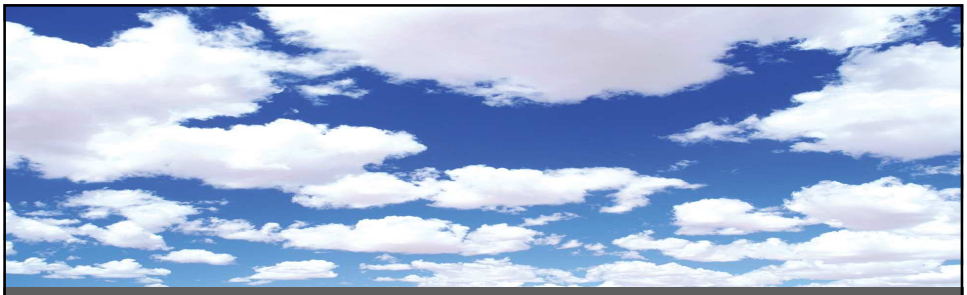


Challenges in front of New Member States related to REACH Implementation

19 April 2007 – Bratislava

Jean-Claude Lahaut
Joanna Karolina Warnel

cefic

WHAT IS IN REACH ?

2

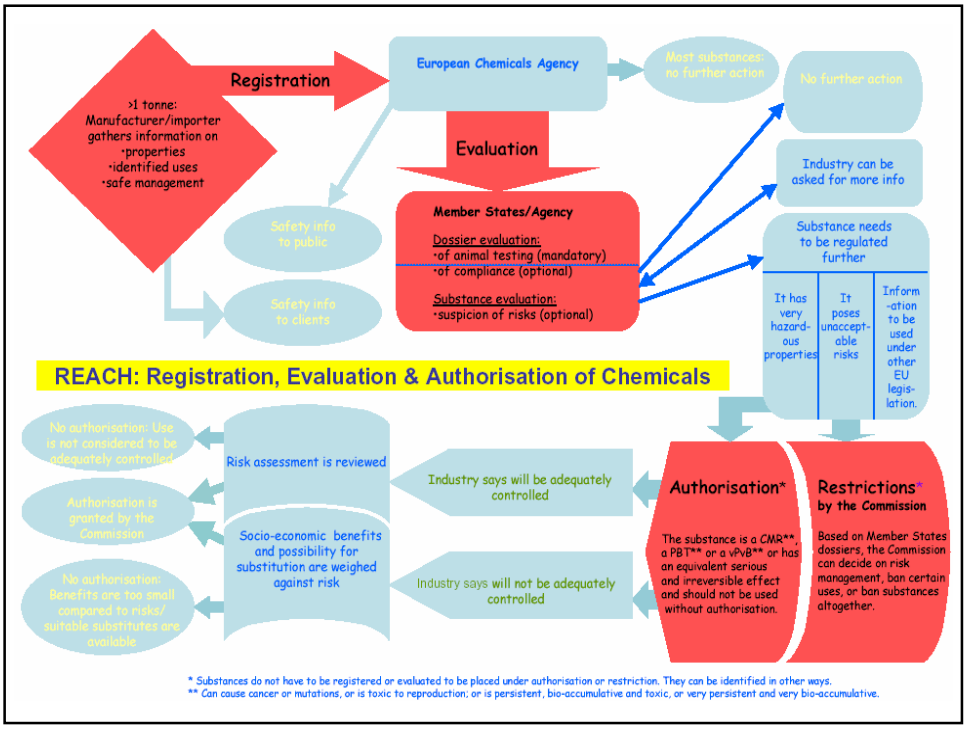
Main Steps in REACH

A single system for non-phase-in (new) and phase-in (existing) substances

- **Pre-Registration: data sharing and avoidance of unnecessary testing**
- **Registration of substances of 1 ton or more per M/I/year**
- **Information in the supply chain; downstream users**
- **Evaluation of dossiers by Member States**
- **Authorisation for substances of very high concern**
- **Restrictions – the safety net**

The Agency to manage the system

3



General issues - Title I

Scope

- **REACH covers:**
  - **Manufacture, import, placing on the market and use of substances**
  - **Substances "on their own", in preparations or in articles**
- **General exemption from scope: radioactive substances, substances to custom supervision, non-isolated intermediates, waste**
- **Specific exemptions from parts of REACH set out in those Titles**

5

Registration – Title II

What do I have to register?

