SIEF Agreement for the Substance Formaldehyde, CAS 50-00-0, EINECS 200-001-8

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

* BASF SE (Carl-Bosch-Strasse 38; D-67056, Ludwigshafen/Rhein; Germany), **Lead Registrant** for the Substance Formaldehyde, *acting on behalf of the Members of the Formaldehyde Consortium*, CAS 50-00-0, EINECS 200-001-8

and

* the SIEF Participant signatory of the present Agreement (hereinafter referred to as "**Non-Lead Member**")

Hereinafter individually referred to as a “Party” or collectively as the “Parties”.

Preamble

Whereas the Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (“**REACH**”)imposes on manufacturers and importers as well as on only representatives the obligation to register the substance Formaldehyde, CAS 50-00-0, EINECS 200-001-8 (hereinafter referred to as the **“Substance**”) within the prescribed deadlines;

Whereas the Parties and/or their Affiliates A) have registered the Substanceand/or B) submitted an inquiry and have agreed on the identity and the sameness of the Substance, and thus are participants of the same Substance Information Exchange Forum (“**SIEF**”) as registrants for that Substance under the meaning of Article 29 of REACH;

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

Whereas the Parties are aware that they and/or their Affiliates have co-operation and data sharing obligations with other SIEF participants;

Whereas, the Lead Registrant prepared and submitted a Joint Registration Dossier to the Agency for the Substance;

Whereas the Non-Lead Member has the intention to register or registered the Substance;

Whereas the European Commission adopted the Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing (the “**Implementing Regulation 2016/9**”), which entered into force on 26 January 2016, that inter alia defines more clearly what the terms ‘*fair, transparent and non-discriminatory*' mean for data and cost sharing obligations within REACH;

Whereas the Agency states in its REACH Guidance on data sharing of January 2017 that the SIEF participants have to agree in writing certain SIEF operational rules concerning data sharing, rights on the developed information and sharing of costs, including a reimbursement mechanism, in accordance with the aforementioned criteria of fairness, transparency and non-discrimination;

Whereas the Commission Implementing Regulation (EU) 2019/1692 of 9 October 2019 on the application of certain registration and data-sharing provisions provides that registrants continue to have data-sharing obligations under REACH, and therefore registrants may continue to use communication platforms to coordinate such obligations, and the Parties intend the existing SIEF to be such a platform;

Therefore, with a view to fulfilling their regulatory obligations under REACH 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 participants (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 Registrant (Title II);

under the terms and conditions set forth in this Agreement.

# THE PARTIES HAVE AGREED UPON THE FOLLOWING:

## Definitions

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

**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 legal entity.

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

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

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

**Joint Registration Dossier**: The data that the Parties are required to submit jointly to the Agency in order to register the Substance, pursuant to Article 11 (1), paragraph 2 and 4 or Article 19 (1) paragraph 2 of REACH.

**Only Representative:** A natural or legal person established in the European Union (“**EU**”) appointed by a non-EU manufacturer to fulfil the obligations applicable to importers under REACH, as permitted by Article 8 of REACH.

**Party/Parties**: the signing parties to this Agreement, having the quality of either:

1. **Lead Member**: a Member of the Joint Submission who is subject to the registration requirements under REACH, who participates to the SIEF discussions in order to compile the Joint Registration Dossier.
2. **Lead Registrant**: a Member of the Joint Submission who is subject to the registration requirements under REACH , which is appointed as Lead Registrant as defined under Article 11 (1) of REACH on which the Non-Lead Member agrees hereto.
3. **Non-Lead Member**: a Member of the Joint Submission being neither a Lead Member nor a data holder (Article 28 (7) of 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 an Only Representative and/or a Third Party representative.

**Substance:** Formaldehyde, CAS 50-00-0, EINECS 200-001-8.

**Third Party Representative:** A natural or legal person appointed pursuant to Article 4 of REACH.

Title I: SIEF OPERATING RULES

## Confidentiality

* 1. The Parties shall:

1. 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 the Information, as well as of any request by competent authorities relating to the disclosure of that Information.

