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Member of the Belgian Supreme Court Bar

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February 11, 2025

#### TO WHOM IT MAY CONCERN

Dear Applicant,

#### Ethylbenzene ('EB') REACH Consortium Re:

This document contains the relevant information for purchasing a letter of access 'LoA' for joining the joint REACH registration for the substances:

#### ETHYLBENZENE EC 202-849-4; CAS 100-41-4

prepared by the EB REACH CONSORTIUM. In addition, this PDF provides the relevant earlier SIEF communications issued by the Lead Registrant / Consortium.

If you wish to purchase a LoA, please fill in the next pages 'LoA APPLICATION FORM' and pdf them to the attention of ReachTeam@jonesday.com. You will then receive a pre-payment notice by email for payment of the LoA price. As soon as we have received your payment in full, we will confirm that payment has been received and you will receive the joint submission token and any other necessary documentation (Chemical Safety Report, Guidance on Safe Use as the case may be) that you may need to join the Joint Submission via the ECHA REACH-IT portal (please see the ECHA Guidance on joining the Joint Submission). Potential registrants have to submit their individual parts (Article 10 (a) (i), (ii), (iii) and (x)) of the IUCLID 5/6/7 registration dossiers separately to ECHA by the relevant deadline.

Invoices for paid LoA fees will be issued by the Consortium on a periodic basis as soon as a sufficient number of LoAs have been processed and pre-paid.

If you have any questions, please do not hesitate to contact:

Preslava Dilkova at <a href="mailto:p.dilkova@jonesday.com">p.dilkova@jonesday.com</a> / Telephone +32-2-645-1433



# **Letter of Access ('LoA') Application Form**

# Ethylbenzene ('EB') REACH Consortium

LoA will be issued per legal entity. Please fill in the application form for each legal entity within an affiliated group of companies.

(To be filled in and emailed back to reachteam@jonesday.com)

#### NOTE:

- \* By completing and sending the LoA application form to Jones Day, you shall be considered as having accepted the terms of the respective SIEF Agreement overleaf.
- \* Only once formal invoices will have been issued and settled, the LoA will be considered as issued and effective.
- \* LoA applicants will be informed by separate email or via SIEF communication if the CSR and guidance on safe use will be prepared jointly and also **submitted jointly**, or rather whether they will be prepared jointly but will have to be **submitted individually**. In the latter case, LoA applicants will receive the CSR and guidance on safe use via a luclid so-called "export file" and must then insert it themselves into their individual REACH registration.

	Substance:		
	□ Ethylbenzene: EC 202-849-4; CAS 100-41-4		
	Current Prices LoA:		
□ 10	☐ Up to 100 tons: EUR 5,322.21 (excl. VAT) ☐ 100 - 1000 tons: EUR 15,838.29 (excl. VAT)		
	termediate or above 1000 tons, without CSR: EUR 35,218.57 (excl. VAT) bove 1000 tons: EUR 46,472.08 (excl. VAT)		

Please fill in applicable joint submission category. Any change in category (higher tonnage or change from intermediate to full substance registration) will require notification to Jones Day to adapt price.

Restrictions (optional):			
a.	<ul> <li>□ 'Opt-out' pursuant to Article 11 (3) for the following mandatory joint parts.</li> <li>□ Article 10 (a)</li> <li>□ Article 10 (a) (iv),</li> <li>□ Article 10 (a) (vi),</li> <li>□ Article 10 (a) (vii),</li> <li>□ Article 10 (a) (ix)</li> </ul>		

Identification			
Company:			
REACH-IT UUID Number:			
Company reference name or number (optional):			
VAT number:			
If you do not fill out a VAT number, you will be charged 21%.			
Address:			
Postal Code: Country: Country:			
Please give full details of person authorized to make the application:			
Mr □ Ms □ Dr □			
Last Name: First Name:			
Phone Number: Fax Number:			
E-mail address:			

Registration			
In his re	egistration, the Applicant acts:		
a.	☐ for himself		
b.	□ as <b>Only Representative</b> pursuant to Article 8 REACH <u>for the following non-EU manufacturer</u> ; Please give full contact details of <b>non-EU legal entity</b> represented by Only Representative <i>If you act on behalf of several non-EU legal entities that are not related to each other, please fill in new application form for each of your principals.</i>		
	Company:		
	Address:		
	Postal Code: City:		
	Last Name: First Name:		
	Phone Number: Fax Number:		
C.	E-mail address:□ as <b>Third Party Representative</b> pursuant to Article 4 REACH.		
	Do you want to disclose the name of the party you represent? a. □ Yes b. □ No		
	Company Name:		
	REACH-IT UUID Number:		
	Address:		
	Postal Code: City: Country:		
	Mr □ Ms □ Dr □		
	Last Name: First Name:		
	Phone Number: Fax Number:		
	E-mail address:		

	Applicable Joint Submission:			
Is the c	Is the <b>company to be invoiced</b> the same as the legal entity registering under REACH?			
a.	□ Yes			
b.	□ No			
	If no, please give full company details of legal entity to be invoiced:			
	Company:			
	VAT number:			
	If you do not fill in a VAT number, you will be charged 21%.			
	Address:			
	Postal Code: City: Country:			

#### **General Terms and Conditions:**

- The right of referral only gives access to the Joint Registration Dossier of the substance for the registration as specified above.
- 2. The right of referral is solely granted in favor of the Applicant (and, only where applicable, the Affiliates listed herein), and is not transferable to any other entity or person.
- 3. Unless otherwise specified below at 6., the Applicant is not authorized to receive any copies of the Joint Registration Dossier nor is the Applicant authorized to inspect or view the Joint Registration Dossier or any related specific document in whole or in part, outside the general inspection period granted by the Consortium and outside the conditions set out in the SIEF Agreement.
- 4. This Letter of Access shall in no event be construed as granting the Applicant any property rights whatsoever in the Joint Registration Dossier.
- 5. Nothing in this letter shall require the Consortium members to file any additional data.
- 6. In as far as the Joint Registration Dossier may contain a chemical safety report ("CSR") and guidance on safe use, and the Applicant is participating in joint submission for those parts of the dossier, or has otherwise acquired rights to them, those will be made available to the Applicant as needed and may be used by it in as far as needed for purposes of safe handling and elaboration of eSDS and must be filed by it individually if set out in the SIEF Agreement.
- 7. If the Applicant has chosen to prepare itself the CSR, exposure scenarios and guidance on safe use, but does otherwise fully participate in the Joint Registration Dossier, it shall receive an electronic copy of parts Article 10 (a) (iv), (vii) and (ix) REACH of the Joint Registration Dossier and shall have the rights to use for this purpose only the (robust) study summaries and other information contained therein as well as to refer to the full study reports on which basis the (robust) study summaries have been developed.
- 8. In any event and regardless of the rights and restrictions set forth above, the Applicant shall always receive a list of uses which are covered by the CSR, the proposed classification and labeling as well as the PNECs and DNELs where available.

This Letter of Access does not create any rights for third parties or any liability towards third parties in relation to the data for which access is granted.

This letter of access is issued by the above Lead Registrant or Consortium Members and they have prepared the respective registration dossier(s). No attorney-client relationship with Jones Day is created by signing this LoA application / change form / the SIEF / Cooperation / Joint Submission Agreement or payment of the LoA (proforma) invoice.

Applicant's certifications and undertakings:

- 1. The Applicant hereby declares that it is aware of, agrees and complies with the provisions of the SIEF Agreement issued by the Lead Registrant, which shall apply in its entirety in addition to the provisions set out hereunder.
- In case the Applicant has applied for an intermediate LoA only, the Applicant hereby declares that it is aware that registration as an intermediate pursuant to Articles 17 and 18 REACH is conditional upon fulfillment of the conditions set out there under.
- 3. The Applicant declares that it has wired the Letter of Access Pre-payment fee to the following bank account within 30 calendar days of signature of this Letter of Access. The joint token will be issued after receipt of the pre-payment. The invoice for the Letter of Access / Joint Submission will be issued after pre-payment has been received, but at the latest at the end of the applicable year of registration (end 2010, end 2013, end of 2018, as the case may be).
- 4. If Applicant chooses not to disclose the Third Party represented, Jones Day reserves the right to appoint a neutral party that is entitled to audit the accuracy of the Third Party Representative's submission whilst guaranteeing the confidentiality of the Third Party. The Third Party Representative hereby agrees to such third party audit.

I have read and I agree	with the legal	Terms of the A	greement.
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Signature of LoA applicant:	
Name:	
Date:	

AVOCATS - ADVOCATEN

MICHÈLE GRÉGOIRE<sup>(4)</sup>
Avocat à la Cour de cassation
Advocaat bij het Hof van Cassatie
Member of the Belgian Supreme Court Bar

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(10)Member of the Ukrainian Bar
(10)Member of the Ukrainian Bar

February 11, 2025

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# REACH - SIEF Communications Ethylbenzene ('EB') EC 202-849-4; CAS 100-41-4

# Communications (3):

- SIEF Communication dated January 9, 2024 (*re-issued February 15, 2024*) (Dossier update) (1 page)
- SIEF Communication dated December 20, 2018 (including Cooperation Agreement for the post May 31, 2018 period ("post-SIEF") (28 pages)
- SIEF Communication dated July 15, 2014 (dossier updated) (1 page)
- SIEF Communication dated September 30, 2010 (including SIEF Agreement) (32 pages)

AVOCATS - ADVOCATEN

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GEOFFROY VAN DE WALLE

ALEXANDRE VERHEYDEN(3)

PHILIPP WERNER<sup>(7)</sup>

DIRECT NUMBER: +32.2.645.14.60 E-Mail: uschliessner@jonesday.com

January 9, 2024 *(re-issued February 15, 2024)* 

**ELECTRONIC MAIL** 

#### TO WHOM IT MAY CONCERN

Dear Joint Registrants,

Re: Joint Registrants Communication Ethylbenzene ('EB') REACH Consortium REACH Registration Ethylbenzene EC 202-849-4; CAS 100-41-4 - Dossier update 2023/24

Lead Registrant Lyondell Chemie Nederland B.V. within the framework of the Ethylbenzene REACH Registration Consortium has proceeded to a dossier update at the end of 2023, which has now passed the ECHA checks. If you have previously purchased a letter of access with a CSR, you may request now the new CSR from us under the below contact address, providing the details of your previously purchased LoA and UUID number. Please note that the CSR has been prepared and filed jointly. The dossier update consists of the following:

- Conduct and include QSAR for skin sensitisation
- Long-term fish testing proposal
- Update on all data-gaps which mainly focused on removing TCC/QW as appropriate
- New IUCLID entry for Take. et al, 2020
- Reworking the exposure assessments into Chesar
- Improvement of the carcinogenicity summary section
- Update of the CSR based on the above.

