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# SIEFs AND CONSORTIA: COOPERATION UNDER REACH

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# COOPERATION UNDER REACH: OUTLINE

1. Obligations under the Substance Information Exchange Forum ('SIEF')
2. SIEF v. Consortium
3. Why a consortium?
4. Consortia variations and emerging models
5. Protecting your commercial interests:
  - ✓ Data Sharing
  - ✓ Confidentiality
  - ✓ Third Party Representatives
6. Anti-trust law compliance

# COOPERATION UNDER REACH: SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): BASICS

➤ REACH coordination not limited to SIEF participation

➤ What is a SIEF?

Mandatory communication forum for potential registrants of the same phase-in substance

➤ Purpose of SIEF:

- ✓ Separate SIEF for each phase-in substance
- ✓ Avoid duplication of studies (animal testing) required for registration
- ✓ Forum to harmonise classification and labelling ('second objective')

# COOPERATION UNDER REACH: OBLIGATIONS ON SIEF PARTICIPANTS

## ➤ Obligation on SIEF participants:

- ✓ checking whether required study involving tests is available within SIEF
- ✓ mandatory disclosure of existing studies involving tests required for registration
  - vertebrate studies ( ‘participants must request’ and owner must provide)
  - non-vertebrate studies (only mandatory to provide if participant requests)
- ✓ collectively identify and carry out required new studies unavailable within SIEF through lead participants
- ✓ resolve any differences in classification and labelling

# COOPERATION UNDER REACH: SIEF v. CONSORTIA

## ➤ What SIEF is not:

- ✓ A SIEF is not a consortium/ task force (industry confusion)

## ➤ Aspects of SIEF which differ from consortia:

- ✓ Membership, and obligations to request and give data, mandatory for pre-registrants
- ✓ Overseen by ECA
- ✓ motivated principally by public sector interests (avoidance of unnecessary animal testing)

## ➤ Consortia:

- ✓ Voluntary
- ✓ Motivated by mutual benefit of Members

## COOPERATION UNDER REACH: OPTIONS FOR COOPERATION

- No obligation under REACH to form or join a consortium
- Form of mandatory cooperation (data sharing, classification and labelling, joint submission of data towards registration ('OSOR'), election of lead participant and lead registrant) not specified
- Different options for cooperation between potential registrants of same substance:
  - ✓ Virtual communication forum with no binding rules
  - ✓ *Ad hoc* email communications between potential registrants construed as contractual terms
  - ✓ Bilateral agreements between data owner and data purchaser
  - ✓ Pre-consortium agreement with confidentiality agreement
  - ✓ Consortium agreement

# COOPERATION UNDER REACH: WHY CONSORTIA?

- Why choose consortia instead of alternative cooperation vehicles?
  - ✓ Preference for formalised relationship and binding rules ('safer' re confidentiality, anti-trust concerns)
  - ✓ Dedicated structure the only time and resource efficient way to cooperate in mandatory (and non-mandatory) areas
  - ✓ Experience of BPD Task Force Agreements
  - ✓ Multilateral cooperation necessary to share costs of purchasing existing data
  - ✓ increased ability to influence competitors' approaches to data-gap filling and registration



# COOPERATION UNDER REACH: WHY CONSORTIA?

- ✓ stronger position v. ECA (including appeals)
  - ✓ smaller companies may prefer to lean on major M/I's who take lead
  - ✓ pressure from DUs on their suppliers to join consortia (to ensure listing of their 'identified use')
- Main disadvantage: Time and costs of setting up and/or participating in consortia



# COOPERATION UNDER REACH: WHEN TO FORM CONSORTIA?

- When to form a consortium depends on why formed
- No advantage to early consortium membership *per se*, but good reasons why preferable
  - ✓ Formal cooperation framework pre-SIEF for checking ‘sameness’ with others pre-registering under same substance identifier.
  - ✓ Sufficient time to set up consortium? Transitional period for M/I’s of substance quantities > 1,000 tonnes per year ends 1.12.2010 (‘no data, no market’ begins).

# COOPERATION UNDER REACH: VARIATIONS IN CONSORTIA FORMATION

- Variations in post-SIEF consortium formation
  - ✓ One consortium incorporating all SIEF members
  - ✓ Two or more consortia sharing data between them in SIEF: for example, where different classifications for same substance with different purity profiles or using different processes
  - ✓ One consortium, with independent parties (for example pure data holders) outside
  - ✓ Exchange of existing data, development of new data and cooperation at registration stage? Or only some?
  - ✓ Covering 'family' of substances, so active on a number of different SIEFs
  - ✓ Consortia in different SIEFs exchange data for read across purposes

# COOPERATION UNDER REACH: EMERGING MODELS

- Three different models already being used by different industry sectors
- Open consortium model
  - ✓ examples in metals sector, driven by international trade association
  - ✓ open to all SIEF participants for relevant substance (avoids competition concerns regarding entry conditions)
  - ✓ rationale:
    - maximise efficiencies by incorporating majority, if not all, SIEF participants under same cooperation framework
  - ✓ cooperation on sameness envisaged prior to pre-registration.
  - ✓ ensure mechanisms for cooperation realistic for large membership (quorum, voting, etc.).

