

REACH *Fact Sheet*

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Getting Started in SIEFs – Top Tips

SIEFs (Substance Information Exchange Fora) are independent – they are not “owned” by ECHA. At the same time, they have a critical role within REACH and ECHA wants to do what it can to try to ensure that they succeed in the job they have to do.

SIEFs are formed by companies that intend to register the same substance. They are there to facilitate data sharing between the companies, and hence avoid duplication of studies and to agree classification and labeling where there is a difference between registrants. Members also need to provide others with existing studies, react to requests by others for information and work collectively to identify and carry out additional studies should they be needed. All this work is intended to lead to a single joint submission for each substance, with the minimum of additional animal testing and cost.

Industry stakeholders have made ECHA aware that there have been difficulties in

getting some SIEFs started and potential problems with communication between members.

ECHA recently chaired a meeting of industry stakeholders and staff from the Commission. The meeting sought to discuss the problems that had arisen, clarify the requirements of SIEF members and help to ensure sharing of best practice between industry stakeholders.

The notes below are aimed at companies and highlight the main areas of discussion and potential solutions. ECHA recognizes that this is a new process and that other issues are likely to arise and further discussion may be needed. We will continue to give our support, within the limitations imposed by REACH, to help to ensure that SIEFs and registrants can fulfill the tasks that they are asked to do. ECHA has also prepared *Guidance document on data sharing* to help SIEFs complete their tasks which is relevant to some of the issues raised below.

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WHY THIS IS URGENT FOR YOUR COMPANY

It is really important that you get involved in the most appropriate SIEF for your substance as soon as possible.

This is the first time this has been done, the deadlines are tight and SIEF members may take time to agree upon critical issues. So if you have not started, start now. The deadlines for submission of registrations are laid down in the REACH regulation – ECHA does not have the power to change them - so you need to make sure that you do not miss them. According to the law, if you do not have a valid registration by that time, your manufacture or importing would need to cease.

DOCUMENT WHAT YOU DO

As noted below, some of the problems with SIEFs are concerned with communication or the lack of it. For example, inactive or non-responding SIEF formation facilitators, lack of response from potential SIEF members, or in determining the need to split or merge SIEFs. Given these communication difficulties, it is important to record what you have done and why, in the event of any challenge later.

THE SIEF FORMATION FACILITATOR (SFF)

The SFF role was not defined in REACH. However, the intention was to allow a volunteer to initiate the SIEF to encourage companies to work together. An outline of the role is provided in *the Guidance document on data sharing* (section 4.5.2. page 38).

Where the current SFF isn't working, or is perhaps using the pre - SIEF as an opportunity to earn money or blocking or slowing down the process, SIEF members may ask the SFF to give up the role and set a deadline for a response. In any

event, SIEF members are free to work around the SFF, perhaps using their own information text field in the pre-SIEF page in REACH-IT to post comments, or outside of REACH-IT, perhaps via their own webpage or website.

SIEF members are advised to keep a record of their actions in response to problem SFFs.

DEALING WITH PRE-REGISTRANTS OR SIEF MEMBERS WHO DO NOT RESPOND

Some SIEFs potentially have a very large number of members. However, many of these may choose not to have any active involvement. At the extreme, some organizations may not respond to e-mails or the e-mail addresses given may not exist.

Where a company does not respond to an e-mail, try again; if the e-mail bounces back, try fax. If there is no response there should be no further need to contact them but do document the action taken. Please remember that SIEF members should have the opportunity to make contact should they wish – they may choose to become active later, or may have joined the SIEF as a new entrant. It will also be helpful to download the XML file of pre-registrants at regular intervals to see if any changes to contact details have been made. Please note that communications might be filtered out as spam.

Creating a website to document formation and progress, a newsletter or simply communicating significant issues by e-mail may be helpful, since all SIEF members will still be able to keep track of progress. The essential point is that, having made reasonable attempts to give SIEF members the opportunity to contribute actively, those who do choose to be active also have a chance to make the SIEF deliver.

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IF YOU THINK YOU'RE IN THE WRONG PRE-SIEF

If you entered your substance name in a different way than the other manufacturers and importers when pre-registering, or if you realise during discussions about the sameness of your substances that you do not have the same substance as the other pre-registrants in the pre-SIEF, you may want to look for and join another SIEF.

A useful tool when looking for a more suitable SIEF is *the list of pre-registered substances*. This list contains all pre-registered substances, with the available identifiers such as EC number, CAS number and chemical name with synonyms.

