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# Legal contract: STPP (Sodium Tri Poly Phosphate) SIEF Agreement Contract

## Note for information only

(not part of this legal contract):

*The Lead Registrant, FMC Foret, has prepared the Joint Registration of the Substance in close cooperation with the other members of the "Sodium Tri Poly Phosphate (STPP) Consortium". The Registration Dossier was submitted to ECHA in February 2010 and has been accepted.*

*The STPP 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 Company has delegated to ReachCentrum, Avenue E. van Nieuwenhuysse 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

This SIEF Agreement Contract, hereinafter the "**Agreement**", is entered into for the Substance Tri Poly Phosphate by and between:

- the **Lead Registrant, FMC Foret S.A.**, company with limited liability under Spanish law (sociedad anonima), registered office Plaza Xavier Cugat, 2, Edificio C, planta 3<sup>a</sup>, Parque de Oficinas Sant Cugat Nord 08174 Sant Cugat del Vallés (Barcelona), Spain, **acting in its own name and in the name and on behalf of all Members of the Sodium Tri Poly Phosphate (STPP) Consortium** in accordance with the Sodium Tri Poly Phosphate Consortium Agreement,
- and the SIEF Participant 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> (hereinafter referred to as "**Non-Lead Member**");

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

## Preamble

Whereas the Parties to this Agreement have pre-registered **Sodium Tri Poly Phosphate, as specified in Annex 2, hereinafter "the Substance"**, and have agreed on the identity and the sameness of the Substance as indicated in Annex 2, and on the GHS Classification ("Not Classified", see Annex 2) 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");

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 Sodium Tri Poly Phosphate 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 recognises the Lead Registrant as lead registrant who has submitted 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: 1<sup>st</sup> 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 because the 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), the whole as submitted by the Lead Registrant for the Substance in February 2010

**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 Sodium Tri Poly Phosphate Consortium.
- **Lead Registrant:** FMC Foret, a SIEF participant who is subject to the registration requirements under REACH, and who submitted the Registration Dossier for the Substance, after appropriate information and consultation of the SIEF, in February 2010, and who is thus the Lead Registrant for the Substance 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 Sodium Tri Poly Phosphate Consortium ('Lead Members').
- **Non-Lead Member:** a SIEF participant being neither a Lead Member nor a data holder (article 28 (7) REACH) and that agrees to rely on the Joint Registration Dossier submitted 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>.

**LOAShop:** website operated by ReachCentrum (Avenue E. van Nieuwenhuyse 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

**Sodium Tri Poly Phosphate Consortium:** the "STPP" Consortium initially established in May 2008 for the purpose of REACH registration of the Substance, Sodium Tri Poly Phosphate. 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. 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.

**STPP Consortium Agreement.** The STPP Consortium Agreement, as currently valid is attached to this Agreement (Annex 4), 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.

**The Substance:** Sodium Tri Poly Phosphate, as defined in the sameness definition Annex 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 3 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**

The Lead Registrant has already made available to the Non-Lead Members, on the STPP Consortium's website, a summary of the Substance Registration Dossier and CSR, GHS Classification, list of covered uses and applications.

## **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. The Joint Registration Dossier for the Substance has already been completed, submitted by the Lead Registrant, and accepted by ECHA

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**.
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.
5. 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. Obligations of the Non-Lead Member**

### **Article IX. 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.

### **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

### **General financial rules**

The fees and amounts below are contributions fixed as defined, conform to the financial rules specified in the STPP Consortium Agreement as communicated to the SIEF as from 2008, 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 developed by the STPP 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),**

This payment does NOT enable the Non-Lead Member to become a member of the STPP 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 the REACH Registration Dossier developed by the STPP Consortium for their own REACH Registration of the Substance, and is additional to and independent of the Pro Rata Share, Dossier Contribution Costs and (for companies wishing to join the STPP Consortium only) STPP Consortium Entry Fee.

The Advantage Compensation Payment covers the goodwill, experience and know-how resulting from the work together of the initial STPP Consortium Member companies, and with competent third parties (consultants, Cefic ...), in joint research and collaboration concerning inorganic phosphates through the Cefic Sector Group CEEP over the last 30 years, including work studying, achieving and updating information and knowledge on the Substance and regulatory processes concerning the Substance,

and cooperating in communications and information exchange and joint research concerning the Substance.

