

SMEs and REACH the upcoming difficulties
Responsible Care. Contribution to sustainable chemical industry
in the Balkan region 10 - 11 October 2013 Sofia



Dr. Erwin Annys

spotlight



- 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

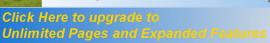


- One hears many ideas, but hardly no global solutions
- " Limited freedom if no changes of
 - " REACH
 - " CLP
 - Fees Regulation

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





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: ?



- 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 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



า 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



า 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)



า 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)

Click Here to upgrade to Unlimited Pages and Expanded Features

1 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

า 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



າ 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)?

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



- 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