- **Substances >1 ton/producer/year**
- **Non-registered monomer substances if present at >2% in a polymer**
- **Substances in Articles if present > 1 ton, dangerous (67/548/EEC) and intended for release**
- **PPORD exempted from registration for 5 (+ 5) years**
- **Polymers – exempted from registration – but EC is committed to consider how polymers can be addressed in the future**
- **Isolated Intermediates - reduced requirements for on site or transported isolated intermediates**
- **Exemption – Annex IV & V**

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Registration – Title II (cont. 1)

Which information?

When? (Phase-in)

Tonnage band	*1-10*	*10-100*	*100-1,000*	*> 1,000*	*CMR 1&2*
TECHNICAL DOSSIER Data – Annex	✓ VI-VII	✓ VI- VIII	✓ VI-IX	✓ VI-X	✓ VI-X
CSR	No	✓	✓	✓	✓
Time after EIF * (years)	11	11	6	3,5	3,5

* Entry into force

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Registration Annexes

What should include the Technical Dossier?

- Identity of manufacturer or importer, identity of substance
- Information about manufacturing process and produced quantity incl. all identified use(s)
- Proposal for classification and labeling
- Recommendations for safe handling (storage, disposal, first aid measures)
- Summary and "robust study summaries" of test data (Annex VI-X)
- Statement, whether information has been generated by testing on vertebrates
- Proposal for additional tests
- Declaration regarding agreement of sharing non vertebrate animal tests

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Registration – Title II (cont.2)

Registration Annexes

- **Annex VII**
  - **Physicochemical properties**
  - **Basic human health data (4 end-points)**
  - **Short term aquatic toxicity**
- **Annex VIIII**
  - **Human health data (including *in vivo*)**
  - **Ecotoxicological data**
- **Annex IX and Annex X**
  - **Long term, repeat dose, chronic, fate etc**
- **Annex XI**
  - **Adaptations of the testing regimes**
- **Exemptions built into Annexes VII to X**

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Registration – Title II Cont. (3)

What is the Chemical Safety Assessment / Report ?

- **Shall consider all stages of the life-cycle of a substance as defined by the identified uses and will contain the following information:**

1. **Human health hazard assessment**
2. **Human health hazard assessment of physico-chemical properties**
3. **Environmental hazard assessment**
4. **PBT and vPvB assessment**

- - - - if dangerous or a PBT or vPvB - - - -

5. **Exposure assessment**
6. **Risk characterization**

- **CSR – Rules defined in Annex I / Point 7**

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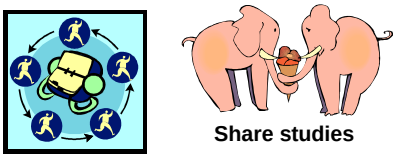
Data sharing and avoidance of unnecessary testing - Title III

First step of the process

Potential registrants to share vertebrate animal studies before Registration - How?

- **Send a enquiry to the Agency with specific information (non phase-in)**
- **Duty to Pre-register – send specific information to the Agency to join a SIEF (Phase in)**
- **Summaries submitted more > 12 years freely available**



Get in contact

Share studies

Agreement – cost compensation

No agreement
- **Study made available – compensation**
- **Repeat study - sanction**

ISC and Downstream Users - Title IV & V

Duty to communicate information in the supply chain

- **Through Safety data Sheet for classified substances**
- **Specific information when no SDS is required**

Downstream Users have also duties!

- **Downstream users must prepare a CSR for a use outside the conditions described in an exposure scenario communicated to him in a SDS**

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Evaluation – Title VI

Substances will be evaluated by the Member States CAs
What will they evaluate?

- **Dossier evaluation**
  - Examination of testing proposal : prevent unnecessary animal testing and ensure quality of tests (Annexes IX & X)
  - Compliance check especially waving statements (up to the CA)
- **Substance evaluation**
  - Clarify the suspicion of risks to human health or the environments of a substance.

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Authorisation - Title VII

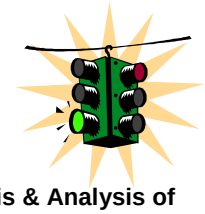
Certain substances need to be authorised before placing them in the market

Which ones?

- **CMRs cat. 1&2**
- **PBTs & vPvBs (according to Annex XIII)**
- **Other substances which can cause irreversible effects in humans or environment – No scientific criteria given**

How to apply for an authorisation?

