

***“FECC : the European voice of the
chemical distribution ”***

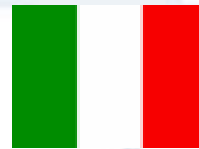
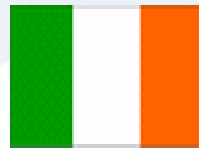
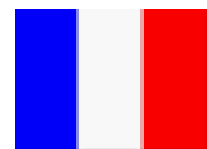
***From Pre-SIEFs to SIEFs –
feedback from the Chemical Distributors/SMEs***

***Hendrik Abma
Director General***

2nd Stakeholder's day ECHA 27 May 2009

- FECC, REACH & Chemical Distribution
- From Pre-SIEFs to SIEFs
- Data and Cost Sharing, Joint Submission

National Associations: 17 *(including Switzerland and Norway)*



Company Members: 32

ALGOL

AVANTEC

AZELIS

BANG & BONSONER

BIESTERFELD

BRENNTAG

BTC Europe

CALDIC CHEMIE

CAMPI Y JOVE

C.H. ERBSLÖH

EIGENMANN & VERONELLI

GROLMAN GROUP

HARKE GROUP

Aug. HEDINGER

NEOCHIMIKI

HSH Chemical Distribution Group

IMCD Group

KRAHN CHEMIE

NORDMANN RASSMANN

OMYA

ORKA

PENTA CHEMIKALIEN

QUIMIDROGA

QUIMITECNICA.COM

R2 Group

SAFECHEM EUROPE

TENNANTS DISTRIBUTION

TER HELL Group

TELKO

UNIVAR Europe

WARWICK INTERNATIONAL GROUP

WELDING

Associate Members: 12

REACH affects the entire supply chain.
Chemical Distributors play a key role

**MANUFACTURERS
/ IMPORTERS**



**Properties of
substances and
safe uses**

DISTRIBUTORS

**Information on
uses of substances**



DOWNSTREAM USERS

Chemical Distributors may have different roles in REACH....

- Importer/Manufacturer: import into the EU (or manufacture) a substance or a substance in a preparation in 1 or more tonnes/year.
- Distributor: only stores and places on the market a substance, on its own or in a preparation, for third parties.
- Downstream user: uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities, e.g. formulation, dilution, re-packaging, etc.

which entails different obligations...

- Importer/Manufacturer: Pre-register and Register imported substances or substances in preparation > 1 t/y
- Distributor: Make sure information is passed up and down in the supply chain
- Downstream user: communication of information on own uses upstream or carry out use assessment
- **Communication in the supply chain: CEFIC/FECC/DUCC common approach**

