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Six years REACH – an industry‘s view

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Outline

- Goals of REACH Regulation (EC) No 1907/2006
- Industry's experiences and fields for improvements
  - Registration
  - Evaluation
  - Authorisation and restriction
  - Communication in the supply chain
- Conclusions

REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals

- Entered into force in June 2007 and is to be implemented stepwise by 2020 (some transitional provisions)
- Reorganizes the whole chemicals policy in Europe
- Shifts responsibility for the safe use of chemicals from authorities to industry
- Should ensure a high level of protection of human health and the environment as well as the free movement of substances … while enhancing competitiveness and innovation.
- Should contribute to realizing the Strategic Approach to International Chemical Management (SAICM) of the United Nations by 2020.

Registration
Stepwise implementation by 2018 on track

- **01.06.2008 Start registration obligation for substances ≥ 1t/a**
- 01.12.2008 End pre-registration to gain transitional terms

- 30.11.2010 End 1st registration phase (substances ≥ 1000 t/a)
- 31.05.2013 End 2nd registration phase (substances ≥ 100 t/a)

⇒ **33,000 registrations for 6,600 substances overall**

- **31.05.2018 End 3rd registration phase (substances ≥ 1t/a)**
  - small an medium sized enterprises increasingly affected
  - more substances than in 2010, 2013

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Registration
Industry's experiences

Much build-up work done by chemical industry

- REACH coordinator/team, product/substance inventories … (concerns product safety, IT, purchase, sales …)
- Concepts & tools for work in „substance information exchange forum"
- Model for consortium agreement, model for toll manufacturer addendum, model for appointment of only representative, letter of access
- Interpretations resolved, guidance on specific issues …

… under difficult (changing) conditions

- Mandatory IUCLID software and REACH-IT of ECHA were still under development, several version changes
- ECHA guidance developed and version changes in parallel to registrations, REACH annexes amended
- New interpretations by authorities (e.g. regarding intermediates)

Registration
Industry's experiences

- Administration of consortia/SIEFs brings more workload than expected
- Updating of dossiers transferred from former regulation to REACH is challenging, as only possible by auxiliary procedures implemented late
- Transfer option for registrations in case of legal entity change was implemented late and is limited to certain cases

Fields for improvements

- Stable regulatory environment is a precondition for improving efficiency
- Contact persons in ECHA needed to check intended approaches
- Guidelines: Focus should be on clarification, practical examples, efficient practical strategies – not on changes/tightening the rules
- Limit updates of registrations to scope laid down in REACH, extra work caused by software and ECHA's workflow changes should be avoided

Evaluation under REACH
Goals and possible outcome

Dossier evaluation

- Goal: Check compliance of registration with REACH provisions
- Since 2011 done by Chemicals Agency ECHA
  - for all testing proposals received during registration
  - for at least 5% of registration dossiers
    (concerns whole dossier or may be targeted to specific aspects)

Substance evaluation

- Goal: Clarify concerns regarding risks to human health or environment
- Since 2012 yearly rolling action plan for 3 years drafted by ECHA
- Evaluations done by Member States within 1 year

Possible outcome of evaluation processes

- No further action; request of further information with time limits

Evaluation of registration dossiers
Industry's experiences

- New requirements and new processes
- Learning from experiences is essential, e.g. with respect to justifications expected by authorities (level of detail, place)
- On the other hand: Competent Authorities must ensure that well-founded expert opinions and alternatives to animal testing are accepted
- So, expectations of industry and authorities have to be aligned. This requires a fair and transparent dialogue

Fields for improvements

- Positive feedback from ECHA to companies after dossier evaluations without objections
- Highlighting of problematic points by ECHA; best practice examples
- Transparent communication on ECHA's screening actions
- Contact persons at ECHA required

Evaluation of substances
Industry's experiences

- Not much experience, as process started in 2012
- Different level of industry involvement depending on lead authority

