, including developing studies and purchasing access to third party owned information where necessary shall be shared in accordance with **Annex 9**.

XI) Administration & Reporting of costs

1. The Secretariat shall administrate and keep records of all expenses, compensations due, values of Information, budgets and payments and all other financial matters, access rights and related issues, as specified in § VI.7
2. The Secretariat will present regularly, or whenever significant developments occur, a costs overview to the Governing Committee.
3. The Consortium's funds will be managed either in a specific separate and guaranteed bank account or in some other way, to be decided by the Governing Committee, which ensures security and transparency. Where this is reasonably feasible, available funds will be managed to provide interest to the Consortium.
4. The Governing Committee shall base decisions on contributions and payments on the principle that provided data shall be assessed and incurred costs shall be split in a fair, transparent and non discriminatory way.
5. The financial year shall run from 1 January to 31 December of each calendar year. However, the first financial year shall run from the date of Entry into Force until 31st December of the same year, but shall take into account all relevant spending and costs incurred prior to the Entry into Force of this Agreement, as indicated in Annex 11.
6. Each year, the Secretariat shall submit to the Governing Committee, for approval, the accounts of the past financial year and the budget for the following year, presented according to recognised accounting procedures.
7. When, for appropriate reasons, the budget agreed by the Governing Committee has to be increased in the course of the financial year, the decision must be taken by the Governing Committee either prior to the changed spending, or as rapidly as possible in the case of urgent and necessary costs.

XII) Limitation of liability

1. The Members 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. Subject to § XII.3 below each Member shall assume liability for the correctness of the Information which he makes available to other Members and that he is authorised to do so. No warranty for acceptance of the Information by the Agency at the dossier evaluation (according to Title VI REACH) is given.
3. The Member who submits Information to other Members will indemnify them in respect of any claims for unauthorised use or breach of the intellectual property rights of any third party relating to that Information which results from its use by the persons and under the conditions under which it was submitted.
4. Except as specifically indicated elsewhere in this Agreement, none of the Members, including the Lead Companies, shall be held liable for any direct, indirect or consequential loss or damage incurred by another Member in connection with the activities contemplated in this Agreement, unless caused by gross negligence or wilful misconduct.
5. Each Member shall be liable with respect to third parties within the scope of its responsibility. The other Members of the Consortium shall support to the extent possible and reasonable, any Member against whom a liability claim has been made within the scope of this Agreement by a third party in its defence against such claim. If a third party makes a claim against a Member such that the other Members are jointly responsible or share part responsibility through this Agreement or the activities developed under this Agreement, then this Member may ask the other Members to share according to their shared responsibilities any resulting legal actions, arbitration, compensation or costs.
6. The Secretariat acts entirely in its capacity as representative of the Members and bears no individual responsibility or liability for its actions taken in this capacity, with the exception of gross negligence or wilful misconduct. In any case the liability of the Secretariat as agreed in the Consortium Management Service Agreement with the Secretariat will not be overruled by this agreement.
7. Except for gross negligence and wilful misconduct, the Lead Company shall not be liable, to the greatest extent possible under the laws of the relevant jurisdiction, for any direct, indirect, incidental, special, consequential or punitive damages, or any other damages whatsoever arising in connection with the performance of its obligations defined above.

XIII) Duration, termination, modification

1. This Agreement shall be applicable and valid as from the date of Entry into Force. The Consortium shall be formed for the duration necessary to achieve the Registration of all of the Consortium Substances and for as long as any of these Registrations remains valid, unless it is dissolved by a decision of the Governing Committee as defined in § VI.10.
2. This Article and the provisions relating to the protection of confidentiality (§ IV), ownership and use of Information (§ V), dispute resolution and applicable law (§ XIV) and limitation of the liability (§ XII) shall survive the termination of this Agreement. In particular all Confidential Information, and in particular Study reports, Study summaries and robust Study summaries, should be kept confidential indefinitely, that is without limits of time other than limits fixed by applicable copyright law, by REACH or by other applicable contracts or legislations
3. Upon termination of the Consortium and after payment of all obligations of any kind to or by the Members and other parties, the Governing Committee shall decide on the method of liquidation and the distribution of the Consortium's remaining funds. Before dissolution or termination of the Consortium all remaining joint and severable rights and obligations of the Members resulting from this Agreement shall be settled.
4. Amendments to this Agreement must be decided as specified in § VI and must be in written form to be effective.

XIV) Dispute resolution and applicable law

1. The Members shall first attempt to settle amicably any dispute arising out of this Agreement.

If differences remain, each Member shall have the right to submit its observations in writing to the Governing Committee, which shall have to reply in writing stating the reasons for the decision within 2 months.

Should such amicable settlement fail, the 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 Chairperson. The arbitration decision shall be binding on the parties. The arbitration rules of the ICC shall be applicable. The place of any hearing shall be Brussels and the language of the arbitration shall be English.

2. This Agreement shall be governed by the laws of Belgium.
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.
4. This Agreement constitutes the entire agreement and supersedes all other prior agreements and understandings, both written and oral, between the Members with respect to the subject matter hereof.

XV) Signatures

This Agreement has been made in as many originals as signatories below, each signatory below receiving one copy.

