21 September 2009

Model Cooperation Agreement between SIEF Lead Members
according to REACH Regulation (EC) No 1907/2006[1]

The present cooperation agreement between SIEF Lead Members has been elaborated by the Cefic Legal Aspects of REACH Issue Team on the basis of REACH requirements, the available guidance, in particular the Guidance on data sharing and the European Law in force.

Please note that this model is by no means intended to be mandatory or prescriptive. It should rather serve primarily as basis for discussion in order to ensure that all interested parties address a range of aspects when considering legal framework for their cooperation.

The passages in italic in this Agreement identified as "options" are binding on the Parties only if they have been specifically retained in each case. Ultimately, it is for the Parties to assess the appropriateness of the provisions on a case-by case basis and decide what elements they wish to adopt and at what level but when making any decisions it is recommended that these issues should be taken in consideration[2].

Companies are to apply this model at their own risk and Cefic will not accept any warranties resulting from the use of or reliance on this document and its application.

For Cefic and its members: for further clarifications and questions, contact Vincent Navez, Cefic Legal Counsellor. Tel. +32 2 792 75 10 - E-mail: vna@cefic.be

[1] *Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 136 of 29.5.2007*
[2] *Adjustments may be necessary in order to comply with the national law applicable according to the Article XIV.*

Cooperation agreement between SIEF Lead Members

Between

[A], *[insert address]*
(**hereinafter referred to as "Lead Registrant"**)

and
[B], *[insert address]*

and
[C], *[insert address]*

…

Hereinafter individually referred to as "**the Party**" and collectively referred to as "**the Parties**".

Preamble

Whereas the Parties to this Agreement have pre-registered [*designation of the Substance(s) name*] and are Participants of the same Substance Information Exchange Forum ("SIEF") as potential registrants for that/these Substance(s) under the meaning of Article 29 of the European Community Regulation EC 1907/2006 ("REACH");

Whereas the Parties want to be the Lead Members in the SIEF;

Whereas the Parties are also interested in exchanging rights to use the studies necessary for the registration under REACH of the Substance(s) for their registration under REACH;

Whereas pursuant to Article 11(1) REACH the Lead Registrant is obliged to submit the Joint Registration Dossier;

Therefore, with a view to fulfill their regulatory obligations under REACH in respect to the Substance(s) and with a view to fulfill their leading role in the SIEF, the Parties undertake to cooperate and share human and financial resources under the terms of this agreement in order to prepare and to compile jointly the Joint Registration Dossier (hereinafter the "Purpose").

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:

Parties: being the signing parties to this Agreement:

> **-Lead Member**: SIEF participant who is subject to the registration requirements under REACH for the Substance(s), who participates actively to the SIEF discussions in order to prepare and to compile jointly the Joint Registration Dossier.

-Lead Registrant: the Lead Member who is responsible for submitting the Joint Registration Dossier to the European Chemicals Agency ("ECHA") on behalf of the participants of the SIEF, assuming it [*has been / will be*] legitimately appointed as lead registrant pursuant to Article 11 (1) REACH by the SIEF participants.

Non-Lead Member: SIEF participant being neither a Lead Member nor a data holder (article 28 (7) REACH), that is not a Party to this Agreement and that wants to rely on the Joint Registration Dossier prepared and compiled by the Lead Members *(via an applicable SIEF agreement).*

Affiliate*:* Any legal entity controlling, controlled by, or under common control with, either directly or indirectly, a Party or in case of an only representative, the affiliate of the non-EU manufacturer. 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(s) or to refer to it, either as SIEF participant or as non SIEF participant.

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

Joint Registration Dossier: The data that the Parties are required to submit jointly with the other SIEF participants to the Agency in order to register the Substance(s), pursuant to Article 11 (1), paragraph 2 (*optional: and 4*) REACH.

Substance(s): [*designation of the name and EINECS#/CAS# or other descriptor*].

TITLE I: DATA SHARING AND SUBMISSION OF THE JOINT DOSSIER

Article II. Preparation of the Joint Registration Dossier

1. The Parties shall cooperate for the Purpose of this Agreement. They will endeavour to assign resources and will monitor, control and report to Non-Lead Members on progress, resources and agreed deliverables related to the joint preparation of the Joint Registration Dossier. The Parties shall also handle jointly general SIEF management issues such as setting up agreements via the *[Lead Registrant / external service provider*] with consultants and laboratories, and will manage via the *[Lead Registrant / external service provider*] financials such as preparing a budget, sending invoices, book-keeping, tracking invoices.

2. The Parties make available to each other (robust) study summaries of the studies they own as listed in Annex 1 *(optional: as well as the full study reports of those studies)*.

