Contributions of ECHA to the achievement of the REACH goals

5 Jahre REACH und weitere Beitrage zur Nachhaltigen Chemie

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Content of Discussion

- ECHA & our roles
- REACH Review & contributions to protection of health & the environment
- Achievements to date
- Substance evaluation
- Risk management activities, SVHCs & the Roadmap
- Multi-Annual Work Programme 2014 to 2018, ECHA's Strategic Aims & future work & challenges
- Reaching out to SMEs

ECHA – five years old and growing

- Started on 1 June 2007
- Over 550 staff from 27 countries
- Modern, science-driven organisation, grown rapidly to one of the largest EU agencies.
- Originally REACH
- Since 2009 Classification, Labelling & Packaging Regulation
- Now Biocides & Prior Informed Consent Regulations

REACH & CLP

- **Pre-registration**
- **Data sharing**
- **Registration**
- **Self-Classification**

Industry gathers information and ensures responsible and well-informed management of the risks

ECHA

MSs

- **Evaluation**
  - **Dossier evaluation**
  - **Substance evaluation**

ECHA and MSCAs control and request for further info

- **Authorisation**
- **Restriction**
- **Harmonised C&L**

COM, with support of ECHA and MSCAs, applies community wide risk management measures

Background – past five years

- REACH aims to advance knowledge on the properties & uses of substances:
  - Better safety & control measures
  - Reduced risk for human health & the environment
- REACH & CLP are working well:
  - Registration and Dissemination: wealth of information on properties & uses of chemicals collected & publically available
- Eurostat Baseline study five years update reveals a ”marked increase in quality of data & better control of risk” as a result of the first registration phase

Review on REACH: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0049:FIN:EN:PDF
REACH Baseline update: http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-RA-12-024/EN/KS-RA-12-024-EN.PDF

REACH Review: overall outcomes & recommendations

- REACH is successful so far: it has delivered on all objectives that can be assessed at present
- Some needs for adjustments, but this has to be balanced against legislative stability and predictability: no legislative changes to the REACH Regulation
- Need to assist SMEs more
- Opportunities for improvement by optimizing implementation at all levels
- Commitment of all actors is necessary: ECHA, EU Member States, European Commission, industry and stakeholders

REACH Review: findings relating to protection of health & environment

- ECHA has a key role in the management of REACH:
  - Successful start-up
  - Now working at 'cruising speed'
- Positive initial trends for substances already registered:
  - More & better hazard information
  - Better risk assessment by CSRs
  - Better targeted risk management measures
  - Significant decrease in the risks for exposure
  - Increased moves towards substitution of SVHCs
- Better risk communication in supply chains by improved eSDSs
- Indication that use of CMRs may be reduced (i.e. < half CMRs registered)

Achievements to date

- Dissemination of over 40,000 registration dossiers covering over 10,000 substances
- All confidentiality claims submitted for 2010 deadline dossiers concluded
- C&L inventory published (close to 6 million notifications of >110,000 substances)
- Testing proposals from 2010 first registration deadline examined
- Candidate List of 144 SVHCs & 22 on the Authorisation List

Particular challenges for 2013: a peak year for REACH & ECHA

- Second registration deadline 31/5/13 and follow-up actions
- 5% compliance check target for registrations from the first deadline by the year end
- First authorisation applications to be processed
- Entry into operation of Biocides Regulation in September

Substance evaluation (SeV)

- REACH process **clarifying any potential risk** related to a substance (**outcome**: further data clarifying hazard &/or exposure issues)
- **Community Rolling Action Plan** ('CoRAP') as a 'rolling' 3-year list of substances to be evaluated, updated annually
  - Started in 2012
  - Adoption and publication by end of March each year
  - Draft of the CoRAP published for information in the previous October
- Member States undertake the evaluation within 12 months from the CoRAP publication. Input by industry & stakeholders can be made to the evaluating Member States
- Draft decisions prepared by MSCAs from the 2012 CoRAP under decision making process; publication of first evaluation reports imminent

Picking substances for evaluation

e.g. CoRAP 2013-2015

IT based pre-selection
IUCLID database

Manual screening:
(by ECHA & MSs = 365s)

Outcome of dossier evaluation

MSCA's notifications (Art. 45(5))

List of candidate CoRAP Substances (109s)

Allocation to evaluating MSs (63s)

1st CoRAP 2012-2014 (53s)

Draft CoRAP 2013-2015 (116s)

MSC opinion

adoption and publication

Final CoRAP (115)

Only registered substances

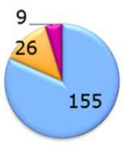
How substances are selected for risk management activities