Importantly, we require that Only Representative registrants confirm to us in their document request that their non-EU Principal is not a Russian based entity (Article 5n(1) of Council Regulation 833/2014), and that in all cases they confirm the name of the non-EU manufacturer. For any follow-up, please contact <a href="Reachteam@jonesday.com">Reachteam@jonesday.com</a>. Thank you very much for your attention.

Kind regards,

Tirsula Schliessner

AVOCATS - ADVOCATEN

MICHÈLE GRÉGOIRE<sup>(6)</sup>

Avocat à la Cour de cassation

Advocaat bij het Hof van Cassatie

Member of the Belgian Supreme Court Bar

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MATTHIEU DUPLAT

KAARLI H. EICHHORN(10)

URSULA SCHLIESSNER (5)

CRISTIANA SPONTONI<sup>(1)</sup> MARIO TODINO<sup>(7)</sup>

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BY ELECTRONIC MAIL

December 20, 2018

#### TO WHOM IT MAY CONCERN

Dear SIEF Members and Joint Registrants,

Re: SIEF Communication Ethylbenzene ('EB') REACH Consortium – REACH REGISTRATION ETHYLBENZENE EC 202-849-4; CAS 100-41-4 Replacement of previous SIEF Agreement

Please find attached the new Ethylbenzene Cooperation Agreement for the period as of June 1, 2018, replacing the previous SIEF Agreement, operational until that day. The new Agreement will be applicable to the relationship of Lead Registrant Lyondell Chemie Nederland B.V. and the REACH Registration Consortium with both existing and new joint registrants.

For any information on purchasing a Letter of Access, please visit our website at www.jonesdayreach.com.

Kind regards,

Ursula Schliessner

Attachment: Cooperation Agreement

#### Cooperation Agreement for REACH compliance after May 31, 2018

This Cooperation Agreement (hereinafter the "Agreement") is entered into by and between:

Lyondell Chemie Nederland B.V. as Lead Company under the Consortium Agreement for REACH registration of Ethylbenzene (hereinafter the "Consortium"), acting in its own name and in the name and on behalf of all members of the Consortium and having previously been appointed as Lead Registrant for the registration of Ethylbenzene (hereinafter referred to as "Lead Registrant")

and

The joint registrant (not being a Consortium member) signatory to the present Agreement (hereinafter referred to as **"Joint Registrant"**)

Hereinafter referred to as "the Parties"

#### **Preamble**

Whereas the Lead Registrant submitted a joint registration dossier and successfully registered Ethylbenzene [CAS No: 100-41-4; EC No: 202-849-4], (as further defined herein to as "**Substance**") before the European Chemicals Agency ("**Agency**") in accordance with Article 10 of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (hereinafter referred to as "**REACH**") in 2010;

Whereas numerous legal entities either as Consortium members or by purchasing a letter of access joined the joint registration;

Whereas the Parties to this Agreement agreed on the identity and the sameness of the Substance and were thus participants of the same Substance Information Exchange Forum ("SIEF") as registrants for that Substance under the meaning of Article 29 of REACH;

Whereas for that purpose the Parties concluded a SIEF Agreement on September 30, 2010;

Whereas, pursuant to Article 29(3) REACH, SIEFs shall only be operational until June 1, 2018;

Whereas, REACH registration dossiers must be updated from time to time and whereas the Substance may be subject to further regulatory scrutiny by the Agency or Member States;

Whereas, further future Joint Registrants may wish to join the joint registration of the Substance;

Whereas, therefore the cooperation of the Lead Registrant and the Joint Registrants should continue beyond June 1, 2018;

Whereas, the cooperation of the Lead Registrant and the Joint Registrants under the SIEF Agreement was smooth and the principles of the former cooperation under the SIEF Agreement should therefore be maintained;

Whereas the Parties agree that the principles of the joint submission of data set out in the SIEF Agreement will continue to apply to the current Agreement;

Whereas the Parties acknowledge that their cooperation should reflect the changes brought by the Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing in accordance with REACH (hereinafter referred to as the "Implementing Regulation 2016/9");

Whereas the Parties are aware that they have co-operation and data sharing obligations with other participants of the joint registration for the Substance;

Whereas REACH requires existing Joint Registrants and/or potential Joint Registrants to make every effort to reach an agreement on sharing the data and to ensure that the cost of sharing the Information required for registration are determined in a fair, transparent and non-discriminatory way.

Therefore, with a view to fulfilling their regulatory obligations under REACH after the last registration deadline of May 31, 2018 set out in Article 23(3) of REACH in respect to the Substance.

THE PARTIES HAVE AGREED UPON THE FOLLOWING AGREEMENT:

#### **Article I. Scope and General Obligations**

- 1. The current Agreement replaces the existing SIEF Agreement, which is set out in its entirety as **Annex 1** hereto. However, the Parties shall continue to apply the following terms, conditions and principles laid down in the SIEF Agreement which becomes an integral part of the present Agreement, in particular:
- (i) Article I Definitions;
- (ii) Article II Confidentiality;
- (iii) Article III, except point 1 Compliance;
- (iv) Article IV Legal personality;
- (v) Article V Regular report of the preparation of the Joint Registration Dossier;
- (vi) Article VI Participation in the joint submission of data by multiple registrants;
- (vii) Article VII Grant of right to use the (robust) studies summaries in the Joint Registration Dossier and to refer to the full study reports;
- (viii) Article VIII Information on the submission of the Joint Registration Dossier;
- (ix) Article IX, except point 5 Financial compensation for the Joint Registration Dossier;
- (x) Article X Ownership of Information;
- (xi) Article XI Limitation of liability in the SIEF;
- (xii) Article XII, except point 1– Term and termination;
- (xiii) Article XIII Legal entity change;

- (xiv) Article XIV Administration and reporting of costs;
- (xv) Article XV Dispute resolution and applicable law.

#### Article II. Compliance

Article III. 1. of the SIEF Agreement shall be replaced as follows:

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 the Implementing Regulation 2016/9 and Section 7 (Information sharing under competition rules) of the ECHA Guidance on data-sharing (Version 3.1, January 2017), as may be adapted from time to time.<sup>1</sup>

Each Party shall, with respect to such Party's activities in relation to this Agreement, comply with all applicable laws and regulations, including export, import, and sanctions laws, regulations, orders, and authorizations to include without limitation, the Export Administration Regulations (EAR), International Traffic in Arms Regulations (ITAR), and regulations and orders administered by the Treasury Department's Office of Foreign Assets Control. Such performance shall apply to the export, re-export and import of controlled technology, data, software, services, and/or hardware. Accordingly, Party or Parties shall not transfer Information without the appropriate government export authorization. Each Party shall be individually responsible for its compliance with any applicable laws and regulations. No Party shall be required to indemnify another Party with regard to legal compliance.

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

The following new point 8 shall complement Article VI.

8. The Lead Registrant shall settle any inquiry or regulatory scrutiny of the Agency or other competent authorities (including but not limited to draft compliance check decisions, substance evaluation, Annex XV REACH dossiers, Risk Management Options Analyses etc.) connected to the Substance in compliance with REACH and Regulation 1272/2008 and in a way to minimize related expenses. This shall also apply to inquiries of other third parties (including but not limited to other potential Joint Registrants). In the event that such inquiries or regulatory scrutiny could lead to additional costs to be shared by the Joint Registrants or if there could be a critical impact to the uses of the Substance (e.g. classification, risk management issues, etc.) the Lead Registrant shall inform the Joint Registrants promptly of any inquiry or regulatory scrutiny of the Agency or other competent authorities or other third parties. The Parties shall cooperate closely and consent on any formal responses to such inquiry or scrutiny without undue delay. Should a Joint Registrant fail to react or unduly delay its comments or unreasonably withhold its consent to the Lead Registrant's responses to such inquiry or regulatory scrutiny, the Lead Registrant may respond on its own. Any related Cost and Expenses shall be charged to the Joint Registrants as 'Joint Registration Compensation'.

https://echa.europa.eu/documents/10162/23036412/guidance\_on\_data\_sharing\_en.pdf/545e4463-9e67-43f0-852f-35e70a8ead60

#### Article IV. Financial compensation for the Joint Registration Dossier

Article IX point 5 of the SIEF Agreement shall be replaced as follows.

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 due to regulatory scrutiny or inquiries of the Agency, other competent authorities, or third parties or due to requirements pursuant to Article 22(1)(e) of REACH, the resulting costs will be equally divided between all Joint Registrants who are required to incorporate the new information into the Joint Registration Dossier.

#### Article V. Term and termination

This Agreement shall be in force for as long as there is a valid Joint Registration for the Substance. The Lead Registrant shall be entitled to terminate this Agreement at any time with prior written notice of one month if he is no longer subject to registration obligations in relation to the Substance.

#### Article VI. Annexes

- 1. The SIEF Agreement shall be set out as **Annex 1** to this Agreement.
- 2. The Cefic REACH Competition Law compliance guidance set out in Annex 1 of the SIEF Agreement shall be complemented by Section 7 (Information sharing under competition rules) of the ECHA Guidance on data-sharing (Version 3.1, January 2017), as may be amended from time to time.
- 3. A new <u>Annex 2</u> with the Substance Identity Profile and classification and labelling shall be attached to this Agreement. The Lead Registrant may amend this Annex 2 unless a simple majority of the Joint Registrants expressly objects.
- 4. A new **Annex 3** laying down the Letter of Access cost shall be attached to this Agreement.<sup>2</sup>

Since the Letter of Access pricing mechanism has been running smoothly since submission of the Joint Registration Dossier, the Lead Registrant shall reserve its right set out Article 4(5) of the Implementing Regulation 2016/9 not to amend this model. The Joint Registrant will be provided with a detailed list of studies and related costs upon request.

#### **Article VII. Miscellaneous**

1. The Parties shall be validly bound by this Agreement when the Joint Registrant has either given its consent to this Agreement through the communication IT Platform through which the letters of access are issued, or by signing it, or by paying letters of access; or by not expressly objecting to the Agreement within 30 days of its issuance.

This document is not new as such, i.e. it was previously provided as Appendix 5 to the SIEF Communication of September 30, 2010.

