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SIEF - KEY PRINCIPLES

The purpose of a Substance Information Exchange Forum (SIEF) is to help registrants of the same substance to share information about the substance and to avoid duplication of testing.

Currently the main activity for companies that pre-registered substances last year is to form SIEFs and make them operational as early as possible. This is critical for data sharing and the subsequent preparation of joint registration dossiers. Time available for data sharing is relatively short, especially for those who need to submit their registrations to ECHA before 1 December 2010.

FROM PRE-SIEFs TO DATA SHARING

Pre-SIEF

- The concept of the pre-SIEF was not foreseen in the REACH Regulation, but was introduced, with support from industry, in order to bring pre-registrants together to facilitate SIEF formation.
- REACH-IT automatically placed companies who pre-registered substances with either the same name or chemical identifiers in the same pre-SIEF.
- Companies in each pre-SIEF must decide, based on detailed consideration of the substance identity, whether the substance in question can in fact be regarded as the same.
 - Pre-registrants of the same substance will form one SIEF.
 - Those pre-registrants who discover they have different substances should seek to form or join other SIEFs. The pre-SIEF page in REACH-IT has a “Similar to” box to help companies identify the most appropriate pre-SIEF.
- The contact information of all other pre-SIEF members is available in REACH-IT. This information can be downloaded from REACH-IT into an XML file (see the REACH-IT Industry User Manual – Part 5).

SIEF Formation Facilitator

- The SIEF Formation Facilitator (SFF) role was created to initiate and conduct discussions after pre-registration, and to facilitate the exchange of information and data which is required in order to form a SIEF.
- Any pre-registrant may volunteer via REACH-IT to be the SFF.
 - Any companies volunteering to be a SFF must be willing to take the initiative to contact the other participants within their pre-SIEF with a view to forming the SIEF.
 - SFFs have no management role beyond facilitating discussions and they have no legal basis to force other pre-SIEF participants to co-operate with them.
 - SFFs cannot demand information or fees for their services unless mutually agreed.
- The SFF role is not formally recognised under REACH, therefore pre-registrants have no obligation to use a SFF to form a SIEF.
- Data in REACH-IT may only be used for the purposes of meeting legal obligations under the REACH Regulation. The data may not be used for other purposes.
- A SFF can review their position at any time and decide not to continue in this role (see Guidance on Data Sharing).
- ECHA advises all companies to decide what role they wish to take in the SIEF. The chemical manufacturers' association (CEFIC) and distributors' association (FECC) have agreed on a proposal that includes the harmonised classification of pre-registrants according to their desired level of SIEF involvement and an early identification of SFFs. The proposal is available on the CEFIC website at: <http://cefic.org/Templates/shwStory.asp?NID=719&HID=714>

SIEF Formation

- A SIEF is formed when companies have agreed that their substance is the same.
- Companies in the SIEF are free to choose how they communicate and organise themselves.
- ECHA will not participate in discussions between potential registrants and will not confirm or disallow the creation of a particular SIEF.
- ECHA recommends that companies contact their relevant trade associations for further advice on how best to proceed from pre-SIEFs to SIEFs

Lead Registrants

- All SIEFs must select a Lead Registrant. This is a mandatory role laid down by the REACH Regulation. The role is not automatically given to the company that facilitated the formation of the SIEF.
- REACH does not specify rules as to how the Lead Registrant should be selected. The Lead Registrant must act with the agreement of the other assenting registrants and submit the Joint Dossier, which contains information on the intrinsic properties of the

substance. The other registrants then only have to submit their company-specific information.

- Lead Registrants are perhaps more likely to submit their registrations well before the first registration deadline in 2010.
- The Lead Registrants preparing for the first registration deadline are advised to inform ECHA of their nomination. These nominations should be sent by e-mail to:

lead-registrant@echa.europa.eu

Consortia

- Consortia are a more formal type of co-operation between registrants set up in order to provide practical help with SIEF data-sharing obligations and the preparation of registrations. There is however no requirement to form consortia under the REACH Regulation. It is possible that several consortia could be formed among the members of one SIEF or that one consortium could cover registrants from different SIEFs, e.g. in the case of related substances.

Further information

Detailed information on (pre-)SIEFs can be found in the Guidance on Data Sharing and in the REACH-IT Industry User Manual Part 5.

Guidance on Data Sharing:

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| • Sections 4.3 and 5.1 | Data sharing obligations |
| • Chapter 4 and section 4.5 | Formation of a SIEF |
| • Section 4.5.2 | Role of SFF and role of Lead Registrant |
| • Section 8.3 | Lead Registrant: appointment and tasks |
| • Chapter 10 and section 10.1 | Forms of cooperation to share data |

REACH-IT Industry User Manual – Part 5 (Pre-SIEF):

- **Figure 6:** “View Pre-SIEF Information tab” shows how the contact information of participants in a pre-SIEF can be exported as an XML file by clicking on the <XML> link.
- **Figure 27:** “Stop (pre-)SIEF Formation Facilitator role” demonstrates how an SFF can step down from his/her role, by: clicking on the <Stop Facilitator> button.

Specific provisions can be found in the [REACH](#) Regulation:

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| • Articles 25(1)(2), and 29(3) | Data sharing obligations |
| • Article 29 | SIEF formation |
| • Article 11 | Joint Submission |