



10th Stakeholders' Day Conference

Beyond Registration – A Lead Registrant's Perspective on the Evaluation Process

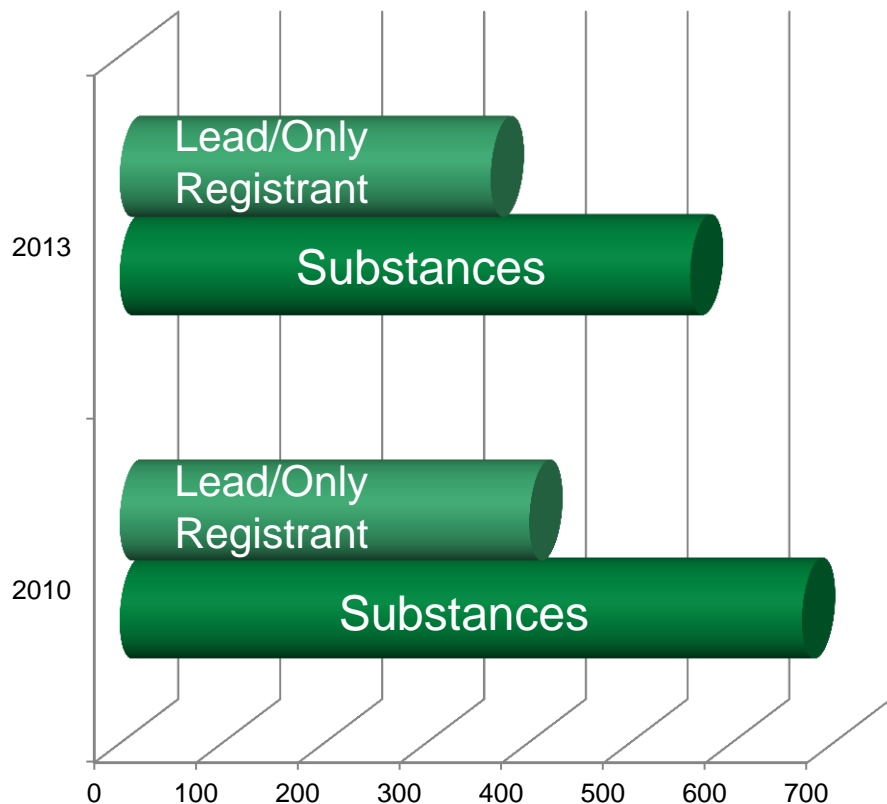
150 years

 **BASF**

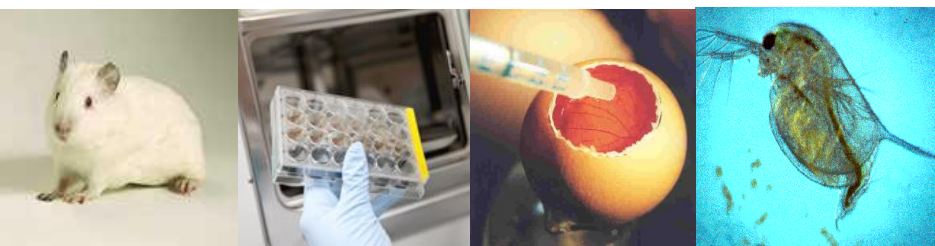
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REACH Efforts @ BASF



- 50 legal entities within the EU (plus 40 outside the EU)
- 30 REACH-coordinators in operating divisions
- 130 substance coordinators
- 70 toxicologists, ecotoxicologists, documentalists and experts for physico-chemical data
- External consultants as additional support



Example: Styrene

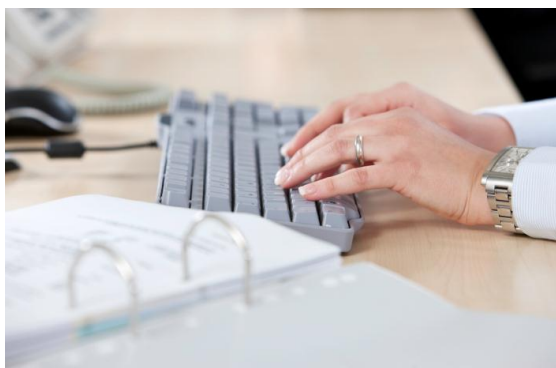
- REACH Technical Dossier (2010)
 - ▶ ca. 4200 pages
 - ▶ > 600 references
 - ▶ 819 pages CSR
- 2 updates so far
- eSDS*:
 - ▶ 68 pages, 54 pages thereof covering information about uses and corresponding exposure scenarios
 - ▶ after update: 90 pages, 71 pages thereof covering use and exposure scenarios



*eSDS: Extended Safety Data Sheet

Beyond Registration

- > 2000 regulatory/business driven dossier updates
- 341 decision letters received (dossier/substance evaluation)
- 113 substances subject to CoRAP*



*CoRAP: Community Rolling Action Plan

Experience with CoRAP

- Limited experience
- Parallel processes: compliance check & BPR* vs. CoRAP*
- Cosmetics regulation: marketing ban and new testing require
- ECHA focuses on details and dismisses Weight of Evidence
- Questionable requirements



[...] but only states that the induction of phase II catabolism in rats may have no human relevance. In order to reject rat data, proof that these are of no relevance for humans is needed. Since counter-arguments have been presented to all the [...]

Experience with CoRAP

- Cooperation with MSCAs* proved fruitful
- Industry is gaining experience in more efficient communication and documentation
- Industry consultation essential before RMOA*
- PACT* is a good first step to initiate cooperation



**Take and
adequately
consider
industry input**

**Increase
practicability
and decrease
bureaucracy**

*MSCA: Member State Competent Authority
RMOA: Risk Management Option Analysis
PACT: Public Activities Coordination Tool

150 years



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