This Agreement is endorsed by ReachCentrum as far as its involvement is concerned and ReachCentrum hereby confirms that it will fulfil the role as the Secretariat. The Members by the signature of the present designate ReachCentrum as the Secretariat from the data of Entry into Force of this Agreement and as until decided otherwise by the Governing Committee.

For and on behalf of **REACH Centrum**, Avenue E. van Nieuwenhuysse 6, 1160 Brussels, Belgium, Mr Alain Perroy

Signature:
on (date of signature):

For and on behalf of **BK Giulini GmbH**, Roberto Wurst (Director BU Bekaphos) and Dr. Alexander Maurer (Vice President Global Phosphates)

Signature:
on (date of signature)

Signature:
on (date of signature)

For and on behalf of **Chemische Fabrik Budenheim KG**, Mr Christian Kohlpaintner, CEO and Chairperson of the Board, and Mr Hans-Jürgen Reinheimer, Director Business Line Phosphoric Acid

Signature:
on (date of signature):

Signature:
on (date of signature):

For and on behalf of **FMC Foret S.A.**, Javier Carratalá, Managing Director,

Signature:
on (date of signature):

For and on behalf of **Prayon SA**, Mr Yves Caprara, Chief Executive Officer and Mr Jean Braham, Phosphates Direction President

Signature:
on (date of signature):

For and on behalf of **Thermphos International BV**, Mr. Joachim Koppers, Business Unit Director and Dr. Rob de Ruiter, Director,

Signature:
on (date of signature)

For and on behalf of **CECA S.A.**, Mr. Christophe Villain, General Director,

Signature:
on (date of signature)

Annex 1 – List of Consortium Substances, Lead Companies, Highest Tonnage bands

1. Modification of information given in Annex 1:

The table indicates for each Substance the highest Tonnage Band of the Tonnage Bands indicated confidentially to the Secretariat by each Member for the Substances for which the Member is Directly Concerned. This highest Tonnage Band is automatically updated if a Member communicates to the Secretariat information demonstrating that their Tonnage Band for a Substance has changed and if this results in a change to the highest Tonnage Band indicated. The change is notified immediately by the Secretariat to all Members and is validated by the following Governing Committee meeting as specified in § VI.10.2.

The Substances are principally identified by their EINECS number(s).

The names of Substances, formulas, and CAS numbers given in this list are as best identified to date, may be incomplete (other names or CAS numbers may be used for some Substances, chemicals with similar formulae may be considered to be the same Substance, etc) and are indicative only. These elements of information can be modified by decision of the Technical Committee.

The other elements given in this table (list of Consortium Substances, Lead Company for each Substance) can be modified as defined in § VI.10.2.

2. Impurities:

This agreement covers Registration of the Consortium Substances. Impurities depend on production processes, and will be declared, where required, separately and independently by each Registrant, directly or confidentially via the Secretariat, for their own products.

3. Hydrates

Conform to Annex 1 of REACH, the Registration will, in each case and where appropriate, also cover the hydrate forms of the Consortium Substances below.

4. Table of Consortium Substances

See updated table on website

See updated table on website

See updated table on website

See updated table on website

See updated table on website

Annex 2 – Identified Uses

1. Non confidential use categories

This Agreement covers the following non-confidential use categories of the Consortium Substances, which are to be included in the Registration activities, and in particular in the Chemical Safety Assessments, developed within this Agreement.

NOTE: where relevant, this Agreement covers only the REACH requirements for which the Consortium Substances is NOT exempted under other regulations applicable, for example: human food additives drinking water treatment, medical, animal feed, pharmaceutical, cosmetics, ...

The specific Identified Uses for each one or group of the Consortium Substance(s) will be indicated more precisely, within the general use categories specified below, in the Registration Dossiers.

- a) detergent and cleaning products intended for domestic, institutional and industrial usage ;
- b1) industrial and manufacturing processes, ceramics and porcelain, construction products and refractory materials, metal treatment, paper manufacture, plastics, polystyrene and polymers, rubbers, molecular sieves ;
- b2) coatings, paints and enamels, pigments
- b3) flame retardants
- b4) textiles
- b5) tyres
- c) water treatment (treatment of waste water, closed process water circuits ...) ;
- d) drinking water treatment, see NOTE above: may in some cases be excluded from REACH Registration by REACH (Art. 2);
- e) cosmetics and baby care: see NOTE above, these uses are excluded from Title IV of REACH only (supply chain information) because covered by the Cosmetics Directive 76/768/EC ;
- f) human foods, animal feeds, medical and pharmaceutical products: see NOTE above, excluded from REACH Registration by REACH (Art. 2)
- g) fertilisers, agricultural and horticultural
- h) biofuels, industrial oil treatment and additives

2. Confidential uses

Where a use is considered “confidential”, then this use will NOT be covered by the Chemical Safety Assessment, and the Member will be responsible for itself carrying out Registration, Information and documentation requirements for this “confidential” use.

3. Identification of “confidential” uses

The process of identifying uses considered “non-confidential” (Identified Uses) will be as follows:

- a Member wishing to include an use in the Identified Uses covered by this Agreement, beyond those already listed, will indicate this use in confidentiality to the Secretariat;
- the Secretariat will ask all Directly Concerned Members whether they object to the addition of this use, without indicating which company requested the addition;
- all such Members will reply in confidentiality to the Secretariat;
- if none of the Members objects within 21 days, then the Secretariat will inform the Members that this use is added to the list of Identified Uses; if one or more Members objects then the use will not be added to the list and the Secretariat will inform all Members of this decision, without indicating how many or which Members objected.

