

## What is a Letter of access?

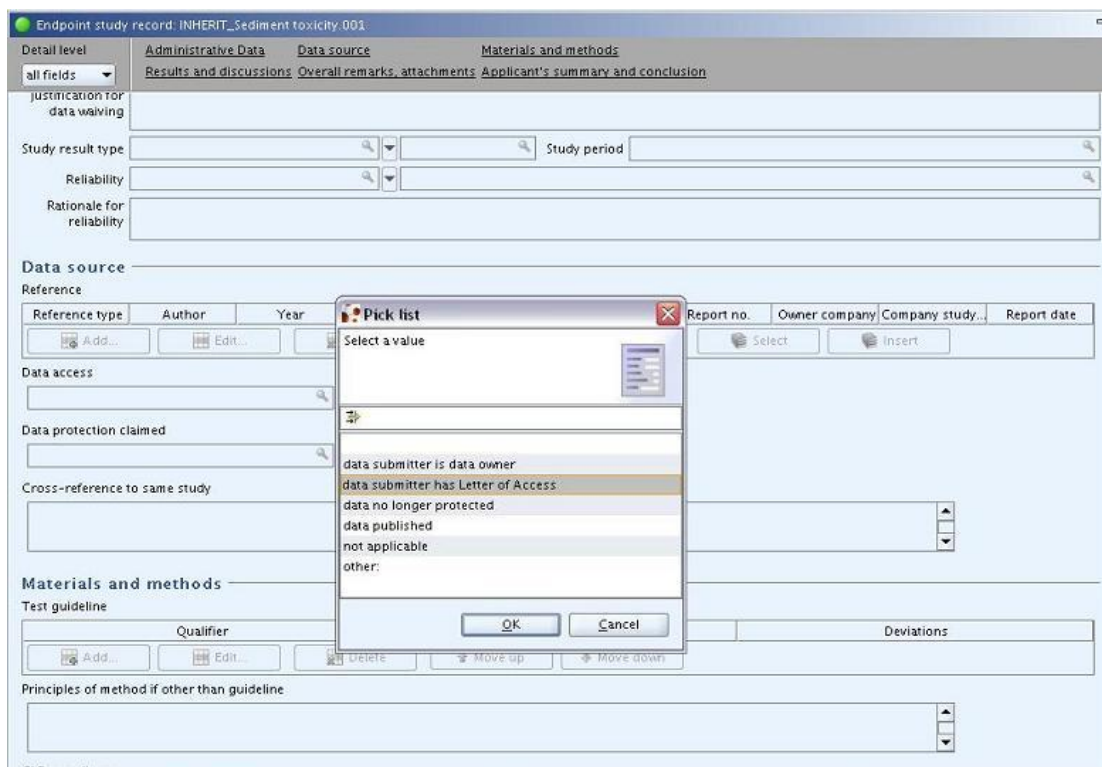
Article 10(a) of the REACH Regulation includes: *“Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (vi) and (vii) for the purpose of registration”*. The LoA may serve this purpose as proof of the right to refer.

The concept ‘Letter of access’ (LoA) entails two main types/ principles:

- LoA granting permission to use/ refer to a single/set of study(ies) by a Data owner
- LoA that allows a SIEF member to refer to the entire Joint Submission (JS) (i.e. all studies used for the JS) for a certain tonnage band

All the considerations below are valid for both types. It is recommended to define very clearly what are the rights entailed in each case. Depending on the rights granted, prices may be different.

The REACH Regulation does not include any provisions on LoA and there is no need to attach a LoA to the IUCLID5 registration dossier. The registrant just makes a statement about he has permission to refer via a LoA in the corresponding section of IUCLID5 (see image below):



The screenshot shows the 'Endpoint study record: INHERIT\_Sediment toxicity.001' window. The 'Data source' section is active, and a 'Pick list' dialog box is open over it. The dialog box contains a list of options for data access, with 'data submitter has Letter of Access' selected. The background window shows various fields for study details, including 'Justification for data waiving', 'Study result type', 'Reliability', 'Rationale for reliability', 'Reference' table, 'Data access', 'Data protection claimed', 'Cross-reference to same study', 'Materials and methods', 'Test guideline', and 'Principles of method if other than guideline'.