**The Advantage Compensation Payment is fixed at 20 000 Euros for LoA for >1,000 tonnes.**

## **Commitment deadline and payments**

### **Commitment deadline**

Non-Lead Members which signed an agreement with the STPP Consortium to purchase the right of access to the REACH Registration Dossier, before the commitment deadline fixed at 30<sup>th</sup> November 2009, benefit from specific financial conditions, as specifically communicated to all SIEF participants for the Substance prior to this deadline.

No objection was received from any SIEF participant to this procedure which was necessary to accompany the early preparation, dossier testing and submission in February 2010 of the STPP Registration Dossier by the Lead Members.

## **Payments and access**

### **Initial LoA cost estimate and reimbursements**

The Lead Registrant has calculated the Joint Registration Compensation, as above and according to the financial rules specified in the STPP Consortium Agreement (including Advantage Compensation Payment), on the basis of the number of Lead-Members intending to register the substance for 2010 plus the number of Non-Lead Members having signed agreement to purchase LoA by the commitment deadline indicated above:

- |                   |       |                              |
|-------------------|-------|------------------------------|
| • >1,000 tonnes   |       | <b>= 68 020 Euros ex-VAT</b> |
| • 100-1000 tonnes | = 68% | = 46 254 Euros ex-VAT        |
| • 10-100 tonnes   | = 40% | = 27 208 Euros ex-VAT        |
| • <10 tonnes      | = 24% | = 16 325 Euros ex-VAT        |

To obtain right of access the Non-Lead Member must pay in full this amount, plus the LOAShop handling fee, plus any additional costs as indicated below.

### **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 above.

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 STPP Consortium Agreement financial conditions already communicated to the SIEF since 2008. 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 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 via LOAShop. One such request can be made at no cost if the Token initially sent had a remaining validity of <14 days, otherwise the LOAShop handling charge will be charged again.

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: Substance sameness and GHS**

EC number:	231-838-7 237-004-9
EC name:	Pentasodium triphosphate Triphosphoric acid, sodium salt
CAS number (EC inventory):	7758-29-4 13573-18-7 15091-98-2
CAS number:	7758-29-4 13573-18-7 15091-98-2
CAS name:	Sodium tri polyphosphate Sodium tri polyphosphate hexahydrate
IUPAC name:	Pentasodium triphosphate
Molecular formula:	$\text{Na}_5\text{P}_3\text{O}_{10}$ $\text{H}_{5-x}\text{P}_3\text{O}_{10}\text{Na}_x$ (where x is approximately 5) $6\text{H}_2\text{O}\cdot\text{Na}_5\text{P}_3\text{O}_{10}$
Molecular weight range:	367.862 – 475.8
Structural formula	$\text{NaO}-\overset{\text{O}}{\parallel}{\text{P}}-\text{O}-\overset{\text{O}}{\parallel}{\text{P}}-\text{O}-\overset{\text{O}}{\parallel}{\text{P}}-\text{ONa}$ <p style="text-align: center;"> <math>\text{ONa} \qquad \text{ONa} \qquad \text{ONa}</math> </p>
Composition All as % dry weight, after excluding water.	<ul style="list-style-type: none"> <li>• Substance &gt;90% purity</li> <li>• All impurities &gt; 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</li> <li>• All hazardous impurities are &lt; 0.1%</li> </ul>
Granulometry	Respirable content of 35-36% and the following range of granulometry characteristics: <ul style="list-style-type: none"> <li>• &gt;5.5<math>\mu\text{m}</math> 64 – 81%</li> <li>• 3.5 – 5.5<math>\mu\text{m}</math> 0.02 – 0.16%</li> <li>• 2.0 – 3.5<math>\mu\text{m}</math> 0.09 – 0.20%</li> <li>• 0.3 – 2.0<math>\mu\text{m}</math> 0.04 – 0.10%</li> <li>• &lt;0.3<math>\mu\text{m}</math> 0.00 – 0.08%</li> </ul>
GHS Classification and Labelling	Not Classified

# **Annex 3: 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](http://ec.europa.eu/comm/competition/index_en.html)).

