



Conclusions of SIEF Workshop 30/03/09



1

These slides include the conclusions from the workshop held on 30th of March. The following parties were present: European Commission (DG ENTR & DG ENV), ECHA, AISE, Cefic, Cembureau, Concawe, EFFA, FECC, IMA, Eurometaux, Eurofer, ORO and th US mission to the EU

Disclaimer



The conclusions of the SIEF Workshop as discussed with the participants at the end of the Workshop are not binding ECHA and the Commission.

SFF blocking or not reacting



- **ECHA cannot ‘de-block’ the SFF box** in REACH-IT. ECHA has no legal basis to do so and no means to evaluate any allegations made
- **Document actions taken** to contact the SFF e.g. write registered letter and include a deadline for reaction. The SFF can be by-passed after such deadline
- If SFF continues not to react, it **can be by-passed** outside REACH-IT
- Consortia & SIEFs are encouraged to **communicate** these decisions publicly
- Individual companies are advised to include the ‘new’ LR identification in the **comments field in REACH-IT**

3

Some SIEF Formation Facilitators (SFF) are blocking the process. They do not react to demands to ‘untick’ the box nor they take any initiative. Question was asked whether it was ‘allowed’ to by-pass these SFFs. It was reminded that the SFFs have no legal role as they are not even mentioned in the REACH Regulation.

ECHA was requested to de-select the SFF box for those SFFs who are posing problems. Unfortunately ECHA is unable to do so.

SIEF members not responding



- No reply means **dormant status** -> **no further systematic individual contact needed**
- **Document 'efforts'** to contact all members, give everyone possibility to get information and upgrade their categories at later stage
- It is strongly advised to have **general communication / progress report to entire SIEF**. These reports can be burdensome and can be done e.g. via reference to consortia website
- Some companies may have indicated a **wrong email** in the REACH-IT: keep error message back to justify why they were not contacted
- **Check spam!**: consider communication to warn companies to check junk mail folder

4

SFFs, LRs, consortia etc. are sending out the SIEF surveys and establishing communications with all (pre-)SIEF members. Some of these members do not react to these communications. Issue was whether it is possible to ignore these entities who do not answer emails.

Main point is to send out regular activities reports to the entire SIEF. This will allow the passive members to monitor the progress and follow-up with individual actions when needed.

Misuse of (pre-)-registration numbers



- **Pre-registration numbers cannot be sold**
- **'Faking' (pre-)registration numbers is an enforcement issue**
- To be raised by companies or industry associations at the Forum or with individual Member States Competent Authorities

5

It seems that pre-registration numbers are being sold in internet. Some companies, particularly Only Representatives (OR) are concerned that mala-fide companies can just copy pre-registration numbers and use them to import chemicals into EU.

This is an enforcement issue. If such practices are noticed, the corresponding enforcement authorities should be made aware.

Nobody taking initiative in SIEF



- Cefic advises its members to **take on the SFF role** themselves or discuss among major players who should do it
- Major DUs to contact their suppliers and encourage them to take on SFF role and kick-start discussions
- ECHA will consider publication of **list of substances due in 2010 with no SFF/LR** yet
- In some SIEFs, there is **no interest in registration** e.g. Hg case
 - Only recyclers: at least one should register to have all exempted.
Cost of registration can be shared through e.g. association
 - In some SIEFs, DUs have taken the initiative to send out the SIEF survey

6

Some SIEFs are still 'orphan' i.e. there is no SFF nor LR, or consortium, and no company has initiated any communication. If these SIEFs' registrations are due in 2010, actions must be taken without delay.

'Major' companies are invited to consider taking action.

Multiple LR per substance



- The REACH Regulation foresees **only one Joint Submission (JS) per substance. More than one LR/JS per substance should therefore be avoided.**
- Document **efforts to talk with other groups** and reach agreement
- Potential **violation of data sharing obligations**: issue for courts and **enforcement**
- One JS including different CSR is always possible
- **Functional mailbox** at ECHA to notify LR nominations: only purpose to anticipate no. of joint submission. ECHA will take no decision on who is the lead if more than one is notified.

7

More than one consortia exist for some substances. This may eventually lead to more than one LR and Joint submission for the same substance which is not allowed by the REACH Regulation.