Send an application including



- **Identity of the substance and applicant**
- **Request for authorisation**
- **CSA if not registered**
- **Optional information: Socio-economic analysis & Analysis of alternatives**

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THE CHALLENGES OF REACH

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REACH - challenges

The challenge for chemical industry

- assess (including data generation)
- document (Chemical Safety Report)
- register (together with other producers and downstream users)
- communicate (via Safety Data Sheet)

30.000 substances in 11 years

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1. Timing

- Adoption: 30 December 2006
- Entry into force: 1 June 2007
- Gradual application:
  - Information in the supply chain, Fees, Agency: 1 June 2007
  - Registration, Evaluation, Downstream users, Authorisation: 1 June 2008
  - Art 135 (notified substances): 1 August 2008
  - Restriction: 1 June 2009

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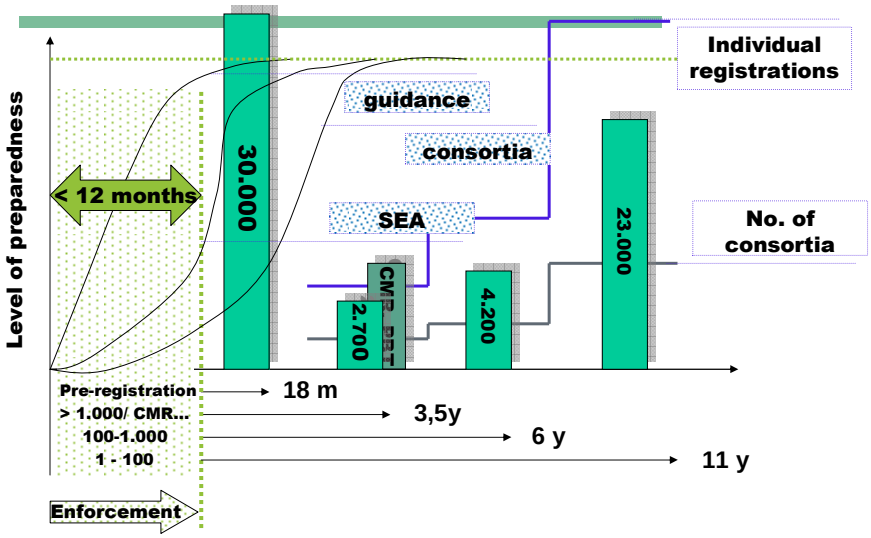
Time is running



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2. Open issues

REACH has explicitly left 13 issues open

They need to be solved in the coming months

By the Community institutions

By the Member States

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Issues to be decided by EU Institutions

- **Registration: Testing methods for intrinsic properties (Art.13.3)**
- **Substance evaluation: development of criteria and priorities (Art. 47.2)**
- **Fees: structure and amount of fees for registration, authorisation and lodging of an appeal (Art. 74.1)**
- **Agency: recruitment of the key posts (Articles 75 et seqq.)**
- **Financial rules applicable to the agency (Article 99)**
- **Legal remedies: procedures for the Board of Appeal (Article 93)**
- **Access to information / confidentiality: the Management Board adopts the practical arrangements for implementing Regulation 1049/2001 including appeals or remedies against partial or full rejection of a confidentiality request by 1 June 2008 (Article 118.3)**
- **Reporting obligations of the Agency: 1 June 2011 (Article 117)**

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Issues to be decided by the Member States

- Appointment of competent authority(ies) in the implementation of REACH and adequate funding (Article 121)
- Establishment of national helpdesks (Article 124)
- Enforcement sanctions: Laying down of the provisions on penalties applicable for infringement of the provisions of the REACH regulation and ensure their implementation. Notification of the list to the COM by 1 December 2008 (Article 126)
- Reporting obligations of Member States and the Agency: 1 June 2010 (Article 117 and 127)
- Invocation of the safeguard clause (Article 129) remains possible

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3. RIPS
Industry engagement in RIPs is pivotal for achieving practical guidance

Cefic is participating in the RIP projects of the Commission by

- ❑ Representing industry positions in major parts of RIP 3 and RIP 4 via nominated representatives for the SEGs (stakeholder expert groups).
- ❑ Active participation in RIP 2 (REACH IT)
- ❑ Leading role in „consortium“ on RIP 3.2.2 – task 4 (exposure scenario & risk management measures for CSA/CSR)
- ❑ Leading role in „partnership“ on RIP 3.3.2 (data requirements & endpoints)
- ❑ Partner in tender for RIP 3.4 (data sharing)

