



SME's support – other ideas
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SME's in the spotlight



- **Cefic Programme Council Product Stewardship**
 - **Concrete proposals needed before the end of this year to simplify REACH for the 2018 deadline, while keeping the information requirements**
 - **A simplification for SME's is by definition a simplification for all companies**
- **The Commission's review is mentioning the difficulties of SME's as a key point**
- **ECHA**
 - **Is referring to SME's in their multi-annual working plan 2014 – 2018**
 - **Has appointed an SME ambassador**

Some figures



- **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: ?**

Some figures



- **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**

Some figures



- **Number of SME's in chemical industry?**
 - **Eurostat: 29.000**
 - **Reality: ?**
- **Role of manufacturer/importer?**
- **Or role as formulator?**
 - **Hence downstream user and having other obligations**
 - **Communication in the supply chain is a key issue**
 - **Extended safety data sheet**
 - **Uses covered and the DU CSA**
 - **Substance in the authorisation process**

Registration 1 – 10 tpa



- **Interpretation of Annex III**
 - **ECHA will provide guidance**
 - **RPA study gives a first indication of difference in price (~50%)**
- **Annex VII is GPS requirement**
 - **Our SAICM contribution**
- **Expected availability of non-testing methods for the information requirements**

Table 5.8: REACH Data Requirements for Substances and Assessment of Other Information Sources

Data category/ Endpoint	QSAR (incl. Expert Systems)									
	QSAR Performance			QSAR Domain			Linked Domain	QSAR Regulatory Acceptance	Performance	
	2006	2012	2018	2006	2012	2018			2012	2012
Boiling point	GOOD	GOOD	GOOD	GOOD	GOOD	GOOD	PC 2	GOOD	-	-
Relative density	NA	GOOD	GOOD	NA	GOOD	GOOD	PC 3	GOOD	-	-
Vapour pressure	GOOD	GOOD	GOOD	GOOD	GOOD	GOOD	PC 2	GOOD	-	-
Surface tension ¹	FAIR	POOR	POOR	FAIR	POOR	POOR	PC 4	POOR	-	-
Water solubility	GOOD	GOOD	GOOD	GOOD	GOOD	GOOD	PC 5	GOOD	-	-
Partition coefficient (K _{ow})	GOOD	GOOD	GOOD	GOOD	GOOD	GOOD	PC 6	GOOD	-	-
Flashpoint	NA	POOR	POOR	NA	POOR	POOR	PC 7	POOR	-	-
Flammability	NA	POOR	POOR	NA	POOR	POOR	PC 8	POOR	-	-
Explosive properties	NA	POOR	POOR	NA	POOR	POOR	PC 9	POOR	-	-
Self-ignition temperature	NA	POOR	POOR	NA	POOR	POOR	PC 10	POOR	-	-
Oxidising properties	NA	POOR	POOR	NA	POOR	POOR	PC 11	POOR	-	-
Granulometry	-	-	-	-	-	-	-	-	-	-
Stability in organic solvents	NA	POOR	POOR	NA	POOR	POOR	PC 13	POOR	-	-
Dissociation constant	GOOD	GOOD	GOOD	GOOD	GOOD	GOOD	PC 14	GOOD	-	-
Viscosity	NA	FAIR	FAIR	NA	FAIR	FAIR	PC 15	GOOD	-	-
Human Health Endpoints										
Acute	FAIR	FAIR	GOOD	FAIR	FAIR	GOOD	HH 1	FAIR	FAIR	GOOD
Skin irritation/corrosion	GOOD	GOOD	GOOD	GOOD	GOOD	GOOD	HH 2	GOOD	GOOD	GOOD
Eye irritation	FAIR	FAIR	GOOD	FAIR	FAIR	GOOD	HH 2	GOOD	GOOD	GOOD
Skin sensitisation	FAIR	FAIR	FAIR	GOOD	FAIR	GOOD	HH 3	FAIR	POOR	FAIR
Respiratory sensitisation ¹	GOOD	POOR	FAIR	POOR	POOR	FAIR	HH 3	POOR	POOR	POOR
Repeat dose toxicity	FAIR	FAIR	FAIR	POOR	POOR	FAIR	HH 4	POOR	FAIR	GOOD
Specific organ toxicity	NA	POOR	POOR	NA	POOR	POOR	HH 4	POOR		
Reproductive toxicity	POOR	POOR	POOR	FAIR	POOR	POOR	HH 5	FAIR	FAIR	FAIR
Developmental toxicity	POOR			FAIR			HH 5		FAIR	
Mutagenicity - prokaryotic ¹	GOOD	FAIR	GOOD	GOOD	GOOD	GOOD	HH 6	GOOD	GOOD	GOOD
Mutagenicity - eukaryotic ¹		(GOOD as per REACH)					HH 6		GOOD	

Registration 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**

Registration 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**

Registration 10 – 100 tpa



- **Information requirements**
 - **Comparable information on potential alternatives and regulatory acceptance in the RPA study**
- **Chemical safety assessment**
 - **CHESAR as a good guideline for less experienced risk assessors, but who can help those without experience?**

CSR/ES roadmap – can it help?



- **Will be presented tomorrow**
 - **Offering tools and solutions**
 - **But the work has to be done by someone who understands what he/she is doing**
 - **How to select the best service provider as an SME?**



Thanks for your attention