Pre-SIEF discussions on sameness of substance



RIP 3.10

Agreement on same substance



SIEF Formation



SIEF obligations apply

Data sharing

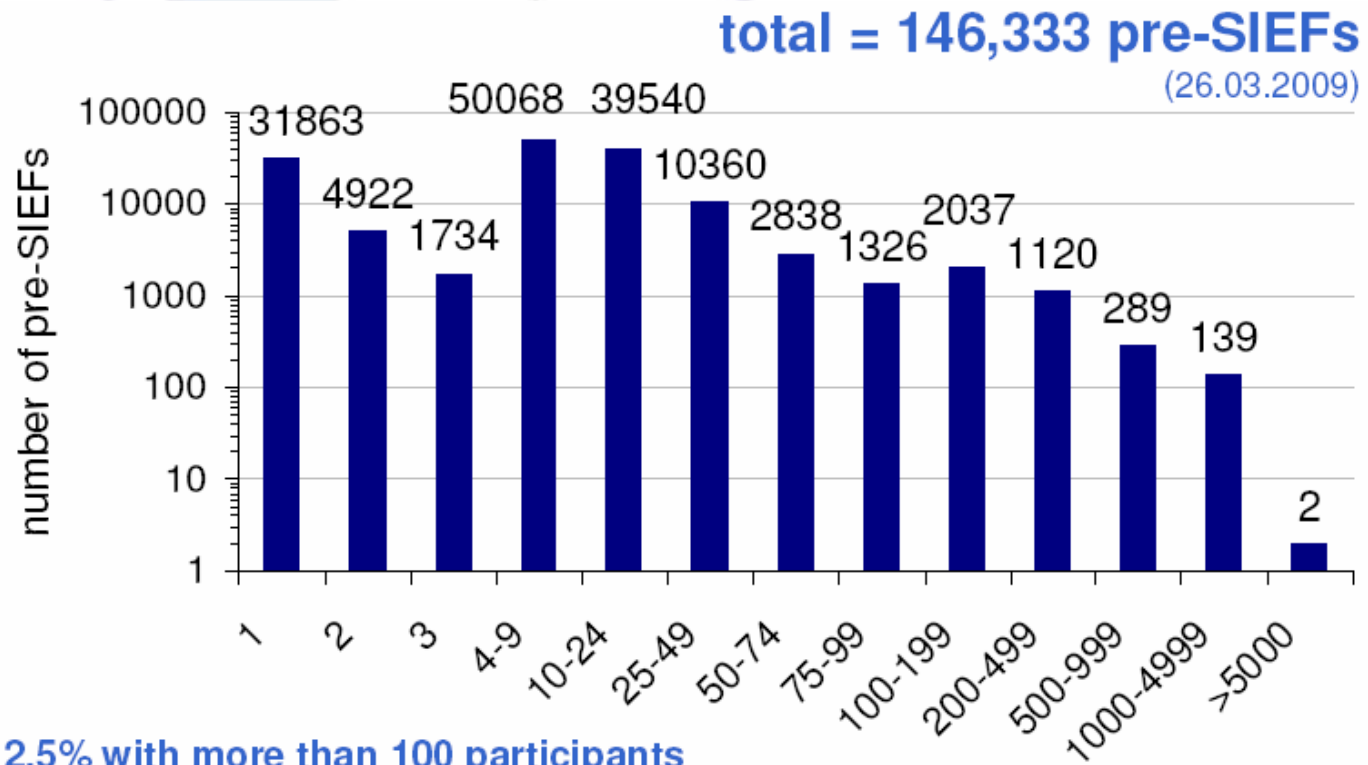


or Opt-out

Joint submission

Pre-SIEFs: state of play (source: ECHA)

- 2,750,000 pre-registrations
- 65,000 LEs signed up (85% as SMEs)



- Unforeseen No. of pre-SIEFs and participants
 - ✓ Partly because of double pre-registrations
 - ✓ Overcrowded pre-SIEFs that cannot be functional
 - ✓ Already proposals to register as isolated intermediate to cover most of uses and “get over with it” (Consequence: minor/specialised uses will be lost - impact on SMEs)

DUs - right to inform their uses to their suppliers 1 year before the relevant registration deadline.

Advice: wait until end of September

Start up for SIEFs for 2010 deadline takes longer than expected

- Agreement on substance sameness and model contract discussions take too long
- Lack of knowledge of REACH - various backgrounds (ex. business, regulatory etc.)
- Companies might prefer to work in consortia because of time limitations
- Companies are waiting for 'someone else' to initiate discussions

SIEF Formation Facilitators (SFF)

- SFFs not active enough in some cases
 - ✓ Problematic communication
 - ✓ Difficult to cope with the workload
 - ✓ Limited exchange of information between members so far
- SFF role not legally recognised under REACH
- SFF has no right to demand information or fees (unless mutually agreed)
- Eventually by pass the SFF
- ECHA's/COMM's advice: Document what you do!

Active participant in (pre-)SIEFs?

- ☹ Time-consuming
- ☹ Often scarce resources devoted to REACH compliance
- 😊 Opportunity to influence discussions including cost sharing

SIEF Coding- Leading/Involved/Passive/Dormant

- Uncertainty on changing from dormant to active status
 - ✓ Opportunity to influence cost sharing (?)
- System designed for “get on with it”
 - ✓ Distribution more dynamic

Guidelines on cost sharing: affordable for SMEs!

*REACH (Art. 30): SIEF participants shall make every effort to share costs in a **fair, transparent and non-discriminatory** way*

- According to volume
- Principles also apply to new studies
- Freedom of choice: Historic vs replacement
- Mark-up factors supported by documentation

Guidelines on cost sharing: affordable for SMEs!

- Possibility of reduction factors (often old and overvalued data)
- Risk premium only in some circumstances
- Value for administrative costs
- Only one study per endpoint will be compensated
- Only payment for data needed for registration
- Payment at moment of registration

➔ Recommendation: be aware of the guidelines for discussions on cost sharing

Issues to consider:

- Who will be the Lead Registrant (LR)?
 - SFF and/or LR compensated?
 - Agreement on joint submission and cost sharing
 - Confidentiality/legitimate possession
 - Mandatory sharing of animal testing
(*validation of “in-vitro’ tests ?*)
 - Competition law rules apply!
- **Guidelines on Data Sharing jointly developed by CEFIC, AISE, Eurometaux & FECC**

Phase-in:

Identification of available information (internally)



Agreement on cooperation and cost sharing



Sharing of available information



Identification of information gaps



Search for needed information / New study



Data and Cost sharing



Joint submission

www.fecc.org

Thank you for your attention!

2009: FECC celebrates its
55th
anniversary

Fecc
annual
congress

Hilton Kalastajatorppa, Helsinki
22/24 June 2009

2009

“REACH-ing excellence in the supply chain”

Key note speaker: Geert Dancet, Executive Director, European Chemical Agency (ECHA)

Visit:
www.fecc-congress.com

and find out more about the excellent networking programme, speaker programme with high level speakers from the industry, the accommodation, the partner programme and more...