

# REACH Review: Industry activities and views

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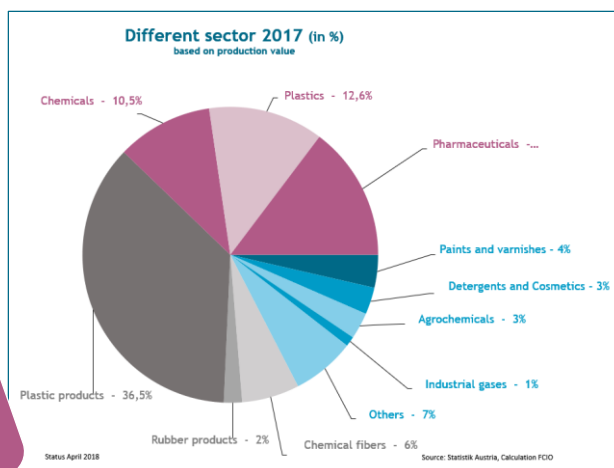
## Chemical Industry in Austria

- **Facts and Figures 2017**

- 250 Companies
- 44.650 Employees
- 15,3 bn € Production value

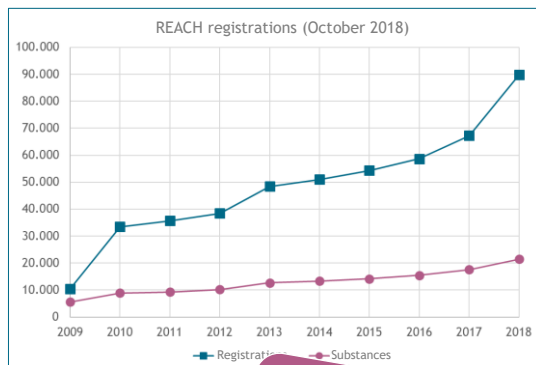
- **Manufacture of substances via chemical synthesis**
- **Formulation of mixtures**
- **Production of articles**

Austria  
Registrations: 1 187 (1%)  
Substances: 855 (3%)  
Companies: 203 (1%)



## REACH is delivering

- Registrations today
  - 90 627 dossiers for
  - 21 601 substances by
  - 14 135 companies
- REACH: most comprehensive regulatory framework for the safe use of chemicals
  - enormous amount of resources necessary for this achievement
  - improvements always possible
    - REACH review shows possible areas
- Chemical industry (manufacturers and down stream users) committed to further contribute



Adaptations only in a stable and predictable environment



## REACH Review: dossier quality & updates

- Strong commitment of the chemical industry to improve “compliance, quality and understanding of the registration dossiers”
  - Update of registration dossiers key on the basis of REACH Art. 22
    - after third registration deadline more resources available
    - advanced understanding of uses, integration of use maps (jointly developed with down stream users)
- Common understanding of “data quality” necessary
  - Integration of alternative methods to animal testing in working practice and authority acceptance necessary
    - new “in vitro” methods
    - grouping and QSARs
- Enhancement of dossier up-dates via adapted IT tools
  - e.g. REACH-IT, compatible new IUCLID versions, dissemination of information



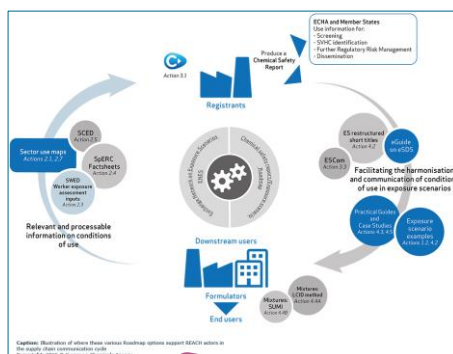
Further implementing measures not necessary!



## REACH Review: communication in the supply chain

- Improvement of workability and quality of (extended) SDS necessary

- Already very demanding requirements in REACH Annex II
  - extended SDS significantly adds to complexity
- CSR/ES Roadmap and ENES network already play an important role in providing harmonised tools and formats
  - due to complexity no straight forward implementation possible
  - simplification with the focus on “safe use of chemicals” necessary (e.g. “use maps”, SUMI)
- Promotion of already developed tools in the supply chain
  - Language often a barrier for speeding up developments



“Out of the box” thinking necessary!