The Parties by their duly authorized representatives, sign this Agreement

ame of legal entity:
treet:
IP-Code :
ity:
ountry:
ontact Name:
ontact Email:
lace:
ate:
gned by:

# For Lyondell Chemie Nederland B.V.

Name of legal entity: Lyondell Chemie Nederland BV

Street: Delftseplein 27E

ZIP-Code: 3013 AA

City: Rotterdam

Country: The Netherlands

Contact Name: Rene de Graaff

Contact Email: rene.de.graaff@lyb.com

Place: Rotterdam

Date: December 18, 2018

signed by:

#### ANNEX 1 – SIEF Agreement (September 30, 2010)

#### **SIEF Agreement**

for Ethylbenzene (CAS N°: 100-41-4, EINECS N°: 202-849-4 and name: Ethylbenzene)

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

Lyondell Chemie Nederland B.V. as Lead Company under the Consortium Agreement for REACH for Ethylbenzene (hereinafter the "Consortium"), acting in its own name and in the name and on behalf of all members of the Consortium (hereinafter referred to as "Lead Registrant")

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

Hereinafter referred to as "the Parties"

#### Preamble

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

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

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

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

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

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

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

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

- 1. to agree on the operating rules governing the exchanges of information between the SIEF potential registrants (Title I);
- 2. to agree on the rules regarding the rights to participate in the joint submission of data, to use the (robust) study summaries and to refer to the relevant full study reports in the Joint Registration Dossier developed by the Lead Members (Title II);

under the terms and conditions set forth in this Agreement.

THE PARTIES HAVE AGREED UPON THE FOLLOWING:

#### Article I. Definitions

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

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

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

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

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

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

- **-Lead Member**: a SIEF participant who is subject to the registration requirements under REACH, who participates to the SIEF discussions in order to compile the Joint Registration Dossier and who is a member of the Consortium.
- **-Lead Registrant**: a SIEF participant who is subject to the registration requirements under REACH, which the Non-Lead Member agree hereto to appoint acting as Lead Registrant as defined under Article 11 (1) REACH. The Lead Registrant is a member of and duly represents and acts in the name and on behalf of the other members of the 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 prepared and/or made available by the Lead Registrant, on his own behalf, for its Affiliates, and/or on behalf of the represented potential registrants in case he is a third party representative.

#### Title I: SIEF OPERATING RULES

#### Article II. Confidentiality

#### 1. The Parties shall:

- a) treat all Information as confidential and not disclose it to third parties, unless regulatory disclosure requirements apply. Each Party shall advise immediately the other Parties in writing of any disclosure or misuse by any Party or a third party of Information, as well as of any request by competent authorities relating to the disclosure of that Information.
  - Disclosure of Information as required for legal and/or regulatory purposes including the REACH Regulation, shall only take place by the Parties in a form (for example short summaries where possible) reflecting the minimum information required to be disclosed. This restriction does not apply to the Party who has provided the Information.
- b) use the Information only for the Purpose or otherwise as permitted under or in accordance with this Agreement.
- c) disclose the Information to their employees, Affiliates, external experts and/or consultants and if the Non-Lead Member is an only representative or a third party representative, the non-EU manufacturer(s) or the legal entity(ies) represented by any of them, only on a need to know basis and only to the extent absolutely necessary for the Purpose or otherwise as permitted under or in accordance with this Agreement. Each Party shall have in place policies and procedures to ensure the confidentiality of Information, and require that its external experts and/or consultants also have such policies and procedures in place to ensure their compliance with these confidentiality obligations.
- 2. The obligations specified in Article II.1 above shall not apply to Information for which the receiving Party can reasonably demonstrate that such Information:
  - a) was known to the receiving Party on a non-confidential basis prior to its disclosure pursuant to this Agreement;
  - b) is publicly known at the time of disclosure or thereafter becomes publicly known without breach of the terms of this Agreement on the part of the receiving Party;
  - c) becomes known to the receiving Party through disclosure by sources other than the disclosing Party, having a right to disclose such Information,
  - d) was independently developed by the receiving Party without access to the disclosing Party's Information, as evidenced by documentary records,

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

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

#### Article IV. Legal personality

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

#### Article V. Regular report of the preparation of the Joint Registration Dossier

- 1. The Lead Registrant undertakes to inform the Non-Lead Member regularly on the development of the Joint Registration Dossier according to the general guidance in regard to SIEF management attached as Annex 2 to this Agreement.
- 2. In particular, in case the chemical safety report 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 chemical safety report without undue delay.
- 3. The Non-Lead Member undertakes to make all best efforts to check proactively and regularly all up-dated Information that is made available by the Lead Registrant on the development of the Joint Registration Dossier.
- 4. The Parties agree that such communication may be channelled via the use of the SIEFReach IT-platform.

# TITLE II: DATA SHARING AND JOINT SUBMISSION OF THE DOSSIER 1. OBLIGATIONS OF THE LEAD REGISTRANT

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

- 1. According to Article 11 (1) REACH, the Parties hereto agree to have the Joint Registration Dossier for the Substance submitted by the Lead Registrant on behalf of the Non-Lead Member having fulfilled its obligations under Article IX to this Agreement, at least 3 months before end of the applicable registration deadline. Upon demand of the Agency, within the requested deadline and to the extent necessary, the Lead Registrant agrees to complete the Joint Registration Dossier.
- 2. Notwithstanding anything to the contrary under this Agreement, the Parties remain individually responsible to comply with REACH, in particular, but not limited to, in relation to the individual submission of the information required under Article 11(1) REACH.
- 3. The participation in the Joint Registration Dossier may deviate per requesting Non-Lead Member according to its tonnage band or possible opt-outs for certain endpoints.
- 4. If the Non-Lead Member 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<sup>1</sup> obligations with the name, address and other relevant data of the represented legal entity within six (6) months before the registration due date. Upon receipt of such information, the Lead Registrant shall submit the Joint Registration Dossier also on behalf of such legal entity.
- 5. The Lead Registrant shall open a joint submission object in REACH-IT.
- 6. The Lead Registrant shall pay the fee (in accordance to Article 11 (4) REACH) as invoiced by the Agency for the submission of the Joint Registration Dossier without undue delay.
- 7. The Lead Registrant shall make available the data referred to in Article 11 (1) paragraph 2 and, if applicable, paragraph 4 REACH that have been submitted in the joint submission, to the Non-Lead Member, provided the Non-Lead Member has fulfilled its obligations under Article IX of this Agreement.

Documentation on such topic is available on http://cefic.org/templates/shwPublications.asp?HID=750&T=812 under "Joint submission process in REACH-IT"

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

- 1. Subject to the payment of the Joint Registration Compensation as specified under Article IX of this Agreement, the Lead Registrant grants the Non-Lead Member the non-exclusive, non-transferable and non-terminable right:
- (a) to use the (robust) studies summaries and other Information used in the Joint Registration Dossier within the applicable tonnage band and for which 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
- 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. 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.

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

- 1. Provided the Non-Lead Member has fulfilled its obligations under Article IX, the Lead Registrant shall inform immediately the Non-Lead Member of the creation of the joint submission object in REACH-IT and shall provide the valid security token number and the name of the joint submission.
- 2. The Lead Registrant shall inform immediately the Non-Lead Member of the submission of the Joint Registration Dossier to the Agency and provide documentation of the same.
- 3. The Lead Registrant shall further communicate the confirmation that the joint registration has been successful and shall inform the Non-Lead Member of the reception of the relevant registration number that has been obtained from the Agency without undue delay.

#### 2. OBLIGATIONS OF THE NON-LEAD MEMBER

#### Article IX. Financial compensation for the Joint Registration Dossier

- 1. Before execution by the Lead Registrant of its obligations pursuant to Title II.1 of this Agreement, the Non-Lead Member shall compensate in a fair, transparent and non-discriminatory way the Lead Registrant with a "Joint Registration Compensation" for the development and submission of the Joint Registration Dossier and the rights granted under Article VII.
- 2. The Joint Registration Compensation 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 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.
- 3. Expenses referred to above shall be allocated equally, in a transparent, fair and non discriminatory way, to all SIEF participants with the intent to register the Substance, taking into account the following exceptions:
  - a) Where a Non-Lead Member registers the Substance in a tonnage band lower than the one covered by the Joint Registration Dossier, it shall only be requested to compensate for those parts of the Registration Dossier that it is included in and for those studies it receives a right to refer for.
  - 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 those parts of the Joint Registration Dossier that are submitted jointly.
- 4. Based on the above, a payment notice/ an invoice will be sent to the Non-Lead Members for their cost share after their request for joint submission (2010, 2013, 2018 and first time registrants). The Non-Lead Members will only receive the valid security token number after receipt of the payment. Payment is due within thirty (30) days as of the date of the payment notice.
- 5. In case new studies have to be purchased or performed after conclusion of this Agreement, the resulting cost will be equally divided between all SIEF participants who are required to incorporate the results of these new studies into their registration dossier, unless they claim to opt out in accordance with Article 11 (3) REACH.

- 6. 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.
- 7. 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
- 8. 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. Payer shall be entitled to any refund of withholding taxes.
- 9. 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, 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 2018.
- 2. This Article and the provisions relating to the protection of confidentiality (Article II), ownership of Information (Article X), dispute resolution and applicable law (Article XV) and limitation of the liability (Article XI) shall survive the termination of this Agreement. With regard to the studies, the obligations specified in Article II of this Agreement shall survive for a period of twelve (12) years following the initial submission to the Agency. With regard to all other Information, the obligations specified in Article II shall survive for a period of 5 years after termination of the SIEF.
- 3. The Lead Registrant has the right to terminate its functions as lead registrant under the cumulative conditions that:
- -it has been validly replaced in its functions within the SIEF;
- -its assignee has accepted to be bound by the obligations of the Lead Registrant under this Agreement; and
- -the Non-Lead Member has been notified about such replacement.
- 4. The Non-Lead Member has the right to terminate the present Agreement subject a prior written notice to the Lead Registrant at the latest nine (9) 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 and electronic records, records on expenses, books of account, correspondence, memoranda and receipts.
- 3. The Lead Registrant will accept a validation of the relevant data by an external auditor upon request of a Non-Lead Member. The cost associated with the audit will be for the account of the requestor.

#### 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 CEPANI arbitration rules 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, through the communication IT platform specified under Article V.

The Lead Registrant shall maintain an updated list of SIEF Participants which have agreed to the terms and conditions to the present Agreement and will make it available upon request or through the communication IT platform.

# ANNEXES:

# Annex 1

# Cefic guidance on competition compliance

Please see website:

http://www.cefic.be/files/downloads/Cefic-REACH-guidance-DO-&-DON'T.pdf

#### Annex 2

# General guidance in regard to SIEF management

Please see website:

http://cefic.org/Files/Publications/ListofTasks%20 in%20 SIEF-Cefic-May 09.x ls

# ANNEX 2 - Substance Identity Profile - Classification & Labelling

The substance **ethyl benzene** is a mono-constituent substance (organic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).