Disclosure of the Information as required for legal and/or regulatory purposes including REACH, 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.

1. use the Information only for the Purpose or otherwise as permitted under or in accordance with this Agreement.
2. 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 the 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.
   1. The obligations specified in II.1 above shall not apply to the Information for which the receiving Party can reasonably demonstrate that such Information:
3. was known to the receiving Party on a non-confidential basis prior to its disclosure pursuant to this Agreement; or
4. 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; or
5. becomes known to the receiving Party through disclosure by sources other than the disclosing Party, having a right to disclose such Information, or
6. was independently developed by the receiving Party without access to the disclosing Party’s Information, as evidenced by documentary records.

Specific items of the 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 the 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.

* 1. With regard to studies, the obligations specified in this Article shall remain in effect for a period of twelve (12) years following the initial submission to the Agency.

## Competition Law compliance

* 1. The Parties acknowledge that any activities carried out under this Agreement have to be carried out in full compliance with EU competition law, in particular but not limited to Articles 101 and 102 TFEU as well as any applicable national laws. The Parties explicitly agree to observe Cefic REACH competition law compliance guidance attached as Annex 1 to this Agreement.
  2. Should it become apparent at any time that 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.

## 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.

## Communications on the Joint Registration Dossier

* 1. The Lead Registrant undertakes to inform the Non-Lead Member regularly on the developments of the Joint Registration Dossier.
  2. In particular, in case the CSR is included in the Joint Registration Dossier, the Lead Registrant undertakes to inform the Non-Lead Member on the list of uses to be covered in that CSR without undue delay.
  3. The Non-Lead Member undertakes to make all best efforts to check proactively and regularly all updated Information that is made available by the Lead Registrant on the Joint Registration Dossier.
  4. The Parties agree that such communication may be channelled via the use of electronic communications and/or the relevant the joint submission object in REACH-IT as mentioned under Paragraph VIII.1 of the present Agreement.

TITLE II: DATA SHARING AND JOINT SUBMISSION OF THE DOSSIER

## Participation in the joint submission of data

* 1. In accordance with Article 11 (1) or Article 19 (1) of REACH, the Parties hereto agree to have the Joint Registration Dossier for the Substance submitted by the Lead Registrant on behalf of the Non-Lead Member having fulfilled its obligations under Article IX to this Agreement. Upon demand of the Agency, within the requested deadline and to the extent necessary, the Lead Registrant agrees to complete the Joint Registration Dossier.
  2. Notwithstanding anything to the contrary under this Agreement, the Parties remain individually responsible to comply with REACH, in particular, but not limited to, in relation to the individual submission of the information required under Article 11 (1) or Article 19 (1) of REACH. For the avoidance of doubt, a CSR, if required by REACH, will always have to be submitted individually by each Party.
  3. The participation in the Joint Registration Dossier may deviate per requesting Non-Lead Member according to its tonnage band or possible opt-outs for certain endpoints.
  4. If the Non-Lead Member requests the submission of the Joint Registration Dossier on behalf of an Affiliate, the Non-Lead Member shall notify the Lead Registrant with its Affiliate’s name, address and other relevant data documenting the status of Affiliate. Upon receipt of such information, the Lead Registrant shall transfer the token for the access to the Joint Submission to the Non-Lead Member for such Affiliate.
  5. If the Non-Lead Member is an Only Representative and requests the submission of the Joint Registration Dossier on behalf of a legal entity represented by him in the SIEF, the Non-Lead Member shall notify the Lead Registrant under confidentiality obligations with the name, address and other relevant data of the represented legal entity. Upon receipt of such information, the Lead Registrant shall transfer the token to the Only Representative for its access to the Joint Submission on behalf of the represented legal entity.
  6. If Non-Lead Member is a Third Party Representative and requests the membership to the Joint Registration Dossier on behalf of a legal entity represented by him in the SIEF, the Non-Lead Member may notify the Lead Registrant, under appropriate confidentiality obligations, with the name, address and other relevant data of the represented legal entity. Upon receipt of such information, the Lead Registrant shall transfer the token to the Third Party Representative for the access to the Joint Submission by the represented legal entity.
  7. The Lead Registrant has opened a joint submission object in REACH-IT and, in accordance to Article 11 (4) of REACH, has paid the registration fee as invoiced by the Agency for the submission of the Joint Registration Dossier.
  8. The Lead Registrant shall make available the data referred to in Article 11 (1) paragraph 2 or Article 19 (1) paragraph 2 of REACH that have been submitted in the Joint Submission (and when applicable the CSR as defined according to Article I of this Agreement), to the Non-Lead Member and/or Non-Lead Member’s Affiliate notified under Paragraph VI.4 of this Agreement, provided the Non-Lead Member and/or the Non-Lead Member’s Affiliate has/have fulfilled the relevant obligations under Article IX of this Agreement.

