ECHA's New Strategy to Ensure Data Quality in REACH Registrations

Mind the Gap – Data Availability in REACH Registrations, BfR-Workshop, 2 March 2015, Berlin

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Availability of REACH and CLP related information

Availability of REACH and CLP related information

- The ECHA REACH Registration Database has information on
  - 13,003 unique substances from 50,164 registration dossiers (including those from previous legislation)
  - generated by industry in line with their responsibilities under the EU chemicals legislation
- The ECHA C&L Inventory has information on 117 000 substances from over 6 million C&L notifications
- Unique sources of information on the chemicals manufactured and imported in Europe
- Covers hazardous properties, classification and information on how to use them safely

Effects of REACH and CLP related information - 1

- Valuable resource for advancing the safe use of chemicals and for the replacement of the most hazardous ones by safer alternatives
- European Commission review of the REACH Regulation (published in 2013):
  - *"REACH has brought significant improvements in the management of chemical risks through the registration, evaluation, authorisation and restriction processes."*
- Eurostat monitoring of REACH effects:
  - Marked increase in the quality of data as a result of the first REACH registration and marked decrease in the risk associated to substances already registered

Effects of REACH and CLP related information - 2

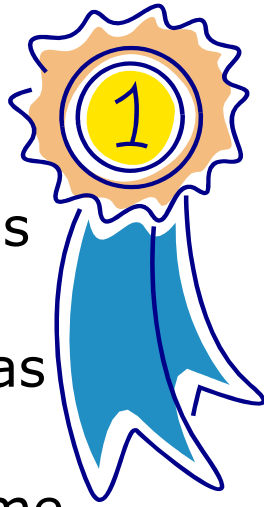
- Increased information has resulted in changes in hazard classification, with the majority becoming more stringent
- Increased information in the chemical supply chain and improved safety data sheets is resulting in more appropriate risk management measures
  - contributing to observed reduction in nominal risk
  - has benefited end-users, such as article producers

Effects of REACH and CLP related information - 3

- REACH and CLP data have allowed authorities systematically screen substances on the EU market and has improved the prioritisation of the substances for further action

Quality of REACH related information

Quality of information - 1



- High quality chemical information is information that is scientifically sound, understandable and reliable
- Quality of information available for risk assessment has improved if compared with the pre-REACH situation
- However, the Commission REACH review indicates some key shortcomings - may hinder achievement of the benefits:
  - Many REACH registration dossiers are non-compliant with REACH information requirements
  - Registrants not documenting sufficiently chemical safety assessment

Quality of information - 2

- By the end of 2013 ECHA had concluded compliance checks for over 1 000 registration dossiers over 100 tonnes submitted for the first REACH registration deadline
- **69%** of these evaluated dossiers were found to be partly or substantially non-compliant
- Main reasons for shortcomings:
  - deficiencies in substance identity (SID) information
  - insufficient justification for not submitting the required studies
  - missing information in chemical safety report
- NB: quality of SID information has since improved
  - 71% of dossiers submitted in 2013 did not present shortcomings in SID, increasing to 78% in 2014

Quality of information - 3

- Evaluation Report 2014 – published 26 February 2015
  - Largely similar findings as before - **61%** of evaluated dossiers found to be partly or substantially non-compliant
    - NB: Due to selection of dossiers with clear indications of potential non-compliance, this proportion is not a reliable indicator of the overall data quality of the whole registration database
  - In 72% of cases, the evaluation could be completed as the registrant had complied with the decision
  - The compliance rate has grown from 2013, when 64% of the registrants provided the information requested