The following public name is used: ethylbenzene

# **Substance identity**

EC number:	202-849-4
EC name:	
CAS number (EC inventory):	
CAS number:	100-41-4
CAS name:	Ethylbenzene
IUPAC name:	Ethylbenzene
Molecular formula:	C8H10
Molecular weight range:	106.165

#### Structural formula:



# Overall information on composition

Composition	Related composition(s)
Ethylbenzene (legal entity composition of the substance)	See registrant specific section 1.2 in IUCLID
Ethylbenzene (boundary composition of the substance)	

Name: Ethylbenzene (Boundary Composition)

State/form: Liquid

Degree of purity: >99 - <100 % (w/w)

Description: The manufacturing process is registrant specific.

#### Constituents

Constituent	Typical concentration	Concentration range	Remarks
Ethyl benzene EC no.: 202-849-4	ca.99.5 % (w/w)	>99 - <100 % (w/w)	

# Classification & Labelling

Implementation: EU

The substance is classified as follows:

Table 1: Classification and labelling according to CLP / GHS for physicochemical properties

Hazard class	Hazard category	Hazard statement	Reason for no classification
Explosives:			conclusive but not sufficient for classification
Desensitised explosives:			data lacking
Flammable gases and chemically unstable gases:			conclusive but not sufficient for classification
Flammable aerosols:			conclusive but not sufficient for classification
Oxidising gases:			conclusive but not sufficient for classification
Gases under pressure:			conclusive but not sufficient for classification
Flammable liquids:	Flam. Liquid 2	H225: Highly flammable liquid and vapour.	
Flammable solids:			conclusive but not sufficient for

Hazard class	Hazard category	Hazard statement	Reason for no classification
			classification
Self-reactive substances and mixtures:			conclusive but not sufficient for classification
Pyrophoric liquids:			conclusive but not sufficient for classification
Pyrophoric solids:			conclusive but not sufficient for classification
Self-heating substances and mixtures:			conclusive but not sufficient for classification
Substances and mixtures which in contact with water emit flammable gases:			conclusive but not sufficient for classification
Oxidising liquids:			conclusive but not sufficient for classification
Oxidising solids:			conclusive but not sufficient for classification
Organic peroxides:			conclusive but not sufficient for classification
Corrosive to metals:			conclusive but not sufficient for classification

Table 2: Classification and labelling according to CLP / GHS for health hazards

Hazard class	Hazard category	Reason for no classification
Acute toxicity - oral:		conclusive but not sufficient for classification

Hazard class	Hazard category	Hazard statement	Reason for no classification
Acute toxicity - dermal:			conclusive but not sufficient for classification
Acute toxicity - inhalation:	Acute Tox. 4	H332: Harmful if inhaled.	
Skin corrosion / irritation:			conclusive but not sufficient for classification
Serious damage / eye irritation:			conclusive but not sufficient for classification
Respiratory sensitisation:			conclusive but not sufficient for classification
Skin sensitisation:			conclusive but not sufficient for classification
Aspiration hazard:	Asp. Tox. 1	H304: May be fatal if swallowed and enters airways.	
Reproductive Toxicity:			conclusive but not sufficient for classification
Reproductive Toxicity: Effects on or via lactation:			conclusive but not sufficient for classification
Germ cell mutagenicity:			conclusive but not sufficient for classification
Carcinogenicity:			conclusive but not sufficient for classification
Specific target organ toxicity – single exposure:	Affected organs: Route of exposure:		conclusive but not sufficient for classification
Specific target organ toxicity – repeated	STOT Rep. Exp. 2 Affected organs: hearing organs	H373: May cause damage to organs <or affected,="" all="" if="" known="" organs="" state=""> through prolonged or repeated</or>	

Hazard class	Hazard category	Hazard statement	Reason for no classification
exposure:	Route of exposure:	exposure <state cause="" conclusively="" exposure="" hazard="" if="" is="" it="" no="" of="" other="" proven="" route="" routes="" that="" the="">.</state>	

Table 3: Classification and labelling according to CLP / GHS for the environment

Hazard class	Hazard category	Hazard statement	Reason for no classification
Hazards to the aquatic environment (acute/short-term):			conclusive but not sufficient for classification
Hazards to the aquatic environment (chronic/long-term):	Aquatic Chronic 3	H412: Harmful to aquatic life with long lasting effects.	
M-Factor acute:	l		
M-Factor chronic:			
Hazardous to the ozone layer:			conclusive but not sufficient for classification

Signal word: Danger

Hazard pictogram:

Figure 3.1.



GHS02: flame

Figure 3.2.



GHS07: exclamation mark

Figure 3.3.



GHS08: health hazard

#### **Hazard statements:**

H412: Harmful to aquatic life with long lasting effects.

H225: Highly flammable liquid and vapour.

H304: May be fatal if swallowed and enters airways.

H332: Harmful if inhaled.

H373: May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

#### Precautionary statements:

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P240: Ground and bond container and receiving equipment.

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P273: Avoid release to the environment.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P301+P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor/...

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P331: Do NOT induce vomiting.

P501: Dispose of contents/container to ... ...in accordance with local/regional/national /international regulations (to be specified). Manufacturer/supplier or the competent authority to specify whether disposal requirements apply to contents, container or both. (in accordance with local/regional/national/international regulations (to be specified)).

Page 23 of 27 ANNEX 3

# **Price Calculation LoA**

# 1. Consortium Budget

APPROVED BUDGETS		2008	8 budget
ALL ROVED DODOEIO		Со	st (€uro)
Ethyl-benzene preparation of Consortium agreement. Review of Competition Law Issues. Consortium Kick-off meeting	MLA	€	9,760
Meeting and follow-up work to finalize consortium legal documents and business plan. Setting up of bank account for consortium	MLA	€	4,980
Assistance in setting up Technical Committee and working groups and provision of services as required in particular review of minutes	MLA	€	3,520
Steering Committee meetings prior to the registration date plus preparation and debriefing	MLA	€	25,760
Technical Committee support including preparation, attendance, preparation of agenda and minutes, follow up and action lists of meetings maintaining records of progress vs agreed targets, coordination Technical Committee and Technical Consultant	MLA	€	5,280
Accounting fee	MLA	€	6,000
Annual management and archiving fee	MLA	€	5,000
Level 2 consultant		€	30,000
TOTAL APPROVED BUDGETS		€	90,300

APPROVED BUDGETS		2	2009 budget Cost (€uro)
Assistance in setting up Technical Committee and working groups and provision of services as required in particular review of minutes	MLA	€	7,840
Steering Committee meetings prior to the registration date plus preparation and debriefing	MLA	€	27,040
Miscellaneous legal advice	MLA	€	20,000
Accounting fee	MLA	€	10,000
Annual management and archiving fee	MLA	€	5,000
Task Force Exposure scenario : preparation, participation & debriefing (half day meeting)	MLA	€	4,000
Technical Committee support including preparation, attendance, preparation of agenda and minutes, follow up and action lists of meetings maintaining records of progress vs agreed targets, coordination Technical Committee and Technical Consultant	Altran	€	50,000
IUCLID 5 file	Dow	€	38,644
Lab for phys chem tests	Harlan	€	19,767
Preparation of the CSR	Cintox	€	86,800
Exposure scenarios	Quantor	€	35,100
TOTAL APPROVED BUDGETS		€	304,191

APPROVED BUDGETS			0 budget
Assistance in setting up Technical Committee and working groups and provision of services as required in particular	MLA	€	ost (€uro) 8,640
Steering Committee meetings prior to the registration date plus preparation and debriefing	MLA	€	28,480
Accounting fee	MLA	€	10,000
Annual management and archiving fee	MLA	€	5,000
Legal advice & third party communication	MLA	€	20,000
MLA IT On-Line tool	MLA	€	1,500
LOAS (€ 750 per LOA - based on 50)	MLA	€	37,500
Task Force Exposure scenario: preparation, participation & debriefing (half day meeting)	MLA	€	3,150
Technical Committee support including preparation, attendance, preparation of agenda and minutes, follow up and action lists of meetings maintaining records of progress vs agreed targets, coordination Technical Committee and Technical Consultant	Altran	€	28,620
Extended archive retention	Harlan	€	1,210
IUCLID 5 file	Dow	€	48,414
ECETOC Workshop	Cintox	€	2,500
Exposure scenarios (environmental aspects)	Cehtra	€	19,870
Budget Reserve Data Licensing Access		€	20,000
TOTAL APPROVED BUDGETS		€	234,884

# 2. LoA Price Calculation

ETHYL BENZENE LOA CALCULATION - 1000t dossier	TOTAL		15 Members
2008 budget	€ 90,300.00	€	6,020.00
2009 budget (excluding licensing of studies)	€ 304,191.00	€	20,279.40
2010 Budget (excluding LoA budget)	€ 197,384.00	€	13,158.93
Expenses	€ 4,500.00	€	300.00
TOTAL	€ 596,375.00	€	39,758.33
Admin cost (15%)		€	5,963.75
TOTAL WITH ADMIN COST		€	45,722.08
Handling Fee		€	750.00
TOTAL LOA PRICE		€	46,472.08

CSR & ES budget	TOTAL	% of total budget
CSR - Cintox (2009 budget)	€ 86,800.00	
ES - Quantor (2009 budget)	€ 35,100.00	
ES - CEHTRA (2010 budget)	€ 19,870.00	
TOTAL CSR & ES budgets	€ 141,770.00	24.80%

ETHYL BENZENE LOA CALCULATION (w/o CSR & ES)	TOTAL		15 Members
2008 budget less 24.80%	€ 67,905.60	€	4,527.04
2009 budget less 24.80%	€ 228,751.63	€	15,250.11
2010 Budget less 24.80%	€ 148,432.77	€	9,895.52
Expenses	€ 4,500.00	€	300.00
TOTAL	€ 449,590.00	€	29,972.67
Admin cost (15%)		€	4,495.90
TOTAL WITH ADMIN COST		€	34,468.57
Handling Fee		€	750.00
TOTAL LOA PRICE		€	35,218.57

#### **Notes**

- 1. Full price including CSR
- 2. For intermediate dossier, no CSR will be charged
- 3. LoA price is a fixed price except if substantial new work to be conducted post 2010
- 4. There will be no reimbursement (overflow income will be used for post 2010 ECHA required work and 50% of the remaining funds will be used depending on the fair value of studies (original invoice value minus 30%) to reimburse data owners for license fee waivers provided pursuant to License Fee Waiver Agreements of Ethyl Benzene REACH Consortium with ACC and SSC respectively)

5. For 100 to 999 tons : €15,838.29 6. For 1 to 99 tons : €5,322.21

\* \* \*

### JONES DAY

BERNARD AMORY
RENATO ANTONINI (1)
CHARLOTTE BREUVART (2)
VINCENT BROPHY
SEBASTIEN CHAMPAGNE
SERGE CLERCKX
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URSULA SCHLIESSNER (4) ALEXANDRE VERHEYDEN (3)

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(2) Member of the Paris Bar

(3) Member of the New York Bar

(4) Member of the Düsseldorf Bar

(5) Member of the District of Columbia Bar

(6) Member of the Turin Bar

July 15, 2014

### TO WHOM IT MAY CONCERN

Re: Ethylbenzene ('EB') REACH Consortium – REACH REGISTRATION ETHYLBENZENE EC 202-849-4; CAS 100-41-4 – DOSSIER UPDATE

By Electronic Mail

Dear Letter of Access Licensees and SIEF Members,

This is to inform you that the Ethylbenzene REACH Consortium has recently prepared and the Lead Registrant Lyondell Chemie Nederland BV has filed with ECHA a REACH registration dossier update.