## Management of activities DO & DON'T

<b>✓ DO</b>	<b>✗ DON'T</b>
<b>REACH ACTIVITIES AND EC COMPETITION LAW</b>	
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
<b>COMPETITION COMPLIANCE</b>	
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
<b>ORGANISATION OF ACTIVITIES</b>	
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
<b>TYPE OF ACTIVITIES</b>	
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
<b>WORKING UNDER REACH</b>	
DO limit your activities to what is strictly required under REACH	DO NOT go beyond activities which are strictly required under REACH
<b>OVERSIGHT AND SUPERVISION</b>	
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
<b>RECORD KEEPING</b>	
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
<b>NECESSARY VIGILANCE</b>	
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
<b>LEGAL ADVICE</b>	
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](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 or 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.

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# **Annex 4: Sodium Tri Poly Phosphate (STPP) Consortium Agreement**

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

# Consortium Agreement for the REACH Registration of Sodium Tri Poly Phosphate (STPP)

pursuant to requirements of the European REACH Regulation

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# Sodium Tri Polyphosphate 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 in **Annex 4**.

## Members

At the date of Entry into Force of this Agreement

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,

Tonnage band: > 1 000 tonnes/year

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

Tonnage band: > 1 000 tonnes/year

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,

Tonnage band: > 1 000 tonnes/year

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,

Tonnage band: > 1 000 tonnes/year

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 Rittthem, The Netherlands,

Tonnage band: > 1 000 tonnes/year

NOTE: Nilefos not signatory

# Preamble

Whereas the Members (see Definitions) are Manufacturers / Importers / Only Representatives, as defined in REACH, of the Substance described in Annex 1 with registered head offices or affiliates in the European Union.

Whereas the Substance has phase-in status according to Article 3 (20) of REACH and each of the Members intends to pre-register the substance individually or via a representative.

Whereas REACH imposes on Manufacturers and Importers an obligation to register the Substance 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 to the European Chemicals Agency.

Therefore, with a view to fulfilling their regulatory obligations, 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 a harmonised set of data and for Registration and a Registration Dossier,
- manage Pre-Registration, Registration and access to this REACH Registration Dossier and to relevant data before and after the Date of Registration, in particular with relation to: other potential REACH Registrants of the Substance, potential REACH Registrants of other substances with potential read-across to/from the Substance, 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 Substance or relevant to or related to the Purpose.

# Copyright

This Agreement text is based on the model text developed by Cefic for its member companies and Sector Groups, 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 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. 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 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;

**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 Substance 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 Substance 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;

**Deadlines for registration:** the date by which the Substance must be registered at the latest as specified in Article 23 of the REACH Regulation;

**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;

**Identified Uses:** of the Substance are those defined in Annex 2.1 of this Agreement, as referred to in Article 3, sub 26 of the REACH Regulation;

**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;

**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:** 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 Manufacturers / Importers / Only Representatives, as defined in REACH, of the Substance 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 Substance 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 not excluded from voting on a given issue;

**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 the Substance 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 Substance and which are of relevance for Registration;

**Substance:** for the purpose of this Agreement, is defined 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;

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 Substance and in particular to pursue jointly the following objectives:

- (1a) define and agree the identity and the sameness of the Substance and its regulatory status
- (1b) develop Core Data for the Substance fulfilling the highest tonnage band requirements applicable to at least one of the Members, including where appropriate the following actions:
- Gather and assess available data on the Substance 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 Substance), appropriate and feasible, define and agree for which other substances the available Information might be relevant for Registration of the Substance, 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 uniform classification, and where necessary uniform labelling, conform to applicable legislation;
  - Coordinate the compilation and the submission of the Registration by the Lead Company;
  - Gather information on use and exposure categories of the Substance, conditions of use and exposure to humans and environment for the Identified Uses of the Substance;
  - Perform a risk assessment according to scientific principles and regulatory guidelines with the intention to show a safe production and use of the Substance for the Identified Uses;
  - Initiate testing where a higher tier risk assessment is needed to demonstrate safe manufacturing, transport, handling and use of the Substance in for the Identified Uses.

