



European Commission

Substance Information Exchange Forum (SIEF)

“R” in REACH – Who needs to do what when?

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SIEF formation - Flow of events (1)

1. Submit **pre-registration** information by potential registrants (Article 28.1)
 - *Substance identification: EINECS number, CAS number, Name*
 - *Company and contact information*
 - *Deadline for registration and tonnage band*
 - *“Read across possibilities “*
 - *Do you want to act as SIEF formation facilitator?*
2. **List of substances** is published (Article 28.4)
3. **Data holders** are brought into the system (Article 28.7)

SIEF formation - Flow of events (2)

4. Submitters of the same identifier are brought together (REACH-IT): “**Pre-SIEF**”
5. Potential registrants must **check whether their substances are the same**
6. **Agreement** on the sameness: SIEF is ‘born’ (Article 29)

SIEF formation – Key issues

- ◆ Be aware that SIEF formation is an **industry led process** – **no confirmation by Agency!**
 - ◆ In many cases **EINECS=SIEF**, but:
 - ❖ Substances within one EINECS number too different: **several SIEFs** may be formed
 - ❖ Different EINECS numbers reflect the same substance: **one SIEF** may be formed
 - ◆ Industry must assess the **sameness** (RIP 3.10!)
- ⇒ ***Data sharing obligations must be fulfilled! (i.e. it is not allowed to form two SIEFs for the same substance)***

The SIEF formation facilitator

- ◆ SFF should **organise discussions** on sameness and SIEF formation
- ◆ **First come – first serve:**
 - ❖ first potential registrant **indicating his willingness** to act as SFF will be identified by REACH
- ◆ SFF will have a **free field** on the substance website to give key messages (has one/several SIEF(s) been formed, where to find further information etc...)
 - ❖ However, available space will be limited – industry should organise the communication within a SIEF themselves (e.g. own tools)!
- ◆ SIEF should consider the best time to hand over facilitation from SFF to **lead registrant**

SIEF operation - Flow of events

7. (Forced) **data sharing** mechanism apply (Article 30)
8. **Joint submission** for the same substance (Article 11)

What is a Substance Information Exchange Forum (SIEF)?

- ◆ Platform to:
 - ❖ **share data** among:
 - potential registrants of the same phase-in substances (manufacturers and importers)
 - data holders for that substance (downstream users and other stakeholders)
 - ❖ **avoid unnecessary testing**
 - ❖ **agree on classification and labelling**
- ◆ Suitable platform to organise the mandatory **joint submission** of data

Consortium vs. SIEF

- ◆ ***A SIEF is not the same as a consortium!***
 - ❖ SIEF participants are **free to organize themselves** as they see fit
 - Co-operation and collective approaches highly encouraged
 - Consortium is one possible form of co-operation
 - Individual route can also be chosen
- ⇒ ***REACH text gives mainly rules for filling individual information gaps – however, in reality, **co-operation** will be necessary also to **agree on an appropriate information package*****

The different steps in data sharing (“collective route”)

- ◆ **Individual gathering** of available information
- ◆ **Agreement** on the form of **co-operation/cost sharing** mechanism
- ◆ **Collection and inventory** of all available information
- ◆ **Evaluation** of available information
- ◆ Consideration of information needs, identification of **data gaps** and collection of other available information
- ◆ **Generation** of new information/testing proposal
- ◆ **Sharing of data and costs**
- ◆ **Joint submission** of data

Who will participate in data sharing?

- ◆ **Potential registrants:**
 - ❖ **Manufacturers**
 - ❖ **Third party representatives**
 - ❖ **Importers**
 - ❖ **Only representatives**
 - ❖ **First time manufacturers**
- ◆ **Data holders:**
 - ❖ **Early registrants**
 - ❖ **Downstream users**
 - ❖ **Any other stakeholders**

Who will see whose contact details?

- ◆ After pre-registration, a **substance website** will be formed for each EINECS/CAS number/ other identity code
 - ◆ All **potential registrants** will be able to see:
 - ❖ **each others** contact details
 - ❖ contact details and information from **data holders**
 - ❖ identified **read-across** possibilities
 - from this substance to other substances
 - from other substances to this substance

*Note that read-across possibilities **can also be identified after pre-registration!***

 - ❖ **free fields** for short announcements (SIEF formation facilitator, other participants)
- ⇒ *If you have concerns on confidentiality, **use Third Party Representative!***

Confidential Business Information

- ◆ Assess whether information is commercially sensitive
- ◆ Several **mechanisms** are possible to protect CBI:
 - ❖ **Third party representatives** (to keep identity confidential)
 - ❖ **Third party experts/consultants** (e.g. to verify sensitive information)
 - ❖ **Confidentiality agreements**
 - ❖ **etc.**

Competition issues

- ◆ Information to be exchanged under REACH is **unlikely to be problematic** under EC Competition law rules
- ◆ However, ensure that:
 - ❖ Information exchange **does not include problematic data** (e.g. exact production or sales volumes)
 - ❖ **Limit frequency** of exchange
 - ❖ In case of doubt, use **third party experts** etc.
 - ❖ **Do not abuse the occasion...**

Joint submission

- ◆ **Obligatory** jointly submission:
 - ❖ information on the hazard properties of the substance
 - ❖ classification and labelling
- ◆ **Voluntary** joint submission:
 - ❖ Chemical Safety Report (CSR)

⇒ ***Joint submission also applies to early registrants!***

How does joint submission work?

- ◆ **A lead registrant is appointed** by mutual agreement
 - ❖ should already early on ensure that the necessary information is collected and prepared for joint submission
- 1. **Lead registrant submits the joint information** (and his own registration)
 - ❖ classification and labelling
 - ❖ study summaries and robust study summaries
 - ❖ testing proposals
- 2. **All other registrants submit separate information**
 - ❖ identity of manufacturer and substance
 - ❖ information on manufacturing and use

Opt-out from joint submission

- ◆ Opt-out possible, if:
 - ❖ Disproportionately costly
 - ❖ Disclosure of CBI
 - ❖ Disagreement with lead registrant on selection of information
- ⇒ ***Opt-out does not apply for data sharing as such***
- ⇒ ***Must be fully justified in each case***
- ⇒ ***Opt-out dossiers will be prioritised for evaluation***
- ⇒ ***Opt-out can result in higher fees (no reduction for joint submission)!***

Cost sharing

- ◆ **Costs must only be shared for information:**
 - ❖ that a registrant is **required to submit**
 - ❖ at the time **when** a registrant is **required to submit** the information
- ◆ **Costs must be shared in a **fair, transparent and non-discriminatory way****
- ◆ **If SIEF participants cannot reach an agreement, costs shall be shared **equally****
- ◆ **Guidance provides rules on**
 - ❖ valuation of **data quality**
 - ❖ **types** of eligible costs
 - ❖ sharing costs in case of **multiple available studies**



Timing for the guidance

- ◆ **Draft final report** by the consultant: early July
- ◆ **Endorsement by Member States:** either the September or December CA meeting

Further Information

<http://echa.europa.eu>

http://ec.europa.eu/enterprise/reach/index_en.htm

<http://ec.europa.eu/comm/environment/chemicals/reach.htm>

<http://ecb.jrc.it/REACH/>