Screenings

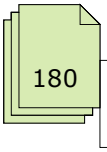
- Done by MS, group of MSs, ECHA

Annex XIV recommendations
- Prioritisation: generic approach papers, 5 prioritisation rounds
- Entries and exemptions: generic approach, LADs
- 3 amendments of AXIV

SVHC identification



Σ 144 substances



RMOs
- ~ 180 done on single substances or groups of substances

Authorisation application and granting
- Designing and management of application process with MS and stakeholders
- Clarification of open issues
- Processing now first applications

Political support for the 2020 SVHC Roadmap

- In 2010 Vice-President Tajani & Commissioner Potočnik committed to 'have a candidate list of 136 Substances of Very High Concern by the end of 2012': this was achieved
- In 2013 they committed to a 2020 Roadmap:
  - to 'have all relevant currently known SVHCs included in the candidate list by 2020'
  - to deliver this 'should build on the RMO framework, setting out clear milestones, deliverables and division of work between COM, MSs & ECHA'
- Development & agreement on the Roadmap:
  - MSCAs, COM & ECHA discussions November 2012 to March 2013
  - Competitiveness Council in February 2013
  - Environmental Council in March 2013

SVHC Roadmap Implementation plan

Implementation plan:

- Workshop for MSCAs in April 2013
- Draft plan discussed in July 2013 *ad hoc* MSCAs meeting
- Aim to agree on & publish the implementation plan by end 2013
- Stakeholder workshop planned to inform & seek feedback

Groups of substances:

- CMRs 1A/1B
- Sensitisers
- PBTs / vPvBs
- Endocrine Disrupters
- Petroleum/coal stream substances which are CMRs or PBTs/vPvBs

Main elements of the SVHC Roadmap

- Screening of substances
  - Identification of substances for further work
- Risk management option (RMO) analysis
  - identification of the regulatory instruments to be used
- Communication to increase predictability & transparency
  - Public version of the implementation plan
  - Periodic plans for screening & RMO
  - RMO conclusions
  - Report on progress

Multi-Annual Work Programme 2014 to 2018 & Strategic Aims

Four strategic aims developed to support prioritisation & guide how ECHA:

- approaches its activities
- allocates resources
- motivates its staff

1. Getting better quality data from industry
2. Using data intelligently for identifying and addressing chemicals of concern
3. Becoming the regulatory science hub
4. Using resources efficiently and effectively

Main body of the text will remain unchanged, with milestones to be revised annually

Future work and challenges for ECHA

- Dossier evaluation
  - Examination of Testing Proposals from the second registration deadline
  - Compliance checks of at least 5% of dossiers
    - Targeted CCHs based on evolving Areas of Concern & full CCHs
- Substance evaluation work: mix of decisions, assessments & co-operation planning
- Help industry improve the quality of
  - Registrations
  - Chemical Safety Reports
  - Exposure Scenarios
- Active involvement in the CSR/ES roadmap – a cross-stakeholder plan of actions

Future work and challenges for ECHA (continued)

- Scientific challenges, e.g.
  - Non-test methods
  - Nanomaterials
  - Endocrine disruptors
  - Mixture/combined exposure (eco)toxicity
- Co-operation with other EU agencies & non-EU regulators: e.g. US, Canada, Australia & Japan
- Implement Biocides & PIC Regulations

REACH & CLP for SMEs

- More inexperienced registrants (SMEs, 'near SMEs') expected for the 2018 registration deadline.
- SMEs not only registrants, i.e. they are mainly DUs with obligations to communicate in the supply chain
- Country-specific differences, large variety, medium to micro
- Implementation of REACH depends on SMEs adequately fulfilling their obligations
- Many SMEs still unaware of REACH (DU) duties

ECHA's on-going support to SMEs

- Training of national helpdesks (through HelpNet)
  - Frontline public actors supporting SMEs
- Supportive services for duty holders
  - ECHA Helpdesk
  - User manuals for ECHA's IT tools in all official EU languages, IUCLID pop-ups
  - ECHA-term, Chesar link to ESCom (Exposure Scenario communication)
  - Webinars, video tutorials
  - ENES (clarifying, exemplifying & standardising ESs)

Initiatives ahead to help SMEs

- Reviewing SME needs for 2018
- Questionnaire to SMEs having registered 2013
- Addressing costs associated with preparing registration dossiers
  - Recommendations on cost and data sharing (LoA) together with COM & industry associations
- Providing user-friendly support material
  - More 'guidance in a nutshell', simpler language
  - Revised SME pages on ECHA website
- Explore simplification of IT-tools