- (2) Prepare for REACH Pre-Registration of the Substance, which is to be done by each Member or its representative (as required by REACH), prepare a Registration Dossier for the Substance, and prepare all data and information necessary for these purposes
- (3) Mandate the Lead Company to carry out a Joint Submission 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 Company at least three months before the deadline for Registration applicable to the Member(s) within the highest tonnage band.
- (5a) Continue the cooperation between Members relating to Registration of the Substance 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 Substance, relevant to participation in Substance Information Exchange Forums (SIEF) for the Substance, and relevant to answering enquiries from participants in SIEF for the Substance 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 Substance SIEF concerning all issues relating to Registration of the Substance, or concerning the use of Information developed or collected through this Agreement and/or contained in the Substance Registration Dossier 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 Substance Registration Dossier 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 Substance, 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 Substance Registration Dossier and to other Information developed through this Agreement, including defining, collecting and distributing payments for the purchase of these access rights.

## **II. 2) Management of access to the REACH Registration Dossier**

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 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.

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

- be at the time of requesting Membership a manufacturer of the Substance in the European Union, or an importer of the Substance into the European Union) in quantities susceptible to require REACH Registration, or be susceptible to begin such an activity in the future ; or be an “Only Representative” of such a company
- 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, under “importer of the Substance” are included importers of detergents and/or other formulations containing the Substance, where the Substance “is intended to be released under normal or reasonably foreseeable conditions of use”.

Note: access to the Registration Dossier, 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 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 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 fulfills 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 Dossier 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 Dossier developed by the Consortium, nor any rights of access to these.

## 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 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, including Information concerning the uses and conditions of use of the Substance within the 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. The principal elements of Information thus provided are listed in 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 Dossier 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 relevant for the Registration of the Substance, 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 the Registration Dossier 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 Dossier developed within this Agreement, except as specified hereafter, **for purposes of REACH Registration of the Substance 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 **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) for purposes of REACH Registration of the Substance 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 Dossier 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 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 Substance 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 Dossier, 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 the Substance, 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 Dossier 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 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 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.

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 Chairman, for a period of two years renewable, preferably from the Lead Company.

Meetings of the Governing Committee shall be convened at least once every six months up until completion of REACH Registration of the Substance, 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;
- 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 Dossier, 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 Chairman 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 Chairman. Meetings of the Technical Committee shall be convened by its Chairman 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;
- 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 Substance, evaluating the Substance 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 Dossier, including the determination of data gaps, waivers and surrogate data;

- Approval of the Registration Dossier 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 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 Chairman, 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, and subject to the subcontractor being also independent from all Consortium Members. The legal responsibility for the subcontracted tasks remains with the Secretariat. 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 Substance, 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 Dossier and other Information, including proposing conditions and appropriate levels of payments in accordance with Annex 9;
- 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 Dossier 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 Chairman 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 and to sign:

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

The Governing Committee may empower the Technical Committee Chairman 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 Chairman 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, 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 Chairman 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);
  - replacement of the Lead Company (the actual Lead Company does not vote);
  - 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 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);
  - authorisation of sale, rights of access, etc., to the Registration Dossier 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);
  - 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.

### **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 Chairman 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 Chairman 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 is:  
**FMC Foret SA.**

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 Members and in the format specified by the Agency, the Registration Dossier, Core Data, Chemical safety Report and Guidance on safe use as necessary for Registration of the Substance, at least two months before the deadline for Registration applicable to the Member(s) within the highest tonnage band.

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 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 Dossier.

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 Dossier.

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.

## 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;
- Inform the Secretariat of any significant change with respect to legal status or organisation of the Member or of its Affiliates;

- 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 Dossier, 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 31<sup>st</sup> 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 Company, 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 the Substance and for as long as this Registration 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 chairman. 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 date 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**, Ytzhak Peretz, Managing Director,

Signature:  
on (date of signature)

For and on behalf of **Chemische Fabrik Budenheim**, Mr Christian Kohlpaintner, CEO and Chairman 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 Willy Marlier, 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)

# Annex 1 - Substance identification

## 1. The Substance

**The Substance covered by this Agreement is: Sodium tripolyphosphate**

The following (A, B and C) are considered to be ONE substance for REACH Registration purposes, and to be covered by this Agreement and in particular by the REACH Registration Dossier which will be developed within this Agreement.