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RIP projects timetable

RIP N°	Name	Starting date
3.2-2	TGD on preparing the CSR (Guidance Development)	Start April 2006 (12 months)
3.3-2	TGD on Information Requirements (Guidance Development)	Start Dec 05 (12 months)
3.4	Guidance document on data sharing (pre-registation)	Start Sept 06 (9 months)
3.5-2	TGD on Downstream User Requirements (Guidance Development)	Start June/ July 06 (10 months)
3.6	Guidance on C&L under GHS	Start Oct 06 (8 months)
3.7	Guidance on application for authorization	Start Sept 06 (8 months)
3.8	Guidance on fulfilling requirements for articles	Final comments April 2006
3.9-2	Guidance on carrying out a SEA (Phase 2 Guidance Development)	Start June/ July 2006 (12 months)
3.10	Guidance on performing substance ID check	Final comments sent March 2006

FIRST STEP IN REACH

Pre-Registration

Preparation for pre-registration and registration- content

Inventory building & information in the supply chain

- **Manufacturers/ Importers**
- **Downstream Users**
- **Distributors**

Pre-registration

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How to prepare for REACH(1)? Manufacturer/Importer

1. **Produce your company inventory of substances and preparations**
2. **Define for each substance/preparation your own status (M/I, distributor, DU, legal entity) and your position in the supply chain**
3. **Determine if your company is the manufacturer, importer of the substance/preparation or purchased by your company from a supplier within the EU**
4. **Determine if applicable:**
   - **Non isolated intermediate**
   - **On-site isolated intermediate**
   - **Transported isolated intermediate**
5. **For manufactured and /or imported polymers the monomers they are made from and the other constituents used for manufacturing of polymer**

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How to prepare for REACH (2)? Manufacturer/Importer

6. Establish the annual volume of manufactured or imported substances and the composition of preparations
7. Identify the CAS# (and if possible the EINICS or ELINCS) of manufactured or imported substances
8. Identify and list your customers per substance and per preparation

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How to prepare for REACH (3)? Manufacturer/Importer

9. Collect available information
   - Intrinsic properties
   - Animal testing results owned by company
   - C&L
   - SDS
10. Ensure there is clarity about the ownership of data
    - Arrange legal framework for use and ownership
11. Establish which legal entity is involved as M/I for which substance/preparation

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How to prepare for REACH (4)? Manufacturer/Importer

12. Identify and list your suppliers per substance and preparation
13. Compile readily available information on uses and conditions of use
    - List your customers
    - Own workplace and customers
    - Industrial, professional, consumer use
14. Identify gaps of information
15. Try to find out if your supplier will register for REACH-standard questionnaire is being prepared and will be circulated by Cefic

Example for template can be found at:
http://mineco.fgov.be/organization_market/Reach/REACH_TOOL_NL.xls - 3785.0KB

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How to prepare for REACH? Distributor

Inventarisation of substances that you distribute

- Overview of your suppliers
- Overview of your customers
- Intensify contacts with suppliers and customers
- Try to collect usage data
- Check if your supplier will pre -registrer

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Prepare for pre-registration

Data required for pre-registration :

- **Name of substance**
- **Name in IUPAC nomenclature or other international chemical name(s)**
- **Other names**
- **EINECS or ELINCS no (if available and appropriate)**
- **CAS# and Name (if available)**
- **Other identity code (if available)**
- **Name and address of potential registrant**
- **Name of contact person**
- **Name/ address of third party representative (if applicable)**
- **Envisaged deadline for registration and tonnage band**
- **Substance(s) which you intend to use for read-across approach or (Q)SAR**

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Pre-registration of Phase-in Substances

Pre-registration of phase-in substances ⇨ database

- **Agency publishes the list of substances by 1 January 2009**
  - Names of the substances
  - EINECS or CAS N°s or other identity code
  - First envisaged registration deadline
- **A DU using a substance not appearing on the list may notify the Agency of his interest in the substance and give the details of his current supplier. The Agency shall publish on its website the name of the substance and on request provide contact details of the downstream user to a potential registrant.**
- **Possibility for 1st time M/I to benefit from the transitional period.**
- **M/I of substances < 1 t/yr, DU and 3rd parties may submit information to the Agency to take part in the SIEF**

