

EXPLANATORY NOTE: OBLIGATIONS AND LIABILITIES OF THE LEAD REGISTRANT IN THE SIEF

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Introduction

Guidance on REACH usually concentrates on REACH requirements, defining which the obligations of the respective actors involved in REACH are. But what happens if the Lead Registrant (LR) submits the joint dossier incomplete or not in time and causes damage as a consequence?

With a view to analysing the relations in the SIEF between the LR and the other SIEF members it is indeed appropriate to elaborate on the issue of the obligations and the liability of the LR. To tackle the questions of liabilities of the LR may also be a useful approach to set up preventive and due diligence measures by establishing bilateral relationships between the LR and each of the other SIEF potential registrants.

As reminder, the SIEF Lead Members are the members of the SIEF Category 1 and form the SIEF Leadership Team, according to the SIEF survey based on the implementation of the [Cefic recommendation](#). Under the SIEF categorisation, the Lead Members are in charge of the preparation of the dossier. When there is a consortium in place in the SIEF, it is assumed that the consortium is the SIEF Leadership Team. It is also assumed that the LR is a member of the SIEF Leadership Team.

In order to use a single description, the Non-Lead members are the other SIEF participants with intention to register (members of categories 2 and 3). They will receive SIEF progress reports from the SIEF Leadership Team and be invoiced for the data they need for the corresponding registration, according to costs sharing principles agreed in the SIEF via the SIEF agreement.

I. AGREEMENT IN THE MEANING OF ART. 11 REACH AS STARTING POINT FOR OBLIGATIONS AND LIABILITIES

Following Art.11(1) REACH the LR is the registrant who submits the information specified in Art. 10(a)(iv), (vii) and (ix) and any relevant indication under Art.10(a)(viii) with the agreement of the other assenting registrant(s). The registrants may decide between themselves that the LR submits the information specified in Art. 10(a)(v) and (b) and any relevant indication under Art.10(a)(viii) on behalf of the others too.

As a consequence, a contractual arrangement by and between the joint registrants to nominate the LR and to assign his duties is needed and preconditions to create obligations and liabilities of the LR vis-à-vis the assenting registrants in the SIEF.



Especially when the LR volunteers and informs the SIEF members that he will take over the role (instead of a LR election), a proposal as volunteer LR without the contractual assent of the other joint registrants is not legally sufficient to be responsible and liable as LR. The same applies to the opening of the Joint Submission object in REACH-IT by the LR. **Only an assent of the other assenting registrants, preferably done in the form of a written contractual arrangement**, that formalises the appointment as LR, as for example covered by the [Cefic model SIEF agreement](#), **formalises the start of the obligations of the LR and the commencement of the corresponding liabilities.**

II. OBLIGATIONS OF THE LEAD REGISTRANT

The obligations of the LR as provided under REACH are rather limited and relate to the joint submission.

1. Obligations of the Lead Registrant during the joint submission phase

a) Mandatory object of the agreement between LR and assenting SIEF participants (REACH regulatory obligations)

The LR is taking the lead in the registration process, since he is pursuant to Art. 11(1)(2) and 19(1)(2) REACH acting with the agreement of other joint registrants and is responsible for submitting the “joint registration dossier” on behalf of the other joint registrants.

The LR is fundamentally responsible for submitting the information of the Joint Registration Dossier required to be submitted jointly according to Art. 11(1)(2) and 19(1)(2) REACH. An assent of the other joint registrants must cover this obligation. Written contractual arrangements are recommended and their scope can be much broader than only covering the obligations of the LR, as the Cefic model SIEF agreement.

b) Voluntary objects of the agreement between LR and assenting SIEF participants

Where the joint registrants so decide, on a voluntary basis, the LR can also jointly submit the Guidance on Safe Use of the substance and the Chemical Safety Report (Art. 10(a)(v) and (b) and 11(1)(4) REACH).