Such changes to the list of Identified Uses will be immediately effective as the information by the Secretariat to the Members and will be ratified by decision of the Governing Committee at its next meeting.

Annex 3 – not used

Annex 4 – Affiliates of Members

This is an indicative list of the Members' Affiliates as at the date of Entry into Force of this Agreement. The status of "Affiliate" depends on the actual real legal ownership links with the Member, according to the criteria set under Definitions. Inclusion in this list is only indicative and does not confer this status if these ownership criteria are not in reality true, and vice versa.

This list may evolve as ownership of legal entities is modified in the future.

Members will notify the Secretariat whenever changes in ownership result in a modification of this list of Affiliates, indicating which legal entities should be added to or removed from this list of Affiliates (and providing legal name, address and registration numbers, and any relevant indications regarding Registration Band tonnage changes).

Proof of the legal ownership links specified in Definitions must be supplied to the Secretariat, but without providing any information about % share ownership or other confidential data.

New Members must provide to the Secretariat the list of their Affiliates, including the above indicated information and proof.

Changes to this list of Affiliates will be immediately effective as of receipt of notification by the Secretariat and will be ratified by decision of the Governing Committee at its next meeting.

In order to have the Registration Dossiers submitted by the Lead Company on behalf of their Affiliates, the Member concerned notifies the names and addresses of its Affiliates to the Secretariat in writing at least thirty (30) days before submission, so the Lead Company is able to include their names and addresses as required in Annex VI Section 1.2 of the REACH Regulation.

List of affiliates removed

List of affiliates removed

List of affiliates removed

Annex 5 – Existing Studies

A list of Existing Studies and Information provided by the Members as at the date of Entry into Force of this Agreement has been established, approved by these Members, and is held and maintained by the Secretariat.

This list indicates which Member(s) own the Information and the expected value of each study, as established according to the principles of Annex 8. This list is not necessarily complete and exclusive, that is Existing Members and New Members may provide further Existing Information during the development and submission of the Consortium Substances Registration, and this will be evaluated as specified in Annex 8. The list will also be modified by the Secretariat in the case of any new information becoming available, for example further studies or new information concerning the value of a given study (expert assessment leading to revision of the Klimisch category).

All modifications of this list will be communicated by the Secretariat to all Members (revised list, indicating the changes made) and will be considered approved if no Member objects within one month. In case of objection, the question will be submitted to the Technical Committee, and in the case of no agreement within the technical Committee to the Governing Committee.

This list may also include Information which is known to the Members to exist and is free for use without necessitating a Letter of Access because it is included in published literature or in reports commissioned by public organisations.

Annex 6 – Specified external experts

The following third parties will have access to the Confidential Information under the same conditions as the Members as defined in section IV:

- 1) CEFIC, avenue E van Nieuwenhuysse 4 bte 2, B 1160 Bruxelles – Belgium ;
- 2) Mr Christopher Thornton, consultant, TECC Sarl, 27 impasse de Charges, 38300 Bourgoin Jallieu, France ;
- 3) The Secretariat, as appointed ;
- 4) Myra L. Weiner, TOXpertise LLC, 100 Jackson Avenue, Princeton, NJ 08540 USA.

Annex 7 – Typical current costs of Studies and tests

The costs for Studies and tests as given for “average price – all labs” in Fleischer (2007, as below) are used as the basis for the “basic cost” (ex-VAT) valuation for Studies as defined and used in **Annex 8**.

It is noted that these costs will be updated where appropriate to take into account inflation or evidence of general evolution of relevant study prices over time.

Reference is to: M. Fleischer (2007), J. Business Chem., Vol. 4, Issue 3, p. 96-114

For information only: this article was at the date of Entry into Force available for download at http://www.wirtschaftschemie.de/journal/2007_iss3_96-114.pdf

Annex 8 – Valuation and access to information

The following rules will generally apply for the valuation of the Information i) contributed by Members or third parties, or ii) generated or established by activities under this Agreement by the Consortium, which together with the aforementioned Information are made available to Members or to third parties.

The aforementioned reports 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.

1. Scientific evaluation

For reports, which are contributed by individual Members, the supplier provides the Consortium with the report itself and available summaries in the form of an IUCLID data set and a robust summary. The robust summary may also be integrated into the IUCLID data set.

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 Technical Committee, 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 Technical Committee 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.

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)

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).

2. Calculation of value

1) 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 the list of typical study costs in Annex 7, updated to take into account inflation and developments in study prices.
- § 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.

2) The above value of the Study will then be adjusted according to its **Klimisch category evaluation**, by multiplying $K \times BC$, 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

3) **Administrative and risk costs:**

- § In general, the following fixed surcharges will be added to the cost
 - à +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 Member contributing a report to the consortium was exposed to the risk that the investments made in the Study are of minor or no benefit; the other Members, new parties or parties wishing to acquire a specific Study are not exposed to this risk since they already know the Study result; and
 - à +15% to cover **management and administrative costs (choosing and briefing laboratory, managing contracts and payments)**
 - à 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

4) % 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 Consortium Substances, and for no other uses, for all Members and all companies purchasing access rights to the Registration Dossiers, as specified in this Agreement, for Studies made available to the Consortium as specified under § V.1 (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 Consortium Substances);
- § **50%**, corresponding to authorisation to access for REACH Registration for **only one** of the 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 Consortium Substances.