### **Isn't the signature of the SIEF Agreement sufficient?**

The granting of access rights by the Lead Members to the entire Joint Submission to Non-Lead Members is secured via the [SIEF agreement](#) in place.

The LoA will be useful in case of review by the enforcement authorities, where they ask the registrant for evidence of the fulfilment of the conditions from the above-mentioned article 10.

The signature of the SIEF agreement by a SIEF member cannot act as a proof of the legitimate possession or permission to refer. The SIEF Agreement itself cannot bring that proof because if a Non Lead Member signs the SIEF Agreement but does not pay the compensation when he is invoiced, the LR will not grant the right to use/ to refer to the data.

The SIEF agreement and the LoA do not substitute each other but are complementary. Their combination is recommended:

- the SIEF agreement, to be preferably signed *at the beginning of the SIEF process*, with agreement, among others, on cost sharing criteria
- the LoA to be delivered as certificate of the grant of the access rights *at the end of the data sharing process following the payment* of the due compensation,.

### **Should I pay to be part of a Joint Submission without knowing what is in the dossier?**

In some cases, the potential registrant may not be willing to purchase a right to refer to the Joint Submission without having been able to check the content of the submission first. This needs to be sorted out between the potential registrant and the Lead Registrant/ consortium.

In practice this may lead to difficulties in case a member needs to prepare his own CSR, without having access to certain pieces of information.

In addition, it should be noted that the information regarding the agreement on classification & labelling must be shared within the SIEF regardless of the type of Joint Submission

### **What do I receive when paying for the data? Is it just the token? Or should I receive the data included in the dossier?**

It is not advised that SIEF members only receive the token following the payment of the relevant compensation to be part of a Joint Submission.

As a minimum, SIEF members should have access to the information submitted by the LR on behalf of the Joint Submission members (article 11(1) paragraph 2). This means that by paying a LoA in order to participate to the Joint Submission, the SIEF members should have access to the endpoints results for which they have paid for as well as a copy of the robust study summaries, and study summaries if available, unless flagged as confidential. In this case, only the result will be made available.



If the Chemical Safety Report (CSR) is to be submitted jointly, a draft CSR should be made available to all JS members in advance, in order to allow them to check whether their uses are covered. Indeed SIEF members need to extract the information from the CSR in order to prepare the Exposure Scenarios to be attached to the extended SDS.

If the CSR is *not* submitted jointly, the information received should allow companies to write their own CSR. In some cases, the hazard assessment part of the CSA is jointly performed and the exposure assessment and the risk characterisation is carried out separately by each registrant.

### **Know what you pay for!**

The SIEF agreement and the subsequent LoA should clearly indicate the scope covered by the Joint Submission.

It is strongly recommended that both documents define very clearly what SIEF members will receive as well as the scope of the JS i.e. whether the CSR will be part of the JS or not.

### **If I pay for the Letter of access, does it mean I become 'owner' of the data?**

No, unless clearly stipulated. In principle the LoA gives permission to refer to a certain study or set of studies, or to the full Joint Submission for REACH registration purposes only, but it does not transfer ownership.

It is actually not advised to negotiate the transfer of ownership of studies within SIEFs. This may complicate the process, particularly in case of newcomers.

### **The role of LoA in enforcement**

Enforcement authorities must be made aware of the potential breaching of REACH article 10 if companies do not compensate the relevant party(ies) in the SIEF (no legitimate possession or permission to refer).

In this context, companies are invited to have their LoA available to the enforcement authorities in order to demonstrate whether:

- the company has appropriate Letters of Access for all Legal entities registering.
- the tonnage band for which the registration was submitted and the one for which the Legal Entity got permission to refer to are consistent. In case of a change in tonnage band (increase), the Legal Entity should check with the Lead Registrant if the data it got permission to refer to should not be broadened.