Factsheet

SIEF, data sharing and joint submission

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Data sharing under REACH is the core principle to avoid unnecessary testing on animals and reduce registration costs.

The REACH Regulation requires companies registering the same substance to share data and to jointly submit their registration dossier. For phase-in substances, all existing and potential registrants that have pre-registered the same substance are part of a substance information exchange forum (SIEF) that aims to:

- facilitate the exchange of information on available data between co-registrants;

  and

- agree on classification and labelling where there is a difference between co-registrants.

In addition to REACH, the Implementing Regulation[1] provides rules on how data should be shared and how negotiations for data sharing should be conducted.

[1] Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing

ORGANISING A SIEF

From pre-SIEF to SIEF

If potential registrants use the same substance name or numerical identifier, such as an EINECS number, to pre-register their substance, REACH-IT automatically places them in the same pre-SIEF page. The pre-SIEF page is a technical platform introduced by ECHA to find all pre-registrants of a the same substance. REACH-IT (version 3.1) also has a search functionality, which can be used to check whether the substance has been already registered or if there already is someone who has created the joint submission object. In the latter case, the preparations for a new joint registration have already started.

Before forming a SIEF and negotiating the sharing of data, pre-registrants should make sure that their substances are the same.

Substance sameness should be established according to the *Guidance for identification and naming of substances under REACH*. This step is crucial before any data-sharing activity: it makes sure that time and resources are invested on the right substance from the very start.

If some pre-registrants conclude that they have a different substance, they should find the other pre-registrants and registrants of that substance.

ECHA will not participate in the discussions between the pre-registrants and has no role in confirming or rejecting their substance sameness.

Supporting the formation of SIEFs

To ease the start of SIEF activities, a SIEF Formation Facilitator (SFF) role was created in REACH-IT. However, as this role is not formally recognised by REACH, the pre-registrants have no obligation to use an SFF.

Any pre-registrant can volunteer for this role. This can be done through REACH-IT. The volunteering company will need to contact the other pre-registrants and start exchanging the information required to agree on substance sameness and to organise data sharing. The SFF can rethink its position at any time and decide to step down (see *Guidance on data sharing*).

SFFs cannot ask for service fees unless they are mutually agreed.

Additional help on how to agree on substance sameness and organise data sharing is available through industry associations.

Cooperating within a SIEF

The members of the SIEF can decide how to organise their cooperation, which takes place outside of REACH-IT. Cooperation can vary from a simple structure (e.g. IT tools to communicate between all SIEF members) to a more structured and complex organisation (e.g. involving separate consortia).

For large SIEFs, consortia may be a more efficient type of cooperation to comply with the data-sharing obligations and to prepare the registrations. However, there is no requirement to form consortia under REACH.

DATA-SHARING AGREEMENTS

Sharing data in a SIEF

To fulfil their data-sharing obligations under REACH, SIEF members first need to get an overview of the studies available in the SIEF.

SIEF members must ask each other whether any of them already has the study needed. If the study is available, the SIEF members must make every effort to find a fair, transparent and non-discriminatory agreement on data sharing. If the owner of an existing study performed on vertebrate animals refuses to provide either proof of the costs for the study or the study itself within one month, or otherwise does not make every effort to find a fair, transparent and non-discriminatory agreement on cost sharing, the other potential registrants can file a data-sharing dispute to ECHA.

Data-sharing obligations also apply to studies that do not involve testing on vertebrate animals and SIEF members are obligated to make every effort to find a fair, transparent and non-discriminatory agreement on data sharing. However, no dispute can be filed if the negotiations fail, and SIEF members will have to agree to conduct a new study for those who need it.

If a study is not available in the SIEF, members will need to agree on how to get the missing data. Animal testing should be considered only as a last resort.

The SIEF members need to agree on how they share the costs for both existing and new studies. Registrants are only required to share the costs for information they need to fulfil the registration requirements of their tonnage band. Cost sharing must be determined in a fair, transparent and non-discriminatory way.

Data-sharing disputes

If there is a disagreement, REACH and the Implementing Regulation offer the following remedies:

1. **Disputes resulting from a disagreement on who shall conduct a new study**:

   If there are disputes on who shall perform a new study, ECHA can decide which SIEF member will be requested to conduct the test on behalf of the others.

2. **Disputes on sharing data and the joint submission**:

   SIEF members have to make every effort to reach an agreement in a fair, transparent and non-discriminatory way. A dispute can be filed to ECHA only as a last resort after all efforts and arguments have been exhausted and the negotiations have eventually failed.

When sending a dispute to ECHA, the SIEF members have to provide the documentary evidence (e.g. emails) to demonstrate the efforts they have made. ECHA also requests documentary evidence from the data owner. ECHA then assesses the efforts of both parties to meet their obligation to reach an agreement on sharing the data and/or an agreement on the joint submission.

Finally, ECHA decides whether or not to grant permission to continue with the registration without the fulfillment of the relevant information requirement, if the vertebrate animal data has not yet been submitted.

If data has been already submitted to ECHA, the Agency decides whether or not to give permission to refer to this data to allow the other SIEF members to proceed with their registrations.

For disputes related to joint submission, ECHA decides whether or not to grant an opt-out token to the existing joint submission.

If ECHA's decision is not favourable to the SIEF members, they must resume negotiations with the data owner. If the data-sharing negotiations fail again, the dispute can be resubmitted.

In cases where ECHA cannot give permission to refer to the disputed data because it does not involve vertebrate animal testing, the national enforcement authorities can penalise the owner of a study if they have not fulfilled their data-sharing obligations.

Joint submission

Multiple registrants of the same substance must submit information jointly on the intrinsic properties of the substance. The preparation of the joint dossier may be coordinated by one of the potential registrants but can also be done by any other person appointed by the SIEF members, such as a consultant or a consortium.

However, the potential registrants must agree on a lead registrant for the joint submission. The lead registrant submits the joint part of the registration dossier before any of the other registrants submit their own dossiers.

IMPORTANT: *The role of lead registrant is not automatically given to the company that facilitated the formation of the SIEF.*

The lead registration dossier should be submitted at least two months before the deadline to give enough time for the other registrants to submit their own registrations. The other registrants only have to submit their company-specific information in a member dossier.

Lead registrants are encouraged to inform ECHA of their nomination. ECHA will then be able to help them as well as guide other potential registrants of the same substance to the right SIEF. ECHA does not confirm or reject any lead registrant nominations.

FURTHER INFORMATION:

Key information for preparing for the 2018 registration deadline: http://echa.europa.eu/2018.

Support for working together with your co-registrants: http://echa.europa.eu/support/registration/working-together

Data sharing and disputes (regulatory information): http://echa.europa.eu/regulations/reach/registration/data-sharing

Guidance on data sharing: http://echa.europa.eu/guidance-documents/guidance-on-reach?panel=datasharing#datasharing

Guidance for identification and naming of substances under REACH: http://echa.europa.eu/guidance-documents/guidance-on-reach?panel=ident_nam_subst#ident_nam_subst

http://echa.europa.eu/reach-2018

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