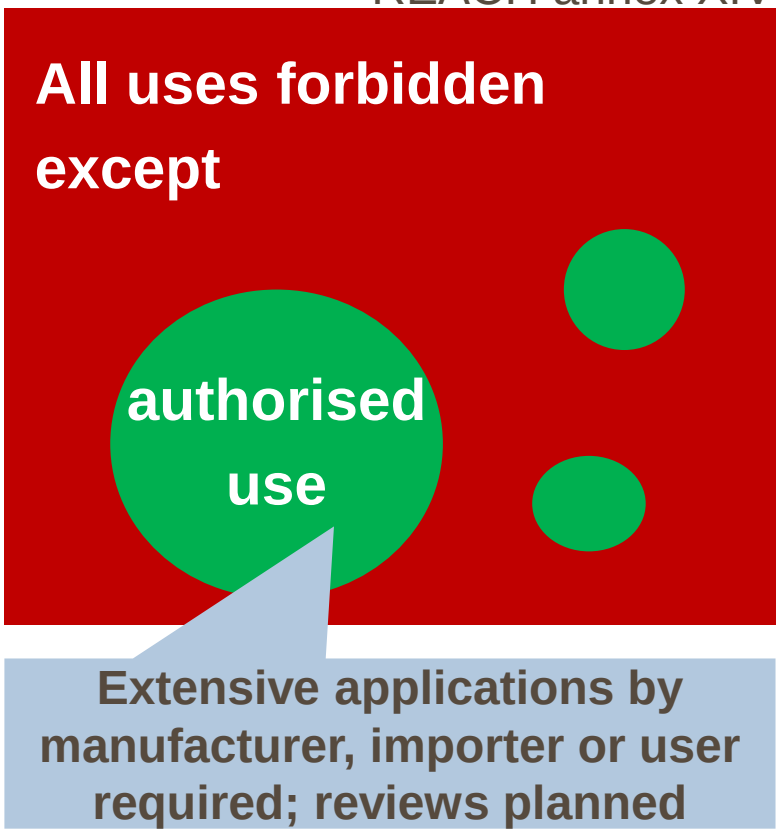
Fields for improvements

- Involvement of registrants at an early stage: EU-wide approach required
- Balance information requests to companies to information items/ studies that are proportionate and well justified by lead authorities

Authorisation and restriction
Different approaches to limit uses of substances

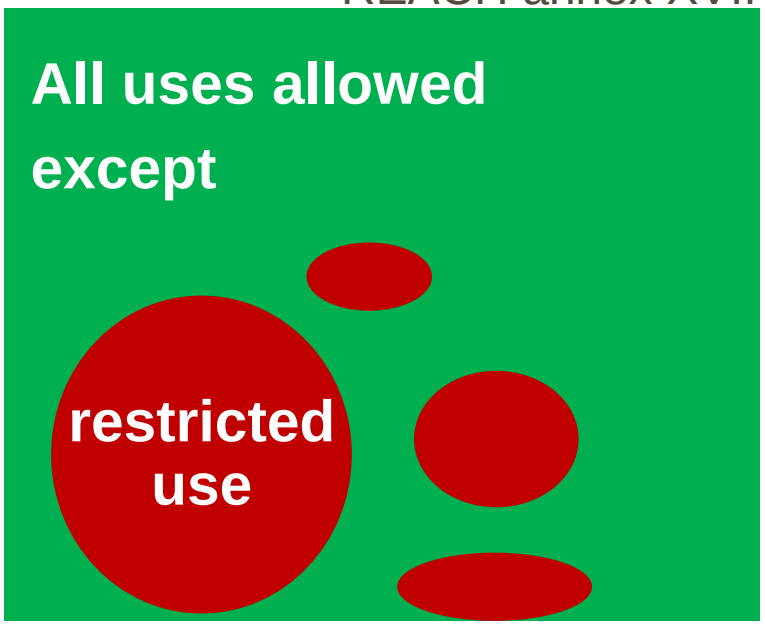
Authorisation
new process established under REACH

