

A close-up photograph of a microscope, showing the objective lenses and the stage. The image is in a blue-tinted color scheme.

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# COOPERATION IN THE SIEF AND REACH ENFORCEMENT

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*Chambre Belge du Commerce Chimique  
REACH Seminar September 17, 2009*

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# OUTLINE

1. SIEFs and Consortia – relevance to distributors?
2. SIEF Issues in progressing registration dossier
3. Enforcement of REACH
4. Antitrust/competition law aspects

# DISTRIBUTOR'S PERSPECTIVE

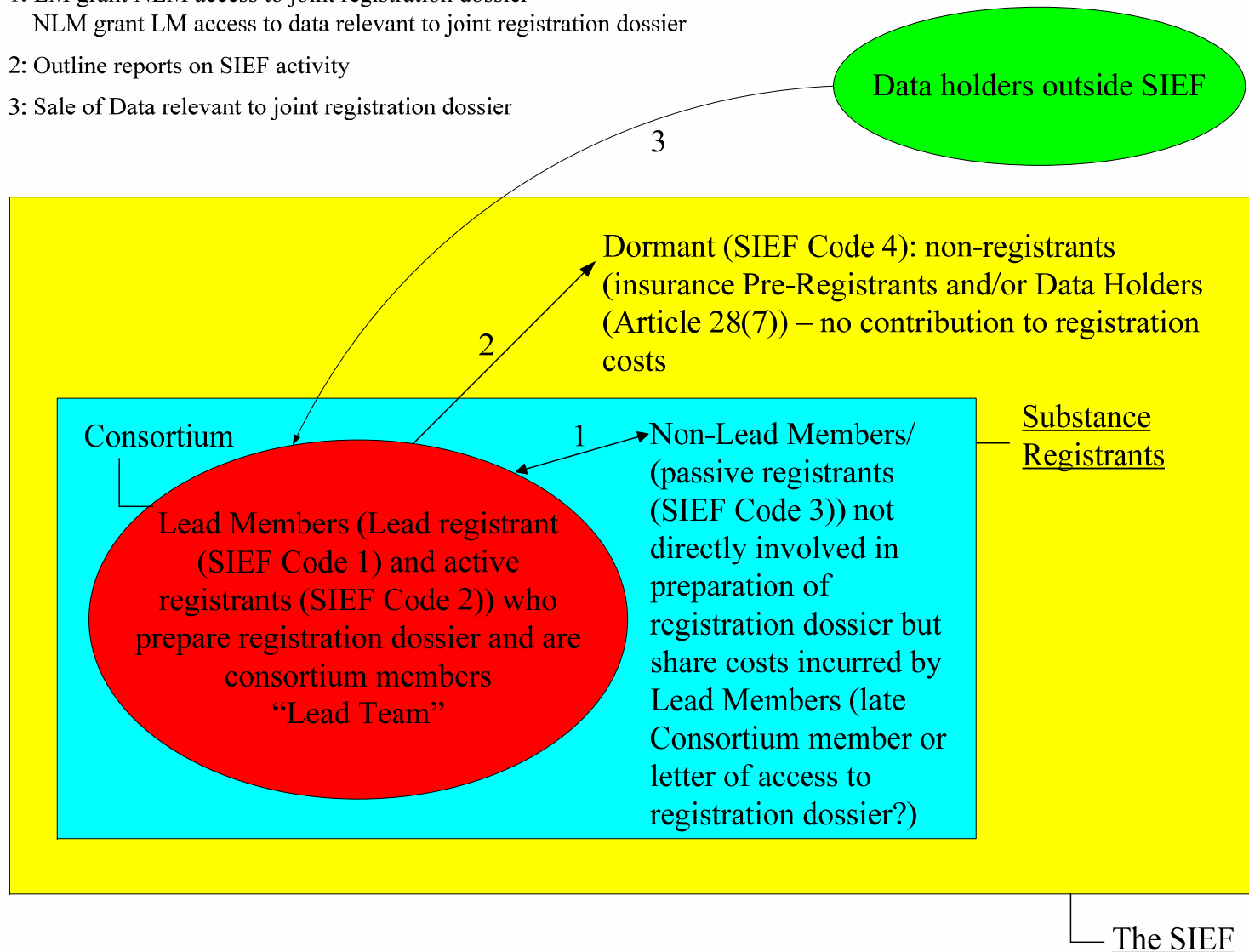
- 3 ways participation in SIEFs relevant to distributors:
  - ✓ Distributors may also be importers (responsible for physical introduction of substance into EU)
  - ✓ Distributors may act as OR
  - ✓ Distributors may pre-register to access SIEF to sell relevant data on substance ('data-holder')
  
- In every case, supply chain management:
  - ✓ Supplier awareness
  - ✓ Who will be registrant?
  - ✓ Continuity

# PROGRESS TOWARDS REGISTRATION DOSSIER SUBMISSION- STATE OF PLAY

- Clock ticking for November 30, 2010 deadline high volume (>1,000 tonnes)/dangerous substances
- CEFIC: “SIEF not working”: behind CEFIC anticipated timetable:
  - ✓ Sameness discussions finished? SIEF yet in existence?
- Previous focus or Consortium/Lead Member activity:
  - ✓ Manage relationship with registrants outside consortium?

