

# REACH – Substance Information Exchange Forum (SIEF)

If you have pre-registered a substance then you will be part of a Substance Information Exchange Forum (SIEF). **The UK Competent Authority is not involved in the operation of SIEFs**; however this leaflet is a starting point to help you understand things you should consider when operating within a SIEF. More detailed guidance on how SIEFs will operate is in the ECHA guidance on data-sharing.

## What is a Substance Information Exchange Forum?

A Substance Information Exchange Forum (SIEF) is formed automatically within REACH-IT. It is comprised of all the relevant stakeholders (see below) for each substance. There is a separate SIEF for each substance with a different EC/CAS number. You can view all the members of the SIEF through the REACH-IT system where you made your pre-registration. There is no option to opt out of a SIEF, but you can decide how active you wish to be within it. The SIEF has the following aims:

- to facilitate, for the purposes of registration, the exchange of information between potential registrants and others with relevant information with a view to sharing data on the intrinsic properties of the substance and fulfilling the mandatory obligation to share all animal test data, thereby avoiding the duplication of studies; and
- to prepare a joint lead registration dossier of data for registration of the substance; and
- to agree, if possible, the classification and labelling of the substances.

SIEFs are comprised of all legal entities who:

- have pre-registered a phase-in substance;
- have registered a phase-in substance early;
- are the data-holders for a substance for which the European Chemicals Agency (ECHA) holds a data package, (for example, for an active substance used in a biocidal or plant protection product);

A SIEF can also choose to invite any data-holders (e.g., downstream users or other stakeholders) who have registered in REACH-IT as having relevant information they could share with potential registrants. These data-holders do not gain automatic entry to the SIEF. The full SIEF members are not obliged to include these data-holders.

Each SIEF shall be operational until 1 June 2018 (the last registration deadline in REACH). REACH does not set precise rules for how a SIEF should operate. Consequently, this is up to the individual SIEF members collectively.

## SIEF formation and the pre-SIEF

Before a SIEF can operate effectively two things need to happen. Firstly, the pre-registrants need to find some way of working together to discuss how the SIEF will operate (who will coordinate it, methods of communication, who will be the lead-registrant, rules for late joiners, etc). Once the initial SIEF has formed, its members will need to compare the substance each has pre-registered to find out if there is sufficient similarity (e.g. the form, purity and impurity profile) to allow data sharing and a valid joint submission of data. During this stage, the 'pre-SIEF' exists. The Pre-SIEF was not foreseen in the REACH Regulation, but this concept was introduced, with support from industry, in order to bring pre-registrants together to facilitate SIEF formation.

The initial formation of the SIEF can be carried out by a SIEF Formation Facilitator (SFF). The SFF is not a legally defined role in REACH but was introduced into the REACH-IT system as a way of 'getting things started'. Pre-registrants could volunteer to be the SFF when submitting their pre-registration. One of the first tasks for SIEF members to agree upon is who will coordinate the pre-SIEF and help facilitate the formation of the SIEF. The SFF may go on to become the Lead Registrant, although this does not necessarily have to be the case. It is possible for a SIEF to operate without a facilitator; it is possible that the SIEF members may agree to "buy in" a SFF. Many pre-registrant companies will have already contacted other SIEF members with a view to taking on this role. Where a number of companies have indicated that they wish to be the facilitator, the SIEF members can decide between them who is to take the role, or if it is to be shared. It is important that you are content from a business point of view with the company acting as facilitator.

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If nobody has indicated that they wish to be the SFF, then somebody may need to take the initiative (if it is considered that an SFF is required). This could be for example, the company for whom the substance has the highest commercial/strategic importance.

Once the pre-SIEF discussions have taken place to identify whether the substances pre-registered by each company are sufficiently similar to allow for joint submission, work for the preparation of the registration dossier can start. In some cases, it may be found that, although pre-registered as the same substance, the entities from different sources are not sufficiently similar and the SIEF will need to split into 2 or more separate (sub-)SIEFs. This split could be due to for example, differences in the purity/impurity profile of the substances or because the EINECS entry used covers a wide range of distinct substances (e.g., those for plant extracts).

## SIEF

Once the potential registrants have reached agreement on substance sameness, SIEFs are then ready to proceed.