## Grant of right to use the (robust) study summaries in the Joint Registration Dossier and to refer to the full study reports

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

1. 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;
2. to refer to the full study reports on which basis the (robust) study summaries have been developed (for the avoidance of doubt, copies of the full study reports will not be provided); and
3. to grant the rights referred to under (a) and (b) hereabove to the Non-Lead Member’s Affiliates notified under Paragraph VI.4, with the right to sub-license such rights only to their Only Representatives.
   1. Notwithstanding the foregoing, if the Non-Lead Member is an Only Representative or 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 Paragraph VI.5.
   2. The rights granted under this Article can be exercised only for the purpose of compliance with REACH requirements 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 Information shall be subject to a separate written agreement.

## Information on the submission of the Joint Registration Dossier

* 1. Provided the Non-Lead Member has fulfilled its obligations under Article IX, the Lead Registrant shall inform immediately the Non-Lead Member of the creation of the joint submission object in REACH-IT and shall provide the valid security token number and the name of the joint submission.
  2. The Lead Registrant shall inform immediately the Non-Lead Member of the submission of the Joint Registration Dossier to the Agency and provide documentation of the same. For the avoidance of any doubt, the term documentation includes, but it is not limited to, the relevant IUCLID file.
  3. The Lead Registrant shall further communicate the confirmation that the joint registration has been successful.
  4. The Non-Lead Member shall inform *mutatis mutandis* the Lead Registrant about any changes in tonnage band registration and information requirements that could have an impact on the joint submission and the data and cost sharing rules mentioned under the present Agreement. The changes above shall become effective and operational vis-à-vis the Lead Registrant and the other members of the Joint Submission.

## Financial compensation for the Joint Registration Dossier

* 1. The Non-Lead Member shall compensate in a fair, transparent and non-discriminatory way the Lead Registrant with a “Joint Registration Compensation” for the development and submission of the Joint Registration Dossier and the rights granted under Article VII above.
  2. The Joint Registration Compensation is set out in Annex 2 and will comprise the following elements:

1. Administrative costs reasonably incurred by the Lead Members and the Lead Registrant including but not limited to, secretarial services, management of confidential data and costs of external experts and provided that they are justified appropriately irrespective of their nature.
2. Costs to acquire rights to use existing studies of an individual Lead Member and costs for studies jointly developed by the Data Owner(s) according to Annexes VI, VII, VIII, IX and X of REACH.
3. Costs for rights to use studies from Data Owners, if the Lead Registrant is authorised by Data Owners to transfer to Non-Lead Member the rights specified under Paragraph VII.1.
4. When applicable, costs for the CSR which is made available by the Lead registrant to Non-Lead Member on an individual request (not included in the Joint Registration Dossier).
5. Costs for preparing and updating the Technical Dossier including preparatory work like literature search, assessment of available data and writing (robust) study summaries.
   1. Both the study and administrative costs referred to above shall be allocated according to Annex 2 to this Agreement, in a transparent, fair and non-discriminatory way and in full compliance with the Implementing Regulation 2016/9, to all Members of the Joint Submission with the intent to register or registered the Substance, taking into account the following exceptions:
6. 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 those parts of the Joint Registration Dossier that it is included in and for those studies it receives a right to refer for.
7. Where the Non-Lead Member decides, based on Article 11 (3) of 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.
   1. Based on the above, the Lead Registrant will send an invoice to the Non-Lead Member for the sharing of the costs mentioned above after the request to join the joint submission. The Non-Lead Member will only receive a valid security token number after payment of the invoice for the Joint Submission Compensation. Payment is due within 1 (one) month after receipt of the invoice issued by the Lead Registrant or any legal entity acting on his behalf.
   2. In case new studies have to be purchased or performed or other dossier preparation, administrative or other cost have to be engaged after conclusion of this Agreement, the resulting cost will be divided in accordance with Annex 2 to this Agreement between all Members of the Joint Submission who are required to incorporate the results of these new studies into their registration dossiers, unless they claim to opt out in accordance with Article 11 (3) REACH. The Non-Lead Member will be granted on these new studies the same rights as referred to under Paragraph VII.1a).
   3. Upon signature of the present Agreement, the Parties agree to be bound by the cost sharing mechanism mentioned under Annex 2 herein. Furthermore, the cost sharing mechanism shall be based on the criteria of fairness, transparency and non-discrimination, and shall take into account, inter alia, the following factors: (i) the variable number of registrants joining the Joint Submission; (ii) any additional information requirements for the successful submission of the Joint Registration Dossier; (iii) future costs including, but not limited to, the costs arising from a decision adopted by the Agency in accordance with Title VI of REACH.
   4. Parties hereby agree to be bound by the recalculation of the study and non-study costs related to registration made by the Lead Registrant after the 2018 registration deadline and successively on a regular basis at the discretion of the Lead Registrant, and to share subsequently the aforementioned costs in a fair, transparent and non-discriminatory manner.
   5. When cost and income estimations related to the Joint Registration Dossier change, in particular after the aforementioned 2018 recalculation, additional payments or refunds respectively may be initiated by the Lead Registrant. For both payments and refunds a threshold of 1.000 € per joint registrant is applicable. Based on the above paragraphs and when necessary, the Lead Registrant will send an invoice to the Non-Lead Member. Payments are due within 1 (one) month after the invoice issue by the Lead Registrant or any legal entity acting on his behalf.
   6. If the SIEF comprises various Affiliates of the Non-Lead Member, the Non-Lead Member shall be subject to the obligation to compensate the Joint Registration Dossier calculated on the basis of the single highest tonnage band of the Non-Lead Member and all its Affiliates. Accordingly, the Affiliates of the compensating 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 with the rights and obligations pursuant to this Agreement, including the confidentiality obligations under Title I, Article II of this Agreement.
   7. 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 and any other invoice pursuant to Paragraph 8 above per non-EU entity and its Affiliates. The Affiliates of each of the non-EU entities 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 and without additional payment pursuant to Paragraph 9 above. In that case, the Only Representatives being a Non-Lead Member that has paid the compensation is responsible for compliance of the Affiliates with the rights and obligations pursuant to this Agreement, including the confidentiality obligations under Title I, Article II of this Agreement.
   8. 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 and any other invoice pursuant to Paragraph 8 above per entity and its Affiliates. The Affiliates of each of the entities represented by a Third Party Representative being a Non-Lead Member, shall also have the right to refer to the Joint Registration Dossier under the same conditions and without additional payment pursuant to Paragraph 9 above. In that case, the legal entity that has paid the compensation is directly responsible for compliance of the Affiliates with the rights and obligations pursuant to this Agreement, including the confidentiality obligations under Title I, Article II of this Agreement.
   9. Upon signature of the present Agreement, the Non-Lead Member shall be bound by the obligation to inform the Lead Registrant of any changes in their corporate structure that can have an impact on this Agreement. In case the Affiliates companies mentioned above cease to meet the definition of Affiliate set out under Article I of this Agreement following changes in their corporate structure, these legal entities shall request separately a Letter of Access to the Lead Registrant and compensate individually and separately the Lead Registrant for any rights granted under this Agreement. These obligations shall be legally binding as from the date of non-fulfilment of the definition set out under Article I of this Agreement.
   10. All payments due hereunder shall be net payments, i.e. free of any bank or transfer charges or similar charges and without deduction of any taxes, levies or other dues payable. If payer is required to withhold any tax or to make any other deduction from any such payments, then the said payments shall be increased to the extent necessary to ensure that, after making of the required deduction or withholding, payee receives and retains (free from any liability in respect of any such deduction or withholding) a net sum equal to the sum which it would have received and so retained had no such deduction or withholding been made or required to be made (gross-up amount). If upon application of the beneficiary any withholding tax can be reduced, or refunded, or an exemption from withholding tax is granted, payer shall file on behalf of payee for such reduction, refund or exemption. Payee shall render any assistance to payer to obtain such withholding tax reduction, refund or exemption. Payer shall be entitled to any refund of withholding taxes.
   11. Indirect taxes, including but not limited to Value Added Tax (VAT), Goods and Service Tax (GST), service tax, business tax, as applicable pursuant to the relevant tax law, shall be borne by payer. However, payer is entitled to withhold any payment of indirect taxes unless payee has provided payer with a sufficient invoice for purposes of indirect taxation.

