Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

REACH
Member States` perspective to accelerate the program

Alexander Nies

Federal Ministry for the Environment,
Nature Conservation and Nuclear Safety
Directorate Environmental Health, Chemical Safety
Bonn

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

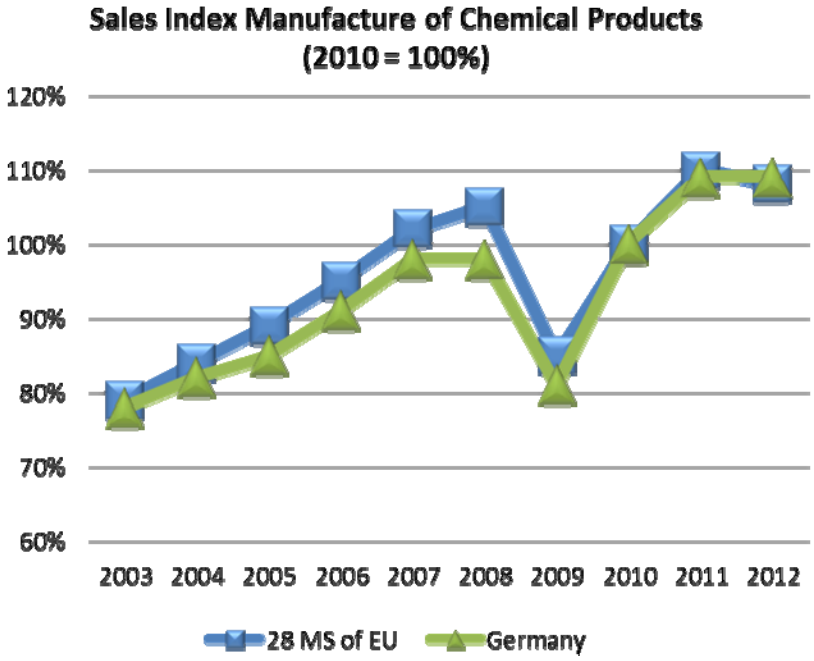
Content

- Achievements
- **R**egistration
- **E**valuation
- **A**uthorisation and Restriction (Risk Management) of **Ch**emicals
- Challenge nanomaterials
- Summary/Conclusions

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Achievements – general appreciation

- REACH is working, no fatal drawbacks
- Challenge has been mastered
- Industry accepts REACH
- ECHA at cruising speed
- REACH triggers chemical regulations in other parts of the world



Reference: Eurostat

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Achievements - Highlights

- Two registration deadlines mastered
- Evaluation of more than 500 testing proposals
- Two Community Rolling Action Plans
- Restriction processes initiated
- Identification of some 150 SVHCs
- More than 20 SVHCs in Annex XIV

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Challenges (1) – Dossier quality

- Considerable number of dossiers needs improvement
- Improvement needed in early stages of dossier processing (preparation, submission)
- Special issue: Substance identity
- Crucial role of completeness check

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Challenges (1) – Dossier quality

- Art. 20 para 2 says
  "The Agency shall undertake a completeness check of each registration in order to ascertain that all the elements required under Articles (…) have been provided. The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted."
- Possibilities to reject dossiers with deficiencies should be used to the extent possible at the registration stage
- Technically challenging, but crucial
- Limitations of IT tools should be overcome by manual activities if needed

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Challenges (1) – Dossier quality

- Considerable number of dossiers with unclear description of substance identity
- Art. 20 para 3 says:
  "Once the registration is complete, the Agency shall assign a registration number to the substance concerned...."
- Clarification of substance identity
  - is legally prescribed
  - must take place before registration number is assigned
  - avoids tremendous trouble in all subsequent steps

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Challenges (2) – Compliance Check

- Paradigm change with REACH:
  Provision of all relevant data for substances on the market is industry´s responsibility
- Main control instrument of ECHA: Compliance Check
- Compliance checks can examine the whole dossier or parts of it (Art. 41 para 1)
- Selection of dossiers for compliance check is an important strategic step

