Top questions **for Substance Information Exchange Forum (SIEF)** participation

SIEF participation is an integral part of the European Union's (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation. SIEFs are important in supporting the "One Substance, One Registration" (OSOR) principle, minimising unnecessary animal testing, and managing costs through data sharing. SIEFs are formed automatically through REACH-IT to facilitate preparation of a joint lead registration dossier for a substance and to encourage agreement among members on classification and labelling.

Generally, one SIEF exists per phase-in substance. SIEFs have no prescribed legal form, and are independently managed by industry; the European Chemicals Agency (ECHA) is not involved in their operations. The global chemicals industry has been presented with significant, often unfamiliar, challenges by the concept and functioning of SIEFs under REACH. Through years of experience in SIEF participation on our clients' behalf, Acta has identified the following questions to consider when participating in a SIEF:

Has an appropriate SIEF formation facilitator (SFF) been appointed?

While there is no legal requirement for an SFF, it is beneficial that the initial stages of SIEF cooperation are facilitated by an SFF with suitable project management skills and a genuine interest in registering the substance. SFFs perform numerous important tasks, including bringing together potential registrants to form a SIEF and facilitating agreement on cost sharing. Beware of "rogue SFFs" taking on the role via REACH-IT for commercial reasons.

Has a lead registrant (LR) been appointed?

Details of active LRs are available on the ECHA website, provided their identity is not confidential. If an LR has not been officially appointed, SIEF participants can indicate their interest in becoming the LR. The European Chemicals Industry Council (CEFIC) advises that "if there is already a candidate (LR), he should also consider taking on the role of SFF."

Has substance sameness been established?

SIEFs typically share with pre-registrants a substance identity profile (SIP). As a potential registrant, if your substance agrees with the purity profile in the SIP, you can register your substance as part of the joint submission by the SIEF. If your substance is outside the purity levels agreed within the SIP, you may need to provide a justification for this or possibly submit a full registration of your own.

Has the level of SIEF participation been determined?

Regardless of LR appointment, companies must decide if their role in the SIEF will be "leading" (strong market position and available resources to lead and drive registration to completion); "involved" (intention to register and interest to participate in the dossier creation process); "passive" (intention to register but limited resources or interest to participate actively in discussions); or "dormant" (no intention to register).

Are consortium agreements, cooperation agreements, SIEF agreements, and data sharing agreements in place?

Formalisation of SIEF arrangements through the aforementioned agreements has proven beneficial. Typically, consortium or cooperation agreements are used as a legal framework for the lead members; SIEF agreements are utilised between the lead members and all non-lead members with the intention to register; and data sharing agreements are implemented between the LR and data owners whose data are part of the joint submission.

Is data compensation occurring in a "fair, transparent and non-discriminatory" manner?

ECHA's "Guidance on Data Sharing" and CEFIC's "SIEF Guidance" should be reviewed by SIEF participants to understand properly the key principles of data sharing under REACH. SIEF participants can determine appropriate methodologies for data compensation, provided these methods are "fair, transparent and non-discriminatory." "Equal" and "proportional" cost sharing, including consideration of the quality of studies, has proven useful in SIEFs.

Are SIEF communications timely?

SIEF communications from the SFF or LR are made at key points during the registration process (***e.g.***, to share use information to be included within the lead registration). Delays in communication may occur when a SIEF member is attempting to contact the SFF or LR, particularly when these roles are not assumed by the same company. The timeliness of communications can be affected by the responsiveness of the SFF or LR, or by the nature of the substance (***e.g.***, substance-based complex regulatory requirements can contribute to delays).

Has confidential business information (CBI) been protected?

SIEF members should identify CBI early on and decide which information will be disclosed in the SIEF. Parties may enter into confidentiality agreements; prepare non-confidential versions of relevant documents; use an independent third-party or trustee; or appoint an Only Representative or Third Party Representative to address CBI concerns. A fee may be payable to ECHA for CBI claims. Opting out from the joint submission due to CBI concerns is no longer permissible.

Is compliance with competition law adequate?

All activities under REACH, including SIEF formation and participation, must comply with European- and national-level competition law. SIEF participants should review carefully the relevant sections of the Treaty on the Functioning of the EU (TFEU) and the CEFIC REACH Competition Law Compliance Guide.

As the REACH **2018** deadline quickly approaches, it is important that the chemicals industry develops comprehensive approaches towards SIEF participation and REACH compliance. Review of regulations, guidance documents, opinions, and recent cases will allow industry to be suitably prepared for the multitude of challenges presented by the theoretical and practical complexities of SIEFs under REACH.

Regulatory consulting firm Acta, with offices in Manchester, Washington, D.C., Beijing, and Brussels (through partner EPPA), offers comprehensive REACH compliance services.

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