# THE VARIOUS PLAYERS IN PREPARATION OF THE REGISTRATION DOSSIER

- 1: LM grant NLM access to joint registration dossier  
NLM grant LM access to data relevant to joint registration dossier
- 2: Outline reports on SIEF activity
- 3: Sale of Data relevant to joint registration dossier



# SIEF COOPERATION ISSUES RE REGISTRATION-LEAD REGISTRANT PERSPECTIVE

- From perspective of SFF/Lead Registrant
- Time pressure to forge ahead with dossier presentation (consortium/SIEF Agreements, data availability questionnaire, etc.)

YET

- Reliant on voluntary cooperation of other registrants

# SIEF COOPERATION ISSUES RE REGISTRATION

- Critical gap between cooperation REACH requires in practice and means to achieve this
  - ✓ SIEF obligations (requesting vertebrate studies available in SIEF, providing proof of study costs) not binding until SIEF formed
  - ✓ SFF can't force "collective" data sharing approach on SIEF participants (even if more efficient)
  - ✓ SIEF participants don't have to join consortium or sign a SIEF agreement: only comply with basic REACH obligations

# SIEF COOPERATION ISSUES RE REGISTRATION – SIEF AGREEMENT

- CEFIC suggest bilateral Agreement: Lead Registrant (on behalf of Lead Members) and individual SIEF participant
- Why necessary?
  - ✓ Non-Lead Members not contractually bound by consortium agreement
  - ✓ Certain provisions of consortium agreement (data cost sharing) dependent on agreement of Non-Lead Members

# SIEF COOPERATION ISSUES RE REGISTRATION – SIEF AGREEMENT

## ➤ Purpose of SIEF Agreement:

- ✓ Formal election of Lead Registrant (Article 11 (1), 2<sup>nd</sup> paragraph)
- ✓ Legitimises Non-Lead Members participation in joint registration dossier
- ✓ Respective obligations re preparation of joint registration dossier
- ✓ Rights to joint registration data on payment of data/administrative costs
- ✓ Confidentiality and competition law issues

# SIEF COOPERATION ISSUES RE REGISTRATION – SILENCE OR NON-COOPERATION

- LR experience very low SIEF participant response rate: 15% (LR conference Brussels, 11 September 2009)
- The legal consequences of silence?
  - ✓ Can Lead Registrant be elected ‘by default’ (without positive affirmation)?
    - Ensure window to object, with cut-off date
  - ✓ No response to SIEF Agreement?
    - Not contractually bound if does not ‘sign’

# SIEF COOPERATION ISSUES RE REGISTRATION – SILENCE OR NON-COOPERATION

- Consequences of refusal to sign/non-adherence to SIEF Agreement (likely?):
  - ✓ NLM must still share its data relevant to joint registration and pay equal share of costs under REACH
  - ✓ LR must still file joint dossier on NLM's behalf- but how to recover administration costs?
  - ✓ No obligation on NLM to grant LR rights to sub-licence data to other registrants – prevents centralisation of rights on Lead Registrant

# SIEF COOPERATION ISSUES RE REGISTRATION – NLM PERSPECTIVE

- Costs comparison: join consortium v. letter of access to joint registration dossier?
  - ✓ (Economic downturn) liquidity issue – postpone up-front consortium costs by buying data from consortium at later date
  - ✓ Relevant to later deadline registrants only
  - ✓ May finally pay more (‘Sweat Equity’/’Additional’ charge)
- Non-Lead member share of generic costs of registration dossier:
  - ✓ Calculated fairly?
  - ✓ Establish direct benefit of costs incurred to NLM?
  - ✓ Should all consortium costs be recoverable from non-lead members? – grey area

# SIEF COOPERATION ISSUES RE REGISTRATION – NLM PERSPECTIVE

## ➤ CEFIC Model ‘a basis for discussion’

- ✓ Not a ‘cut and paste’ document
- ✓ Must reflect consortium agreement terms (where appropriate)
- ✓ CEFIC Model not a *fait accompli* – can counterpropose

## ➤ Where no Lead Registrant yet proposed?

- ✓ Any choice but propose yourself in order to meet registration deadlines?
- ✓ Costs incurred (for example, draft consortium / SIEF agreements) without guarantee of reimbursement (will they sign SIEF Agreement?)

