

A close-up photograph of a microscope's objective lenses and eyepiece, set against a blue background. The microscope is the central visual element on the left side of the slide.

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SIEFs AND CONSORTIA: COOPERATION UNDER REACH

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COOPERATION UNDER REACH: OUTLINE

1. SIEF Obligations
2. SIEF v. Consortium
3. Why a consortium?
4. When to form a consortium?
5. Consortia variations and emerging models
6. Protecting your commercial interests:
 - ✓ Limit Access to Data
 - ✓ Confidentiality
 - ✓ Visibility and Third Party Representatives
 - ✓ Agree Data Evaluation and Cost Sharing Principles
 - ✓ Anti-Trust Law Compliance

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

- Pre-register or face EU marketing ban until full registration
- What is a SIEF?
 - ✓ Mandatory communication forum for potential registrants of the same phase-in substance submitting info to ECHA
 - ✓ Pre-registrants become SIEF participants once agree on substance sameness
- Purpose of SIEF:
 - ✓ Avoid duplication of studies (animal testing) required for registration
 - ✓ Cost efficiencies for registrants

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 ECHA
- ✓ 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. ECHA (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.
- ✓ 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
 - ✓ 'Historic value' or replacement value?
 - ✓ Management costs? Risk premium?
 - ✓ Costs shared proportionate to production or sales volume of each purchase?

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 ECHA 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 or require payment before user needs it
- ✓ 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. Don't blindly adopt standard form consortium agreement (seek legal advice)!
- Consider appointing third party representative prior to pre-registration to retain anonymity.