## Ownership of Information

* 1. This Agreement does not grant any ownership rights or change existing ownership rights to any of the Information provided under this Agreement to the Non-Lead Member, on whatever form and whenever, by the Lead Registrant, including without limitation, the Joint Registration Dossier.
  2. The Information provided by the Lead Registrant to the Non-Lead Member shall consist in any and all data and/or studies:

1. Individually developed by one of the Lead Members;
2. Collectively developed by the Lead Members for which they have acquired valid title or right to use; and
3. Acquired from Data Owner(s) for which the Lead Members, or the Lead Registrant as the case may be, have been granted valid rights.
   1. Neither this Agreement nor any disclosure of the 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

## 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 provided 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/or entitled to grant rights therein or, that he has fulfilled the obligations mentioned under Paragraph VII.4 above, **(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.

## Termination

* 1. This Agreement shall enter into force as from the date of signing of this Agreement by both Parties. This Agreement shall remain in full force and effect until it is terminated by mutual agreement of the Parties or upon completion of all regulatory obligations existing between the Parties under REACH, unless terminated by the Non-Lead Member in accordance with Paragraph XII.4 set out below.
  2. This Article and the provisions relating to the protection of confidentiality (Article II), financial compensation for the Joint Registration Dossier (Article IX), ownership of Information (Article X), limitation of the liability (Article XI) and dispute resolution and applicable law (Article XV) 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 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.
  1. The Non-Lead Member has the right to terminate the present Agreement subject to a prior three (3) months written notice to the Lead Registrant. The termination shall be effective at the end of the aforementioned notice period provided that the Non-Lead Member fulfils its obligations under this Agreement. No reimbursement shall be due and all the rights deriving from this Agreement will be withdrawn *ex nunc*. Notwithstanding the above, the Non-Lead Member shall continue to fulfil its own individual obligations deriving from REACH.

## Legal entity change of the Non-Lead Member

The consent of the Lead Registrant shall not be required in case the Non-Lead Member 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 Lead Registrant without undue delay. In case a non-EU entity changes its designated Only Representative, the provisions outlined in the first sentence shall apply *mutatis mutandis*.

## 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 and electronic records, records on expenses, books of account, correspondence, memoranda and receipts.
  3. The Lead Registrant is required to have the relevant data validated by an external auditor annually if requested to do so by a unanimous decision of the Members of the Joint Submission, the costs of such an external audit to be shared according to Paragraph IX.2.

