



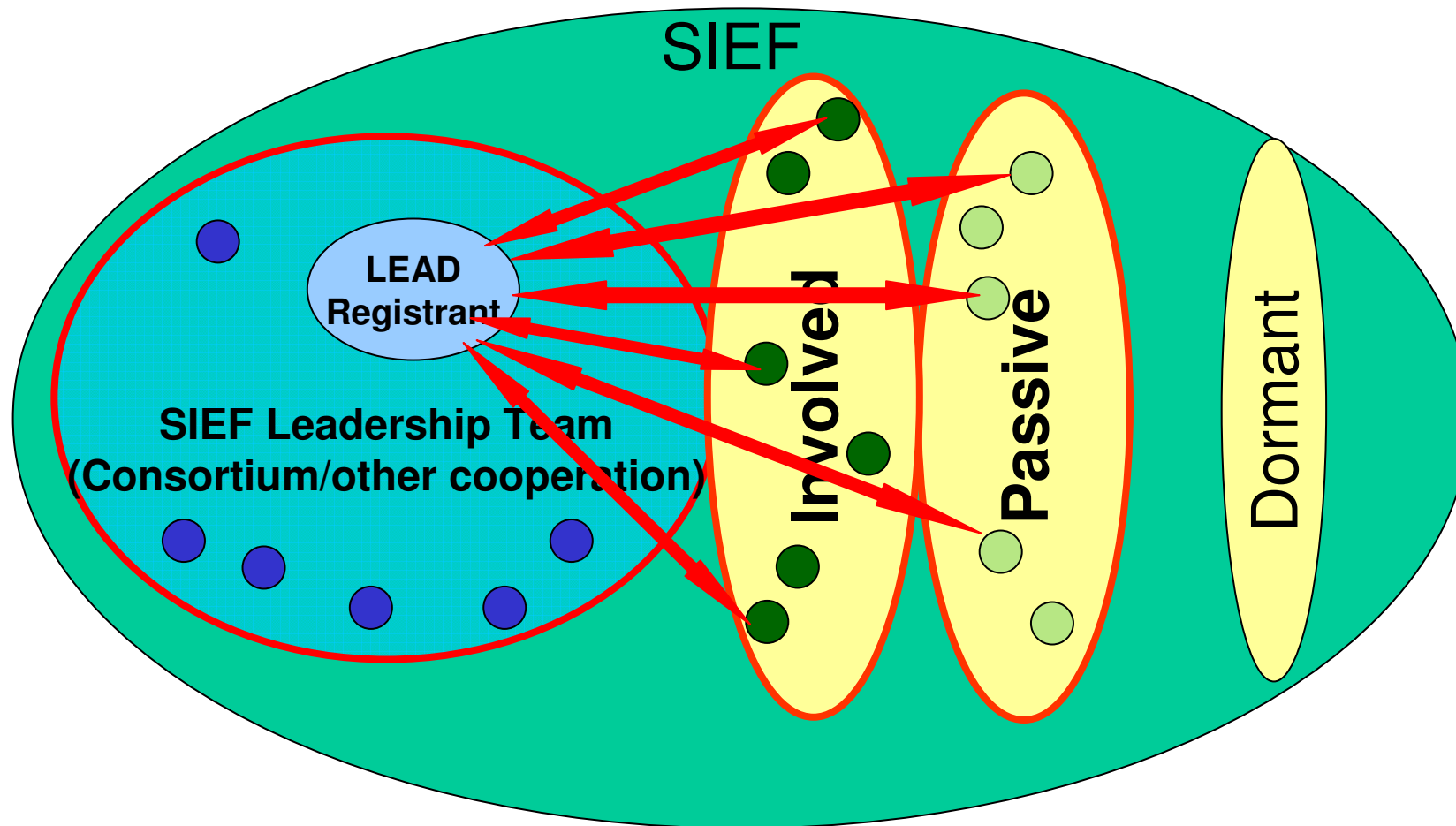
Cefic model SIEF Agreement: benefits and practical aspects

CEFIC Legal Aspects of REACH Issue Team (LARIT)



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SIEF agreement: link between SIEF Leadership Team and other SIEF participants (potential registrants)



↔ = SIEF agreement: bilateral agreement between the SLT represented by LR and each SIEF participant.

SIEF agreement: starting point



- ✓ REACH: legal requirements of:
 - cooperation and communication in the SIEF
 - data sharing
 - cost compensation
 - joint submission (except opt-out claim)

- ✓ From a legal perspective, is this sufficient to initiate SIEF process?
 - ✓ Large number of SIEF participants
 - ✓ Many SIEF participants not really familiar with REACH requirementswhich will create a lot of **legal uncertainty**

- ✓ Therefore, **SIEF Operating rules** are strongly recommended
 - ✓ According to ECHA Guidance, the SIEF Leadership Team (e.g. the consortium) cannot just work stand-alone but should regularly interact with other SIEF participants
 - ✓ Enforceable contractual arrangement setting out rights and obligations will be required

Legal uncertainty in absence of SIEF legal framework



Example of questions addressed by the SIEF agreement :

- ✓ What if a SIEF participant misuses the information he receives from the Lead Members and discloses it to another company?
- ✓ What if a non-consortium member files a claim against the consortium for not being properly informed on the preparatory process of the Dossier ?
- ✓ What is the basis for a Lead Registrant to communicate the completion of the joint registration dossier to the other SIEF members?
- ✓ As a SIEF participant, do I need bilateral data sharing agreements with all data owners ?
- ✓ What are the liabilities of the Lead Registrant if things “go wrong” with the registration?