REACH requires that a Lead Registrant (LR) must be identified. As noted above this could be the SFF, but does not have to be, particularly if the SFF is a company with no registration duty. In many cases it seems likely that the LR will be a company whose registration deadline is in the highest tonnage band relevant for the specific substance. Importantly, one SIEF member cannot just *take* the LR role, it must be decided and agreed upon by the SIEF.

The LR's role is to produce the 'Lead dossier' to which the other joint registrants will refer. That is, the LR will submit a complete dossier containing all the tonnage dependant data for physico-chemical, toxicological and environmental properties. Joint registrants submit 'partial dossiers' containing information specific to their company; for example, information about their identified uses, their production volumes or their 'version' of the substance (e.g., to account for different impurities). In these joint submissions, instead of study summaries, they simply refer back to the lead dossier.

Further information on the registration process can be found in [UK REACH CA Information Leaflet Number 16 - Registration](#).

It is possible to appoint a Third Party Representative (TPR) to represent you in the SIEF. This can be for commercial confidentiality reasons (e.g., to conceal your identity from competitors in the SIEF). Alternatively a TPR could be used to provide expertise in negotiating the data-share. However, the TPR does not register on your behalf or assume responsibility in law for your registration.

There are certain obligations placed on all members of a SIEF:

- to react appropriately to information requests from other SIEF participants; and
- to provide other participants with existing studies on request.

There are also certain obligations placed on those members of a SIEF who are potential registrants:

- to request missing information from other SIEF participants;
- to collectively identify needs for further studies to comply with Registration requirements;
- to make arrangements to perform the identified studies where required; and
- where possible, agree on the classification and labelling of the substance

## Practical Issues for consideration

### SIEF participation

The degree of participation within a SIEF is a business decision that each company must make for itself. In order to identify the companies likely to be active participants within a SIEF, SFFs and potential LR's have sent round questionnaires requesting this information. The European Chemicals trade body CEFIC have defined four roles covering the positions SIEF members could take. These four roles are: Leader, Active, Passive and Dormant. Whilst not having legal status in REACH, these four roles appear to be appropriate descriptors and are widely used in questionnaires.

If a company has little to contribute to the SIEF and indeed may not have to ultimately register, then dormant may be an appropriate status to take. This status would be appropriate to a company that had

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pre-registered a substance which they will ultimately not need to register because an exemption from registration will apply (e.g., a recycler or re-importer). However, companies in this situation should ensure that a registration will be submitted to enable them to take advantage of the exemption (e.g. sufficient evidence of “sameness” between the recovered and virgin substances, and the need to have safety data available).

## Pre-registration errors

If a company has pre-registered a substance in error, or has no intention of submitting a full registration, then they may wish to deactivate their pre-registration. This is done in the pre-SIEF part of REACH IT. Deactivation is reversible and does not invalidate the pre-registration, i.e., it allows the company to continue to manufacture/import the substance until the relevant registration deadline. However, it indicates to other SIEF participants that the company has no interest in the ongoing discussions. Even if a company has de-activated their pre-registration, this pre-registration will still remain valid and they will still be members of the SIEF and the obligations placed on them as outlined above will remain.

If, during the pre-SIEF “sameness” check, a company considers that their substance is the same as one or several substances pre-registered under (an)other identity code(s). Then they should gain access to the other SIEF for the same substance pre-registered under a different identity using the 'similar substance' tab in their pre-registration in REACH-IT. This does not, however, change the original pre-registration. Therefore, this is not a mechanism to allow registrants to change the chemical identity of the substance they have pre-registered.

## REACH Information requirements

SIEF members should work together to assess the current level of available data. If a data gap is identified, then the SIEF should work together to fill this gap. Conducting a new study in animals should be the last resort and alternative approaches to filling the gap should be explored first. For example, the SIEF could consider whether read across from a study that it knows of on a similar substance can be used or if the end point can be estimated from structural activity relationships. For higher tonnage registrations ( $\geq 100$  tonnes) the additional animal testing triggered by the higher tonnage bands should not be conducted until the testing proposal has been agreed by ECHA. If a study is required then the study should be commissioned by one member on behalf of the others and all reasonable steps should be taken to agree who commissions this study; if there is no agreement, ECHA will specify who will commission it. All participants who require access to a study contribute to the costs of the study, and all have an equal right to the full study report.