## REACH Review: enhanced risk management (I)

- SVHCs, substitution, authorisation and restriction contribute to half of the actions points
  - **Action 4:** Tracking substances of concern in the supply chain
  - **Action 5:** Promote substitution of SVHCs
  - **Action 6:** Simplification for a more workable authorisation process
  - **Action 7:** Early socio-economic information for possible regulatory measures
  - **Action 8:** Improve Restriction Procedure
  - **Action 9:** Further enhance Member State involvement in the restriction procedure
  - **Action 10:** Frame the application of the precautionary principle
  - **Action 11:** Interplay between authorisation and restriction
- Effective EU-wide risk management key for the future acceptance of REACH by all stakeholders
  - proportionality vs. precautionary principle
  - level playing field between EU and non-EU companies

Right choice of regulatory risk management only with proper RMOA possible!



## REACH Review: enhanced risk management (II)

- RMOA - Risk management option analysis
  - Structured, early involvement of all actors in the supply chain necessary
  - Options outside chemical regulations need to be considered (e.g. OSH, other product regulation)
- Simplification of authorisation
  - regulatory initiatives for low tonnages and spare parts welcomed
  - additional considerations for process chemicals used in closed systems necessary
- Restrictions not only as safety net
  - EU wide restrictions in stead of (still existing) national requirements to ensure coherence of internal market
  - Restrictions of substances subject to authorisation to set level playing field between EU and non-EU companies
    - assessment on a case by case basis

Enhanced REACH risk management sufficient to ensure "non-toxic" environment



## REACH Review: precautionary principle

*This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle. - REACH Art. 1(3)*

- Precautionary principle together with proportionality applied in any EU decision making process
  - Uncertainty considerations already at the RMOA step
  - Better evaluation of scientific uncertainties in any RAC/SEAC opinions
    - SVHC identification
    - Inclusion of substances in Annex XIV
    - Restrictions

Evaluation of scientific uncertainties also for CLH opinions necessary!



## REACH Review: interfaces

- REACH and OSH
  - some REACH requirements exist because EU OSH regime perceived to be ineffective (e.g. authorisation of carcinogens and mutagens)
  - important to avoid overlaps and even conflicting requirements
    - also taking national situations (competent authorities and enforcement into account)
  - RAC vs. SCOEL: science based decision making is key
    - Role of social partners in establishing OELs need to be ensured
- REACH and waste
  - Stronger role of ECHA in SVHC communication for waste management already established by waste regime
  - Interface between REACH & waste key in circular economy discussions (**Commission Communication**)
    - Public consultation still ongoing until October 29, 2018

Clarification of other interfaces still necessary (e.g. REACH & biocides, CLP & other legislation)!



## REACH Review: other issues

- REACH & nano
  - REACH Annexes already amended to properly cover nano forms
  - Review and revision of „nano definition“ still needed
- Low tonnage substances
  - any change potentially with high impact for SMEs
  - Ongoing discussions on CMRs and Annex III exemptions
- Polymers
  - Right strategy for polymers under further assessment
    - Identification of relevant polymers
  - Stronger ECHA involvement in polymers due to plastic strategy
    - Micro plastic restriction dossier

Further development of REACH a matter of time!



## Summary

- 10 years of REACH experience: it works!
  - Chemical industry and down stream users have put an enormous effort and resources to make it work
  - Strong commitment to further improvements in dossier quality and communication in the supply chain
- Acceptance on alternative approaches to animal testing needs to improve
- Adaptations and simplification of processes necessary
  - to further enhance the safe use of chemicals through the supply chain
  - to ensure workability, especially for SMEs
- Enhanced risk management via authorisation, restriction and other regulatory options vital for the continuous success of REACH
  - proper risk management option analysis as key step

Let's REACH for the next 10 years!



## Thank you ...

**... for your attention!**

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