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SECOND STEP IN REACH

Substance Information Exchange Forum (SIEF) (for Phase in Substances)

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SIEF for Phase-in Substances

- **SIEF = Substance Info Exchange Forum**
  - All potential registrants (M/I who have submitted the pre-registration information to the Agency for the same substance)
  - All downstream users and third parties who have submitted information to the Agency
  - Biocides and PPP notifiers whose information is held by the Agency
  - Registrants who have submitted a registration for that phase-in substance before 1 June 2018
  - Operational until 11 years after entry into force
- **Aim: facilitate for the purpose of registration the exchange of information to minimise duplication of tests and to agree on classification and labelling**
- **SIEF participants provide others with existing studies, react to requests by others, identify needs for further studies and arrange to carry them out.**

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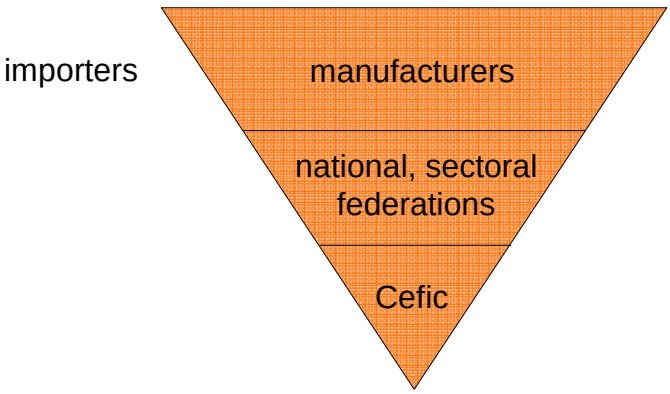
The chemical industry and REACH



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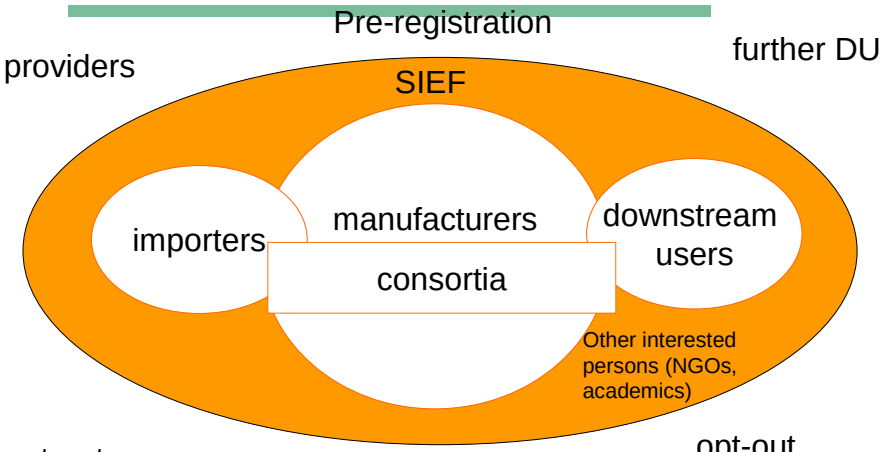
SIEF in REACH



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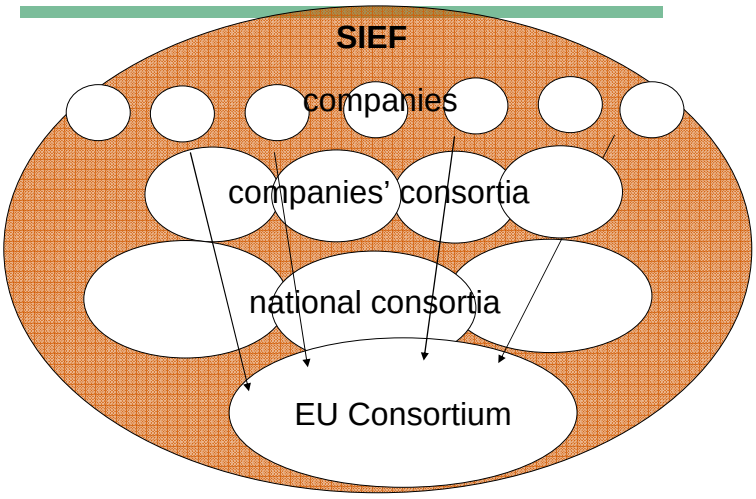
Consortia



ECHA

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THIRD STEP IN REACH

Sharing Data ?