3. The Parties grant each other the limited, non-transferable and non-terminable right to use existing (robust) study summaries of the studies listed in Annex 1 and the permission to refer to the existing full study reports owned by the respective Party for the limited purpose of registration of the Substance(s) according to REACH. *Optional: The rights to use and the permission to refer are also granted to Affiliates of the Parties, with the right to sub-license such rights only to their only representatives.*

4. Any Information that might have to be generated jointly in the context of registration and/or evaluation or other REACH requirements will be carried out by the Lead Registrant in its own name and on its own as well as on the other Parties' account. Each of the joint owners shall obtain a copy of the full study report. The Information referred to in the first sentence may be used by the Parties who have contributed to the costs thereof *[for own purposes / for fulfilling any regulatory and legal requirements and for no other purpose / for complying with the requirements pursuant to the REACH Regulation]* and shall not for the period of 12 years from the date of initial submission to the Agency be sold, licensed or otherwise made available to third parties by any Party without prior written approval of *[all / majority of 2/3 / other]* remaining owners who have financially contributed to the costs thereof unless otherwise agreed by the Parties.

5. The Parties shall review and approve the Joint Registration Dossier before its submission to the Agency by the Lead Registrant.

Article III. Submission of the Joint Registration Dossier

1. The Lead Registrant, assuming its legitimate appointment by the SIEF participants, shall submit to the Agency as lead registrant pursuant to Article 11 (1) REACH the Joint Registration Dossier for the registration of the Substance(s) with the agreement of and on behalf of the other Parties at least *[2]* months before end of the registration deadline applicable to the Party/ies within the highest tonnage band.

If a Party requests the submission of the Joint Registration Dossier on behalf of an Affiliate, that Party shall notify the Lead Registrant with its name, address and other relevant data documenting such status of Affiliate within *[x]* month(s) before the registration due date. Upon receipt of such information, the Lead Registrant shall submit the Joint Registration Dossier also on behalf of such Affiliate.

2. The Lead Registrant will complete the Registration Dossier upon demand of the ECHA if necessary.

3. If agreed upon by the Parties according to article X.1 of this Agreement, the Lead Registrant shall duly apply for non-disclosure according to Article 10(a)(xi) REACH with respect to information which may be kept secret according to Article 119 (2) REACH.

4. 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.

5. After submission of the Joint Registration Dossier, the Lead Registrant shall provide the other Parties with a complete set of copies of the Registration Dossier submitted.

Article IV. 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 by a Party.

2. 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.

Article V. Costs sharing

1. The value of existing studies made available by a Party to other Parties according to Article II.3 shall be jointly determined by the interested Parties on the basis of an evaluation of the scientific quality, adequacy and relevance in relation to the achievement of the Purpose.

Comment [v1]: For example the scientific quality of the study and the replacement values may be respectively determined in accordance with the Klimisch et al. method and the "Fleischer List".

2. The following costs related to the preparation of the Joint Registration Dossier shall be shared between the Parties:

a) Administrative expenses reasonably incurred by the Parties including but not limited to, secretarial services, management of confidential data and costs of external experts.

b) Expenses to acquire rights to use (robust) study summaries or to refer to existing studies of an individual Party and costs for studies jointly developed by the Parties according to Annexes VI to VIII of REACH.

c) Expenses to acquire rights to use (robust) study summaries or to refer to studies from Data Owners.

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

a) Where a Party registers the Substance(s) in a tonnage band lower than the one covered by the Joint Registration Dossier, it shall only be requested to compensate for those parts of the Registration Dossier that it is included in and for those studies it receives a right to refer to.

b) Optional: Where a Party 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 those parts of the Joint Registration Dossier that are submitted jointly.

4. For the submission of the Joint Registration Dossier the parties shall share their costs as follows:

a) The rights to use according to Article II.3 will be compensated on an equal basis of taking into account the number of Parties that need the study for their registration (or the registration of their Affiliates) under REACH. (*optional: The amount to be compensated per study will be [x] % of the value determined by the Parties*.) The price calculation is based on the agreement that the studies may only be used for REACH purposes. (*optional: The payments are due on …)*.

It is understood that the Lead Registrant only has to compensate those studies that are needed by the Lead Registrant or its Affiliates for its/their registration, even though the Lead Registrant will receive all studies in order to be able to compile the Joint Registration Dossier.

b) Optional: For the preparation and submission of the Joint Registration Dossier, the Lead Registrant shall be paid by the other Parties an amount of … €. This payment is due on ….

c) Costs for further studies that might have to be carried out according to Article II.4 will be shared equally. After contribution of the costs, the Lead Registrant shall pass on joint ownership rights to the Party/ies in need of the studies.

5. In case Non-Lead Members get access to the Joint Registration Dossier according to Article VI, the cost settlement obtained from Non Lead Members is allocated to the respective Party/ies that is/are owner(s) of the studies and to the Lead Registrant for preparing and submitting the Joint Registration Dossier *(optional: with an amount of ….. €)*.

6. 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.

7. 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.

Article VI. Access to the Joint Registration Dossier granted to Non-Lead Members

1. Access to the Joint Registration Dossier to Non-Lead Members will be granted by the Parties *(via the SIEF agreement based on the Cefic model*. *The Lead Registrant will sign the SIEF agreement acting in its own name and in the name and on behalf of all the Parties)*.