Once you have found a more suitable or more specific identifier for your substance (which is then considered as “another” substance by REACH-IT), you can use REACH-IT to view the pre-SIEF of this “other” substance. For this, you need to update your pre-registration by adding this “other” substance in the “similar substances” tab. From the pre-SIEF page of your substance, you will then be able to navigate to the pre-SIEF page of this “other” substance. You will not be listed as a member of this pre-SIEF, so you have to take the initiative and get in contact with the pre-registrants to explain that you wish to join the SIEF.

SPLITTING OR MERGING OF PRE-SIEFS

Some SIEFs may need to split or merge after members' discussions about the sameness of their substance.

That's fine. If you do split, it's important that you follow the appropriate *Guidance for identification and naming of substances*, keep a record of the decision and the reasons for it. We suggest using the “similar substances” tab, as above, to view the pre-SIEF you want to merge with.

If the split produces two substances judged to be different but both covered by the same identifiers, then it is important to

clearly document why the substances are considered to be different and hence why a single joint submission was not thought to be acceptable.

Companies are encouraged to look at *the list of pre-registered substances* and check whether their substance appears more than once on the list, perhaps under a slightly different name. Merging the SIEFs would help ensure data sharing and minimize the need for animal testing.

LEAD REGISTRANT

There can be only one Lead Registrant and one Lead Registrant dossier for a substance. The Lead Registrant will typically be the company most involved in that substance – they may produce the most or hold most of the data. The two might not be the same.

The Lead Registrant is appointed by agreement within the SIEF and ECHA has produced guidance on how to determine who should be Lead Registrant (*Guidance on data sharing*, section 8.3 page 83). It is important to document the agreement by which the Lead Registrant was appointed. The guidance contains reference to a potential default mechanism if no-one volunteers: the EU manufacturer or importer with the highest capacity for production or import. Please note that it is for SIEF members to agree among themselves on who will be the lead for the joint submission, ECHA will not decide who shall have this role.

SIEFS THAT CONTAIN CONSORTIA

Companies in SIEFs may get together in consortia in order to prepare one or more parts of the joint submission, or to work across several joint submissions for different substances (*Guidance on data sharing*, sections 10.2 to 10.7 pages 95 to 102).

While this may be an efficient way of working, consortia members must take note that they still have co-operation and data sharing obligations with other

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potential SIEF members from the pre-SIEF, who are not in the consortia.

TIMING OF SUBMISSIONS

In order to make sure that the requirements of Article 11 (1) of the REACH Regulation are fulfilled, ECHA recommends that the submission of the lead registrant dossier is made first, allowing time for the completeness of the submission to be checked and given a registration number. To help support this process ECHA will distribute, before the end of the year, a module to allow companies to check the completeness of their IUCLID 5 dossiers. The current Business Rules (which ensure that the submission is “fit to process”) have already been released in REACH-IT *Data Submission Manual 8*. Taken together, these will allow companies to create complete and processable dossiers, minimizing the need for a second round of submissions.

Other members of the SIEF may submit their dossiers closer to the deadline.

ECHA will further clarify the timing of the lead and individual dossier(s) in order to ensure that industry can meet the respective registration deadline while fulfilling all legal requirements.

LOW VOLUME SUBSTANCES WITH EARLY REGISTRATION DEADLINES

If you produce or import a substance below the 1,000 tonne level, you have a deadline for submission of registration of 2013 or beyond, unless your substance is classified for certain hazardous properties presented in Article 23 of REACH. However, some members of the pre-SIEF may have indicated a 2010 registration date, indicating a higher tonnage.

In these cases it would be reasonable, where the lead registrant and other SIEF members only need to meet a later deadline, to contact those who indicated

an earlier deadline and establish what their intentions are. If they do not respond, document the attempts to make contact. If there is no response it would be reasonable to work to the deadline appropriate to the other members of the SIEF.

If a dossier is submitted ahead of the other members of the SIEF, it will have to be changed to reflect the joint submission when that is subsequently made.

OPT OUT

REACH allows companies to opt out from part of the Joint submission under certain circumstances, which must be documented.

Companies choosing to opt-out should be aware of the need to justify their action and the obligations they still have as members of a SIEF. Companies should be aware that opting out will trigger the payment of a higher fee and opt out submissions are likely to be a priority to be looked at and evaluated at a later stage.

DATA OWNERSHIP

Those compiling submissions cannot assume that published information may be used for REACH registration for free, although it may be possible to use the content of a published article in a different form. The appropriate national copyright and/or data protection law must be respected and should be checked.

FURTHER INFORMATION

Hyperlinks to documents on the ECHA website:

- [Guidance on data sharing](#)
- [List of pre-registered substances](#)
- [Guidance for identification and naming of substances under REACH](#)
- [Data Submission Manual 8](#)
- [REACH Regulation](#)