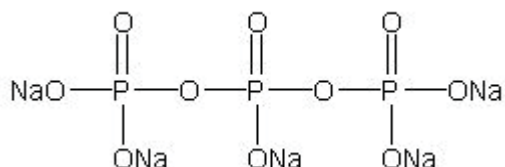
**A]** The standard CAS Number for the Substance:

CAS Number: 7758-29-4

EINECS Number: 231-838-7

Also known as: Pentasodium triphosphate, or Triphosphoric acid, pentasodium salt, or Pentasodium triphosphate.

$\text{Na}_5\text{P}_3\text{O}_{10}$



**B]** The following is also considered, for REACH purposes, to be the same substance:

CAS Number: 13573-18-7

EINECS Number: 237-004-9

$\text{H}_5\text{P}_3\text{O}_{10}\text{Na}_x$  – where x is approximately 5 ( $4.5 < x < 5.5$ )

**C]** Conform to Annex 1 of REACH, the Registration of the above will also cover the **hydrate form** of the Substance below:

CAS Number: 15091-98-2

EINECS Number: not applicable

Also known as: Sodium tripolyphosphate hexahydrate.

$6\text{H}_2\text{O}\cdot\text{Na}_5\text{P}_3\text{O}_{10}$

## 2. Impurities:

This agreement covers Registration of the Substance. 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.

# Annex 2 – Identified Uses

## 1. Non confidential uses

This Agreement covers (as “**Identified Uses**”) all the following non-confidential uses of the Substance, which are to be included in the Registration activities, and in particular in the Chemical Safety Assessment, developed within this Agreement.

NOTE: where relevant this Agreement covers only the REACH requirements for which the Substance is not exempted because of coverage under other regulations: human food additive, medical, animal feed, pharmaceutical, cosmetics, other uses covered by these uses.

- a) detergent uses:
  - domestic, institutional and industrial detergents and cleaners,
  - laundry, dishwasher and other detergents ;
- b) uses in industrial and manufacturing processes, in particular in the following industries and processes:
  - use in construction materials
  - use in ceramics manufacture
  - metal and surface treatment
  - leather manufacture (tannery)
  - textiles processing industries
  - manufacture of paints, varnishes, coatings, printing inks, mastics, etc
  - chemical industry
- c) uses in water treatment
  - addition to drinking water (mains supply, localised treatment ...)
  - treatment of waste water (flocculation)
  - addition to closed process water circuits (for example domestic or institutional boiler/heating circuits, cooling waters, industrial process waters ...)
- d) uses in cosmetics
  - stabiliser for toothpastes
  - stabiliser in other cosmetics uses

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.
- e) uses in human foods, animal feeds, medical and pharmaceutical products: see note above, excluded from REACH implementation by REACH (Art. 2).

## **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 Members whether they object to the addition of this use, without indicating which company requested the addition;
- all 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 applicable - company information**

*Names, addresses, representatives and tonnage bands of Consortium Members*

*This information is already given in the text of the agreement*

## Annex 4 – Affiliates of Members

This list indicates the Members' Affiliates as at the date of Entry into Force of this Agreement. 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) but without providing any information about % share ownership or other confidential data.

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 Dossier 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.

### **Thermphos International BV:**

Omnisal GmbH  
Dessauer Strasse 128  
D-06886 Lutherstadt Wittenberg  
Germany

Thermphos UK Ltd.  
Trinity Street, Oldbury  
West Midlands, B69 4LA UK  
United Kingdom

**FMC Foret SA, BK Giulini GmbH, Chemische Fabrik Budenheim KG, Prayon SA:** No Affiliates

## Annex 5 – Existing Studies

List of Existing Studies provided by Members as at the date of Entry into Force of this Agreement, with value as established according to the principles of Annex 8. This list is not necessarily complete and exclusive, that is Members may provide further Existing Information (not included in this list) during the development and submission of the Substance Registration, and this will be evaluated as specified in Annex 8.

