EUROMETAUX
EUROPEAN ASSOCIATION OF METALS

Issue sheet on pre-SIEF & SIEF

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1. Introduction

The aim of this document is to clarify the role of the pre-SIEF and SIEF in the Registration of existing chemicals and explain the rights and obligations of companies within these structures. Decisions taken in the context of the (pre-)SIEF are the responsibility of industry and ECHA will not intervene in these decisions.

2. Pre-SIEF

Through its pre-registration of a phase-in[1] substance, a company has expressed its "interest" to register. The legal text of the REACH Regulation (Art 29(1)) foresees that:

> *All potential registrants, downstream users and third parties who have submitted information to the Agency in accordance with Article 28, or whose information is held by the Agency in accordance with Article 15, for the same phase-in substance, or registrants who have submitted a registration for that phase-in substance before the deadline set out in Article 23(3), shall be participants in a substance information exchange forum (SIEF).*

The pre-SIEF is not a concept included in the REACH Regulation, but has been introduced, with the support of industry, in the guidance on data sharing. Instead of immediately becoming a member of the SIEF, companies that have pre-registered a substance will first become members of the pre-SIEF.

The aim of the pre-SIEF is to bring together companies who believe that they are dealing with the same substance, to comply with data sharing requirements and achieve, in a next step, the joint submission of a Registration file (see Art. 11 (substance) and Art 19(isolated intermediates)).

The guidance document specifies the tasks of pre-SIEF members as:

- The establishment of the sameness of the substance(s) pre-registered under a specific identifier for the purpose of SIEF formation, in line with the "ECHA guidance document on identification and naming of substance[2]"; and
- Verification if their substance has not been pre-registered under other identity codes.

Subsequently, it is possible to freely merge multiple pre-SIEFs into one and vice versa; After the above steps have been completed, the official SIEF can be formed. Pre-registrants are advised to form the SIEF as soon as possible.

What is the SFF and what are his role and obligations?

[1] Art. 3(20) of the REACh Regulation

[2] http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf

In order to facilitate the formation of the SIEF, the role of "SIEF Formation Facilitator (SFF)" was created in the context of the guidance document[3] and the REACh-IT system.

Additional ECHA guidance specifies[4] that:

- Pre-registrants can appoint themselves as the SFF, as long as no one has ticked the SFF box in the REACH-IT system, and therefore indicate to the other pre-SIEF members that he is willing to take the initiative to contact the other pre-SIEF members.
- The SFF-role is not legally binding, does not entail any obligations and one is free to revise its position at any time.
- The SFF-role has no management role beyond facilitating the discussions and has no legal basis to force others to cooperate with them.
- SFFs cannot demand information or fees for their services, unless mutually agreed.
- As the role of SFF is not formally recognised under REACH, the pre-registrants have no obligation to use the SFF to form a SIEF. In case of the latter, it will be important that one actor is coordinating the work.

Does the determination of the sameness of a substance for the purpose of pre-SIEF formation require information on the exact/full composition of the substance?

No, as the exact composition of the substance, including information on minor constituents and/or impurities, is not relevant to determine sameness. The "guidelines on identification and naming of substance[5]", outlines that a substance may be considered the same if it has the same name. When this criterion is not considered sufficient, other criteria might be used. For a full overview of the criteria, we refer to the guidance document[5].

Steps to be taken when you realise that you ended up in the wrong pre-SIEF?

If after the sameness check, a company realises that the substance should have been pre-registered under a different EINECS number, and that the company should be in a different SIEF. The company should contact the correct SIEF and proceed with data sharing and registration for the correct substance.

ECHA has unofficially confirmed that it will not correct pre-registrations in REACH-IT. Instead, the following steps are recommended for companies which have made mistakes during their pre-registration:

- In your REACH IT pre-registration window, enter a reference to the correct substance in the "similar substances" box;
- Get in touch with the SIEF formation facilitator of the correct SIEF and explain that your company wants to proceed with the registration of that substance;
- Proceed with data sharing in the correct SIEF and join the registration efforts for the correct substance;

3 ECHA guidance document on data sharing
4 ECHA SIEF key principles
5 ECHA guidance document on identification and naming of substances

- Include your pre-registration number in the Registration file, indicating the reasons why the substance identity of the pre-registered substance does not respond with the substance identity of the registered substance. (such as: reasons for selection of initial EINECS N°, communications with SIEF members on sameness, advice from consortia if any, etc.)

Note that the above steps are appropriate only for the correction of a pre-registration based on a legitimate mistake.

If the company pre-registered for an unrelated substance to the one that it manufactures or imports, ECHA advises that the company should suspend any activities involving the substance and proceed with the registration, as required by the REACH Regulation, before resuming its activities.