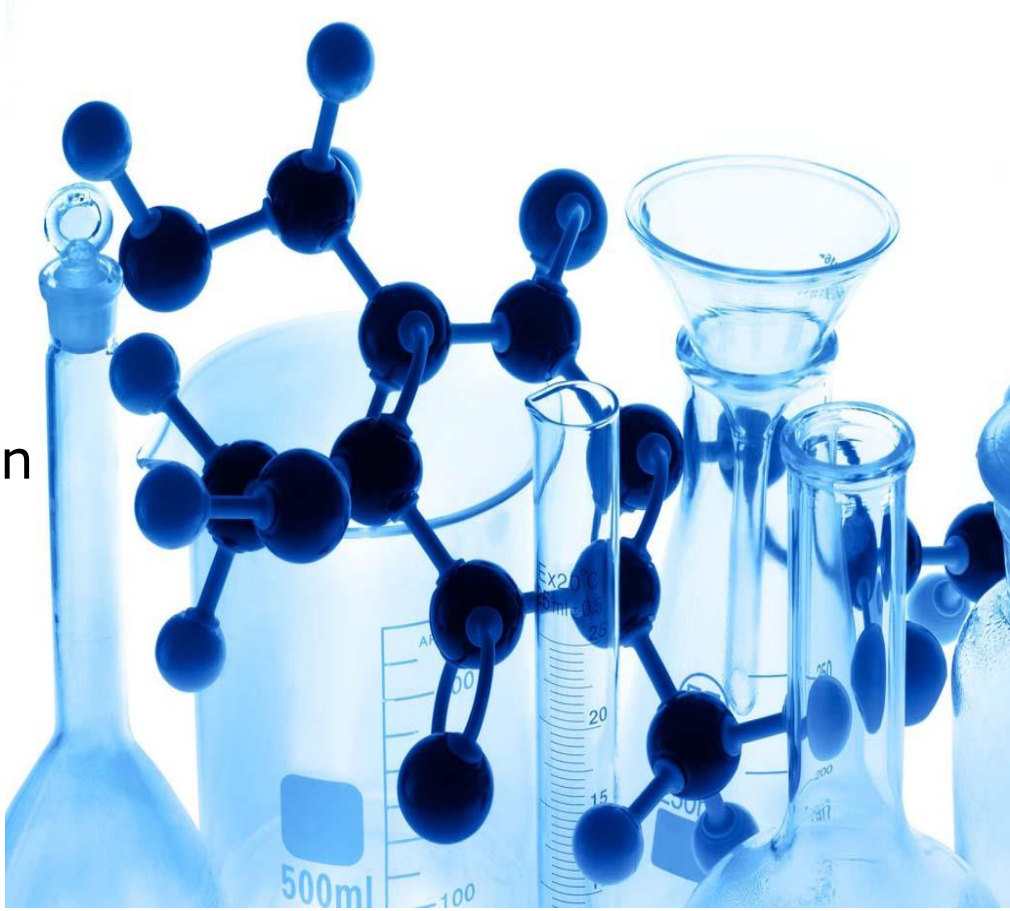
Quality of information - 4

- Improved quality of the information in the REACH registration dossiers is one of ECHA strategic objectives
- ECHA has strengthened and continues to enhance its dossier compliance check activities and other measures to improve dossier quality
- To maximise the impact on the safe use of chemicals, ECHA is changing how it selects and checks the compliance of registration dossiers
  - **Revised compliance check strategy**

Revised compliance check strategy

Revised compliance check strategy

- Strategy builds on internal review and involvement of MSCAs and stakeholders
- ECHA's Management Board endorsed the new strategy in September[1]
- Implementation starting from 2015 onwards



[1] **Published at:** http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf

Safer chemicals - focusing on what matters most

- Focus on checking information on substances that have biggest impact on improved protection of people and the environment
- Selection of substances for compliance check (CCH) - aligned with the selection of substances for substance evaluation and regulatory risk management measures
- Outcome of CCH better integrated with other REACH and CLP processes
- CCH and other regulatory measures to improve data quality will be better coordinated with non-regulatory measures
  - Link to ECHA's second Strategic Objective

Priorities for CCH

- Integrated selection and priority setting:
  - In selecting dossiers for compliance check and other measures, priority is given to substances which have
    - one or more suspected data gaps in the higher tier human health or environment endpoints (see below) **and**
    - high potential for exposure of humans or environment and hence relevance for safe use

- Priority is given to standard, lead and individual dossiers of chemicals produced in volumes over 100 tonnes per year (i.e. the two highest tonnage bands)

Priorities for the implementation of the integrated screening according to the new strategy - details

- The substances / dossiers are selected for action based on screening of the hazard information in the registration dossiers or based on estimation of hazard using external data
- The high potential for exposure of humans or environment leading to high selection priority is indicated by
  - **either** low level of control or use sector with high potential exposure
  - **or** use of substances in articles with high potential exposure