The member registrants will in their own separate registration submit a limited set of information, with reference to the joint registration of the LR for the rest of the information

c) Practical duties deriving directly from the regulatory obligations

The first duty of the LR is to create a joint submission in REACH-IT system on the ECHA website (see Cefic document [Joint Submission Process in REACH-IT](#)).

In order to create this joint submission, the LR will need to indicate the name of the Joint Submission, as agreed among the SIEF Members that will take part to the Joint Submission.

Where needed and after agreement of the joint registrants, the LR shall indicate in REACH-IT whether a Guidance on Safe use, Chemical Safety Report (CSR) and a review by assessor will be provided.

However, the SIEF participant can also submit its own CSR within its individual dossier if it is needed for any reason.

The LR is also responsible to technically submit the joint registration dossier via the REACH-IT system.

The LR has the general duty of disclosure of the token number to member registrants.

In respect of communication, the LR acts as contact point with ECHA in relation to the joint registration dossier as well as with other relevant SIEFs for read across purposes. In practice, it implies that the LR forwards any request for information from ECHA or from the other SIEFs to the joint registrants.

If appropriate, the LR will also have to request to ECHA confidential treatment of jointly submitted data (Art. 119(2) and 10(a)(xi) REACH) upon demand from the other registrants. In that regard, the LR has also the duty to submit the justification of the request to the authorities.

d) Additional contractual obligations

In view to meet the REACH legal requirements, REACH actors may decide to introduce additional rights and obligations by contractually agreeing on enforceable contractual arrangements. These rights and obligations are not covered by the REACH Regulation, but the joint registrants may agree to govern them by contractual arrangements by and between them.

1) Between the LR and the Non Lead members (SIEF Agreement)

It is particularly recommended that the Lead Members of the SIEF put a structured SIEF process in place with the other SIEF participants and agree on confidentiality obligations, data sharing, cost compensation and participation in the Joint Submission of the Dossier, as also proposed by the Cefic model SIEF agreement.

Consequently, **new contractual obligations can be indeed created within the SIEF, in particular for the LR**. We can mention for example the obligation of disclosure by the LR to the other SIEF members of the data that have been submitted in the joint submission (article VI.8 model SIEF agreement), the obligation of disclosure of the token number by the LR to the SIEF participants only after payment of their relevant Joint Registration Compensation and within a contractually agreed deadline (Art. VIII.1 and IX.4 model SIEF agreement) or the obligation of communication to the SIEF participants of the successfulness of the joint submission.

These obligations are **only enforceable between the contractual parties**: any SIEF member that does not sign said SIEF agreement would not benefit from these rights.

2) Among the Lead Members (Consortium/Cooperation agreement)

Since the LR is member of the SIEF Leadership Team (either a Consortium or other form of Cooperation between the Lead Members of the SIEF), the LR shall also be bound to the obligations formulated in the corresponding legal framework (either a consortium agreement or the cooperation agreement between Lead Members).

2. Obligations after the joint submission phase

The update of the joint registration dossier in case of relevant changes according to Art. 22 REACH, is in principle an obligation of each registrant individually when the changes concern the individual parts of the joint registration. When it comes to the joint parts of the registration, the joint registrants should inform the lead registrant of updates and/or new registrant joining and the lead registrant should update the joint dossier accordingly.

In some situations, as in the case for example if new results of studies may change the classification & labelling or the CSR, individual updates would increase the complexity of the process and it is strongly advisable to set up some agreement in the SIEF with the LR in that regard.

3. Withdrawal and change of the Lead Registrant

a) Withdrawal of the Lead Registrant

In case of change of the LR in a Joint Submission, the joint registrants need to appoint a new LR.

LR can only withdraw from REACH-IT when there is a successor or when he is the only member. Once a contractual framework is in place (SIEF Agreement), a LR cannot unilaterally decide to step down as LR: a successor has to be appointed by the joint registrants and the successor must then take over the LR role in REACH-IT¹. SIEFs shall remain operational at least until 1 June 2018 and there must be always a LR within the joint submissions.