This update contains an updated CSR including revised exposure scenarios, and a general update of the dossier including new literature. In addition, the substance was classified as aquatic chronic toxicity 3, with H412. The previous 2010 SIEF communication recommended classification as STOT Re 2 with H373 (hearing organs) is maintained (and has been harmonized by Commission Regulation 605/2014). The CSR has been filed jointly. GSU must be filed individually.

Previous LoA licensees may request from the Consortium Manager Jones Day the updated CSR. If you have any questions, please do not hesitate to contact:

Ursula Schliessner at <u>uschliessner@jonesday.com</u> / Telephone +32-2-645 1460.

For purchase of letters of access, please go to www.jonesdayreach.com

Kind regards,

Ursula Schliessner

Partner

<sup>&</sup>lt;sup>1</sup> The previous 2010 SIEF communication recommended classifications as Irritation / Corrosion Eye Category 2, Skin Category 2, STOT SE- Cat 3 for Respiratory tract irritation have been removed from the dossier (not supported by RAC).

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Atlanta
Brussels
Denver
Los Angeles
New York
Philadelphia

San Diego

San Francisco
Washington, D.C.

McKenna Long & Aldridge

2, Avenue de Tervueren 1040 Brussels, Belgium Telephone: (32-2) 278-1211 ■ Telefax: (32-2) 278-1200

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Flavia Distefano <sup>1</sup>
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<sup>1</sup> Member of the Rome Bar <sup>2</sup> Member of the Düsseldorf Bar <sup>3</sup> Member of the Georgia Bar

Advocaat-Avocat - Member of the Brussels Bar

URSULA SCHLIESSNER (32-2) 278-1224

EMAIL ADDRESS uschliessner@mckennalong.com

September 30, 2010

BY ELECTRONIC MAIL

### TO WHOM IT MAY CONCERN

**Re:** REACH: SIEF Communication Ethyl Benzene (EC number 202-849-4)

Dear SIEF Member:

McKenna Long & Aldridge LLP act as Manager of the Ethyl Benzene REACH Consortium (the 'Consortium'). The Consortium has developed the REACH joint registration dossier for ethyl benzene, as well as Chemical Safety Report, Exposure Assessment, and Guidance on Safe Use.

Further to the earlier SIEF communications and the SIEF agreement (<u>Appendix 1</u>) issued by Consortium Member Lyondell Chemie Nederland BV who has been appointed Lead Registrant, we are writing to you today on behalf of Lyondell and the Consortium to notify you that the joint registration dossier for ethyl benzene has been finalized, submitted to ECHA, and has passed the Business Rules. Set out below and overleaf is critical information for your perusal as well as about the <u>next steps to be taken by SIEF members</u>.

### 1) <u>Data</u>

Lyondell posted a preliminary list of data to the SIEF in the fall of 2009. Calls for additional data were not successful. Please note that the Consortium has based its dossier to a large extent on the data used for the EU Reg. 793/93 risk assessment report undertaken for the substance. Further data has been added.

We shall assume that you agree with the Consortium's selection of data for use in the joint registration dossier per Article 11 (1) and 29 (3) REACH.

#### 2) Joint Registration Dossier - Inspection Period

The final joint registration dossier will be made available for inspection at the offices of McKenna Long & Aldridge LLP during office hours between <u>October 4, 2010 and October 18, 2010 upon appointment taken at least 48 hours in advance.</u>

IUCLID Chapters 4-7, as well as 11 and 13, and 1.1, 1.5, 2.1, 2.2 and 3.5 will be made available to co-registrants upon request after 7) below has been completed.

### 3) Substance Identity and Classification & Labeling

Substance sameness was agreed earlier in the SIEF. Substance identity is set out in **Appendix 2** hereto. Based on the data available and reviewed, the C&L also attached as Appendix 2 was submitted in the dossier as communicated and agreed earlier in the SIEF.

### 4) DNEL & PNECs

Based on the data available and reviewed, the DNELs and PNECs attached as **Appendix 3** have been derived and were submitted in the dossier.

### 5) CSR

The CSR was prepared jointly and has been submitted jointly.

### 6) <u>Uses and Guidance on Safe Use (GSU)</u>

A proposed list of uses has been communicated by Lyondell on December 29, 2009 to the SIEF. The final list of uses and use descriptors is attached as **Appendix 4**.

The GSU was prepared by the Consortium but was not submitted jointly. It will be provided to co-registrants as part of the Letter of Access upon request, so that they can consider the content in preparation of their own GSU that they will individually file with ECHA.

### 7) <u>Participation in Joint Submission - Letters of Access</u>

We would further kindly ask those SIEF members who wish to participate in joint submission to fill in a Letter of Access (LoA) application at <a href="www.mlalaw.eu">www.mlalaw.eu</a>. An on-line tool will guide you through the procedure, options (e.g. different tonnage band prices) and payment requirements. For your information, the price for an LoA (1,000 tons) will be €46,472.08 (excl. VAT where applicable) and is set as a fixed price (post 2010 cost may be charged later though, see XI. 5 of SIEF Agreement) based on the current number of Consortium Members (15) (as requested by the License Fee Waiver Agreements concluded between the Consortium Members and the major data owners (SSC and ACC)). Detailed price calculations are set out in <a href="Appendix 5">Appendix 5</a>. Once your LoA application has been duly accepted and payment has been made, you shall automatically receive the joint submission token to file the individual parts of your ethyl benzene registration dossier. <a href="Participation in joint submission is conditional upon completing the procedure and obtaining an LoA at www.mlalaw.eu">www.mlalaw.eu</a>.

Thank you very much for your attention.

Kind regards,

Ursula Schliessner

Partner, McKenna Long & Aldridge LLP

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Appendices: 5

### **Appendix 1 - SIEF Agreement**

for Ethylbenzene (CAS N°: 100-41-4, EINECS N°: 202-849-4 and name: Ethylbenzene)

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

Lyondell Chemie Nederland B.V. as Lead Company under the Consortium Agreement for REACH for Ethylbenzene (hereinafter the "Consortium"), acting in its own name and in the name and on behalf of all members of the Consortium (hereinafter referred to as "Lead Registrant")

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

Hereinafter referred to as "the Parties"

#### Preamble

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

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

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

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

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

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

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

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

- 1. to agree on the operating rules governing the exchanges of information between the SIEF potential registrants (Title I);
- 2. to agree on the rules regarding the rights to participate in the joint submission of data, to use the (robust) study summaries and to refer to the relevant full study reports in the Joint Registration Dossier developed by the Lead Members (Title II);

under the terms and conditions set forth in this Agreement.

THE PARTIES HAVE AGREED UPON THE FOLLOWING:

### Article I. Definitions

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

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

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

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

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

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

- **-Lead Member**: a SIEF participant who is subject to the registration requirements under REACH, who participates to the SIEF discussions in order to compile the Joint Registration Dossier and who is a member of the Consortium.
- **-Lead Registrant**: a SIEF participant who is subject to the registration requirements under REACH, which the Non-Lead Member agree hereto to appoint acting as Lead Registrant as defined under Article 11 (1) REACH. The Lead Registrant is a member of and duly represents and acts in the name and on behalf of the other members of the 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 prepared and/or made available by the Lead Registrant, on his own behalf, for its Affiliates, and/or on behalf of the represented potential registrants in case he is a third party representative.

### Title I: SIEF OPERATING RULES

### Article II. Confidentiality

#### 1. The Parties shall:

- a) treat all Information as confidential and not disclose it to third parties, unless regulatory disclosure requirements apply. Each Party shall advise immediately the other Parties in writing of any disclosure or misuse by any Party or a third party of Information, as well as of any request by competent authorities relating to the disclosure of that Information.
  - Disclosure of Information as required for legal and/or regulatory purposes including the REACH Regulation, shall only take place by the Parties in a form (for example short summaries where possible) reflecting the minimum information required to be disclosed. This restriction does not apply to the Party who has provided the Information.
- b) use the Information only for the Purpose or otherwise as permitted under or in accordance with this Agreement.
- c) disclose the Information to their employees, Affiliates, external experts and/or consultants and if the Non-Lead Member is an only representative or a third party representative, the non-EU manufacturer(s) or the legal entity(ies) represented by any of them, only on a need to know basis and only to the extent absolutely necessary for the Purpose or otherwise as permitted under or in accordance with this Agreement. Each Party shall have in place policies and procedures to ensure the confidentiality of Information, and require that its external experts and/or consultants also have such policies and procedures in place to ensure their compliance with these confidentiality obligations.
- 2. The obligations specified in Article II.1 above shall not apply to Information for which the receiving Party can reasonably demonstrate that such Information:
  - a) was known to the receiving Party on a non-confidential basis prior to its disclosure pursuant to this Agreement;
  - b) is publicly known at the time of disclosure or thereafter becomes publicly known without breach of the terms of this Agreement on the part of the receiving Party;
  - c) becomes known to the receiving Party through disclosure by sources other than the disclosing Party, having a right to disclose such Information,
  - d) was independently developed by the receiving Party without access to the disclosing Party's Information, as evidenced by documentary records,

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

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

### Article IV. Legal personality

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

### Article V. Regular report of the preparation of the Joint Registration Dossier

- 1. The Lead Registrant undertakes to inform the Non-Lead Member regularly on the development of the Joint Registration Dossier according to the general guidance in regard to SIEF management attached as Annex 2 to this Agreement.
- 2. In particular, in case the chemical safety report 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 chemical safety report without undue delay.
- 3. The Non-Lead Member undertakes to make all best efforts to check proactively and regularly all up-dated Information that is made available by the Lead Registrant on the development of the Joint Registration Dossier.
- 4. The Parties agree that such communication may be channelled via the use of the SIEFReach IT-platform.

