

EXPLANATORY NOTE: CONFIDENTIALITY OBLIGATIONS ON REACH DOSSIER & NOTIFICATION OF INFORMATION TO EPA UNDER US TSCA §8(e)

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Companies involved in REACH process and operating in the US should adopt due diligence measures and take care of protection of confidential information when they deal at the same time with submission of information to US Environmental Protection Agency (EPA).

I. US TSCA duties

On one hand, Section 8(e) of the U.S. Toxic Substances Control Act (TSCA) establishes important requirements on chemical manufacturers, importers, processors, and distributors that operate in the US, for disclosure of "substantial risk" information. In appropriate cases, that may trigger the need to report information that has been exchanged via the REACH process (in a consortium, in the SIEF, etc).

Section 8(e) provides, "*Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who **obtains information** which reasonably supports the conclusion that such substance or mixture presents a **substantial risk** of injury to health or the environment shall immediately inform the Administrator [of the U.S. Environmental Protection Agency (EPA)] of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.*" Guidance on the scope of the information which EPA considers to be subject to this requirement is available at <http://www.epa.gov/oppt/tsca8e/index.html>. This guidance provides important details on what kinds of information trigger section 8(e) reporting requirements¹.

This requirement applies to entities in the U.S. (including importers), not to exporters from the EU to the U.S. However, in some cases where EU entities have knowledge of such information, their U.S. affiliates may have that knowledge also. In addition, in some cases EPA may infer that the U.S. affiliate has that knowledge, particularly where the U.S. entity is the parent of the EU affiliate. In those cases, EPA may consider that the U.S. affiliate is required to submit such information to EPA.

EPA requires information from studies to be submitted within 30 calendar days of an individual capable of appreciating the significance of the information receiving it. Typically, submissions include only short **summaries** of the information, not complete copies of studies. In some cases EPA may respond with a request for additional information.

EPA posts submissions under TSCA section 8(e) on [its website](#). EPA has issued guidance that it will not accept confidentiality claims for chemical identities in section 8(e) submissions

¹ See also the [EPA Section 8\(e\) FAQ](#).



if the chemical identities appear on the public version of the TSCA Inventory. EPA may accept confidentiality claims for other information, such as submitter identity, where the submitter can justify such claims. EPA will not accept confidentiality claims for the substantive information in the section 8(e) submission. Accordingly, submitters should prepare their submissions carefully.

II. REACH information and potential contractual arrangements

On the other hand, in the context of the REACH process, the same companies may be subject to specific confidentiality obligations.

a) Consortium member and consortium agreement

When a company is a REACH consortium member and the information is coming from the consortium members, that disclosure of information to US authorities should respect at the same time the confidentiality obligations agreed with the other consortium members via the terms of the consortium agreement. In that regard, the terms of Cefic template consortium agreement (art. IV, 1.a) states that when disclosure of consortium data are required for legal and/or regulatory purposes, disclosure shall only take place by the Members in a form (for example short summaries where possible) reflecting the minimum information required to be disclosed and the Member shall advise immediately the other Members and the consortium manager in writing of any disclosure.

b) SIEF member and SIEF agreement

The same rules applies when a SIEF member is provided with some confidential information by the Lead Registrant during the process of dossier preparation (e.g. circulation of a draft dossier) or during the process of data sharing in view of the submission of the dossier by the SIEF member (e.g. in case of CSR to be submitted individually by each co-registrant, the generic CSR prepared in the consortium is shared in the SIEF). In case the SIEF member envisages submitting (part of) such information to EPA, the confidentiality obligations set up according to the contractual arrangements in place in the SIEF (e.g. SIEF agreement) should prevail.

III. Balance between the 2 processes: recommendation

Companies shall have in place internal policies and **effective procedures** to ensure the confidentiality of information to prevent any undue disclosure.

A member of a consortium/SIEF shall achieve the compliance with its TSCA duties and take care at the same time of the protection of the commercial interests at stake in the REACH process. In that sense, the member of the consortium/SIEF should make all efforts to summarise and shorten the information to be submitted to EPA and check the non-CBI nature of the information.