5) **Calculation if several studies are available** covering the same endpoint:

§ In general, calculation of cost shares due by the different Members 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, September 2007”

§ **In all cases, payment will only be considered due by the Consortium for Information which is necessary for the REACH Registration Dossiers for one or more of the 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 Consortium Substances, and to which the Consortium has access for use in the Registration Dossiers (existing studies already provided by existing Members, studies developed by the Consortium, publicly available Information, Information for which the Consortium has already paid for access rights from a third party ...), then the Consortium will **not pay to access further Studies or Information**, unless specifically required to ensure the validity of the Registration Dossiers.

§ In the above case, a New Member owning additional Information which would have been adequate for Reach Registration in place of Information used by the Consortium, may nonetheless subtract from the total consortium costs on which their Pro Rata Share is calculated (Z in Annex 9.5B) the value of this Information or the value of the relevant existing information already available (whichever is the lower figure) as indicated in the Agency Guidance referred above

§ Where several Existing Studies are available for the same endpoint for a given Consortium Substance then the Key Study for each endpoint will be identified and the Pro Rata Share due by each 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
- Members 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)

3. Summary table: Rules of access

	Member Directly or Indirectly Concerned by a given product and having contributed financially to the Information development	Member NOT Directly or Indirectly Concerned by a given product And NOT having contributed financially to the Information development	Company purchasing access to the Registration Dossiers or to Information contained therein for REACH Registration of one or more of the Consortium Substances	Company purchasing access to the Registration Dossier(s) or parts thereof for other purposes
Information developed within this Agreement	Joint owner. Receives full copy of Registration Dossiers and also copies of full study reports, etc. Use for any regulatory purpose for the Member or its Affiliates Rights may not be sold or transferred.	Has NO ownership or access rights. But may at any time decide to contribute to Information development cost (becomes Indirectly Concerned)	Receives full copy of Registration Dossier(s). Does not receive copy of study reports, summaries or other data. Use for REACH Registration of the specified Consortium Substances only	To be negotiated with the Secretariat and decided by the Governing Committee on a case by case basis
Information owned by Members	Use for REACH Registration of the specified Consortium Substances only. Does not receive copy of study reports, summaries or other data, except as included in the Registration Dossiers.			To be negotiated directly with the Information owner (unless a mandate for negotiation has been given to the Secretariat)
Information owned by third parties referred in the Registration Dossiers	Use for REACH Registration of the Consortium Substances only. No other rights unless explicitly transferred by the Information owner			

Annex 9 – Financial rules

1a. 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 new Member or by a party purchasing access rights, until :

- § all payments due have been effectively received by the Secretariat;
- § the recipient has accepted, by written signature, agreement to the conditions of access. These conditions will either be as specified by the full text of this Agreement and its Annexes, or will be decided as defined in § VI based on this Agreement and its Annexes.

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 particular, if after the Date of Registration, the Agency requests further testing of the Consortium Substances or for other reasons it becomes necessary to develop or supply further Information to support the Registration of the Consortium Substances, then the Members are not obliged to bear these costs and are not obliged to carry out the required work, unless they decide to do so through the Consortium or otherwise. Such further work and costs may be shared between all parties who choose to continue to support the Registration or the work organised in other ways to be defined.

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

- one company's payment will cover its Affiliates as defined in this Agreement;
- payment by an Only Representative of more than one company will be calculated per company, according to the number of companies represented (unless these are Affiliates as covered above);
- Only Representatives will therefore be required to specify and justify the number of companies manufacturing the Consortium Substances (other than Affiliates) effectively being represented, either by listing these companies or in case of confidentiality or anti-trust issues, by depositing the list with a lawyer or other recognised party who will transmit only the number.

A) **Access for REACH Registration of one or more of the Consortium Substances:**

Three different possibilities are open to any non-Member wishing to refer to the Registration Dossiers or part thereof, for Registration of one or more of the Consortium Substances:

- i) to become a Member of the Consortium, subject to respecting the Membership criteria and being accepted as a Member according to the procedures in this Agreement. This results in the rights, as specified in this Agreement for all Members, to refer to the Registration Dossiers for REACH Registration of the Consortium Substances for which the New Member is Directly or Indirectly Concerned.. In this case the new Member must pay **three amounts: the Advantage Compensation Payment, the Pro Rata Share calculated for each of the Dossiers to which the Member wishes to have access, and also the Consortium Entry Fee** as defined below, and will obtain Letter(s) of Access as per the model in Annex 10A;
- ii) to purchase access to one or more **full** Registration Dossier(s) developed by the Consortium without becoming a Member of the Consortium. In this case, the third party must pay **two amounts: the Advantage Compensation Payment and the Dossier Costs Contribution calculated for each of the Dossiers to which the Member wishes to have access** as defined below (but NOT the Consortium Entry Fee), and will obtain Letter(s) of Access as per the model in Annex 10B;
- iii) to purchase access to **part of** one or more of the Registration Dossiers developed by the Consortium without becoming a Member of the Consortium. In this case, the third party must pay a **part** (proportional to the Information access requested) of the two amounts specified in A.ii above, calculated for each Dossier required, and will obtain (s)Letter of Access as per the model in Annex 10B, appropriately modified to limit access to relevant parts of the Information.