Companies active in such groups must make efforts to contact the other consortia or groups working on the same substance in order to comply with data sharing obligations and achieve a joint submission. Efforts to cooperate should be documented.

SIEF Timing



- Manual with **business rules** and later the **Technical Completeness check** (TCC) will be available (Q42009). This will help companies to submit 'correct' dossiers
- Reminder: Registrants can continue to manufacture or import during the periods in **article 21#1**
- Some **tests will not be finished on time**, how to deal with this?. This issue was not in scope of this workshop and will be dealt with in another workshop
- **Submissions of the JS members before the deadline** are valid as long as LR is complete

8

Timing is very short, particularly regarding the completion of the 28-days sub-acute toxicity and reprotox screening tests.

There will be another workshop to discuss what to do if these are not completed on time.

SIEF Timing (cont.)



- **Suggestions** made by industry:
 - to allow JS members to submit right after LR submits without waiting for completion
 - Only LR dossier submitted before the deadline, the others beyond.
- ECHA and Commission will examine whether there are any possibilities to make this process more flexible while respecting the requirements imposed by the Regulation

Split/Merge/Change



- **Change of SIEF:**
 - Current process has communication issues: an alternative will be difficult for ECHA to implement
 - Enforcement: mismatch pre-registration – registration. Intention to do some cross-check. Shall Pre-registration # be indicated in registration dossier? Justification could be added.
 - **SIEF splits** -> two SIEFs can refer to same EINECs # but substances covered have to be different
 - **SIEF merges** -> one of the EINECs will not be included in some registrations. Possible impact in compliance with other legislation? (Commission will check) It is advised to inform ECHA in case of merges (ECHA will indicate how)
- Always document justification why SIEFs are merged or splitted*** ¹⁰

ECHA suggests using the read-across functionality to contact another pre-SIEF. This has some practical limitations as the 'new' pre-SIEF will not see the newcomer, nor will he be included in the XML file. The risk is that the new pre-SIEF can proceed with communications without including the newcomer.

ECHA is unable to provide a more practical solution so companies who wish to change to another SIEF should contact the new pre-SIEF outside REACH-IT.

If a pre-SIEF splits, there will be two (or more) SIEFs referring to the same EINECs number.

If two pre-SIEFs merge, the members may choose one of the two identifiers for the joint submission.

It is recommended to inform ECHA if merges/splits happen. ECHA will make available a process for such communications.

It is advised to include justification of change/merges/split in the registration dossier.

Registration deadline



- Some reg. deadlines in REACH-IT are different from current market reality
- **Documented request** must be done to companies (e.g. letter explaining that the registration is foreseen for a later deadline than the one indicated). If no reply, it is assumed that no real interest in registering earlier (e.g. by 2010)
- **ECHA will not provide information on tonnage bands** upon request

11

In some SIEFs, the deadline for registration is December 2010, whereas the market reality does not show such high volumes in the EU. Companies with a later deadline should inform all SIEF members that the intention is to proceed with a later joint submission. If no reaction is received, it will be assumed that there is no interest to register by 2010.

Relation early registrant - JS



- Some company(ies) can submit an early registration and a JS can be submitted later
- The **early registrant will have to update** his early registration after the JS (in order to comply with JS obligation) **or to justify opt-out** (most likely due to disproportionately costly)

12

A company may have completed the registration for a substance, without waiting for the joint submission. In case the JS happens at a later stage, the obligation to submit jointly still applies and therefore, the early registrant must either update his registration to be part of the JS, or opt-out

Transfer of LR status



- In case of change of LR in a JS, the SIEF **needs to appoint a new LR**
- **Transfer of ownership** of data / dossier / responsibilities must be arranged among SIEF members

Opt-out



- Opt-out will most likely be the **exemption**
- It **needs justification** for each type of information
- **'Partial' opt-out** triggers **all the consequences** of opt-out
- Justifications will be analysed on case-by-case basis
- More details will be given by ECHA & Commission

Published data



- **Published data cannot be used for free** for REACH registration purposes **in all cases** and under all circumstances
- **National** (or eventually **international**) **copyright provisions** must be respected
- If the content of the article is used, in a different form, it may be possible to use
- National provisions must always be checked
- Update of picklists in IUCLID5 (reference to 'published data') could be useful