# COOPERATION UNDER REACH: EMERGING MODELS

## ➤ Closed consortium model

- ✓ limited to founding members
- ✓ restricting further membership not necessarily anti-competitive provided comply with REACH requirements
  - provide data to SIEF members outside closed consortium;
  - participate in SIEF initiatives such as classification and labelling and election of lead registrant and share costs of consortium studies fairly.
- ✓ rationale:
  - deal with only competitors with which have trusted relationship; and
  - management of small consortium administratively more realistic (resources).

## Under some versions of this model:

- create new missing data prior to entry into SIEF to avoid Regulation 'lead participant' requirements; and
- enter SIEF as seller of complete data package only.

# COOPERATION UNDER REACH: EMERGING MODELS

## ➤ Data licensing

- ✓ example in the oil sector, driven by trade associations
- ✓ not a consortium
- ✓ trade association (not its members) creates complete data package, enters SIEF as a data holder and then licences data package to SIEF participants
- ✓ rationale:
  - create new missing data prior to entry into SIEF to avoid Regulation 'lead participant' requirements;
  - enter SIEF in data holder capacity only; and
  - opportunity for SIEF participants to licence all data needs from one source without time and costs of establishing or joining a consortium.
- ✓ disadvantage: still need to establish a cooperation framework for joint submission of data for registration

# COOPERATION UNDER REACH: HOW? WHAT YOUR CONSORTIUM AGREEMENT SHOULD COVER?

- Citation rights only
- Confidentiality provisions:
  - ✓ Restrict access to certain staff (bound by confidentiality agreement)
  - ✓ Provisions to deal with breach of confidentiality by data users or if legally required to disclose
  - ✓ Anonymity through use of third party representative
- Data evaluation and cost sharing

## COOPERATION UNDER REACH: HOW? WHAT YOUR CONSORTIUM AGREEMENT SHOULD COVER?

- Task force activity/ running Costs
- Establish structure and composition: Executive and Technical Committee, Secretariat/ Day to Day Management, Decision making/ voting rules
- Late Entrant Fees – no freeriding on administration costs
- Joint ownership rights (IP) in new jointly developed data and their protection
- Communication with other consortia or individuals



## COOPERATION UNDER REACH: HOW? WHAT YOUR CONSORTIUM AGREEMENT SHOULD COVER?

- When it goes wrong: default and withdrawal of participants, dispute resolution, liability to third parties or between consortium members
- Mechanisms for mandatory cooperation obligations: data sharing (and purchase from outside consortium), data development, classification and labelling, etc.
- Mechanisms for appeal of ECA Decisions
- Antitrust provisions – measures to avoid discrimination or the exchange of commercially sensitive information

# COOPERATION UNDER REACH: AVOIDING EC COMPETITION LAW INFRINGEMENT

- Why you should be wary of infringing EC competition law?
  - ✓ Lengthy investigations
  - ✓ Fines up to 10% global turnover
  - ✓ Void and unenforceable agreements or clauses
  - ✓ Private actions for damages in national courts
  - ✓ Criminal sanctions in some jurisdictions (for example, UK Enterprise Act 2002)
- REACH Regulation ‘without prejudice to the full and complete application of Community competition rules’ (Recital 48)

# COOPERATION UNDER REACH: AVOIDING EC COMPETITION LAW INFRINGEMENT

- Issue 1: Consortium potential cloak for a cartel – exchange of commercially sensitive information between competitors
- Example of commercially sensitive information
  - ✓ Margins, profits, discounts or prices charged to customers/end users;
  - ✓ Names of customers or customer-specific translation information;
  - ✓ Key terms and conditions for sales;
  - ✓ Future strategic, business or investment plans;
  - ✓ Current market shares and sales volumes;
  - ✓ Suppliers and input costs for key materials.

## COOPERATION UNDER REACH: AVOIDING EC COMPETITION LAW INFRINGEMENT

- Adherence to Antitrust Policy. All consortium/ task force members to:
  - ✓ Acknowledge Antitrust Policy before Task Force meeting;
  - ✓ Limit all discussions during meetings to agenda topics;
  - ✓ Protest immediately if discussion becomes sensitive;
  - ✓ Maintain minutes of all meetings;
  - ✓ Presence of lawyer/ compliance officer to ‘wave red flag’
- Incorporate Antitrust policy clause preventing members from exchanging market information
- Use independent third party to collect sensitive data

# COOPERATION UNDER REACH: AVOIDING EC COMPETITION LAW INFRINGEMENT

## ➤ Issue 2: Avoid Discriminatory Behaviour

- ✓ Grounds for refusal of entry to consortium must be objectively justifiable and consistent
- ✓ Entry fees must not be extortionate
- ✓ Data purchasers should not pay different amounts for the same data without good reason

## ➤ Issue 3: Bundling of Data

- ✓ Data owner cannot make sale of required data conditional on other data
- ✓ Competition law offence of tying/ bundling
- ✓ Breach of Regulation: 'Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements' (Article 30(1))

## CONCLUSIONS

- REACH mandates cooperation between SIEF participants, principally in data sharing.
- REACH does not specify the manner of cooperation but potential registrants may strategically favour forming consortia (distinct from a SIEF).
- The type of consortium and when it should be formed will depend on the parties' purpose, although many are preferring pre-SIEF consortia.
- Ensure that terms of consortium agreement deal adequately with key areas: citation rights, confidentiality and EC competition law compliance (seek legal advice!).
- Consider appointing third party representative prior to pre-registration to retain anonymity.