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Regulatory framework
SIEF- data sharing rules for phase-in substances

REACH requires each registrant to be in legitimate possession or have permission to refer to the full study report summarised in the registration file => data sharing system

Before testing is carried out a SIEF participant must first inquire whether a relevant study is available within his SIEF => no time limit for the inquiry

If the study is available:

- He must request that study (mandatory request) => in case of studies involving tests on vertebrate animals (VAS)
- He may request that study (optional request) => in case of all other studies

If the study (VAS/ non VAS) is available AND the owner was requested to provide it :

=> owner must provide proof of costs within 1 month

=> participants should make every effort to agree on sharing of costs (Agency to adopt cost sharing guidance) => if no agreement : equal shares

=> owner gives permission to refer to the full study report

!!! registrants are only required to share in the costs of information that is necessary to satisfy their registration requirements (relevant tonnage band)

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Regulatory framework
SIEF- data sharing rules for phase-in substances

If the owner of VAS refuses to provide proof of costs or refuses to share

=> his registration proceedings stopped & he is sanctioned (Article125)

=> the others can proceed with registration without fulfilling this information requirement (explaining reason for this in the registration dossier)

- If registration containing this information has already been submitted=> Agency gives the permission to refer provided that the potential registrant paid a proportionate share of the cost (Agency to adopt guidance). The first registrant has a claim on the other registrants for an equal share of the cost if he makes the full study report available

- No existing registration of the same substance => and within 12 months study owner does not provide information => prospective registrant repeats the test if allowed by the Agency (Agency decision is subject to appeal)

If the owner of non VAS refuses to provide proof of costs or refuses to share

=> the others act as if the study was not available

If the study is not available

=> SIEF participants agree who performs it =>if no agreement : Agency appoints the registrant (Agency decision is subject to appeal)

=> equal sharing of costs per number of contributors

=> all participants receive the full study report

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Regulatory framework
Joint submission of data by multiple registrants

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Regulatory framework
Joint submission of data by multiple registrants

- **Lead registrant submits the hazard information (and if companies choose the CSR) for each substance => content of core data, as well as deadline dates for registration, depend on production volumes of substance (tonnage bands)**
- **Companies allowed to opt-out of this with genuine reasons (justified-explanation must be submited with the registration file) :**
  - **Joint registration would be disproportionately costly, or**
  - **Would lead to disclosure of information which the registrant considers comercially sensitive and is likely to cause him substantial detriment, or**
  - **Disagreement with the lead registrant on the selection of information**

=> Justification would be assessed during « dossier » evaluation => dossier treated as priority one

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Regulatory framework conclusions

Provisions regarding SIEF and joint submission of data lack coherence

Data sharing triggered by a prealable inquiry in many cases may not be the optimal solution:

- **Available data approach vs. missing data approach?**
- **Help of a SIEF facilitator?**

Burden of organising the communication and smooth cooperation between registrants shifted to the industry => strategic decision : consortium?

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FOURTH STEP IN REACH

REACH Consortium

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What is the advantage of forming a consortium?

- Reduced registration costs
  - Save effort by sharing tasks
  - Share administrative costs, benefit from reduced registration fees
- Technical and scientific advantages
  - Optimise the quality of the registration dossier
  - Avoid inconsistencies in data submitted to the agency
  - Maximise cross reading potential
  - Allow to extend co-operation to CSR if feasible and appropriate
  - Improved risk assessment with enlarged data base on the substance
- Stronger position vis-à-vis the Agency

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And disadvantages?

- Participation in consortium usually ressources and time-consuming
- Less control over the conduct of studies
- Administrative costs

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The way forward- preliminary agreement?

