Development of CSA/CSR in Fine Chemicals

What will be the issues for 2013?
What support is needed?

ECHA STAKEHOLDER EXCHANGE NETWORK ON EXPOSURE SCENARIOS

24TH - 25TH NOVEMBER, 2011

BRUSSELS

Tony Scott

Adviser to EFCG / CEFIC

EFCG
EUROPEAN FINE CHEMICALS GROUP

cefic

My Agenda Today

1. What is EFCG and who are its members?

2. What is a fine chemical?

3. Typical fine chemical manufacturing operations

4. Fine Chemicals - REACH

5. EFCG Position

6. Support needed → May 2013

EFCG
EUROPEAN FINE CHEMICALS GROUP

cefic

Who is EFCG?

- **EFCG = European Fine Chemicals Group**
- **Represents European Fine Chemical manufacturers**
- **EFCG = a sector group of Cefic, Brussels**
- **Formed in December 2004**
  - **43 members (includes 39 companies & 4 trade associations)**

Mission

- **Value creation by sustainable competitiveness, growth and environmental performance of our members through -**
  - **achieving a level playing field globally**
  - **being the voice of the European Fine Chemicals Industry**
  - **promoting innovation**

EFCG Membership 2011

<u>LARGE (11)</u>

Albemarle, BASF, DSM, Evonik, ISP/Ashland, Lonza, Merck, Rhodia, SAFC, Solvay, Sumitomo.

<u>MEDIUM (22)</u>

AllessaChemie, AlzChem Trostberg, Borregaard, Bracco, Cerbios Pharma Derivados Quimicos, Dipharma, Dow Haltermann, Fabbrica Italiana Syntetici, Helsinn, Hovione, Isochem, Kemfine, PCAS, Raschig, Rohner, Saltigo, Schirm, Siegfried, Wacker, WeylChem.

<u>SMALL (6)</u>

Arran Chemical, Chemie Uetikon, Contract Chemicals, Pentagon, Robinson Bros, Seratec.

EFCG Association Members: (4 – 226 sites)

APIC 60 members: Aschimfarma 63, CPA 40, SICOS 63

What is a Fine Chemical?

Commodities → Fine Chemicals → Specialty/Consumer Chemicals

- **Single, pure, chemical substances**
- **Made to exacting specifications**
- **In multi-purpose plants by batch chemical or biotech processes**
- **Low volume (<1000 tpa), high price (>$10/kg, often much higher)**
- **Few applications, often exclusive to one customer**
- **Sold for what they are not what they do**
- **“Building blocks”, “advanced intermediates”, “active ingredients”**
- **Customers: Pharma 60%, Agrochemical 20%, Rest 20%**
- **Market Value ~$85 billion pa (~4% world chemical market)**

EFCG EUROPEAN FINE CHEMICALS GROUP

cefic

Typical Fine Chemical Manufacturing Operations

Large, Medium and Small companies

Customers = other chemical manufacturers, not consumers

- **Batch processes in limited campaigns**
- **Multi-product, multi-purpose, flexible plants**
- **Production, handling of small amounts (<100 tpa, often <<)**
- **Frequent product changes = frequent cleaning**
- **Flexible equipment needed**
  - **charging, reactors, sampling, discharging, packaging**
  - **substance hazards and hence OSH requirements vary**
- **No fully closed systems! (ECHA Dec 10 Guidance)**
  - **need specific equipment/process design**
  - **inflexible, difficult to clean, slow product changeovers**
  - **high operating costs, non-competitive!**

Fine Chemicals – REACH

- Registrations:

2010:	>1000 tpa	few by definition
2013:	>100-1000 tpa	many, not pharma
2018:	>1-100 tpa,	many, mostly pharma

- Substances are either Intermediates or other
- Most supplied to a few professional customers, esp. pharma and agro, who already know substance properties, for end uses covered by existing, non-REACH regulation
- Intermediates: no CSA required = most FC companies
- Others: must be registered - CSA/CSR/ES required

  - customers mostly known, but some unknown

EFCG
EUROPEAN FINE CHEMICALS GROUP

cefic

Fine Chemicals: REACH registration timetable for 2013

From 3Q11 → 1Q12

- **Substance ID, Data sharing, Hazard data**

From 4Q11→ 2Q12

- **Check own uses**
- **Check customer uses**

From 2Q12 → 4Q12

- **Prepare CSA/CSR/ES as needed**

From 1Q13→ 2Q13

- **Complete registration**

EFCG
EUROPEAN FINE CHEMICALS GROUP

cefic

Fine Chemicals - All Company Issues → 2013

- Intermediates/SCC: ECHA Dec 2010 Guidance (expensive/critical)
- Update requirements for SDS Art.31(9)
- Checking own and customer's uses
- ES preparation in good time is dependent upon:-
  - Supply chain issues = dialogue with customers

- **Main Issues are:**
  - Customer lack of knowledge about specific uses
  - Customer confidentiality of key information
  - Lack of in-house expertise to do assessments
  - Selection of outsource expertise where needed
  - Relatively high impact on costs

EFCG
EUROPEAN FINE CHEMICALS GROUP

cefic

Fine Chemicals: Extra SME issues → 2013

- **Intermediates/SCC: ECHA Dec 2010 Guidance (critical!)**
- **ES preparation in good time (much more difficult)**
- **Much less in-house resource than large company**
  - **Typically 10 - 250 staff, < €50m sales**
  - **Less experience with REACH**
  - **Trying to cover legal matters alone**
  - **More substances**
  - **No expert knowledge available**
  - **No foreign language capability**
  - **Not a member of an association**
  - **Costs of external resource**

EFCG
EUROPEAN FINE CHEMICALS GROUP

cefic

EFCG Position - 2013 deadline

- All members recognise their obligations and are addressing them
- Only large company members have enough in-house knowledge, expertise and resources, but still must outsource
- All members know where to go to get the expertise and support they need
- Our 6 SMEs face the biggest challenge, like all non-EFCG SMEs
- EFCG unable to provide direct support for members but will help with guidance and networking as needed

EFCG
EUROPEAN FINE CHEMICALS GROUP

cefic

Fine Chemicals - What support is needed?

1. **Pragmatism on ECHA Intermediate/SCC Guidance**
    - **Even big companies have problems**
    - **Huge extra workload / cost for no improvement in H&S!**
    - **ECHA definition not in legal text**
    - **Flexibility needed at local inspector level**
2. **Education, Education, Education!**

- **Raise awareness at company level – "ActNow2103"**
    - **Need for engagement with what is needed and by when**
    - **Registration requirements → prepare detailed action plan**
    - **Sharing of best practice and knowledge sources**
- **Supply chain communication - raise awareness at DU levels**
    - **How to get dialogue with customers?**
- **Support available from ECHA, Cefic and other service providers**