In consortia, given that part of the information related to the registration dossier that is exchanged in consortium is usually either owned by another consortium member or co-owned by the consortium members, consortia should preferably have also in place a collective process that goes further than the simple notice before a TSCA notification by a

consortium member to the other members. In particular, it is **recommended** that the **consortium members** should **jointly approve** that the regulatory conditions of a TSCA notification are met and should **review** the content of the information to be submitted to EPA.

IV. Risks to be prevented

a) Potential risks

Here some examples of risks that are related to a TSCA notification.

1. Publication of confidential information on the EPA website

The risk of potential issue occurs when the consortium member (or the branch in US) submits to EPA some part or the full content of the (draft of) registration dossier and/or the CSR prepared jointly within the consortium. Therefore, confidential information would be made public (in the case of the CSR, said information being never disseminated on ECHA website).

2. Misuse of the information from the EPA website by SIEF members

A misuse by a SIEF member of the information published on EPA website may directly alter the process of data and cost sharing on consortium dossier in the SIEF and directly affect the sales of Letters of Access in the SIEF.

3. Breach of non-disclosure contractual agreements

At the same time, when part of the published information is extracted from studies owned by a data owner non-member of the consortium, when there are confidentiality obligations in place according to a data sharing agreement with said data owner, the publication of the information may be considered as a material breach of such contract (with potential withdrawal by the data owner of the permission to refer granted in view of the REACH dossier).

b) Ex-post measures

In case a consortium member inadvertently provides confidential information from the REACH registration dossier to EPA, he should inform the other consortium members and should ask without undue delay to EPA to withdraw the information.

When that request is accepted by EPA, in case **alternative information** is request by the US authorities, that consortium member should preferably consult the other consortium members on the content of the information to be submitted in replacement to EPA.

c) Misuse of information from EPA, infringement of REACH and copyright

Depending on the extent of the information submitted to EPA, if some SIEF member that has found out the information on EPA website, decides to make a copy-paste into his IUCLID5 dossier and submits it to ECHA, such dossier may be potentially complete but the registrant would not be in compliance with REACH (potential breach of the requirement of legitimate possession/permission to refer to full study reports- art 10 (a) last indent REACH) and would infringe copyright protection.

Moreover, in this case, the information published on EPA website would have been published without the consent of the (co-)owner(s) of the information (=the Lead Registrant/consortium members) and any implicit permission to refer from such publication

cannot be implicitly derived from the publication. The permission to refer to the dossier, as required by REACH, should be explicitly provided via the purchase of a Letter of Access to the Lead Registrant/consortium.

Furthermore, the Lead Registrant is able via REACH-IT to monitor the participation of each co-registrant in the Joint Submission. In case undue information was published on EPA website, special attention should be preferably paid by the LR on the disclosure of the token number only to SIEF members that have paid the Letter of Access, as the risk of misuse is higher due to the availability of information on the EPA website.

V. Miscellaneous

Protective measures of REACH confidential information should be also applicable in case a company is subject to similar duties of notification in any other place all over the world.

This paper has been developed by the Cefic Legal Aspects of REACH Issue Team.

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Cefic has published and is developing a number of guidance documents. Please visit the REACH section of the Cefic website for more information: <http://cefic.org/en/reach-for-industries-documents-and-tools.html>

Background information:

a) Extract from the Cefic model consortium agreement (art. IV)

Article IV. Confidentiality

The Members shall:

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

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

- b) *use the Information only for the Purpose or otherwise as permitted under or in accordance with this Agreement.*
- c) *disseminate the Information to their employees, Affiliates or external experts and/or consultants only on a need to know basis and only to the extent absolutely necessary for the Purpose or otherwise as permitted under or in accordance with this Agreement. Each Member shall have in place policies and procedures to ensure the confidentiality of Information, 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.*

b) Extract from the Cefic model SIEF agreement (art. II)

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.*