“Key study” indicates a study considered as the “key study” as defined in the Agency “Guidance for the Implementation of Reach, Guidance on Data Sharing, September 2007”, as referred in Annex 8.

The Studies in the column “Study owner: CEEP” in the table below were funded by the members of CEEP (Centre Européen d’Etudes des Polyphosphates, a Sector Group of Cefic - the European Chemical Industry Council) and are property of CEEP. The signature of this Agreement by the CEEP member companies who are also the Initial Members of the Consortium constitutes the decision by CEEP to authorise the use of these studies for REACH Registration of the Substance only for all Members and all companies purchasing access rights to the Registration Dossier, according to the conditions specified in this Agreement, subject to payment to the Initial Members (on a one Member – one equal share basis) of the value indicated below (calculated according to Annex 8).

The Members have access to the Studies in the column “Study owner: Nilefos” for use for Registration of the Substance by letter signed by the study owner

Consortium file n°	Key study	Notes	Study owner				Klimisch category	Fleischer 2007 average price (all labs) €	Risk and administrative costs	Value with risk, admin. costs, Klimisch correction	Value included in Pro Rata Costs (6)	
			FMC Foret	Thermphos	Nilefos	CEEP					Value for Information owner (5)	After 50% for REACH registration for the Substance only
F3	X		X				1 194 €	145%	1 731 €	866 €	866 €	
C2				X		3		145%	433 €	216 €		
F2	X		X			1	1 343 €	145%	1 947 €	974 €	974 €	
C1				X		3		145%	487 €	243 €		





## 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.

## 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](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.<sup>1</sup> 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.

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).

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<sup>1</sup> 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)

## 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
  - +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
  - +15% to cover **management and administrative costs (choosing and briefing laboratory, managing contracts and payments)**
  - these two % are applied independently, and not additively, to the study cost (in general, total of +45%)
- In particular cases, where it can be justified (specific risks, proof of real costs), different figures may be applied

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

- 50%, corresponding to authorisation to use for REACH Registration of the Substance only for all Members and all companies purchasing access rights to the Registration Dossier, as specified in this Agreement, for Studies made available to the Consortium as specified under § V.1

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 Dossier for the Substance.** That is, if Studies or Information are already available, adequate for Registration of the Substance, and to which the Consortium has access for use in the Registration Dossier (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 Dossier.

- In the above case, a New Member owning additional Information, 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, as listed in Annex 5, 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. Indicative summary table: Rules of access**

This summary table is indicative only, the text of the Consortium Agreement and its Annexes fixes the precise rules concerning rights and ownership of information.

	<b>Member</b>	<b>Company purchasing access to the Registration Dossier or to Information contained therein for REACH Registration of the Substance</b>	<b>Company purchasing access to the Dossier or parts thereof for other purposes</b>
<b>Information developed within this Agreement</b>	<p>Joint owner.</p> <p>Receives full copy of Registration Dossier and also copies of full study reports, etc.</p> <p>Use for any regulatory purpose for the Member or its Affiliates</p> <p>Rights may not be sold or transferred.</p>	<p>Receives full copy of Registration Dossier.</p> <p>Does not receive copy of study reports, summaries or other data.</p> <p>Use for REACH Registration of the Substance only</p>	<p>To be negotiated with the Secretariat and decided by the Governing Committee on a case by case basis</p>
<b>Information owned by Members</b>	<p>Use for REACH Registration of the Substance only.</p> <p>Does not receive copy of study reports, summaries or other data, except as included in the Registration Dossier.</p>		<p>To be negotiated directly with the Information owner (unless a mandate for negotiation has been given to the Secretariat)</p>
<b>Information owned by third parties referred in the Registration Dossier</b>	<p>Use for REACH Registration of the Substance only.</p> <p>No other rights unless explicitly transferred by the Information owner</p>		

# 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 Dossier 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 Dossier 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 Substance or for other reasons it becomes necessary to develop or supply further Information to support the Registration of the Substance, 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 Substance:

- 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 STPP (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 the Substance: *three different possibilities*** are open to any non-Member EU wishing to refer to the Registration Dossier or part thereof, for Registration of the Substance:

- 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 this Registration Dossier for REACH Registration of the Substance. In this case the new Member must pay **three amounts: the Advantage Compensation Payment, the Pro Rata Share, and also the Consortium Entry Fee** as defined below, and will obtain a Letter of Access as per the model in Annex 10A;
- to purchase access to the **full** Registration Dossier 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** as defined below (but NOT the Consortium Entry Fee), and will obtain a Letter of Access as per the model in Annex 10B;
- to purchase access to **part of** the Registration Dossier 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 these two amounts and will obtain a 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 the Registration Dossier developed by the Consortium for purposes other than REACH Registration of the Substance (other regulatory purposes, read-across for REACH Registration of other substances, etc), will generally be required:

- 1) 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, Letter of Access and other documents signed with and payments made to the relevant owner;
- 2) for Information, Studies or reports referred in the Substance 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 it fixes the precise financial rules.

	Advantage Compensation Payment	Consortium Entry Fee	Pro Rata Share	Dossier Contribution Costs
<b><u>New Members</u></b>				
	Shared equally between Initial Members only	Shared equally between existing Members	Effectively reduces the share of cost for existing Members	Shared equally between existing Members
- first new Member	20 000 €	20 000 €	Costs x 1/(N+1)	
- second new Member			Costs x 1/(N+2)	
- etc			Costs x 1/(N+etc.)	
<b><u>Companies wishing to refer to the full Registration Dossier for REACH Registration of the Substance (not becoming Members)</u></b>				
- first company	20 000 €	NOT applicable		Costs x 1/(N+1)
- second company				
- etc				
	Corresponds to the goodwill, experience and know-how of 30 years' cooperation between the Initial Members in CEEP	Corresponds to the risk engaged by the Members of the Consortium in initiating and leading the Registration Dossier development.	Corresponds to fair shares of the Registration Dossier and Consortium costs.	
<b><u>Company wishing to refer to part of the Registration Dossier for REACH Registration of the Substance</u></b>				
	Part of 20 000 € proportional to part of Dossier required	NOT applicable		Part of Costs x 1/(N+1), proportional to part of Dossier required
<b><u>Company wishing to refer to all or part of the Registration Dossier for purposes other than REACH Registration of the Substance</u></b>				
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.B2) 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 (i) to become a Member and/or (ii) to use the REACH Registration Dossier developed by the Consortium for their own REACH Registration of the Substance, 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 STPP through the association CEEP (Centre Européen d'Etudes des Polyphosphates, joint industry association established in Belgium over 30 years ago and for the last ten years operating as a CEFIC Sector Group), which have been essential to achieving the establishment of this Consortium and to ensuring conditions appropriate for the timely and effective completion of the Registration Dossier. This includes carrying out the HERA STPP study (2003), see Annex 5, which provided significant starting information for the writing of the Registration Dossier.

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

This Advantage Compensation Payment is fixed at **20 000 Euros**;

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 Substance, 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.

This Consortium Entry Fee is fixed at **20 000 Euros**.

The amount of this Fee is credited to and reimbursed to (shared equally between) all existing Members

### **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 Dossier, including costs of existing and new Information obtained or developed by the Consortium for the Purpose. Participation is as per the cost sharing mechanism specified below 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, as detailed in Annex 5
  - > 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 (shared equally between) all existing Members, so that after this re-accounting, all Members (existing and new) have in effect paid the same equal share of the total costs.
- for existing Members and for any newly joining Member after joining, the Pro Rata Share of all **future costs** engaged by the Consortium, on a one Member – one share basis.

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**

All Consortium costs are shared on a “**one Member – on equal cost share**” basis, that is if the Consortium has N Members then the Pro Rata Share for each Member is 1/Nth of the Consortium costs.

Therefore, if at the date of entry of a new Member into the Consortium:

- the number of Members passes from N to (N+1)
- the Consortium costs engaged up until the date of entry are Z Euros

then

- the new Member must pay [  $Z/(N+1)$  ] Euros for past costs (in addition to the Advantage Compensation Payment)
- each existing Member will be reimbursed [  $Z/(N+1)/N$  ] Euros

and after the date of entry of the new Member, each of the Members will pay an equal share of future costs, that is  $1/(N+1)^{\text{th}}$  part.