## Dispute resolution and applicable law

* 1. The Parties shall first attempt to settle amicably any dispute arising out of this Agreement. Any dispute shall be resolved by arbitration, ousting jurisdiction by ordinary courts, by a panel of three arbitrators. Each party to the dispute will nominate one arbitrator. These two arbitrators will then designate a third arbitrator who will also act as chairman. The arbitration decision shall be binding on the parties. The arbitration rules of the ICC shall be applicable. The place of any hearing shall be Brussels and the language of the arbitration shall be English.

Notwithstanding the above, each Party, at its own expenses, may at any time request from any competent judicial authority any interim or conservatory measure.

* 1. This Agreement shall be governed by the laws of the Kingdom of Belgium, excluding its choice of law rules.
  2. 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 accept to be validly bound by this Agreement on the date of signature of the present agreement in accordance with Article XII above.**

For the Lead Registrant

Signature:

For the Non-Lead Member

Signature:

Annex 1

**Cefic guidance on competition compliance**



Annex 2

**Cost Sharing Model**

**Rules on the Calculation of the Costs and Cost Sharing Mechanism**

**The cost calculation for the joint registration dossier is based on the following cost items:**

**(1) Administrative expenses**

**(2) Cost for studies included in the Joint Registration Dossier**

**(3) Cost for CSR / Guidance on Safe Use**

**(4) Post registration cost-sharing obligations**

**(5) Invoicing and late payment**

These are described below:

1. **Administrative expenses**
2. **Guiding Principle**

The work done by the Lead Members in the Formaldehyde Consortium is aimed at reducing cost and efforts in the preparation of the Formaldehyde REACH registration dossier(s) and is made available to all SIEF Members in need to register the Substance Formaldehyde EC 200-001-8, CAS 50-00-0.

The operational cost of the consortium will be determined in a fair, transparent and non-discriminatory way following the spirit of REACH Article 27 (3) and Article 30 (1).

1. **Cost included**

- Compensation for the work of the ‘Lead Registrant’

- Cost for the joint dossier creation

- Cost for meetings and their organisation

- Cost for secretariat & secretarial services

- Cost for third party services (Trustees, experts) related to the consortium operation

Key for cost sharing of consortium cost:

Administrative costs and dossier costs are shared on the basis of multiplicative factors.

|  |  |
| --- | --- |
| **Volume Range** | **Multiplicative factor** |
| >1000 | 10 |
| 100 - 1000 | 7 |
| 10 – 100 | 3 |
| 1 – 10 and intermediates | 1 |

Any potential registrant can get a letter of access and a token to refer to the Lead Registration dossier for its co-registration as a member of a joint submission under REACH after fulfilling its cost compensation requirements agreed upon.

1. **Cost for studies included in the Joint Registration Dossier**
2. **Guiding Principle**

Study cost sharing as per ECHA Guidance on data-sharing Version 3.1, January 2017

Cost sharing on an ‘equal cost share’ basis for all Lead Members (including the Lead Registrant) / Non-Lead Members requiring a given study after applying the correction factors listed below:

1. A surcharge of 30% as Risk Premium for studies listed in Annex VII - X of the REACH regulation.
2. A surcharge to the total value of experimental costs (substance testing and analysis) is charged for administrative expenses (processing, monitoring and professional support by the commissioning party, travel expenses, archival of the test substance and raw data). The surcharge depends on the experimental value of the study (table 1).
3. Robust summaries contributed by the supplier or developed by experts commissioned by the Technical Committee should be compensated either based on the real costs incurred or by a surcharge of 30% of the value of the admin costs according to the table 1.

Table 1. Surcharge to the total study value of administrative expenses.

|  |  |  |
| --- | --- | --- |
|  | Correction factor | |
| Study value (€) | Administration (€) | Administration (%) |
| 3,000.00 | 750.00 | 25% |
| 5,000.00 | 1,000.00 | 20% |
| 20,000.00 | 3,000.00 | 15% |
| 50,000.00 | 5,000.00 | 10% |
| 100,000.00 | 7,000.00 | 7% |
| 200,000.00 | 10,000.00 | 5% |
| 300,000.00 | 12,600.00 | 4.20% |

Deduction factors may be used to transparently reduce the actual replacement value per end point. The deduction factor will be based on the final replacement value agreed upon.