# ENFORCEMENT - SANCTIONS

- Enforcement of REACH has already begun!
- REACH requires Member States to adopt ‘effective, proportionate and dissuasive sanctions’ for infringements (Article 126)
- Some Member States not yet implemented national enforcement legislation (Austria, Belgium, Italy and Portugal)
- Significant civil and criminal sanctions already adopted in most Member States:
  - ✓ France: 2 years imprisonment and €75,000 fine for M/I of non pre-registered substance; 3 months imprisonment and €20,000 fine for failure to provide recipient with SDS

# ENFORCEMENT - SANCTIONS

- ✓ UK: Maximum £5,000 fine and/or up to 3 months jail for summary conviction; unlimited fine and/or up to 2 years prison following conviction of indictment
- ✓ Netherlands: €18,000 fine and up to 6 months jail for unintentional failure; up to 2 years in jail for intentional failure to comply

# ENFORCEMENT - PROGRAMME

- First Coordinated REACH Enforcement Project started in April '09 (more than 20 Member States):
  - ✓ National inspectors across Europe agree to enforce core “no data, no market” principle, focusing on:
    - Proof of phase-in (existing) substance pre-registration
    - Accompanying SDS (substance preparations)
    - Proof of OR appointment (separate contract with each separate non-EU entity)
- Wide-ranging national authority search, sampling and substance seizure investigation powers (customers officials, health inspectors)

# ENFORCEMENT - PROGRAMME

- “Pragmatic enforcement” policy: no!
- Joint REACH enforcement project “REACH-ENFORCE 1”
  - ✓ At least 200 inspections already
  - ✓ Common Inspection Questionnaire

# ENFORCEMENT – ARE YOU PREPARED?

- 2 obvious enforcement scenarios:
  - ✓ Importer of product entering European Union (or importer's appointed customs clearance agent) requested to provide evidence of compliance (pre-reg numbers/SDS)
    - Examples in Netherlands and Belgium
  - ✓ Premises of EU based DU holding your product → request for REACH compliance documents
- Can you/your importer/your OR/your customs clearance agent, or your DU produce the necessary documents if shipment investigated? (otherwise inevitable business interruption)

# ENFORCEMENT – ARE YOU PREPARED?

- Obligation to keep relevant records for 10 years – breach is an offence even if in absence of more substantive infringements
- CBI issues – for example, providing importer with information on individual components of preparations where enforcement authority requires
- Internal REACH compliance systems and procedures:
  - ✓ Division of responsibilities (OR, appointing company, importer)
  - ✓ Records can be quickly produced and furnished to authorities
  - ✓ Appoint REACH Compliance Officer (for all subsidiaries)
  - ✓ Internal Compliance Manual Advisable

# COMPETITION LAW - RELEVANT CONTEXT AND ISSUES

- Competition law is about protecting free and unrestricted competition in the common market
- Why is this relevant for REACH?
- Two issues to consider:
  - ✓ Cartels: Data exchange
  - ✓ Market access: no registration - no access

# EXCHANGE OF INFORMATION AMONG SIEF/CONSORTIUM MEMBERS

## ➤ Do:

- ✓ Assess and select information that you consider to be sensitive
- ✓ Consider preparing non-sensitive summaries for release to SIEF
- ✓ Abide strictly to the agenda of meetings/discussions among members
- ✓ Keep records and track of what was said and discussed among SIEF/consortium members
- ✓ Report any exchange of information that you think is/may be improper

# EXCHANGE OF INFORMATION AMONG SIEF/CONSORTIUM MEMBERS

## ➤ Don't:

- ✓ Share or solicit sensitive business information with/from competitors  
  
(e.g., information on actual prices, volumes, terms and conditions of sale, market shares, customers are typically sensitive)
- ✓ Engage in discussions unrelated to REACH or substance registration

# MARKET ACCESS AND STRATEGIC BEHAVIOUR

- Data exchange hinders or delays entry of competitors
- Mainly in the context of consortia
- Non price conduct to consider:
  - ✓ Absolute refusal to provide access to relevant data and studies
  - ✓ Adequate disclosure for robustness and relevancy vs. legitimate rights to protect confidentiality
  - ✓ Bundling of data

# EXCESSIVE PRICING

## ➤ Excessive pricing

- ✓ Compensation for studies with adequate degree of relevancy and reliability
- ✓ Three cost methodologies under REACH
- ✓ Pricing in accordance with objective parameters (FRAND principles)
- ✓ Entry fees and membership rules may hinder competition!

# AVOIDING DISCRIMINATORY TREATMENT

- Members vs. non members
- Differentiated treatment must be objectively justified
- Quick look at certain consortium costs:
  - ✓ “Sweat equity”
  - ✓ Volume related cost allocation
  - ✓ “Risk premium”

# CONCLUSIONS

- SIEF cooperation behind schedule and an uncertain process – no obligation to cooperate collectively (even if more efficient)
- Enforcement is a reality – are you prepared to satisfy investigating authorities and minimise business interruption?
- Antitrust: be aware of antitrust issues/inadvertent infringement
  - ✓ The fact that you are carrying out an activity in connection with REACH compliance does not preclude your conduct infringing competition law.