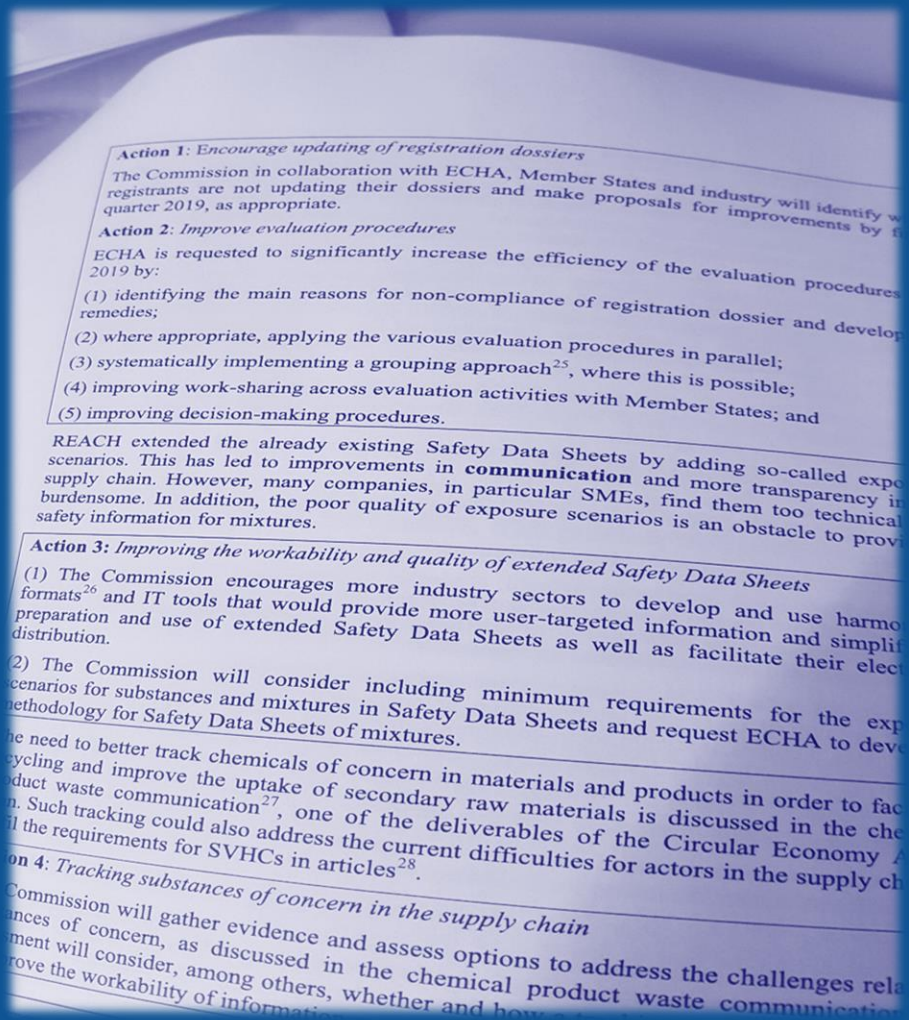


Setting priorities and processes at EU level to address dossier compliance

BfR Berlin, August 2018

Andrej Kobe
European Commission

Outline

- *Case for compliance*
- *REACH review*
- *Activities*

Case for compliance

- *Purpose/objectives for data in registration dossier*
  - ***Hazard; uses & operational conditions > exposure***
    > informed safety assessment leading to adequate risk management
  - **Data fit for purpose, trustworthy, structured, comprehensive, consistent = information, allowing evaluation and use**
  - **Intelligent data generation. Impact: time, resources, animal use**
- *Compliance: adherence to predefined rules addressing these objectives (that can in principle be enforced)*

Data quality vs compliance

- *Completeness check*
- *Evaluation processes*
  - **corrective tool, but with important resource constraints, requiring prioritisation & continuous improvements**

Evaluation evolution

- *ECHA Annual evaluation reports*
  - **Statistical indicators – identify distance to target**
  - **Main deficiency findings and recommendations**
- *Dossier and substance evaluation workshops*
- *Guidance updates and support (e.g. website, RAAF, FAQ etc.)*
- *Adaptation of Technical Annexes (e.g. EOGRTS, sensitisation, nanomaterials), implementing regulation (data sharing)*
- *'Learning by doing' – changes of practice, tool evolution (e.g. AoC)*
  - **Changes often prompted by the evaluated cases**
- *Flanking measures, early interaction with registrants*

- ***Integrated Regulatory Strategy*** *(IRS)*
  - **Joint identification of substances of interest**
  - **Priority endpoints for assessment**

REACH Review 2017

SWD

Conclusions and Actions
Annex 1: Procedural info
Annex 2: Synopsis
Annex 3: Methods
Annex 4: **State of play**
Annex 5: Horizontal issues
Annex 6: Review of ECHA