More than one deduction factor can be applicable for a certain study value:

1. Minus 20% for a Klimisch 2 study;
2. Minus 100% for a Klimisch 3 or 4 study. However, on a case-by-case basis, the Consortium can suggest to include Klimisch 3 & 4 studies if they significantly contributed in the filling of a data gap (e.g. by weighted evidence). The deduction factor must be determined on a case by case basis;
3. Minus 50% for a Letter of Access giving the right to refer to the joint registration dossiers and to the data contained therein only for the purpose of a registration under EU REACH by a co-registrant (no transfer of the actual study report or study data and no co-ownership on the dossier or on the data granted).

If data are to be used for another purpose, a bilateral agreement is to be executed with the data owner.

1. **Cost for CSR / Guidance on Safe Use**

Cost to be determined based on effort. This may lead to different cost for the CSR / Guidance on Safe Use for different uses.

1. **Example**

4 Lead Members (including the Lead Registrant) / Non-Lead Members (A, C, E, F)

CSR / Guidance on Safe Use for e.g. polymer production: 50 000 €

Share per Lead Members (including the Lead Registrant) / Non-Lead Members:

50 000 € / 4 = 12 500 €

**Cost sharing basis**

Costs are re-calculated after each registration deadline and afterwards on a regular basis. The registrants may either be reimbursed (threshold: EUR 1.000,00) or invoiced.

1. **Post registration cost-sharing obligations**
2. **Administrative, dossier and CSR costs**

Registrants are bound to contribute in a fair way to additional administrative, dossier and CSR costs (either already incurred by the Consortium or estimated) after the purchase of a Letter of Access. A provision for future administrative costs may be included in the price of the Letter of Access. The amount of such provision may also depend on the estimation of the workload on the Substance that is reasonably foreseen for the following years.

These costs will be shared according to the standard rules for sharing administrative and dossier costs outlined under Sections 1.) to 3.) above.

1. **Study (data) costs** 
   1. **Voluntary updates**

Study costs linked to voluntary dossier updates will be shared according to the rules set out in Sections 1) to 3) above.

If the Lead Registrant conducts studies not linked to standard REACH requirements but needed in order to defend the Substance before the competent authorities in the interest of all registrants, the related costs will be shared in accordance to the rules set out in Sections 1) to 3) above.

* 1. **Cost sharing following an evaluation decision**

The evaluation of the registration dossier according to Title VI REACH may trigger new requirements (e.g. generation of new data) which would need to be addressed among registrants. Hence data and cost sharing obligations also apply to the studies which will be needed to ensure that the registration is compliant with REACH requirements.

1. Data costs that can be linked to standard REACH endpoints will be calculated according to the rules set out in 1.) – 3.) above and shared among registrants based on their tonnage band requirements.
2. Data costs requested by a final decision on Substance Evaluation, according to Title VI REACH, will be shared according to the rules set out in 1.) – 3.) with the addition of the following rules:
   1. that the costs will be split equally, regardless of the tonnage band of the registration
   2. All legal entities part of the Joint Submission, including affiliates, will pay a share of the costs.
3. Data costs following a final decision of the competent authorities which are not falling under the cases described under i. or ii. above will be shared according to the same rules applicable under ii.
4. **Invoicing and late payment**

Upon request, the Non-Lead Member shall provide invoicing details without undue delay, latest within one (1) month of receipt of the request. All invoices from the Lead Registrant to the Non-Lead Member shall be paidwithin one (1) month of receipt of the invoice. The Co-registrant that does not duly and timely pay an invoice issued by the Lead Registrant pursuant to the provisions of this Annex and the SIEF agreement shall pay an interest at the rate of **8%**. Interest shall be calculated daily and shall be payable to the Lead Registrant on demand.