B) **Access for REACH Registration of other substances or for other purposes:**

Third parties (that is non-Members) wishing to purchase access to the whole or part of one or more of the Registration Dossiers developed by the Consortium, for purposes other than REACH Registration of the Consortium Substances (other regulatory purposes, read-across for REACH Registration of other substances, etc), will generally be required:

- i) for access to Information, Studies or reports owned by third parties to which the Consortium does NOT have ownership and does not have the right to sell or transfer access: access must be directly negotiated with, Letters of Access and other documents signed with and payments made to the relevant owner;
- ii) for Information, Studies or reports referred in the Consortium Substances Registration Dossier and (a) owned by Members, or (b) developed by the Consortium under this Agreement, or (c) owned by third parties and for which the Consortium has the right to negotiate third party access under the terms of this Agreement: access conditions and cost will be negotiated with the Secretariat as a function of the elements for which access is required and of the intended uses, and will be decided by the Governing Committee as specified in § VI.

1b. Indicative summary table : Payments due for Membership and/or Dossier access

This summary table is indicative only, the text above and below fixes the precise financial rules.

<i>Substance* below = Consortium Substance for which the Member is Directly or Indirectly Concerned</i>				
	Advantage Compensation Payment	Consortium Entry Fee	Pro Rata Share	Dossier Contribution Costs
<u>New Members</u>	<i>Shared equally between Initial Members only</i>	<i>Shared equally between existing Members</i>	<i>Effectively reduces the share of cost for existing Members</i>	<i>Shared between existing Members according to number of Substances</i>
- first new Member	5 000 € for each Substance*. Up to maximum 20 000 € for 4 or more Substances*.	5 000 € for each Substance*. Up to maximum 20 000 € for 4 or more Substances*.	Decreasing share as new Members enter (depending on number of Members and number of Substances* per Member)	
- second new Member				
- etc				
<u>Companies wishing to refer to full Registration Dossier(s) for REACH Registration of the Consortium Substances (not becoming Members)</u>				
- first company	5 000 € for each Substance. Up to maximum 20 000 € for 4 or more Substances*.	NOT applicable		Non-decreasing share
- second company				
- etc				
	<i>Corresponds to the goodwill, experience and know-how of cooperation between the Initial Members in PAPA</i>	<i>Corresponds to the risk engaged by the Members of the Consortium in initiating and leading the Registration Dossiers development and to possible future shares of Dossier Contribution Costs</i>	<i>Corresponds to fair shares of the Registration Dossier and Consortium costs.</i>	
<u>Company wishing to refer to part of the Registration Dossier for REACH Registration of one or more Consortium Substances</u>				
	Part of 5 - 20 000 € proportional to part of Dossier required	NOT applicable		Part of Costs Share proportional to part of Dossier required
<u>Company wishing to refer to all or part of the Registration Dossier for purposes other than REACH Registration of the Consortium Substances</u>				
Access conditions and cost to be negotiated directly with the owners of the Information required, or with the Secretariat if the Information owner has given a mandate to the Secretariat (in this case, subject to Administration Fee for Non Members)				

2. Administration Fee

In the case of 1.B(ii) above, an Administration Fee of 15% of the final calculated payable value of the Information, as calculated under steps 1-4 of Annex 8, will be collected by the Consortium to cover the costs of secretariat and administration.

This Fee will NOT be charged to companies purchasing access to part of or to the full Registration Dossier under the conditions specified in 1.A above, as it is in this case covered by the other payments indicated in this Annex.

The Administration Fee is retained by the Consortium (the payable value of the Study or data being transferred to its owner).

3. Advantage Compensation Payment:

This is a one-off payment of a fixed amount required for any non-Member wishing to become a Member and/or to use one or more of the REACH Registration Dossiers developed by the Consortium for their own REACH Registration of the Consortium Substances, and is additional to and independent of the Pro Rata Share, Dossier Contribution Costs and Consortium Entry Fee.

The Advantage Compensation Payment covers the goodwill, experience and know-how resulting from the work together of the Initial Members, and the with competent third parties (consultants, Cefic ...), 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 Consortium Substances.

The Advantage Compensation Payment and 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 over the last five years (2003-2007), and who have participated in the preparation of the Consortium over the period end 2007- 2008.

The Advantage Compensation Payment is fixed at 5 000 Euros per 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 § III.6

The Advantage Compensation Payment is credited and reimbursed only to those Initial Members which are still Members at the time at which the payment is due (an equal share of sum indicated above to each of these Initial Members) and is not due in any part to new Members having joined the Consortium after the date of Entry into Force.

In the case of a non-Member wishing to use only part of the Registration Dossier for their own REACH Registration of the Consortium Substances, then only a fraction of the sum above, defined by the Governing Committee proportional to the Information requested, will be payable.

4. Consortium Entry Fee:

This payment is due by any company which becomes a new Member of the Consortium after the date of Entry into Force (not by Affiliates of Members).

