

A close-up, blue-tinted photograph of a microscope's objective lenses and eyepiece, positioned on the left side of the slide.

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# SIEFs AND DATA SHARING: PRACTICAL ISSUES

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# PHASE-IN SUBSTANCES: SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): PURPOSE

## ➤ Purpose of SIEF:

- ✓ Separate SIEF for each phase-in substance
- ✓ Avoid duplication of studies required for registration
- ✓ Resolve classification and labelling differences between potential registrants of a certain substance

# SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): OBLIGATIONS ON 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

# SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): PARTICIPANTS

- Who are SIEF participants for a certain substance? (Article 29(1))
  - ✓ Pre-registrants (including ‘voluntary pre-registrants’ under Art. 28(4) who want to get into SIEF)
  - ✓ Those whose information held by Agency under Article 15 – *i.e.* substances on positive lists of plant protection and biocidal products Directive automatically ‘regarded as being registered’ (no need to pre-register to be in SIEF)
  - ✓ Registrants prior to 1 June 2018 (including those who failed to pre-register).  
  
(‘all relevant actors submitting information to the Agency on the same phase-in substance’ (Recital 54))
- Timing issue: participants will join SIEF at different stages – practical ramifications

# SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): NATURE OF THE SIEF

- 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
  - ✓ set up by Agency, not by members
  - ✓ motivated principally by public sector interests (avoidance of unnecessary animal testing)
- Consortia:
  - ✓ Voluntary
  - ✓ Motivated by mutual benefit of Members

# SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): COOPERATION WITHIN SIEF

- Neither SIEF nor joint registration provisions require formation of consortia – strategy decision
- However, on a matter of commercial practicality, companies will form consortia within the SIEF because:
  - ✓ SIEF participants will want to cooperate to share costs of purchasing existing data
  - ✓ SIEF participants must cooperate to agree on lead participant to undertake new study

# SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): COOPERATION WITHIN SIEF

- ✓ increased ability to influence competitors' approaches to data-gap filling and stronger position v. ECA
  - ✓ smaller companies may be advantaged by major producers taking lead
  - ✓ pressure from DUs on their suppliers to join consortia (to ensure listing of their 'identified use')
  - ✓ mandatory cooperation for submission of collective registration dossier ('OSOR'), following SIEF data exchange and creation
- Main disadvantage: Time and costs of participation in SIEF and/or consortia

# SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): CONSORTIA VARIABLES

- Variables in consortium formation within SIEF (many different possible types of agreement):
  - ✓ One consortium in SIEF or two or more consortia co-operating regarding data sharing between them?
  - ✓ Consortium covering one substance or ‘family of substances’ (several different SIEFs)?
  - ✓ Exchange of existing data, development of new data and cooperation at registration stage? Or only some?
  - ✓ When formed? Pre-publication of SIEF membership list (1.1.2009), or after?

## SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): LEGAL ISSUES IN CONSORTIA

- Avoid competitors undermining your business: citation rights only
- Establish structure and composition: Executive and Technical Committee, Secretariat/ Day to Day Management
- Antitrust considerations (see later)
- Confidentiality provisions:
  - ✓ Disclosure to third parties limited to extent necessary for Regulation
  - ✓ Provisions to deal with breach of confidentiality by data users or if legally required to disclose

# SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): LEGAL ISSUES IN CONSORTIA

- Data compensation provisions (await RIP 3.4 guidance)
  - ✓ ‘provide proof of cost’ - historic value or current value of studies?
  - ✓ Regulation ‘equal shares’ default mechanism - risk premium?
  - ✓ Costs mechanism flexibility for later purchases of data?
- Task force activity/ running Costs
- Late Entrant Fees – no freeriding on administration costs

# SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): LEGAL ISSUES IN CONSORTIA

- Joint ownership rights (IP) in new jointly developed data and their protection
- Decision making/ voting process
- Default and withdrawal of participants
- Communication with other consortia in SIEF
- Dispute Resolution

# SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): COMPETITION ISSUES

- 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)

# SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): COMPETITION ISSUES

- Cooperation between competitors in SIEF and consortia: Article 81 EC Treaty
  - ✓ ‘REACH without prejudice to the full and complete application of the Community competition rules’ (Recital 48)
- European Commission Opinion:
  - ✓ Common notifications do not normally infringe competition law or constitute participation in a cartel
  - ✓ Makes sense since REACH mandates this

# SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): EXCHANGE OF INFORMATION/ CARTEL

- 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.

## SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): EXCHANGE OF INFORMATION/ CARTEL

- Regulation anticipates competition issues:
  - ✓ Sensitive registration information cannot be submitted via lead registrant (Article 11(1))
  - ✓ ‘Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes or market shares’ (Article 25(2))
- Incorporate Antitrust policy clause: ‘members will not exchange market information in any way that is prohibited by EU competition law’.

# SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): EXCHANGE OF INFORMATION/ CARTEL

- Adherence to Antitrust Policy. All consortium/ task force members to:
  - ✓ Presence of lawyer/ compliance officer to ‘wave red flag’;
  - ✓ Acknowledge this Antitrust Policy before any Task Force meeting;
  - ✓ Inform other appropriate personnel involved in the work of the Task Force about the rules of Antitrust Policy;
  - ✓ Limit all discussions during meetings to the topics in the agreed agenda;
  - ✓ Protest immediately should the discussion or any meeting activity appear to fall within the scope of the above mentioned information to be avoided and leave if continues (otherwise all members who have not protested taken to have agreed);
  - ✓ Maintain minutes of all meetings (which should include note of the acknowledgement of this Antitrust Policy).

# SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): DATA COSTS

- Issue 2: Refusal of Access to consortium must not be anti-competitive
  - ✓ Mandatory sharing of data  $\neq$  mandatory entry to consortia
  - ✓ Prejudice to outsiders – inability to reduce data purchasing costs?
  - ✓ Grounds for refusal of entry objectively justifiable, non-discriminatory and consistent
  - ✓ Late entry fees must be reasonable

## SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF): ACCESS TO CONSORTIA AND DATA COSTS

- Issue 3: Costs for purchase of existing data must be non discriminatory
  - ✓ Breach of Regulation and abuse of a dominant position (discriminatory pricing)
- Issue 4: 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))

# CONFIDENTIAL BUSINESS INFORMATION UNDER REACH

- What information about my business submitted to ECA becomes accessible to my competitors as a result of REACH?
- Not:
  - ✓ Preparation ‘recipe’
  - ✓ Precise use, function or application
  - ✓ Precise tonnage
  - ✓ Links between manufacturer/ importer and DU or distributor

## CONFIDENTIAL BUSINESS INFORMATION UNDER REACH

- Freely available on web, subject to application of confidentiality by submitting party:
  - ✓ Degree of substance purity
  - ✓ Identity of dangerous impurities
  - ✓ Substance trade name
- Public access to documents held by Agency
  - ✓ Agency has ability on own initiative to refuse disclosure on ground of protection of commercial interests
- May opt out of joint registration submission of commercially sensitive information (Article 11(3)(b))

## CONCLUSIONS

- REACH mandates cooperation between SIEF participants in data sharing, data development and registration.
- The manner of cooperation is left to the parties.
- SIEF participants are likely to strategically favour forming consortia and must ensure that their terms are drafted to protect their interests.
- Principal concerns should be protection of CBI and avoiding infringement of EC competition law
- Many questions remain unanswered (for example, data cost sharing)
- Awaiting RIP 3.4 for clarification (8 June 2007)