REACH annex XIV



Restriction
process transferred to REACH

REACH annex XVII



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Authorisation Status

Candidate list for authorisation

- **144 Substances ⇨ Information requirements**
- Identification of substances of very high concern (CMR, PBT/vPvB and equivalent level of concern)
- Additions to the list: ≅ 2 x a year (June, Dec.)
- **Commission goal: include all relevant substances in candidate list by 2020**

Annex XIV substances subject to authorisation

- **22 Substances ⇨ no further use without authorisation granted after sunset date** (Exemption: Intermediates)
- Additions to the list: ≅ 1 x a year

Authorisation Application

- **First application for Authorisation received at ECHA**
- Substance-related deadline for submission of applications to ECHA
- 18 months later: no use unless authorised
- Authorisations granted are subject to regular reviews

CMR: carcinogenic, mutagenic or toxic to reproduction;
PBT: persistent, bioaccumulative and toxic; vPvB: very persistent and very bioaccumulative

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Authorisation
Industry's experiences

- Candidate list for authorisation is seen as a „black list" by some sectors: Regulation stipulates information about candidate substances in articles – market reacts with phase-out of candidate substances.
- The authorisation process is politically affected:
  In 2012 some substances were brought on the candidate list just to gain numbers announced by the Commission – regardless their relevance.
- Application for authorisation is new, costly and subject to reviews:
  Costs and efforts are high. Experience with socio-economic analysis is limited.
- Cooperation of companies has restrictions by competition law.
- Risk Management Options analysis approach for improving the SVHC identification process as proposed by the European Commission beginning of 2013 is supported by industry.

Fields for improvements

- Risk management options analysis (RMO) should be done for each substance to decide on the option(s) best suited for risk management of substance uses
- Companies affected should be involved at an early stage of the RMO to adequately take into account all available knowledge
- Exemptions because of other EU regulations or RMO analysis should be considered when drafting an annex XIV entry.

Supply chain communication
Developments of safety data sheets under REACH and CLP

- Safety data sheets (SDS) remain the main communication instrument
- New SDS format from 2010, new parameters and annex with exposure scenarios under REACH; in addition new classification and labelling scheme acc. to CLP regulation
- Further changes of SDS content required by June 2015 and 2018
- Downstream users need to check whether uses of their substances were taken into account following receipt of the SDS
- Suppliers of mixtures have to consider exposure scenarios of substances when drafting SDS (include information in main body or attachment of annex)

Supply chain communication
Industry's experiences

- More communication between supplier and customer on safe use of substances and mixtures under REACH; many industry activities
- All actors are learning new terminology and assessment steps
- Current SDS are perceived as overly comprehensive and unintelligible
- Initiative started by authorities and industries to improve exposure information and risk management instructions in registrations and safety data sheets; stepwise implementation by 2018

Fields for improvements

- IT tools to be developed to facilitate assessment activities, translation of standardized content required
- Improvement of readability of SDS by harmonisation of content; to be checked where this is possible and where diversity is reasonable
- Simplifications, e.g. for professional end-users/craftsmen

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Conclusions

- Much built-up work has been done by industry and authorities …. and is ongoing
- REACH overall works so far. Judgments on workability for small and medium sized enterprises/complex supply chains are premature.
- Now it is time to learn from experiences to improve processes; therefore a stable regulatory environment is needed as stated in the report on REACH by the European Commission in February 2013.
- Studies already show positive REACH effects for human health and environmental protection. Companies have high registration and staff costs. Thus, effects on competitiveness are to be carefully monitored.
- Overall consequences from REACH for business processes and product portfolios will be assessable after 2018 at the earliest.
- Support from science appreciated: Contributions to non-animal testing approaches by developing alternative tests, support for read-across
- Problems should be solved in a fair communication between authorities and companies/associations concerned.

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More information?

On the internet:

Brochure „REACH und GHS“ (2011)

http://www.vci.de/Services/Publikationen/chemie-report/Seiten/chemie-report-spezial-5-2011.aspx

Article „Five years REACH: lessons learned and first experiences – an industry’s view“ (2013)

http://www.enveurope.com/content/25/1/19

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