helpdesk luxembourg
REACH&CLP
Un service du Luxembourg Institute of Science and Technology
En partenariat avec le Ministère du Développement durable et des Infrastructures
et le Ministère de l'Economie

Actions for the REACH review

Arno Biwer
REACH&CLP Helpdesk Luxembourg
Luxembourg Institute of Science and Technology

REACH&CLP Annual conference
6th December 2018

helpdesk luxembourg
REACH & CLP
Un service du Luxembourg Institute of Science and Technology
En partenariat avec le Ministère du Développement durable et des Infrastructures et le Ministère de l'Economie

Introduction

- Commission General Report on the operation of REACH and review of certain elements {SWD(2018) 58 final},
- Second REACH Review (after 10 years), March 2018
- Part of Regulatory Fitness and Performance Programme (REFIT)

EUROPEAN
COMMISSION

Brussels, 5.3.2018
COM(2018) 116 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

Commission General Report on the operation of REACH and review of certain elements

Conclusions and Actions

helpdesk luxembourg
REACH & CLP
Un service du Luxembourg Institute of Science and Technology
En partenariat avec le Ministère du Développement durable et des Infrastructures et le Ministère de l'Economie

General findings

- Major shortcomings/issues:
  - Non-compliance of registration dossiers
  - Simplification of the authorisation process
  - Ensuring a level playing field with non-EU companies through effective restrictions and enforcement
  - Clarifying the interface between REACH and other EU legislation, in particular that on occupational safety and health (OSH) and on waste
  - Affordability of registration requirements for low tonnage substances and registration of certain polymers
  - Companies struggle response to citizens right to ask companies whether the articles they supply contain SVHCs

helpdesk luxembourg
REACH & CLP
Un service du Luxembourg Institute of Science and Technology
En partenariat avec le Ministère du Développement durable et des Infrastructures et le Ministère de l'Economie

General findings

- Industry responsibilities
  - Update registration dossiers
  - Registration: Rectify important data gaps or inappropriate adaptations to testing
  - Information flow through the supply chain needs to be more efficient (e.g. reduce costs of producing and supplying Safety Data Sheets), especially for SMEs
  - Improve ability of companies to develop specific exposure scenarios (incl. mixtures)
  - Implement obligation to notify substances of very high concern in articles
- Actions by Member States and Commission
  - More effective and harmonised enforcement of REACH
  - Identification of new SVHCs, applying assessment of groups of similar substances
  - Additional information needs for nanomaterials by proposed amendments to the REACH Annexes

helpdesk luxembourg
REACH & CLP
Un service du Luxembourg Institute of Science and Technology
En partenariat avec le Ministère du Développement durable et des Infrastructures et le Ministère de l'Economie

Actions: Knowledge and management of chemicals throughout the supply chain

- Action 1: Encourage updating of registration dossiers
  - Commission, ECHA, Member States and industry: Identify why registrants are not updating their dossiers and make proposals for improvements
- Action 2: Improve evaluation procedures
  - Indirect effect to industry through more evaluation decisions
- Action 3: Improving the workability and quality of extended Safety Data Sheets
  - Industry sectors: Develop harmonised formats and IT tools with user-targeted information for simplified preparation and use of extended Safety Data Sheets incl. electronic distribution
  - Commission will consider setting minimum requirements for the exposure scenarios
- Action 4: Tracking substances of concern in the supply chain
  - Tracking system for substances of concern in the supply chain (Waste Framework Directive)

Actions: Enhanced risk management - Authorisation

- Action 5: Promote substitution of SVHCs
  - Increase support activities to facilitate substitution of SVHCs (e.g. promote capacity building and collaborative networks and promoting R&D investment)
- Action 6: Simplification for a more workable authorisation process
  - Simplified applications: Use of SVHCs in legacy spare parts
  - Simplified applications: low volume applications
  - Assess difficulties for applications for authorisation covering multiple operators
  - Reduce fees for applicants in joint applications for authorisation
- Action 7: Early socio-economic information for possible regulatory measures
  - ECHA, Commission, Member States will consider options to further develop and use available socio-economic information for consideration at the RMOA stage (Risk Management Options Analysis).

Actions: Enhanced risk management - Restriction

- Action 8: Improve Restriction Procedure
  - Clarify information needed from public consultations, including minimum information by industry when requesting derogations from restrictions
  - Identify relevant cases for restriction from ECHA's regular screening activities
  - Identify suitable cases for restricting further CMR substances in consumer articles
- Action 9: Further enhance Member State involvement in the restriction procedure
  - Simplify the requirements for restriction dossiers to increase # of new restriction proposals
- Action 10: Frame the application of the precautionary principle
  - RAC, SEAC to indicate when scientific data do not permit a complete evaluation of risk, what information is needed to address uncertainties, timeline for generating such information, assessment of the potential consequences of inaction; COM to consider if action is warranted on the basis of the precautionary principle
- Action 11: Interplay between authorisation and restriction
  - Consider systematically preparation of a restriction dossier before the sunset date of each Annex XIV substance (authorisation) present in articles (Article 69(2) REACH)
  - Assess interplay between restriction and authorisation to achieve a comparable risk reduction more efficiently through risk management and substitution

helpdesk luxembourg
REACH & CLP
Un service du Luxembourg Institute of Science and Technology
En partenariat avec le Ministère du Développement durable et des Infrastructures et le Ministère de l'Economie

Actions: Coherence, enforcement and SMEs

- Action 12: Interface REACH and OSH legislation
  - Clarify how to use REACH tools (e.g. exposure scenarios, Safety Data Sheets) to enhance the effectiveness of OSH legislation
  - Improve the coordination of national enforcement authorities of REACH and OSH legislation
  - Align methodologies to establish safe levels of exposure to chemicals at the workplace
  - Enhance the role of ECHA's risk assessment committee (RAC) to provide scientific opinions
- Action 13: Enhance enforcement
  - Enhance the role of REACH enforcement authorities as well as customs authorities
  - Based on newly established comparable parameters on enforcement, Member States report annually enforcement activities
- Action 14: Support compliance by SMEs
  - ECHA + Member States to increase efforts to develop, with input from voluntary actions by industry organisations, tailored guidance and support instruments focused on the needs of SMEs, e.g. collection of best practice, generation of sector specific solutions and publication of documents in national languages

Actions: Fees and future of ECHA and need for further assessment

- Action 15: Fees and the future of ECHA (not relevant for companies)
- Action 16: Review of registration requirements for low tonnage substances and polymers
  - Commission to assess the affordability of additional information requirements for low tonnage substances
  - Commission to identify relevant polymers that could be subject to registration

helpdesk luxembourg
REACH & CLP
Un service du Luxembourg Institute of Science and Technology
En partenariat avec le Ministère du Développement durable et des Infrastructures
et le Ministère de l'Economie

Thank you for your attention!

LUXEMBOURG INSTITUTE OF SCIENCE AND TECHNOLOGY | LIST

LE GOUVERNEMENT DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère du Développement durable et des Infrastructures

LE GOUVERNEMENT DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère de l'Économie