# TITLE II: DATA SHARING AND JOINT SUBMISSION OF THE DOSSIER 1. OBLIGATIONS OF THE LEAD REGISTRANT

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

- 1. According to Article 11 (1) REACH, the Parties hereto agree to have the Joint Registration Dossier for the Substance submitted by the Lead Registrant on behalf of the Non-Lead Member having fulfilled its obligations under Article IX to this Agreement, at least 3 months before end of the applicable registration deadline. Upon demand of the Agency, within the requested deadline and to the extent necessary, the Lead Registrant agrees to complete the Joint Registration Dossier.
- 2. Notwithstanding anything to the contrary under this Agreement, the Parties remain individually responsible to comply with REACH, in particular, but not limited to, in relation to the individual submission of the information required under Article 11(1) REACH.
- 3. The participation in the Joint Registration Dossier may deviate per requesting Non-Lead Member according to its tonnage band or possible opt-outs for certain endpoints.
- 4. If the Non-Lead Member 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 confidentiality¹ obligations with the name, address and other relevant data of the represented legal entity within six (6) months before the registration due date. Upon receipt of such information, the Lead Registrant shall submit the Joint Registration Dossier also on behalf of such legal entity.
- 5. The Lead Registrant shall open a joint submission object in REACH-IT.
- 6. The Lead Registrant shall pay the fee (in accordance to Article 11 (4) REACH) as invoiced by the Agency for the submission of the Joint Registration Dossier without undue delay.
- 7. The Lead Registrant shall make available the data referred to in Article 11 (1) paragraph 2 and, if applicable, paragraph 4 REACH that have been submitted in the joint submission, to the Non-Lead Member, provided the Non-Lead Member has fulfilled its obligations under Article IX of this Agreement.

Documentation on such topic is available on http://cefic.org/templates/shwPublications.asp?HID=750&T=812 under "Joint submission process in REACH-IT"

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

- 1. Subject to the payment of the Joint Registration Compensation as specified under Article IX of this Agreement, the Lead Registrant grants the Non-Lead Member the non-exclusive, non-transferable and non-terminable right:
- (a) to use the (robust) studies summaries and other Information used in the Joint Registration Dossier within the applicable tonnage band and for which 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
- 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. 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.

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

- 1. Provided the Non-Lead Member has fulfilled its obligations under Article IX, the Lead Registrant shall inform immediately the Non-Lead Member of the creation of the joint submission object in REACH-IT and shall provide the valid security token number and the name of the joint submission.
- 2. The Lead Registrant shall inform immediately the Non-Lead Member of the submission of the Joint Registration Dossier to the Agency and provide documentation of the same.
- 3. The Lead Registrant shall further communicate the confirmation that the joint registration has been successful and shall inform the Non-Lead Member of the reception of the relevant registration number that has been obtained from the Agency without undue delay.

### 2. OBLIGATIONS OF THE NON-LEAD MEMBER

### Article IX. Financial compensation for the Joint Registration Dossier

- 1. Before execution by the Lead Registrant of its obligations pursuant to Title II.1 of this Agreement, the Non-Lead Member shall compensate in a fair, transparent and non-discriminatory way the Lead Registrant with a "Joint Registration Compensation" for the development and submission of the Joint Registration Dossier and the rights granted under Article VII.
- 2. The Joint Registration Compensation 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 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.
- 3. Expenses referred to above shall be allocated equally, in a transparent, fair and non discriminatory way, to all SIEF participants with the intent to register the Substance, taking into account the following exceptions:
  - a) Where a Non-Lead Member registers the Substance in a tonnage band lower than the one covered by the Joint Registration Dossier, it shall only be requested to compensate for those parts of the Registration Dossier that it is included in and for those studies it receives a right to refer for.
  - 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 those parts of the Joint Registration Dossier that are submitted jointly.
- 4. Based on the above, a payment notice/ an invoice will be sent to the Non-Lead Members for their cost share after their request for joint submission (2010, 2013, 2018 and first time registrants). The Non-Lead Members will only receive the valid security token number after receipt of the payment. Payment is due within thirty (30) days as of the date of the payment notice.
- 5. In case new studies have to be purchased or performed after conclusion of this Agreement, the resulting cost will be equally divided between all SIEF participants who are required to incorporate the results of these new studies into their registration dossier, unless they claim to opt out in accordance with Article 11 (3) REACH.

- 6. 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.
- 7. 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
- 8. 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. Payer shall be entitled to any refund of withholding taxes.
- 9. 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, 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 2018.
- 2. This Article and the provisions relating to the protection of confidentiality (Article II), ownership of Information (Article X), dispute resolution and applicable law (Article XV) and limitation of the liability (Article XI) shall survive the termination of this Agreement. With regard to the studies, the obligations specified in Article II of this Agreement shall survive for a period of twelve (12) years following the initial submission to the Agency. With regard to all other Information, the obligations specified in Article II shall survive for a period of 5 years after termination of the SIEF.
- 3. The Lead Registrant has the right to terminate its functions as lead registrant under the cumulative conditions that:
- -it has been validly replaced in its functions within the SIEF;
- -its assignee has accepted to be bound by the obligations of the Lead Registrant under this Agreement; and
- -the Non-Lead Member has been notified about such replacement.
- 4. The Non-Lead Member has the right to terminate the present Agreement subject a prior written notice to the Lead Registrant at the latest nine (9) 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 and electronic records, records on expenses, books of account, correspondence, memoranda and receipts.
- 3. The Lead Registrant will accept a validation of the relevant data by an external auditor upon request of a Non-Lead Member. The cost associated with the audit will be for the account of the requestor.

#### 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 CEPANI arbitration rules 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, through the communication IT platform specified under Article V.

The Lead Registrant shall maintain an updated list of SIEF Participants which have agreed to the terms and conditions to the present Agreement and will make it available upon request or through the communication IT platform.

### **ANNEXES**:

### Annex 1

### Cefic guidance on competition compliance

Please see website:

http://www.cefic.be/files/downloads/Cefic-REACH-guidance-DO-&-DON'T.pdf

### Annex 2

### General guidance in regard to SIEF management

Please see website:

http://cefic.org/Files/Publications/ListofTasks%20 in%20 SIEF-Cefic-May 09.x ls

### **Appendix 2 - Substance Identity and Classification & Labeling**

## 1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

### 1.1. Name and other identifiers of the substance

The substance ethylbenzene is a mono constituent substance (origin: organic) having the following characteristics and physical—chemical properties (see the IUCLID dataset for further details).

The following public name is used: Ethylbenzene.

**Table 1. Substance identity** 

EC number:	202-849-4
EC name:	ethylbenzene
CAS number (EC inventory):	100-41-4
IUPAC name:	ethylbenzene
Molecular formula:	C8H10
Molecular weight range:	106.165

### Structural formula:



### 1.2. Composition of the substance

### **Name: Ethylbenzene**

Description: The composition of the substance is > 80% ethylbenzene.

Degree of purity: 99.3 — 100 % (w/w)

**Table 2. Constituents** 

IUPAC name	CAS number	EC number	Mol. formula Hill method	Conc. range (%w/w)
Ethylbenzene	100-41-4	202-849-4	C8H10	99.3-100

### Impurities

IUPAC name	CAS number	EC number	Mol. formul a	Concentration	CL&L (67/648/EC)	CL&L (GHS)	Conc. limits for classificatio n (w/w)
Benzene	71-43-2	200- 753-7	С6Н6	Max 0.1% (w/w)	F; R11 Carc. Cat. 1; R45 Muta. Cat. 2; R46 T; R48/23/ 24/25 Xn; R65 Xi; R36/38	Flam. Liq. 2 Carc. 1A Muta. 1B STOT RE 1 Asp. Tox. 1 Eye Irrit. 2 Skin Irrit. 2	≥0.1% (R45)
Toluene	108-88-3	203- 625-9	С9Н12	Max 0.3% (w/w)	F; R11 Repr.Cat.3; R63 Xn; R48/20- 65 Xi; R38 R67	Flam. Liq. 2 Repr. 2 Asp. Tox. 1 STOT RE 2 Skin Irrit. 2 STOT SE 3	≥5.0 % (R63)
Styrene	100-42-5	202- 851-5	C8H8	Max 0.05% (w/w)	R10 R20 R36/37/38 R48/20 R65	Flamm. Liq. 3 Acute tox 4 Eye irritant 2 STOT single 3 Skin irr. 2 STOT RE 1	Xn; R20: C ≥ 12,5 % Xi; R36/38: C ≥ 12,5 %
Xylenes	1330- 20-7		C8H10	Max 0.18% (w/w)			
p-xylene	106-42-	203- 396-5	C8H10		R10 Xn; R20/21 Xi; R38	Flam. Liq. 3 Acute Tox. 4* Acute Tox. 4* Skin Irrit. 2	12,5 % < C < 20 % (Xn; R20/21)
o-xylene	95-47-6	202- 422-2	C8H10				
m-xylene	108-38-	203-	C8H10		R10	Flam. Liq. 3	12,5 % <c <<="" td=""></c>

	3	576-3			Xn; R20/21	Acute Tox.	20
					Xi; R38	4*	%
						Acute Tox.	(Xn;
						4*	R20/21)
						Skin Irrit. 2	,
n-Propyl	103-65-	203-	C9H12	Max 0.05%	R10	Flam. Liq. 3	2,5 % ≤C <
benzene	1	132-9		(w/w)	Xn; R65	Asp. Tox. 1	25%
					Xi; R37	STOT SE 3	(R52-53)
					N; R51-53	Aquatic	,
						Chronic 2	
Cumene	98-82-8	202-	C7H10	Max 0.18%	R10	Flam. Liq. 3	2,5 % ≤C <
		704-5		(w/w)	Xn; R65	Asp. Tox. 1	25%
					Xi; R37	STOT SE 3	(R52-53)
					N; R51-53	Aquatic	,
					,	Chronic 2	
Dimethylbenzen	1330-	215-	C8H14	Max 0.3%			
e	20-7	535-7		(w/w)			
isomers							
∑ C9/C10							
Aromatics							
(diethylbenzene,							
ethyl-							
methylbenzene,							
isopropylbenzen							
e							
n-propylbenzene,							
butylbenzole							
dutylochzoic							
nonaromatics				Max 0.1%			
hydrocarbons,				(w/w)			
(isomeres of C9				,			
alkanes)							
	1	1		1	I		

### 2. CLASSIFICATION AND LABELLING

### 2.1. Classification and labelling in Annex I of Directive 67/548/EEC:

Endpoints	Classification	Reason for no classification
Explosiveness		Conclusive but not sufficient for classification
Oxidising properties		Conclusive but not sufficient for classification
Flammability	F; R 11	
Thermal stability		Conclusive but not sufficient for classification
Acute toxicity	Xn; R 20	
Acute toxicity- irreversible damage after single exposure		

Repeated dose toxicity	
Irritation / Corrosion	
Sensitisation	Conclusive but not sufficient for classification
Carcinogenicity	Conclusive but not sufficient for classification
Mutagenicity - Genetic Toxicity	Conclusive but not sufficient for classification
Toxicity to reproduction- fertility	Conclusive but not sufficient for classification
Toxicity to reproduction-development	Conclusive but not sufficient for classification
Toxicity to reproduction - breastfed babies	Conclusive but not sufficient for classification
Environment	Conclusive but not sufficient for classification

### Labelling

Symbols: F, Xn

Indications of Danger: Harmful

Risk Phrases: R11: Highly flammable

R20: Harmful by inhalation

Safety Phrases: S2: Keep out of reach of children

S16: Keep away from sources of ignition S24/25: Avoid contact with skin / eyes

S29: Do not empty into drains

Specific concentration limits: none

Other Phrases: none

### Recommended Additional Hazards to Harmonized Classification in EU CLP Annex VI Table 3.2

Endpoints	Classification	Reason for no classification
Acute toxicity- irreversible damage after single exposure	R65	
Repeated dose toxicity	R48/20	
Irritation/Corrosion	R36/37/38	

### **Recommended Additional Labelling**

R65 Harmful: may cause lung damage if swallowed.