Integrated screening of substances of concern

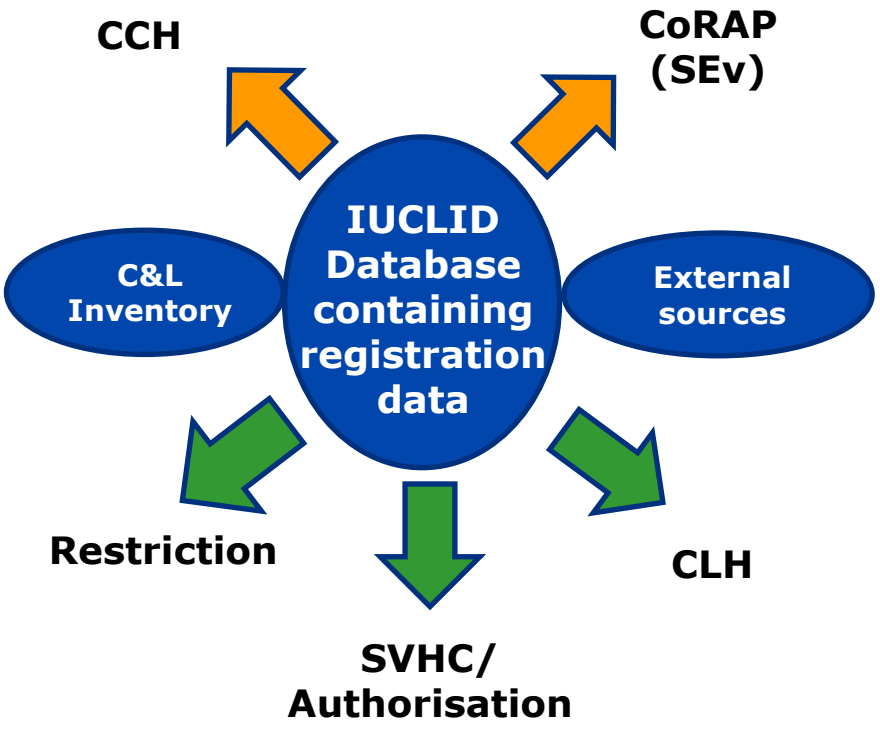
- Use of all available data
- Allocate identified substances to the appropriate process:

Further information generation

- Substance evaluation (SEv)
- Compliance check (CCH)

Regulatory risk management

- Harmonised classification and labelling (CLH)
- Identification of SVHCs (possibly leading to Authorisation)
- Restriction



Scope of CCH - "Fit for purpose"

- "Fit for purpose" CCH instead of "one size fits all"
  - The scope of CCH will be matched with potential concerns identified (e.g. may include relevant endpoints of "equal concern" and elements of CSR)
  - The IT screening results, manual screening and expert judgement all play a role in defining the scope

- The substance identity, to the extent relevant, is always assessed once a dossier is opened for CCH

Main focus in CCH: eight 'super' endpoints

- Main focus in CCH is on eight key endpoints – essential for identification of substances of concern

- Human health
  - genotoxicity
  - repeated-dose toxicity
  - pre-natal developmental toxicity
  - reproduction toxicity
  - carcinogenicity

- Environment
  - long-term aquatic toxicity
  - biodegradation
  - bioaccumulation

Impact on CCH outputs and 5% CCH target for 100-1000 tpa registrations

Planned output - tentative	2015	2016	2017	2018
Number of concluded new CCH	200	225	250	300
Number of draft CCH decisions	155	180	200	240

- Despite reduction in quantitative output if compared with 2012-2013, increase in expected impact
- Assuming 50-50 division of compliance checks on the two highest tonnage band dossiers, by end of 2018 ECHA should have concluded compliance check on 5 % of 100 – 1000 tn dossiers

Challenges in implementing the CCH strategy

- Insufficient use information in the registration dossiers preventing proper priority setting
- Resources available for CCH
- Competing policy objectives between the last resort principle and improving quality of information
- Difficulties in national enforcement of ECHA's decisions

Other measures to improve the information on chemicals

Other ECHA measures to improve quality of information

- ECHA guidance, IT-tools, webinars and website
- Annual ECHA Evaluation report gives feedback and concrete recommendations
- Compliance check decisions published on ECHA's website - important source of learning
- Regularly updated list of potential compliance check substances
- Targeted campaigns to registrants to provoke dossier updates before launching compliance checks
- Improving dissemination of information from registration dossiers online enabling interested parties to see which parts of dossiers have been updated.

Actors to improve quality of REACH related information

- Industry needs to take full ownership of its registration dossiers and proactively work on their quality, even after submission to ECHA
- There is a need to mobilise all actors to initiate also complementary measures besides compliance checks
- An active role of all different actors (MSCAs, ECHA, European Commission, industry and NGOs) is important
  - This project by Germany is a very welcome initiative!

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