This Fee covers:

- § time and staff costs necessary for the existing Members to formally decide upon the request for new Membership according to the decision process specified in this Agreement;
- § Secretariat and other Consortium administration costs resulting from the inclusion of the New Member in the Consortium, including modification of the Consortium Agreement, adjusting the accounting system, recalculating the Pro-Rata Share, issuing corresponding invoices and reimbursements;
- § the new Member's potential financial benefit resulting from their becoming a Member, because of reimbursements of Pro-Rata Share, Dossier Contribution Costs and Consortium Entry Fee

which will benefit them if in the future another company becomes a new Member of the Consortium or purchases access to the Registration Dossier or to other Information developed by the Consortium.

The Consortium Entry Fee is fixed at 5 000 Euros per 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 § III.6

The amount of this Fee is credited to and reimbursed to (shared equally between) all existing Members (existing Members at the time of the Governing Committee decision concerning the admission of the New Member).

5A). Pro Rata Share:

That is, participation by Members in expenses incurred in establishing and managing the Consortium and in producing, managing and submitting the Registration Dossiers, including costs of existing and new Information obtained or developed by the Consortium for the Purpose. These costs are detailed in 5C.

Participation is as per the cost sharing mechanism specified below in 5B which ensures an equal share of these costs between Initial and new Members.

The Pro Rata Share has the following two elements, as specified below:

§ for any newly joining Member, a one-off payment, on joining, to cover the Pro Rata Share of costs engaged by the Consortium up until the date of joining (**past costs**). These costs are the total of the following:

-> costs engaged during the establishment of the Consortium, that is before the date of Entry into Force of this Agreement, as detailed in Annex 11

-> costs of Existing Studies provided by the Initial Members are calculated as per Annex 8 for each Consortium Substance

-> costs engaged by the Consortium from the date of its establishment through until the date of joining of the new Member

The amount above of the Pro Rata Share paid by a new Member is credited to existing Members following the same rules as defined in 5B below, so that after this re-accounting, all Members (existing and new) have in effect paid the same share of the total costs depending on the number of Substances for which they are each Directly or Indirectly Concerned.

§ for existing Members and for any newly joining Member after joining, the Pro Rata Share of all **future costs** engaged by the Consortium, according to the cost sharing basis defined below.

Payment by a New Member of the Pro Rata Share of past costs is due as for other payments as defined in point 8 of this Annex. For the future costs, payment is subject to the same rules as other Members.

Rules defining how are calculated the Members' costs for their work in the consortium are defined below.

5B). Cost sharing mechanism: one Member = one share per Substance

All Consortium costs are shared as follows:

(i) for General Costs of the Consortium (operation, establishment, ...) and for other costs necessary for Registration of all of the Substances

- cost share based on number of products: 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
 $\underline{a} / (\underline{a} + \underline{b} + \underline{c} + \underline{d} + \underline{e})^{\text{th}}$ share

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

ii.a) one Consortium Substance only (eg. a study of this Substance, which is not necessary for read-across for other Consortium Substances):

- each Member 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 Member pays $1/N_s^{\text{th}}$ of costs)

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

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

For example, for the General Costs of the Consortium, if at the date of entry of a new Member into the Consortium:

§ the number of Members passes from N to $(N+1)$

§ \underline{f} = number of Directly Concerned Substances of the $(N+1)$ new Member

§ the General Costs of the Consortium costs engaged up until the date of entry are Z Euros

then

§ the new Member must pay $\underline{f} / (\underline{a} + \underline{b} + \underline{c} + \underline{d} + \underline{e} + \underline{f}) * Z$ Euros
(in addition to the Advantage Compensation Payment)

§ each existing Member will be reimbursed according to the same cost share rules, for example : company A will receive $\underline{a} / (\underline{a} + \underline{b} + \underline{c} + \underline{d} + \underline{e}) * \underline{f} / (\underline{a} + \underline{b} + \underline{c} + \underline{d} + \underline{e} + \underline{f}) * Z$

and after the date of entry of the new Member, each of the Members will pay the revised share of future General Costs as follows, for company A share = $\underline{a} / (\underline{a} + \underline{b} + \underline{c} + \underline{d} + \underline{e} + \underline{f}) * Z$, etc.

The calculation for the costs necessary for the Registration of one or several (not all) of the Consortium Substances are similar, however, a Member will only be liable to pay costs relating to Studies required for the Consortium Substance(s) for which the Member is Directly or Indirectly Concerned according to the relevant Tonnage Band, so that if some Members are not concerned (lower Tonnage Band) by certain Studies, the Pro Rata Share for these Studies for the remaining Members will be higher (division by a smaller number of parts).

If at any time, the list of Consortium Substances for which they a Member is Directly or Indirectly Concerned is modified (as specified in § III.6), then:

- the Member's Advantage Compensation Payment, Consortium Entry Fee and Pro Rata Shares for both Consortium General Costs and specific costs for the Substances concerned are all recalculated, and any resulting amounts due will be collected by the Secretariat and re-accounted to the other Members whose cost share may thus be reduced
- however, for past costs already paid or budgeted by the Consortium no reimbursement will be due as a result of changes reducing the number of a Member's Directly or Indirectly Concerned Substances, and for costs and work underway or already committed by the Consortium the Member will remain obliged to pay according to the cost sharing ratio at the time of the commitment and with the same payment due delays as fixed in §7 of this Annex.