R48/20: Harmful: possible risk of irreversible effects through inhalation.

R36/37/38: Irritating to eyes, respiratory system and skin.

## 2.2 Classification according to Regulation (EC) No. 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures (CLP) Annex VI Table 3.1:

Endpoints	Classification	Reason for no classification
Explosiveness		Conclusive but not sufficient for classification
Oxidising properties		Conclusive but not sufficient for classification
Flammability	Flammable liquid Cat 2	
Thermal stability		Conclusive but not sufficient for classification
Acute toxicity	Acute Toxicity Cat 4	
Acute toxicity- irreversible damage after single exposure		
Repeated dose toxicity		
Irritation / Corrosion		
Sensitisation		Conclusive but not sufficient for classification
Carcinogenicity		Conclusive but not sufficient for classification
Mutagenicity - Genetic Toxicity		Conclusive but not sufficient for classification
Toxicity to reproduction- fertility		Conclusive but not sufficient for classification
Toxicity to reproduction- development		Conclusive but not sufficient for classification
Toxicity to reproduction - breastfed babies		Conclusive but not sufficient for classification
Environment		Conclusive but not sufficient for classification

### Labelling

Pictograms:

GHS02: flame



GHS07: exclamation mark



Signal Words: Danger Hazard Statements:

H225: Highly flammable liquid and vapour

H332: Harmful if inhaled

### Recommended Additional Classification Hazard Categories to Annex VI Table 3.1

Endpoints	Classification	Reason for no classification
Explosiveness		Conclusive but not sufficient for classification
Oxidising properties		Conclusive but not sufficient for classification
Flammability	Flammable liquid Cat 2	
Thermal stability		Conclusive but not sufficient for classification
Acute toxicity	Acute Toxicity Cat 4	
Acute toxicity- irreversible damage after single exposure	Aspiration Category 1b	
Repeated dose toxicity	STOT-RE Cat 2	
Irritation / Corrosion	Eye Category 2 Skin Category 2 STOT SE- Cat 3 for Respiratory tract irritation	
Sensitisation		Conclusive but not sufficient for classification
Carcinogenicity		Conclusive but not sufficient for classification
Mutagenicity - Genetic Toxicity		Conclusive but not sufficient for classification
Toxicity to reproduction- fertility		Conclusive but not sufficient for classification
Toxicity to reproduction- development		Conclusive but not sufficient for classification
Toxicity to reproduction - breastfed babies		Conclusive but not sufficient for classification
Environment		Conclusive but not sufficient for classification

### Recommended Additional Labelling Elements to Table 3.1 Annex VI

Pictogram:

GHS08: health hazard



Hazard Statements

H304: May be fatal if swallowed and enters airways

H373: May cause damage to organs (auditory system) through prolonged or repeated exposure (oral and inhalation routes)

H319: Causes serious eye irritation

H315: Causes skin irritation

H335: May cause respiratory irritation

**Precautionary Statements:** 

#### P210: Keep away from heat/sparks/open flames/ hot surfaces - no smoking

P233: Keep container tightly closed

P240: Ground/bond container and receiving equipment

P241: Use explosion-proof electrical/ventilating/lighting equipment

P242: Use only non-sparking tools

P243: Take precautionary measures against static discharge

P261: Avoid breathing dust/fume/gas/mist/vapours/spray

P264: Wash ... thoroughly after handling

P271: Use only outdoors or in a well-ventilated area

P280: Wear protective gloves/eye protection/face protection

P301 + P310: If swallowed: Immediately call a POISON center or doctor/physician

P302 + P352: If on skin: wash with plenty of soap and water

P303 + P361 + P353: If on skin (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304 + P340: If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P305 + P351 + P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P312: Call a POISON center or doctor/physician if you feel unwell

P321: Specific treatment (see label)

P331: Do not induce vomiting

P332 + P313: If skin irritation occurs: Get medical advice/attention

P337 + P313: If eye irritation persists: Get medical advice/attention

P362: Take off contaminated clothing and wash before reuse

P370 + P378: In case of fire: Use ... for extinction.

P403 + P235: Store in a well-ventilated place. Keep cool.

P405: Store locked up

P501: Dispose of contents/container to ...

Note: nine selected phrases for use on labels shown in bold

### **Appendix 3 - DNELs and PNECs**

Table 3. DN(M)ELs for workers

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal	No dose-response information available	NA <sup>1</sup>	NA	NA	
Acute - systemic effects	Inhalation	No dose-response information available	NA	NA	NA	
Acute - local effects	Dermal	No dose-response information available	NA	NA	NA	
Acute - local effects	Inhalation	DNEL (Derived No Effect Level)	293 mg/m <sup>3</sup>	NOAEC: 879 mg/m³ (based on AF of 3)	irritation (respiratory tract)	Ethylbenzene is acutely harmful and irritating to the eye and respiratory tract by inhalation
Long-term - systemic effects	Dermal	DNEL (Derived No Effect Level)	180 mg/kg bw/day	NOAEL: 2,150 mg/kg bw/day (based on AF of 12)	repeated dose toxicity: ototoxicity	Ethylbenzene is ototoxic in animals (extrapolation from inhalation studies).
Long-term - systemic effects	Inhalation	DNEL (Derived No Effect Level)	77 mg/m³	NOAEC: 231 mg/m³ (based on AF of 3)	repeated dose toxicity: ototoxicity	Ethylbenzene is ototoxic in animals.
Long-term - local effects	Dermal	No dose-response information available	NA	NA	NA	
Long-term - local effects	Inhalation	No dose-response information available	NA	NA	NA	

<sup>\*)</sup> The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "Assessment factor" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.

Table 4. DN(M)ELs for the general population

Exposure pattern	Route	1	DMEL	,	Most sensitive endpoint	Justification
Acute - systemic effects		No dose-response information available	NA <sup>1</sup>	NA	NA	

<sup>&</sup>lt;sup>1</sup> Not Applicable.

Acute - systemic effects	Inhalation	No dose-response information available	NA	NA	NA	
Acute - systemic effects	Oral	No dose-response information available	NA	NA	NA	
Acute - local effects	Dermal	No dose-response information available	NA	NA	NA	
Acute - local effects	Inhalation	No dose-response information available	NA	NA	NA	Peak exposures via environment significantly higher than the DNEL long-term systemic inhalation are not to be expected. Therefore a DNEL acute local inhalation is not applicable.
Long-term - systemic effects	Dermal	No dose-response information available	NA	NA	NA	No long-term dermal exposure of the general population.
Long-term - systemic effects	Inhalation	DNEL (Derived No Effect Level)	15 mg/m <sup>3</sup>	NOAEC: 75 mg/m³ (based on AF of 5)	repeated dose toxicity: ototoxicity	Ethylbenzene is ototoxic in animals.
Long-term - systemic effects	Oral	DNEL (Derived No Effect Level)	1.6 mg/kg bw/day	NOAEL: 63.0 mg/kg bw/day (based on AF of 40)	repeated dose toxicity: ototoxicity	Ethylbenzene is ototoxic in animals (extrapolation from inhalation studies).
Long-term - local effects	Dermal	No dose-response information available	NA	NA	NA	
Long-term - local effects	Inhalation	No dose-response information available	NA	NA	NA	

<sup>\*)</sup> The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "Assessment factor" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.

Table 5. PNEC water

PNEC	Assessment factor	Remarks/Justification
PNEC aqua (freshwater): 0.1 mg/L	10	Extrapolation method: assessment factor  According to the TGD (2008, Table R.10-4) an assessment factor (AF) of 50 can be applied to the NOEC value determined from the long-term invertebrate toxicity test with Ceriodaphnia dubia. Results were available for two long term studies covering two trophic levels (daphnids and algae) and the endpoint selected (1.0 mg/L) represents the same trophic level which generated the lowest endpoint in the acute tests (Daphnia magna, EC50 = 1.8 mg/L). However, as cited in the EU risk assessment, ethylbenzene is a neutral organic substance known to act by baseline

<sup>&</sup>lt;sup>1</sup> Not Applicable.

		toxicity, therefore an assessment factor (AF) of 10 would be sufficient to apply to the lowest selected endpoint of 1.0 mg/L.		
PNEC aqua (marine water): 0.01 mg/L	10	Extrapolation method: assessment factor  The PNECmarine was calculated in the EU risk assessment by applying an assessment factor of 10 to the PNECfreshwater. Therefore, 0.1 mg/I with		
PNEC aqua	18	an assessment factor of 10 provides a PNECmarine of 0.01 mg/L.  Extrapolation method: assessment factor		
(intermittent releases): 0.1 mg/L		According to the TGD (2008, R.10.3.3) an assessment factor (AF) of 100 is applied to the lowest value (EC50) of at least three short-term tests from three trophic levels. The lowest value was determined for Daphnia magna (EC50 = 1.8 mg/L). However, this would result in a PNECintermittent of 0.018 mg/L, which is not appropriate, as it would be lower than the PNECfreshwater (0.1 mg/L). As cited in the EU risk assessment, ethylbenzene is a neutral organic substance known to act by baseline toxicity, therefore an assessment factor (AF) of 18 would be sufficient to apply to the lowest selected endpoint of 1.8 mg/L.		