Communication


EUROPEAN COMMISSION

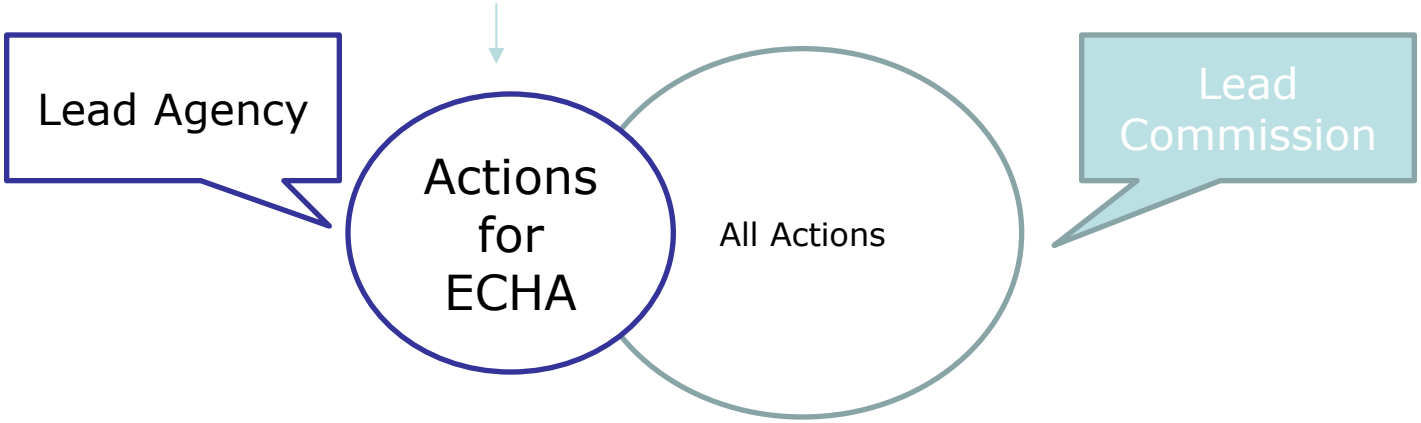
Brussels, 5.3.2018
COM(2018) 116 final

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

{SWD(2018) 58 final}



Published March 2018
Major stakeholder Workshop May 2018, Brussels

Selected findings

- *REACH fully operational, delivering towards objectives*
- *Number of shortcomings, among them non-compliance of registration dossiers*

Review conclusions – priorities 1&2

1. *Registration "Encourage updating of registration dossiers"*
2. *Evaluation "Improve evaluation procedures"*
   - **(1) identifying the main reasons for non-compliance of registration dossier and developing remedies;**
   - **(2) where appropriate, applying the various evaluation procedures in parallel;**
   - **(3) systematically implementing a grouping approach, where this is possible;**
   - **(4) improving work-sharing across evaluation activities with Member States; and**
   - **(5) improving decision-making procedures.**

Follow-up

ECHA & Commission already launched discussion/consultation on the implementation of actions:

- **Workshop May 2018**
- **CARACAL (June 2018, ongoing)**

Follow-up actions I.

- *Inducing dossier updates*
  - ***Clarify expectations: e.g. meaning of 'without undue delay', responsibilities of lead and member registrants***
  - ***Role of updates in continuous compliance of the dossier; should it also be a factor in the evaluation processes?***
- *Further transparency of the update status and evaluation outcomes (dossier life-cycle) – nudge for registrants and information for other actors:*
  - regulators, downstream users, registrants of related substances
- *Sharper and aligned enforcement*

Follow-up actions II. Increasing efficiency

- *Strategic improvements*
  - *(further) integration of evaluation processes within Integrated Regulatory Strategy*
  - *Ensure some information in dossier (e.g. exposure) without resorting to evaluation processes*
  - *Address substances in groups*
  - *Effective interplay between substance and dossier evaluation*
    - ***Legal and procedural, role of different actors (ECHA,MSCA)***
  - *Identify/remedy further reasons for non-compliance*
  - *Support*
    - ***guidance, go/no-go examples, intelligent testing strategies***
- *(Internal) process efficiency and decision making*
  - *Decision templates, MSCA amendments and discussion*
  - *Registrants: in-process updates, deviations from decisions*

Action – Commission specific

- *Implementing regulation and changes to REACH Annexes, where appropriate*
- *Contribute when evaluation decisions are taken by the Commission*
- *Setting priorities. Change to Article 41(5)?*

5. To 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. The Agency shall give priority, but not exclusively, to dossiers meeting at least one of the following criteria:

(a) the dossier contains information in Article 10(a)(iv), (vi) and/or (vii) submitted separately as per Article 11(3); or

(b) the dossier is for a substance manufactured or imported in quantities of one tonne or more per year and does not meet the requirements of Annex VII applying under either Article 12(1)(a) or (b), as the case may be; or

(c) the dossier is for a substance listed in the Community rolling action plan referred to in Article 44(2).

…

7. The Commission may, after consulting with the Agency, take a ***decision to vary the percentage of dossiers selected and amend or include further criteria*** *in paragraph 5 in accordance with the procedure referred to in Article 133(4).*

Conclusions

- *Important progress towards compliance has been achieved, in information regarding individual substances as well as in systemic learnings*
- *Processes in place work but should be further improved*

- *As we expect dossiers to be kept relevant and updated, so will compliance-related processes also require continuous reflection*
  - **new chemicals, methods and intelligent testing strategies, increase in scientific knowledge, ambition to deal more effectively with groups of substances etc.**

- *Issues are best resolved when finding solutions jointly – contribute to the ongoing CARACAL consultation!*

Thank You

Further information:

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