SMEs and REACH the upcoming difficulties

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- The Commission's review has been mentioning the difficulties of SME's as a key issue
- ECHA
  - Is referring to SME's in their multi-annual working plan 2014 – 2018
  - Has appointed an SME ambassador
- Cefic has it high on its agenda
  - Many of our companies have SME's as suppliers
  - A simplification for SME's is by definition a simplification for all companies
- Other industry associations as well

- One hears many ideas, but hardly no global solutions
- Limited freedom if no changes of
  - REACH
  - CLP
  - Fees Regulation

ns of problems

- Registration obligations: yes or no?
  - No registration
    - Other problems are known
      - (e)Safety Data Sheet communication in the supply chain (CSR/ES roadmap)
      - Authorisation
      - CLP classifications of mixtures
  - Yes
    - Intermediate?
      - Yes, no problem if strictly controlled
      - No
        - 1 – 10 tpa
        - 10 – 100 tpa

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- Registrations by SME's (before verification of SME status)
  - 2010: 14%
  - 2013: 20%
  - 2018: ?
- Average registrations per substance
  - 2010: 1/6
  - 2013: 1/3
  - 2018: ?

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- Number of SME's growing and expecting to grow further
- Number of co-registrants is decreasing and expected to decrease even further
- Statistically many 2018 registrations will have only one registrant
  - The good news: no SIEF and SIEF related costs
  - The bad news: no one to help you. There will be even more cases where you even can't buy a letter of access

1 – 10 tpa

- Interpretation of Annex III (full Annex VII requirements versus only physico-chemical data)
  - ECHA will provide guidance
  - RPA study gives a first indication of difference in price (~50%)
- Expected availability of non-testing methods for the information requirements
  - Some indications are given in the RPA study
  - But if justification is more expensive than testing…
- Analytical data supporting the substance identity

n 1 – 10 tpa

- Where to get help?
  - If more than 1 registrant you can share
  - If you are alone …
  - The Commission spent 340 Mio € in research for non testing methods
    - Can these labs be of help?
    - In many countries universities participated, hence less language barriers

1 – 10 tpa

- What can be simplified?
  - IUCLID or REACH-IT light, while maintaining the possibility to use them
  - « Positive » read-across more easily accepted than « negative » read-across (as well valid for 10 – 100 tpa)

1 - 10 tpa

- Different scenarios for non intermediates:
  - 1 – 10 tpa registration for substances already registered in high tonnage bands
  - 1 – 10 tpa registration all registrants between 1 – 10 tpa
    - Full requirements
      - Sharing toxicological and ecotoxicological data
    - Only physico-chemical data
  - 1 – 10 tpa as the only registrant (although not fully reliable check the pre-SIEF (Substance Information Exchange Forum)

10 – 100 tpa

- Just as for 1 – 10 tpa check your situation
  - Already registered in higher tonnage bands?
  - Only registrants for 2018
  - Single registrant for 2018

10 – 100 tpa

- Information requirements
  - Comparable information on potential alternative test methods and Quantitative Structure Activity Relation (QSAR) and regulatory acceptance in the RPA study ordered by the Commission for the Review
  - Cefic LRI has a project on computational toxicology, Ambit, with active participation of a Bulgarian Research Institute

n 10 – 100 tpa

- Chemical safety assessment
  - CHESAR as a good guideline for less experienced risk assessors, but who can help those without experience?
  - How do we ensure that the outcomes of the CSR/ES (Chemical Safety Report/ Exposure scenarios) roadmap are known?

dmap – can it help?

- Launched in July 2013 with the engagement of ECHA/Member States Competent Authorities (including Romania) and industry trade associations
  - Working on tools and solutions that will be offered
  - But the registration of a substance has to be done by someone who understands what he/she is doing
    - How to select the best service provider as an SME?
    - How to find help on substance level (not the scope of the helpdesk activities)?

e done more?

- Continued awareness raising on the obligations under REACH
- Exchange of good and bad experiences
  - The choice of a consultant should not only be based on the cost
- Continued pressure on authorities at all levels to give further help

- Every Member State has the obligation to have a REACH and CLP helpdesk(s)
- These helpdesks meet each other in Helpnet meeting in ECHA
  - Frequently asked questions
  - Next meeting some case studies will be presented
    - Results of SME study in the Netherlands
    - Information and guidance to SMEs in Norway
- Continue to inform them on your daily problems
- Don't wait for 2018 to say we have a problem, let us start all looking now for solutions

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- Two deadlines went relatively smooth
- The third one is different, less information needed but much more substances and recalculated per ton more expensive
- Evaluate your situation now
- Continue to keep this on the agenda in your country and in Europe
- Don’t wait for 2018 to say we have a problem, let us start all looking now for solutions

Thanks for your attention