Article XII.3 of the SIEF agreement covers contractually such situation. It says: *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.*

b) LE change of the Lead Registrant

According to ECHA, if the LR is subject to any Legal Entity change that entails a legal successor, the succeeding company will be regarded as LR.

III. LIABILITIES OF THE LEAD REGISTRANT

As a general remark, **the extent of LR's liabilities will largely depend on the extent of additional obligations that the LR is willing to take contractually.**

¹ See point 3.6.6 of the ECHA [joint submission manual](#): “The lead registrant is not allowed to leave the joint submission unless he assigns the lead to another member and the member accepts the lead assignment”.

1. REACH regulatory liabilities

The LR is responsible for submitting a valid joint registration dossier under Article 11 REACH with the agreement of the other assenting registrants. If he provides no complete joint registration dossier or fails to complete the joint registration dossier within the deadline set, ECHA will reject the registration.

If the LR or member registrants continue manufacturing and/or placing on the market of a substance after the registration deadline without valid registration (for instance when their registration dossier has been rejected), their substance is unlawfully on the market and they risk to be sanctioned by national enforcement authorities.

Under REACH, rejection of the joint registration dossier shall affect without distinction the LR and any member registrant. Accordingly, **the conditions for liability of any specific operator relating to such rejection can only result from contractual arrangements between the joint registrants.**

2. Contractual liabilities and limitation of liabilities

REACH does not govern relationships between the lead registrant, member registrants or SIEF members. Consequently, **it is strongly recommended to set up clear contractual rules on liability of the LR.** Subsequently, in accordance with the legal principle of freedom of contract, **the joint registrants can contractually limit the liability of the LR.**

The Cefic model **SIEF agreement** does so and entails the liabilities of the LR only to damage caused for its SIEF activities by gross negligence or wilful misconduct². Extending the liability of the LR to cases of simple negligence may have indeed a deterrent and counter-productive effect of only few volunteer LRs. Notwithstanding, such contractual limitation is circumscribed since liability for damage caused by gross negligence and wilful misconduct can never be waived in advance under most national laws of European Member States.

In the Cefic model **Consortium and Cooperation Agreement** the limitation of the liability of the LR is similarly proposed.

In regard to data or delays in the submission of the Joint Submission, equally the liability of the LR for any consequence related to the inaccuracy of data submitted by other registrants is limited in the same way.

Therefore, in case such agreements are in place, if the LR fails to register successfully and the individual registrants are consequently forced to stop manufacturing and/or importing, these **can only claim damages from the LR if they can demonstrate that the gross negligence or wilful misconduct of the LR has caused said damages.** However, it is important to note that the LR as a registrant has a clear interest to ensure registration is done properly and on time. It goes without saying that such a registration also relates to its own registration obligations under REACH.

² See article XI.4 Cefic model SIEF agreement: *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.*

3. Liabilities vis-à-vis third parties

Liability of the LR vis-à-vis third parties is subject to the general rules of tort liabilities and cannot be limited by the contractual arrangements between SIEF members (as for example the SIEF agreement). The LR, as any legal person, can be declared liable by a judge in case of a fault causing a damage to a third party, provided the fault, the damage and the causal link between the two, among others, can be demonstrated by the plaintiff.

IV. RECOMMENDATION

It is recommended that when a company volunteers in a SIEF as LR, its announcement (either via REACH-IT, any SIEF IT-platform or by email) contains the following disclaimer:
No representations or warranties are made and no liability will be accepted for damages of any nature whatsoever resulting from the action of the Lead Registrant or the results generated by it, as long as there is no contractual arrangement in place between a SIEF member and the declared Lead Registrant.

This paper has been developed by the Cefic Legal Aspects of REACH Issue Team where more than 50 legal experts from companies participate.

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