- To optimise pre-registration
  Preliminary discussions help to:
  - Identify properly the substance in order to be allocated the right SIEF
  - Ensure that data sharing is optimised through co-ordinated pre-registration with other M/I
  - Maximise cross reading potential
- To study the feasibility of consortium formation
- To discuss modalities and conditions of consortium agreement e.g. cost sharing rules, valuation and evaluation of studies, sweat equity compensation

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Preliminary agreement/ Declaration of intent- content

- Feasibility study => no obligation to form a consortium, only non-binding declaration
- Set of conditions in order to comply with competition law => code of conduct, Cefic competition compliance programme
- Confidentiality clause + third party participation
- Arbitration procedure

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Preliminary agreement- antitrust law concerns

Potential competition law issues- Art.81 (agreements preventing, restricting or distorting competition) and 82 (abuse of dominant position) of the ECTreaty

- **Discrimination/ exclusion of other potential registrants**
  - **Determination of scope- carefully select substance/impurity limits**
  - **Membership criteria-**
    - **Conditions of access must be objective, sufficiently determinated, not go beyond what is necessary for the pourposes of the cooperation , transparent (available to prospective members) and applied in a uniform and non-discriminatory manner,**
    - **Membership should be quasi-automatic, non conditional upon the satisfaction of unnecessary requirements or subject to discretionary decisions of thye existing members over and above fulfilment of the membership criteria;**
      - **Inacceptable- conditions relating to the seize of the company**
      - **Acceptable- limitation of access only to companies active in the sector (company having merely a vague interest and unable to demonstrate a true intention to market or import the substance may be excluded)**

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Preliminary agreement- antitrust law concerns

- Exchange of confidential information
  - Avoid sharing information on:
    - Price and customer policy
    - Production, market, distribution plans
    - Production costs, capacity, sales
    - Details of the full composition of a preparation
    - Precise use, function or application of a substance or preparation
    - Precise tonnage of the substance or preparation manufactured or placed on the market
    - Links between a Manufacturer or Importer and his Downstream User
- Cost sharing
  - Analyse the impact of administrative fees
  - Carefully determine rules if unequal cost sharing

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What to discuss in the framework of preliminary agreement?

Consortium may be organised by a contract between interested parties

Contractual freedom but

⟺

EU competition law

Confidentiality

Specific REACH Regulation provisions

Other applicable sets of law

Consortium usually created as a « task force »

- **No separate legal entity**
- **Flexible, limited in time and scope**

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Consortium operating rules- main provisions

Scope and purpose

- **Substance identity/ purity/ groups of substances => decisive who can become a memeber**
- **Purpose => Substance identity check? Organisation and management of SIEF? Joint submission of data? Evaluation (follow-up of registartion)? Authorisation? Other purpose?**

Membership

- **Categories of members and conditions of admittance**
  - **Regular members**
  - **Associate members/ Observers**
  - **Late members**
- **Transfer/ Withdrawal/ Exclusion => consequences**

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Consortium operating rules- main provisions

Consortium organisation

- Structure, composition, procedure of appointing:
  - Steering committee
  - Technical committee
  - Lead registrant
  - Sectetariat/ Third party
    - day to day management
    - archiving and management of application for registration and access to consortia data
  - Other bodies, e.g. ad hoc groups, contracting labs
- Decision-making process
  - Number of votes per each member/Voting rules
- Representation
- Duration
- Consortium dissolution and wind up, survival clauses

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Consortium operating rules- main provisions

Data evaluation and sharing

- Existing studies vs new studies
- Ownership and citation rights

Costs

- Consortium costs/ Budget
- Data compensation rules (including late entry compensation)
  - Entry fee (to cover administrative costs)
  - Cost of the data (actual <=> current cost)
  - Risk premium (to compensate founding members for higher risk in data development)

Other provisions

- Applicable law
- Jurisdictional venue
- Dispute resolution
- Liabilities- allocation and limitations

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Prepare yourself for data sharing

- Establish your company strategy on consortia
- Consider signing a preliminary agreement in order to
  - correctly identify your substance
  - gain clarity whether or not to participate in a consortium
  - discuss and decide on consortium operating rules
- Need help ?

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Although guidance is not yet finalised there are already many offers to help!

- REACH services seems to be a huge market attracting a lot of commercial service providers with different expertise and service offerings
  - no accreditation scheme foreseen at EU level
  - no quality check available
  - usefulness needs to be assessed by the client himself
- Network of trade associations establishing a coherent platform to provide necessary support for companies

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A natural logical split

National Associations

- Front line help desk
- National language
- Link to MSCAs
- Tools and guidance

Cefic

- Consortia management and registration service
- Provision of standard tools/formats
- Consistency “custodian”
- Training of other service providers
- Help desk (for smaller MSs, non-EU companies, affiliated organisations)

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