Single solution



It is highly recommended that the SIEF Leadership Team (the Lead Members) puts a structured SIEF process in place with the other SIEF participants.

The SIEF agreement comprises :

- ✓ **confidentiality obligations**
- ✓ **data sharing and costs compensation arrangement**
- ✓ **Arrangement on participation in the Joint Submission of the Dossier**

Quick adoption of the SIEF agreement is possible :

- **Very few options in the SIEF agreement**
- **Standardised electronic process of signature (via the relevant SIEF IT-platform)**
- **Only to be submitted to the Involved and Passive SIEF Participants (members of category 2 & 3) which reduces the administrative burden**

Collective benefit: contractual formalisation



The SIEF agreement is the formalisation of :

- ✓ The appointment of the Lead Registrant
- ✓ The use of a particular IT-Platform for SIEF communication (e.g. SIEFReach), to be suggested by the SIEF Leadership Team
- ✓ The joint submission by the Lead Registrant
 - ✓ Formalises the REACH-IT process of Joint Submission and establishes contractually the participation in the Joint Submission
- ✓ The agreement on the proposed cost sharing mechanism
- ✓ The choice of the governing national law for relationship between the Lead Members and the Non-Lead Members and the contractual agreement on dispute resolution
- ✓ The limitation of scope of use of data
 - ✓ REACH purposes only

Collective benefits of the SIEF agreement



- ✓ **standardised data sharing process** avoiding the need of bilateral data sharing arrangements with each data owner
 - ✓ Centralized approach through Lead Registrant
 - ✓ Access to data required for individual submission

- ✓ Agreement on cost sharing principles and costs sharing mechanisms at the beginning of SIEF activities
 - ✓ Facilitating cost calculation and allocation for the Lead Members

- ✓ SIEF agreement serves as evidence to the authorities of agreement within the SIEF
 - ✓ Requirement of documentation of decisions in the SIEF

SIEF agreement: Benefits for Lead Members



- ✓ **Contractual rights and obligations :**
 - **Confidentiality**
 - **Emphasis on competition law compliance**
 - **Structured communication and information flow**
 - **Pro-active behaviour of Non-Lead Members**
 - **Cost sharing / compensation**
 - **Several options**
 - **Payment terms**
 - **Limitation of liability**
 - **Facilitating nomination of a Lead Registrant**

SIEF agreement: Benefits for Non-Lead Members



- ✓ **Contractual rights and obligations :**
 - **Communication flow**
 - **Regular communication from Lead Members**
 - **Assurance about Lead Registrant and Joint submission**
 - **Relevant registration due date**
 - **Access to Data**
 - **Reach Token Number**
 - **Cost allocation**
 - **Fair, transparent and non-discriminatory**
 - **Liability**

Comparison with a simple letter of access



- ✓ **the SIEF agreement is a collective and standardised way for Lead Members (e.g. the consortium) to provide rights on data and to be compensated for the costs for the preparation of the dossier**
- ✓ **Since the SIEF agreement is also an agreement on the cost sharing principles, it means that the Lead Members have already set up and legally covered from the time of the SIEF agreement the costs sharing option discussion (no negotiation in 2010/2013/2018)**
- ✓ **the SIEF agreement covers already in a single agreement all kind of SIEF participants getting access to rights on data (TPR, OR representing several non-EU manufacturers, LE with affiliates in the same SIEF, etc)**

Alignment with the consortium agreement



- ✓ In case of consortium in the SIEF, the consortium to propose preferably the SIEF agreement in accordance to the terms of the consortium agreement
 - ✓ in particular in regard to terms on cost sharing
- ✓ For example, if the consortium agreement comprises an advance compensation payment, this is perfectly transferable into the SIEF agreement, respecting the principle of fair, transparent and non-discriminatory compensation.
- ✓ The 3 cost sharing options in the model are indicative and can be combined and mixed (e.g. no advance payment and no reimbursement as risk premium / all the registrants (2010/2013/2018) pay 50% of their cost in 2009/2010 to the LR and they compensate the LR for the remaining 50% just before their deadline, etc). Other cost sharing factors can legitimately be added.

Conclusions



- ✓ **The SIEF Agreement provides a standardised framework for SIEF discussions and activities**
- ✓ **It has been developed by the Cefic Legal Aspects of REACH Issue Team where more than 50 legal experts from companies participate**
- ✓ **It is posted on the Cefic website and can be freely used as of today by SIEF leading companies**

<http://cefic.org/templates/shwPublications.asp?HID=750&S=33>

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