However, a Member will only be liable to pay costs relating to Studies required 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).

### **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 provided that the party needs to submit the Information according to its tonnage band;
- Costs for new Information developed where required for the Purpose and provided that the party needs to submit the Study according to its tonnage band;
- Costs for a party 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 the Registration Dossier developed by the Consortium **without becoming a Member of the Consortium**. The Dossier Contribution Costs correspond to a fair participation in the total expenses (referred to below as “TX”) incurred in establishing and managing the Consortium and in preparing, justifying, writing and submitting the Registration Dossier and fulfilling other 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 (5C) above, where N is the number of Members at the date of the Governing Committee decision according access. Thus if the total expenses defined above are TX, then the Dossier Contribution Cost payable is  $[TX/(N+1)]$ .

The Dossier Contribution Costs payment is credited to and reimbursed to (shared equally between) all existing Members, 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 costs  $[TX/(N+1)]$ . However, should a further party Y agree later to purchase access to the Registration Dossier developed by the Consortium without becoming a Member of the Consortium, and so pay the Dossier Contribution Costs, then the share paid by the Members will become lower  $[TX/(N+2)$  etc] than that of the parties X and Y  $[TX/(N+1)]$ . 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 for their own REACH Registration of the Substance, 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. 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 is credited:

- 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,
- where relevant, part due for reimbursement to the Member corresponding to its part of CEEP owned Studies or work made available by CEEP 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 Dossier (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.

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

## Model Letter of Access for Members for the Registration of Sodium Tri Poly Phosphate

By this letter, the Members of the Consortium for the REACH Registration of Sodium Tri Poly Phosphate (hereafter referred to as "the Consortium" and "the Substance") agree that the REACH Registration Dossier, 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 Substance 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

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 in March 2008 of the Consortium Agreement between the following initial Members :

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

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 Sodium Tri Poly Phosphate under REACH Regulation

By this letter, the Members of the Consortium for the REACH Registration of Sodium Tri Poly Phosphate (STPP), as indicated below, (hereafter referred to as “the Members”, “the Consortium” and “the Substance”), agree that:

- the REACH Registration Dossier, 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 Substance (hereafter referred to as “the Dossier”)

may be referred to:

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

in order to support

- the Applicant’s Registration of the Substance under REACH

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;
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 nor is the Applicant authorised to inspect or view the Dossier or any related specific document in whole or in part, only the right to refer to the Dossier and its 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 or to any information contained within it 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 STPP, established in 2008 between the following Initial Members : BK Giulini GmbH, Chemische Fabrik Budenheim, 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 Existing Studies, detailed in Annex 5. They will be included in the Pro Rata Share calculations as specified in Annex 9.

All prices below are ex-VAT

### Data gap analysis and complementary assessment – Safepharm – October 2007 – March 2008

Estimative price to be confirmed: GB£ 3,500 = 4,700 €

Tests carried out by Safepharm, launched February 2008

Estimative prices to be confirmed:

- relative density	GB£ 570	= 1,500 €
- skin sensitisation LLNA (mouse)	GB£ 1825	= 2,500 €

### Member company costs:

- Meeting 4<sup>th</sup> September 2007
- Meeting 8<sup>th</sup> November 2007
- Meeting 13<sup>th</sup> December 2007
- Meeting 15<sup>th</sup> January 2008
- Meeting 11<sup>th</sup> March 2008
- - time spent by company personnel preparing Consortium agreement
- - calculation as per rules specified in Annex 9

### Consultant: 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 administrative issues
- - defining and overseeing data gap analysis study, call for proposals for Consortium management, preparation of Safepharm studies above
- - purchase of electronic copies of relevant studies (Infotrieve costs)
- - time spent looking for relevant Studies

Time (fees) 2007	= 10,000 €
Time (fees) 2008 first semester	= 15,000 €
Costs (travel, Studies purchase ...) 2007	= 4,572 €
Costs 2008 prior to Entry into Force, estimate	= 2,000 €

### Cefic – time spent and costs

- - participation of Dominique De Halleux in meetings and coordination or Consortium preparation, June 2007 – February 2008
- - meeting room costs and organisation costs for the meetings indicated above