2. If the Parties have been granted by Data Owners the rights to sub-license the rights to use the (robust) studies summaries and to refer to the full study reports to the other SIEF participants, these rights shall also be transferred by the Parties *(via the SIEF agreement).*

TITLE II: OPERATING RULES BETWEEN THE PARTIES

Article VII. Confidentiality

1. The Parties shall:

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

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

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

c) disclose the Information to their employees, Affiliates, external experts and/or consultants and if a Party is an only 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 VII.1 above shall not apply to Information for which the receiving Party can reasonably demonstrate that such Information:

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

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

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

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

e) becomes subject to disclosure to governmental agency/ authorities with lawful authority to seek such Information.

3. 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 VIII. 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 81 and 82 EC Treaty as well as any applicable national laws. The Parties explicitly agree to observe Cefic REACH Competition Law compliance guidance attached as Annex 2 to this Agreement, in particular with regard to the accession of a new Party 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 IX. 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 X. Organization

1. Decisions between the Parties shall be taken by a majority of the votes.

2. Optional: An external service provider shall be responsible for daily management of the cooperation between the Parties and shall at all times act in the best interests of the Parties.

Comment [v2]: The scope of the services of daily management will be defined by the services agreement with the external service provider

3. All contracts with further external service providers, including laboratories, to perform technical and scientific tasks, shall, upon prior approval of the other Parties, be concluded by the [*Lead Registrant / external service provider*], in its own name and on account of all Parties.

4. If a Party is an only representative, such Party should declare to the Lead Registrant the number of non-EU manufacturers it represents. For cost sharing and voting rights calculation purposes, each non-EU Manufacturer and its affiliates will separately count for one and the combined share will be allocated to the only representative.

Article XI. Administration of costs

1. To finance the activities carried out under this Agreement, each Party, including any new Party, shall pay the provisional amounts to be jointly determined.

2. The [*Lead Registrant / external service provider*] shall prepare a budget, administer and keep records of all expenses incurred including allocation and cost-splitting as well as credits and present a costs overview to the Parties on a [*quarterly*] basis.

3. The [*Lead Registrant / external service provider*] shall administer invoices and the compensation payable to the Parties or from the Parties based on their respective verification. The [*Lead Registrant / external service provider*] shall keep records of the full value of the data obtained/generated.

TITLE III: FINAL PROVISIONS

Article XII. Limitation of liability

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 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 XIII. Term and Termination

1. This Agreement shall enter into force as from … and shall be binding for the duration necessary to achieve the Purpose or at the date corresponding to [e.g. *at the registration deadline for members with a lower tonnage band / at the deadline for the authorities to evaluate the registration dossier /….*].

Upon achievement of the Purpose this Agreement can be terminated by a unanimous decision of the Parties.

2. This Agreement shall become effective upon execution thereof. Neither expiration nor termination of this Agreement shall relieve the Parties hereto from the duty to discharge in full any obligations accrued or due prior to the date of such expiration or termination, and such obligation (until so discharged) shall expressly survive expiration or termination. The obligations set forth in Article II hereof shall expressly survive any termination or expiration of this Agreement.

3. This Article and the provisions relating to the protection of confidentiality (Article VII), ownership of Information (Article IV), dispute resolution and applicable law (Article XIV) and limitation of the liability (Article XII) shall survive the termination of this Agreement. With regard to the studies, the obligations specified in Article VII 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 this Agreement.

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

5. At any time and without cause, this Agreement may be terminated by a Party subject to a six months written notice period. In any event, the terminating Party shall fulfill its financial obligations up to the date of termination, i.e. until the end of the applicable notice period, including all payments related to studies agreed on which have arisen during the time of his participation. The terminating Party shall have no further rights to any results arising out of this Agreement in respect of which he has not fulfilled his financial contribution or to any compensation from subsequent Parties. Any rights granted under this Agreement remain unaffected by the termination and the other Parties shall continue to be entitled to make use of the Information made available by the terminating Party on the conditions specified in this Agreement and provided that that Party has been duly compensated under the conditions defined in this Agreement.

6. This Agreement may be terminated by the non-defaulting Party as to the Party which is in default of any material obligation set forth in this Agreement and which fails to remedy such default within 45 (forty-five) days after written notice thereof. Upon such termination the Party in

default shall not be entitled to rights to use studies until such Party has discharged in full any obligations accrued or due hereunder prior to the date of such termination.

Article XIV. 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 [*e.g. CEPANI, ICC*] 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 [*e.g. 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.

For and on behalf of

XXX ("A")

Signature: _____

Name:

Title:

Date:

For and on behalf of

XXX ("B")

Signature: _____

Name:

Title:

Date:

For and on behalf of

XXX ("C")

Signature: _____

Name:

Title:

Date:

ANNEXES:

Annex 1: Study List

(to be completed)

Annex 2: Cefic guidance on competition compliance

Cefic REACH DO & DON'T.pdf