There is no requirement to notify ECHA of the correction of a legitimate mistake.

3. SIEF

Once the decision on the sameness of the substance to be covered by the SIEF has been agreed upon, the SIEF is formed.

The first task of the SIEF is to reach an agreement on the appointment of a designated "Lead Registrant (LR)[6]". The Lead Registrant is amongst other responsible for taking the lead in the SIEF process and the submission of the joint part of the registration file. Subsequently, the prime activities towards the data sharing and the preparation of the joint submission for registration can start.

While the SIEF is legally defined in the REACH Regulation (see Art. 29), but it is still up to the industry to organize the operation of the SIEF and set the rules.

According to the REACH Regulation the tasks of the SIEF shall be to:

- *share data with the aim to avoid duplication of studies, especially on vertebrates; and*
- *reach agreement on Classification & Labelling (C&L): it is possible for potential registrants agree to disagree on C&L of the substance due to specific reasons (e.g.: impurities, physical form); and*
- *definition of collective testing proposal if needed*
- *carry out missing studies jointly; and*
- *prepare the joint submission file for registration, including the proposals for additional tests.*
- *Each SIEF shall be operational until 1 June 2018*

Who shall participate in the SIEF? (Art 19(1))

All potential registrants, downstream users and third parties (data holders) who have submitted information to ECHA in accordance with Art. 28 or whose information is held by ECHA in line with Art. 15, for the same phase-in substance. But also registrants who have already submitted a registration for that substance before the deadline set out in Art.23(3).

[6] Also see EM issue sheet on Lead Registrant

What are the obligations & rights of the different members of the SIEF?

The obligations and rights of the different actors present in the SIEF, as set out in the ECHA guidance documents, are summarised in the table below:

	Potential registrants	*Data holders*
React to requests for information from other SIEF participants	*X*	*X*
Provide other participants with existing studies upon request	*X*	*X*
Request missing information from other SIEF participants	*X*	
Collectively identify needs for further studies to comply with registration requirements	*X*	
Make arrangements to performed identified studies	*X*	
Agree on C&L, where there is a difference of opinion between members of the SIEF	*X*	
Elect Lead Registrant	*X*	
Agreement on common part of the Registration file (Joint submission)	*X*	

Who is responsible for managing the exchange of information within the SIEF?

Managing the exchange of information within the SIEF may be a continued role of the SFF. Other options could be a) the Lead Registrant who has a clear obligation in the joint submission process or b) a small sub-group of SIEF members (i.e. a SIEF leadership Team (SLT)).

Considering this is a substantial task and that the collected information could be considered as commercially sensitive, the LR, SFF or SLT may propose to use an independent third party or trustee to handle the exchange of (confidential) information.

Recognising that the SIEF tasks require considerably more work than the pre-SIEF, the guidance on pre-registration and data-sharing mentions that it might be appropriate to consider a financial compensation for the resources used by the entity chosen to lead the SIEFs work.

What should be agreed as soon as possible after the formation of the SIEF?

In order to ensure a smooth functioning of the SIEF, once it becomes operational, it is advisable to agree on:

- the form of cooperation (SIEF with agreements, or a consortium) between the SIEF members and possible internal operating rules; and
- who will perform the necessary technical work:
    - potential registrants themselves; or
    - contracted third party; or
    - a combination of the two
- scope of the cooperation:
    - strictly limited to the obligatory part; or

  - to also cover some or all of the following tasks together:
    - guidance on safe use;
    - chemical safety report (with or without generic ES);
    - have information reviewed by an external assessor;
- organisation of the exchange of available data;
- how to channel the communication with other relevant SIEFs, e.g. where read across applies;
- how to ensure a smooth entry of late registrants;
- how to launch queries for data in the SIEF;
- how to keep track of available data within the SIEF.

When discussing these issues, compliance with EC competition law must always be borne in mind.

Does the presence of different impurities that lead to a difference in classification and labelling lead to a distinct SIEF?

No, a SIEF is dealing with a substance that is considered to be the same[5]. As these criteria do not take into consideration impurities or minor constituents, this should not lead to one SIEF splitting into multiple SIEFS. The rationale behind this is that very often data sharing can still be achieved.
For the Classification & Labelling aspects of the joint submission, it is possible to make a distinction within the SIEF and conclude that, on the basis of the composition of the substance (including impurities and minor constituent), the same substance will have a different Classification and Labelling.

Does the existence of different physical forms of the substance lead to the need to split up a SIEF?

Based on the guidance on pre-registration and data-sharing (section 4.5.1), different physical forms of a substance with the same name should be considered to be the same, unless "all data" for one physical form are unusable for the other physical form and sharing of data would make no sense. However, different forms may lead to different Classification & Labelling.