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

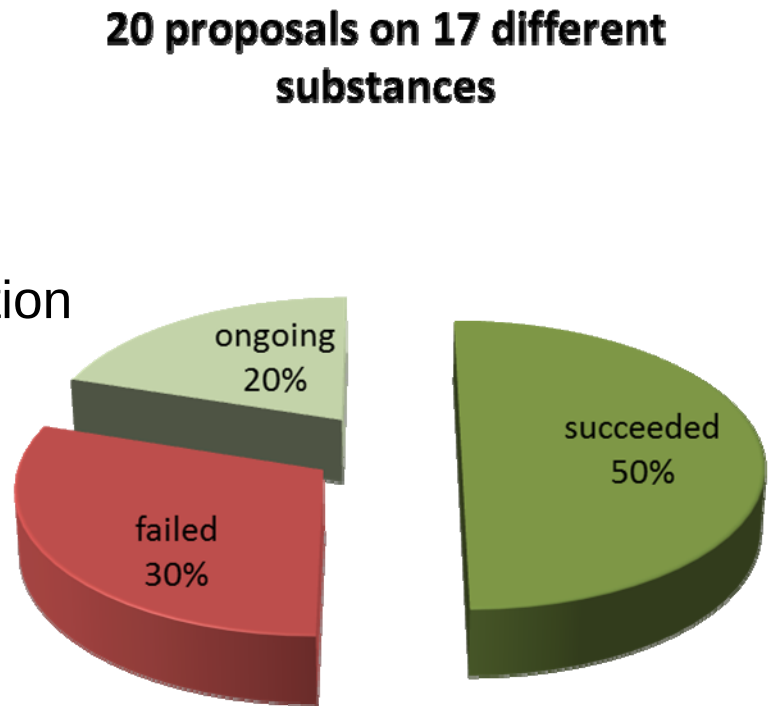
Challenges (2) – Compliance Check

- Art 41 para 5: "The ensure that registration dossiers comply with this Regulation, the Agency shall select a percentage of those dossiers, no lower than 5 % of the total received by the Agency for each tonnage band, for compliance checking."
- Legal interpretation: to fulfil the 5 % criterion the entire dossier (and not only part of it) must be checked for compliance
- If partial (so called) targeted compliance checks are counted then at least key information / endpoints must have been checked
- The less information of a dossier is checked in a targeted compliance check, the more the spirit of Art. 41 para 5 is circumvented
- Further disadvantages of targeted CCs: repeated loops in decision making with ECHA, follow up actions and enforcement

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Challenges (3) - Restrictions

- Very flexible & precise risk management instrument
- By far most demanding process
- requires demonstration of
  - risk
  - Need for community-wide action
  - Socio-economic impact
  - Alternatives
- High failure rate



Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

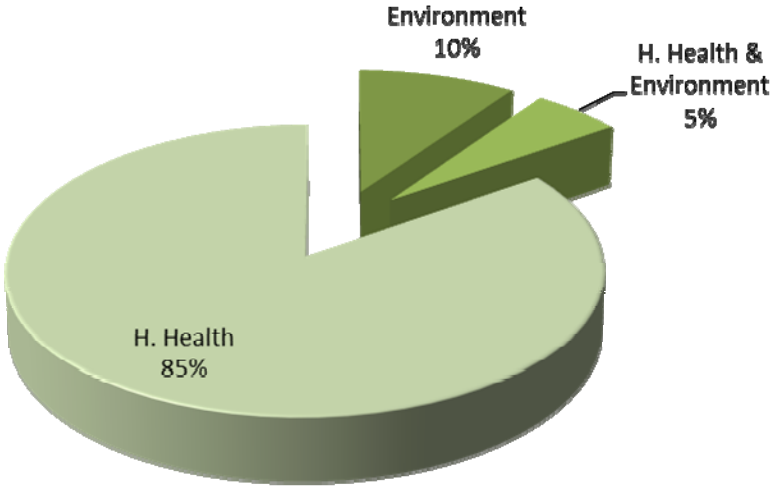
Challenges (3) – Restrictions

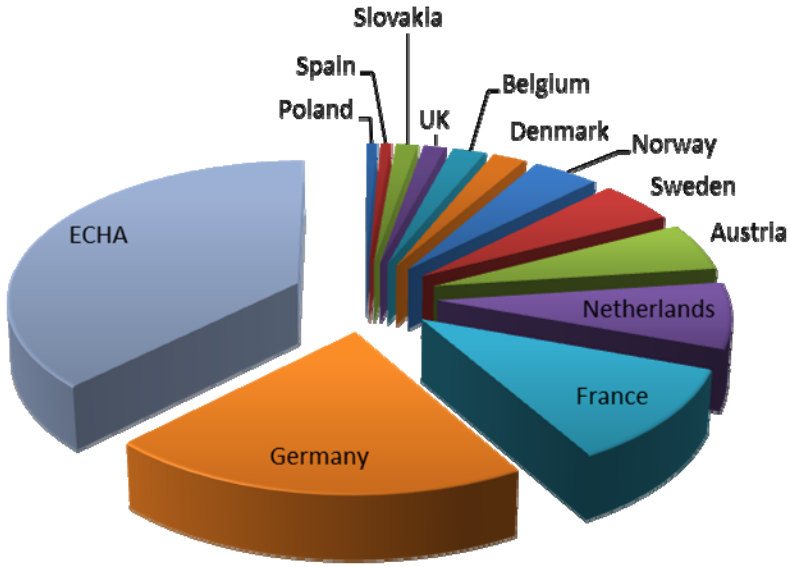
- Regarding restrictions, REACH is an improvement compared to old regime
- Challenging restriction regime adequately corresponds to potential far - reaching impact of restriction decisions
- Deliberations on increased efficiency are presently on-going. Thoughts under discussion :
  - Restriction dossiers need more focus
  - MS support to RAC members to be enhanced
  - Process – related improvements

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Challenges (4) - Authorisation

- The Candidate List: 144 substances (22 on Annex XIV)





Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Challenges (4) - Authorisations

- Germany fully supports the proposed SVHC Roadmap 2020
- Furthermore a Risk Management Roadmap is needed that considers all chemicals and all regulatory options
- 2013 is critical year for authorisation procedures to be started
- Successful authorisations urgently needed to provide confidence in the procedure

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Consumers' Right to be informed

- Request by consumers: information on SVHC and safe use
- Suppliers: provide information within 45 days
- Automatic generation of requests with online tools
- Further simplification: scanning of barcodes with smartphone-app

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Challenge nanomaterials (NMs)

- NM new opportunities – new properties – new regulation needed?
- Commission´s second Regulatory Review on NM and REACH Review discuss the need for adapting REACH to NM
- Proposal from BAuA, BfR, UBA (adaptation of REACH) “NMs and REACH - Background Paper on the Position of German Competent Authorities” (published 1/2013)
- Commission plans to focus on REACH Annexes
- Proposal from BAuA, BfR, UBA for the adaptation of REACH Annexes, 2013

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Challenge NMs and the next steps

- EU Commission; Consultation on the modification of the REACH Annexes on NM (until 13.09.2013)
  - Proposal from EU Commission expected by end of 2013
- Registers of Products Containing NMs
  - National register in FR; in BE and DK consultations for national registers
  - Germany: no national register planned, but support for a European register if planned
  - EU-Commission: Tender for a Study to assess the impact of possible legislation 2013-2014

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Conclusions – acceleration of program

- Industry: improve quality of registration dossiers
- All Member States: increase implementation efforts
- ECHA:
  - Make completeness check an efficient control tool
  - Unclear substance identity is prohibitive for assignment of registration number
  - compliance check: all relevant endpoints of all lead dossiers
  - Make SVHC Roadmap a reality
  - Improve restriction procedures
- Commission: Development of a RMM Roadmap
- Simplify access to information for consumers
- Adaptation of REACH to adequately regulate NMs

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Thank you for your kind attention.

Want to know more about 5 years of REACH?

http://www.enveurope.com/series/FYR