5C). 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 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 according to Annex 8) Existing Information owned by Members (as detailed in Annex 5) and purchased from other parties and required for the Purpose;
- § Costs for new Information developed where required for the Purpose;
- § Costs for a Member accomplishing tasks assigned to it by the Consortium;
- § All other costs engaged conform to this Agreement in order to achieve the Purpose

5D). Rules for company costs

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

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

For participation in a physical meeting:

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

For participation in a telephone meeting:

- § one day staff time as at rate below, including preparation,
- § organisation costs as spent by Secretariat or organisation organising.

Staff time rate:

- § 800 Euros per day / 400 Euros per half day, including secretarial and overheads.

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

6. Dossier Contribution Costs:

This is payable by parties wishing to purchase access to one or more of the Registration Dossiers developed by the Consortium **without becoming a Member of the Consortium**. The Dossier Contribution Costs correspond to a fair participation in the total expenses, relevant to the Registration Dossiers required, incurred in establishing and managing the Consortium and in preparing, justifying, writing and submitting the relevant Registration Dossiers and fulfilling other relevant Registration requirements.

The Dossier Contribution Costs are calculated in the same way as specified under points 5A – 5D of this Annex for the Pro Rata Cost, and include the same elements, but they are calculated **through to the Date of Registration**.

The Dossier Contribution Cost is calculated as in (5B) above at the time of the decision of the Governing Committee decision according access.

The Dossier Contribution Costs payment is credited to and reimbursed to existing Members, using the same cost allocation rules as specified in (5B) above, so that after this re-accounting, the Members at

the date of access purchase and the party X paying the Dossier Contribution Costs have in effect agreed to pay the same equal share of the total General Costs and the same relative share of the Substance-specific costs (depending on numbers of Substances per company). However, should a further party Y agree later to purchase access to the Registration Dossiers developed by the Consortium without becoming a Member of the Consortium, and so pay the Dossier Contribution Costs, then the share of the total General Costs paid by the Members will become lower than that of the parties X and Y, and similarly for the share of the Substance specific costs. This difference is compensated by the Consortium Entrance Fee payable by New Members defined above.

In the case of a non-Member wishing to use only part of the Registration Dossier(s) for their own REACH Registration of the Consortium Substances, then only a fraction of the sum above, defined by the Governing Committee proportional to the Information requested, will be payable.

7. Financial contributions in case of leaving the Consortium

All financial contributions are non reimbursable.

In case a Member should leave the Consortium, either on its own decision or by exclusion and for whatever reason, this Member remains liable to pay:

- § the Pro Rata Share of all Consortium administration and management costs for the calendar years (1 January to 31 December) prior to the Date of Leaving (see §III.3 and §III.4), for the calendar year of the Date of Leaving, and for the calendar year following this calendar year (through to 31 December of the year after the date of leaving);
- § the Pro Rata Share, until the activity is completed, of all Studies, contracts, administrative procedures and other specifically budgeted items of activity engaged prior to the Date of Leaving for the Member's Directly or Indirectly Concerned Substances. The Member leaving thereby acquires a joint ownership of the Information developed under these activities.

8. Consortium accounting system and payments

The Secretariat will establish invoices for payment of all amounts due indicated above. The invoice shall be established rapidly following the relevant decision of the Governing Committee (decision on rights of access, decision on budget and cost sharing ...); the invoice will be accompanied where appropriate with justifications of costs and budgets; payment must be made within 30 days of receiving the invoice. The relevant Letters of Access will be established within 30 days of the Secretariat receiving the payments invoiced.

The Secretariat will maintain a Consortium internal accounting system, where for each Member, for each Substance and for Consortium General Costs are credited and debited:

- § money spent for the Purpose on Consortium preparation, establishment and management (travel and staff time, as above, and other relevant costs),
- § value of Information owned by the Member and made available to the Consortium for the Purpose,
- § money due for relevant shares of Advantage Compensation Payment, Consortium Entrance Fee, Pro Rata Share payment made by a new Member entering, Dossier Contribution Costs payment,
- § payments due for Studies or Information owned by the Member and made available, via negotiation through the Secretariat, to third parties or for purposes other than Registration of the Substance,
- § other payments due to or from the Member for Consortium activities,
- § payments made into or received from Consortium funds.

The Secretariat will also maintain an internal accounting system of all amounts due to and from third parties, both to/from the Consortium and to/from each Member, for access to Information purchased

by the Consortium and/or access of third parties to the Registration Dossiers (all or part thereof) and/or to Information referred in this Dossier or developed within this Agreement.

The Secretariat will collect funds from Members sufficient to cover expected spending, for a period of 3 months – one year, to be decided by the Governing Committee, in order to minimise administrative costs (reduce number of invoices) whilst avoiding excessive advance collection. Invoices received from the Secretariat must be paid within 30 days of receiving them. Where reimbursements of costs or credits are due to Members, the Secretariat will group these and make payments on the same period basis as for fund collection.