### **Table 6. PNEC sediment**

PNEC	Assessment factor	Remarks/Justification
PNEC sediment (freshwater): 13.7 mg/kg sediment dw		Extrapolation method: partition coefficient  No data were available on sediment dwelling organisms, so according to the TGD (2008, R.10.5.2) the PNECsediment is calculated using the
		equilibrium partitioning method (EPM). The PNECwater (0.1 mg/L) was used along with an experimentally derived Koc value of 1331 l/kg. The
		PNECsediment in mg/kg wwt (2.97 mg/kg) was converted to dry weight resulting in a PNECsediment of 13.7 mg/kg dwt.

### Table 7. PNEC soil

PNEC	Assessment factor	Remarks/Justification
PNEC soil: 2.68 mg/kg soil dw		Extrapolation method: partition coefficient  According to the TGD (2008, R.10.5.2) the PNECsoil is calculated using the equilibrium partitioning method (EPM). The PNECwater (0.1 mg/L) was used along with an experimentally derived Koc value of 1331. The PNECsoil in mg/kg wwt (2.36 mg/kg) was converted to dry weight resulting in a PNECsoil of 2.68 mg/kg dwt.

Table 8. PNEC sewage treatment plant

Value	Assessment factor	Remarks/Justification
PNEC STP: 9.6 mg/L	10	Extrapolation method: assessment factor  According to the TGD (2008, R.10.4.2, Table R.10-6) an assessment factor (AF) of 10 can be applied to the EC50 resulting from a test performed with nitrifying bacteria (i.e., Nitrosomonas). The EC50 value used was 96 mg/L.

### Table 9. PNEC oral

PNEC	Assessment factor	Remarks/Justification
PNEC oral: 0.02 g/kg food		According to the TGD (2008, R.10.8.2) the PNECoral is calculated using the lowest NOAEL from a 13-week repeat-dose study in rats with a value of 75 mg/kg/day. The PNEC oral is derived from an oral study using conservative approaches not relevant to sustainability of wildlife populations and thus must be regarded as being conservative for risk assessment. The PNEC oral for secondary poisoning of birds and mammals was determined to be 1.6 x 10(-5) kg/kg.

### **Appendix 4 - List of uses and use descriptors**

Table 10. Uses by workers in industrial settings

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors	
		Manufacturing of ethylbenzene (M1)		Process category (PROC):  PROC 1: Use in closed process, no likelihood of exposure  PROC 2: Use in closed, continuous process with occasional controlled exposure  PROC 3: Use in closed batch process (synthesis or formulation)  PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises  PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities  PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities  PROC 15: Use as laboratory reagent  Market sector by type of chemical product:  PC 0: Other: Not applicable  Environmental release category (ERC):  ERC 1: Manufacture of substances  Sector of end use (SU):  SU 0: Other: 3  Subsequent service life relevant for that use?: no	
				Article category related to subsequent service life (AC): AC 0: Other: Not applicable	
	2	Distribution of ethylbenzene (IU2)	as such (substance itself)	Process category (PROC):  PROC 1: Use in closed process, no likelihood of exposure  PROC 2: Use in closed, continuous process with occasional controlled exposure  PROC 3: Use in closed batch process (synthesis or formulation)  PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises  PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities  PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	

			PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 15: Use as laboratory reagent  Market sector by type of chemical product: PC 0: Other: Not applicable  Environmental release category (ERC): ERC 0: Other: No releases expected  Sector of end use (SU): SU 0: Other: 3  Subsequent service life relevant for that use?: no  Article category related to subsequent service life (AC): AC 0: Other: Not applicable
	Use as intermediate to produce Styrene (IU3)	as such (substance itself)	Process category (PROC):  PROC 1: Use in closed process, no likelihood of exposure  PROC 2: Use in closed, continuous process with occasional controlled exposure  PROC 3: Use in closed batch process (synthesis or formulation)  PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises  PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities  PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities  PROC 15: Use as laboratory reagent  Market sector by type of chemical product:  PC 0: Other: Not applicable  Environmental release category (ERC):  ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates)  Sector of end use (SU):  SU 0: Other: 3  Subsequent service life relevant for that use?: no  Article category related to subsequent service life (AC):  AC 0: Other: Not applicable
4	Use of ethylbenzene as a process solvent (IU4)	as such (substance itself)	Process category (PROC):  PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with

occasional controlled exposure
PROC 3: Use in closed batch process (synthesis or
formulation)
PROC 4: Use in batch and other process (synthesis)
where opportunity for exposure arises
PROC 8a: Transfer of substance or preparation
(charging/discharging) from/to vessels/large containers at non-dedicated facilities
PROC 8b: Transfer of substance or preparation
(charging/discharging) from/to vessels/large containers
at dedicated facilities
PROC 15: Use as laboratory reagent
Market sector by type of chemical product:
PC 0: Other: Not applicable
Environmental release category (ERC):
ERC 4: Industrial use of processing aids in processes
and products, not becoming part of articles
Sector of end use (SU):
SU 0: Other: 3
So v. Sulet. S
Subsequent service life relevant for that use?: yes
Article category related to subsequent service life (AC):
AC 0: Other: Not applicable

### Most common technical function of substance (what it does):

Intermediate to produce styrene Process solvent

2.3. Uses advised against

No uses identified to be advised against.

### **Appendix 5 - Price Calculation LoA**

### 1. Consortium Budget

APPROVED BUDGETS		2008 budget		
ATTROVED BODGETS		Cost (€uro)		
Ethyl-benzene preparation of Consortium agreement. Review of Competition Law Issues. Consortium Kick-off meeting	MLA	€	9,760	
Meeting and follow-up work to finalize consortium legal documents and business plan. Setting up of bank account for consortium	MLA	€	4,980	
Assistance in setting up Technical Committee and working groups and provision of services as required in particular review of minutes	MLA	€	3,520	
Steering Committee meetings prior to the registration date plus preparation and debriefing	MLA	€	25,760	
Technical Committee support including preparation, attendance, preparation of agenda and minutes, follow up and action lists of meetings maintaining records of progress vs agreed targets, coordination Technical Committee and Technical Consultant	MLA	€	5,280	
Accounting fee	MLA	€	6,000	
Annual management and archiving fee		€	5,000	
Level 2 consultant		€	30,000	
TOTAL APPROVED BUDGETS		€	90,300	

APPROVED BUDGETS			<b>2009 budget</b> Cost (€uro)
Assistance in setting up Technical Committee and working groups and provision of services as required in particular review of minutes	MLA	€	7,840
Steering Committee meetings prior to the registration date plus preparation and debriefing	MLA	€	27,040
Miscellaneous legal advice	MLA	€	20,000
Accounting fee	MLA	€	10,000
Annual management and archiving fee	MLA	€	5,000
Task Force Exposure scenario : preparation, participation & debriefing (half day meeting)	MLA	€	4,000
Technical Committee support including preparation, attendance, preparation of agenda and minutes, follow up and action lists of meetings maintaining records of progress vs agreed targets, coordination Technical Committee and Technical Consultant	Altran	€	50,000
IUCLID 5 file	Dow	€	38,644
Lab for phys chem tests	Harlan	€	19,767
Preparation of the CSR	Cintox	€	86,800
Exposure scenarios	Quantor	€	35,100
TOTAL APPROVED BUDGETS		€	304,191

APPROVED BUDGETS		2010 budget	
APPROVED BUDGEIS		Cost (€uro)	
Assistance in setting up Technical Committee and working groups and provision of services as required in particular review of minutes	MLA	€	8,640
Steering Committee meetings prior to the registration date plus preparation and debriefing	MLA	€	28,480
Accounting fee	MLA	€	10,000
Annual management and archiving fee	MLA	€	5,000
Legal advice & third party communication	MLA	€	20,000
MLA IT On-Line tool	MLA	€	1,500
LOAS (€ 750 per LOA - based on 50)	MLA	€	37,500
Task Force Exposure scenario : preparation, participation & debriefing (half day meeting)	MLA	€	3,150
Technical Committee support including preparation, attendance, preparation of agenda and minutes, follow up and action lists of meetings maintaining records of progress vs agreed targets, coordination Technical Committee and Technical Consultant	Altran	€	28,620
Extended archive retention	Harlan	€	1,210
IUCLID 5 file	Dow	€	48,414
ECETOC Workshop	Cintox	€	2,500
Exposure scenarios (environmental aspects)	Cehtra	€	19,870
Budget Reserve Data Licensing Access		€	20,000
TOTAL APPROVED BUDGETS		€	234,884

### 2. LoA Price Calculation

ETHYL BENZENE LOA CALCULATION - 1000t dossier	TOTAL		15 Members
2008 budget	€ 90,300.00	€	6,020.00
2009 budget (excluding licensing of studies)	€ 304,191.00	€	20,279.40
2010 Budget (excluding LoA budget)	€ 197,384.00	€	13,158.93
Expenses	€ 4,500.00	€	300.00
TOTAL	€ 596,375.00	€	39,758.33
Admin cost (15%)		€	5,963.75
TOTAL WITH ADMIN COST		€	45,722.08
Handling Fee		€	750.00
TOTAL LOA PRICE		€	46,472.08

CSR & ES budget	TOTAL	% of total budget
CSR - Cintox (2009 budget)	€ 86,800.00	
ES - Quantor (2009 budget)	€ 35,100.00	
ES - CEHTRA (2010 budget)	€ 19,870.00	
TOTAL CSR & ES budgets	€ 141,770.00	24.80%

ETHYL BENZENE LOA CALCULATION (w/o CSR & ES)	TOTAL		15 Members
2008 budget less 24.80%	€ 67,905.60	€	4,527.04
2009 budget less 24.80%	€ 228,751.63	€	15,250.11
2010 Budget less 24.80%	€ 148,432.77	€	9,895.52
Expenses	€ 4,500.00	€	300.00
TOTAL	€ 449,590.00	€	29,972.67
Admin cost (15%)		€	4,495.90
TOTAL WITH ADMIN COST		€	34,468.57
Handling Fee		€	750.00
TOTAL LOA PRICE		€	35,218.57

### **Notes**

- 1. Full price including CSR
- 2. For intermediate dossier, no CSR will be charged
- 3. LoA price is a fixed price except if substantial new work to be conducted post 2010
- 4. There will be no reimbursement (overflow income will be used for post 2010 ECHA required work and 50% of the remaining funds will be used depending on the fair value of studies (original invoice value minus 30%) to reimburse data owners for license fee waivers provided pursuant to License Fee Waiver Agreements of Ethyl Benzene REACH Consortium with ACC and SSC respectively)

5. For 100 to 999 tons : €15,838.296. For 1 to 99 tons : €5,322.21