If studies are available participants can request that they be shared. Animal test data must be shared. The owner of the study must then provide proof of cost and this cost shall be shared between the participants who require it for their registration. Until such time as they need access, registrants in lower tonnage bands are not obliged to contribute towards the costs of tests required for registration in the higher tonnage bands.

You may find yourself in a SIEF where the LR has a registration deadline earlier than the one you are working towards. This is not an unusual position. The SIEF will work together to produce the hazard data package that will support all participants' registrations. This will be prepared for the LR to submit before the earliest registration deadline. Provided you have negotiated access to the LR dossier, bearing in mind that you only need access to the data relevant to your tonnage band, you can submit your dossier at any point until your tonnage-related deadline.

## SIEF structure

Every SIEF will be different: some will have only a few members; some could have hundreds or even thousands. To some degree this will define how a SIEF will operate. The level of participation is a business decision for each participant to make, but things you should consider include:

- whether you are clear what your objectives are;
- ensuring you do what you need to do, not what others may want you to do;
- only paying for data needed for your registration;
- ensuring you abide by competition law; and
- ensuring you have competent people to represent/assist you.

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In terms of costs incurred, a registrant should only be expected to pay for the appropriate share in the data they require for their registration, not for data required for a higher tonnage band. REACH states that these costs must be “fair, transparent and non-discriminatory”. This could be achieved in a number of ways such as sharing costs equally based on the number of parties involved or proportionally, based on production or sales volumes (tonnage bands). Other cost issues to consider may include:

- should the cost of the study when conducted be the guiding principle or should the cost be based on the current day cost of such a study;
- consideration of the study quality and its perceived worth;
- what if more than one company owns a suitable study;
- what if two studies give conflicting advice; and
- what is the relevance of the study.

A new Commission Implementing Regulation (EU) 2016/9 came into force on 26<sup>th</sup> Jan 2016 further defining the data sharing rights of registrants.

Potential registrants joining a SIEF are given the right to request a breakdown of the study and administrative costs that make up the price for the joint registration. In the interests of transparency, the majority of costs should be study costs or at least attributable to a specific study. This way, members aren't paying costs related to studies they may not need. More information can be found in ECHA's *Guidance on data sharing*.

Any SIEF administration costs incurred due to use of a facilitator or a lead registrant are for you to consider from a business point of view.

## Enforcement

Title III of REACH describes the duties and obligations on SIEF participants, which have been summarised above. These duties typically require, for example, participants to "make every effort" or "take all reasonable steps" to reach agreement about the sharing of studies or the cost of studies. The UK Government's view, as expressed during the consultations on REACH enforcement, is that it is impractical and inappropriate to enforce the majority of these provisions using criminal sanctions. For this reason, the REACH Enforcement Regulations 2008 do not provide for the enforcement of Title III by the national or local enforcing authorities, apart from:

- Article 26(1) – the duty to inquire prior to registration;
- Article 27(1)(a) – the requirement on a potential registrant to request information on vertebrate animal tests from a previous registrant; and
- Article 30(6) – any failure by the owner of a relevant study to provide either proof of the cost of the study or the study itself.

These provisions are enforceable by the Health and Safety Executive (HSE) in Great Britain, and the Health and Safety Executive Northern Ireland (HSENI) in Northern Ireland, This does not mean that the other provisions of Title III are unenforceable; rather, the rights and obligations which are created by these provisions are matters for civil law to resolve as and when appropriate.

## Further information

If you are having difficulty with understanding or collating the technical data required, or with compiling your registration dossier, there are several sources of help available. For example, the guidance documents available on the ECHA website; other members of the SIEF; consultants and/or contract research organisations. Specifically, ECHA produced a webinar concerning SIEF management and data sharing, which can be found in the Support section of the ECHA website.

The UK REACH competent authority cannot offer advice on how to operate within a particular SIEF, as this is a business decision for any company involved. We can offer advice on the application of REACH and its obligations. You can contact the UK REACH Competent Authority's national helpdesk at:

Email: [UKREACHCA@hse.gov.uk](mailto:UKREACHCA@hse.gov.uk)



Website: [www.hse.gov.uk/reach](http://www.hse.gov.uk/reach)