Fund collection will be based on estimative cost sharing between Members based on the number of Directly and Indirectly Concerned Substances for each Member and on expected separation between Consortium General Costs and specific Information and Dossier costs for certain Substances or Groups of Substances. For each fund collection, the Secretariat will propose a total amount to be collected, calendar for collection, and cost sharing between Members to the Governing Committee.

Annex 10A – Model Letter of Access (for Members)

Model Letter of Access for Members for the Registration of one or more Inorganic Phosphates (Consortium Substances)

By this letter, the Members of the Consortium for the REACH Registration of Inorganic Phosphates (hereafter referred to as "the Consortium" and "the Substance(s)") agree that the REACH Registration Dossiers, and also all data, studies, summaries, waiving argumentations, reasoning of testing proposals and/or assessments, and other relevant information submitted by the Consortium in support of the Registration under REACH of the following Substance(s) may be referred to:

- § by **Company XYZ**, which being a Member of the Consortium, and its Affiliates
- § in order to support REACH Registration of the Substance(s)
- § List of Substances: **XXXXXXXXXXXX**

This Letter of Access is subject to and subservient to the terms of the Consortium Agreement signed between the Consortium Members. The rights and obligations resulting from this Letter of Access are as specified in the Consortium Agreement and its Annexes.

"The Consortium" above refers to the Consortium established by signature on **XXXXXXXXXX** of the Consortium Agreement between the following initial Members :

- BK Giulini GmbH
- Chemische Fabrik Budenheim KG
- FMC Foret SA
- Prayon SA
- Thermphos International BV
- CECA SA

Signature: Authorised Representative of the Consortium

Annex 10B – Model Letter of Access (Non Members)

Model Letter of Access for Non Member for the registration of Inorganic Phosphates under REACH Regulation

By this letter, the Members of the Consortium for the REACH Registration of Inorganic Phosphates, as indicated below, (hereafter referred to as “the Members”, “the Consortium” and “the Substance(s)”), agree that:

- the REACH Registration Dossiers, including data, Studies, summaries, waiving argumentations, reasoning of testing proposals and/or assessments owned by Members of the Consortium and submitted by the Consortium in support of the Registration under REACH of the following Substance(s) (hereafter referred to as “the Dossier(s)”)

may be referred to:

- by **Company XYZ** (hereafter “The Applicant”)

in order to support

- the Applicant’s Registration of the Substance(s) under REACH
- list of Substances: **XXXXXXXXXX**

subject to the following conditions:

1. the right to refer is restricted only for the Registration purpose as specified above, that is only for REACH Registration, and only for the Substance(s) listed above;
2. the right of refer is solely granted in favour of the Applicant is not transferable to any other entity or person;
3. the Applicant is not authorised to receive any copies of the Dossier(s) nor is the Applicant authorised to inspect or view the Dossier(s) or any related specific document in whole or in part, only the right to refer to the Dossier(s) and their contents for the purpose specified above is granted;
4. this Letter of Access shall in no event be construed as granting the Applicant any property rights whatsoever in the Dossier(s) or to any information contained within them or elsewhere;
5. the right to refer granted by this Letter of Access is subject to the conditions specified in the Consortium Agreement (including its Annexes), of which the Applicant has received copy / AND/OR / is subject to the specific conditions listed below and annexed to this Letter of Access.

The right to refer is granted subject to the Members receiving the signature in writing by the Applicant of acceptance of these conditions (OR SPECIFY date of this signature).

The right to refer remains subject to the permanent respect of these conditions, and to effective payment of the relevant costs and fees.

“The Consortium” above refers to the Consortium for REACH Registration of Inorganic Phosphates, established in 2008 between the following Initial Members : BK Giulini GmbH, Chemische Fabrik Budenheim KG, FMC Foret SA, Prayon SA, Thermphos International BV

Signature: Authorised Representative of the Consortium

Annex 11 – Consortium preparatory work costs

Estimated costs of preparatory work, engaged for the preparation and establishment of the Consortium, that is **before Entry into Force** of this Agreement, are outlined below. Exact costs will be justified in the Consortium accounts by invoices and receipts.

The costs below are in addition to the Existing Studies specified in Annex 5. They will be included in the Pro Rata Share calculations as specified in Annex 9.

All prices below are ex-VAT

Literature search, data gap analysis and complementary assessment – Safepharma, TOXpertise – as already prepared and partly engaged at the date of Entry into Force

Member company costs:

- § Meeting 11th March 2008
- § Meeting 18th June 2008
- § Meeting 18th September 2008
- § Time spent by company personnel preparing Consortium agreement
- § Calculation as per rules specified in Annex 9

Consultants: ReachCentrum and Christopher Thornton – time spent and costs

- § - meetings as above, including coordination, minutes
- § - coordinating decision making between the future Consortium members to prepare agreements and launch work
- § - preparation Consortium agreement, secretariat contract, other contracts, budgets, cost sharing tools, other administrative issues
- § - defining and overseeing data gap analysis study, call for proposals for Consortium management, preparation of Safepharma studies above
- § - purchase of electronic copies of relevant studies (Infotrieve costs)
- § - time spent looking for relevant Studies

Cefic – time spent and costs

- § - participation of Marc Vermeulen in meetings and coordination of Consortium preparation, June 2007 – October 2008
- § - meeting room costs and organisation costs for the meetings indicated above