Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

Substance evaluation: Viewpoint of the German CA

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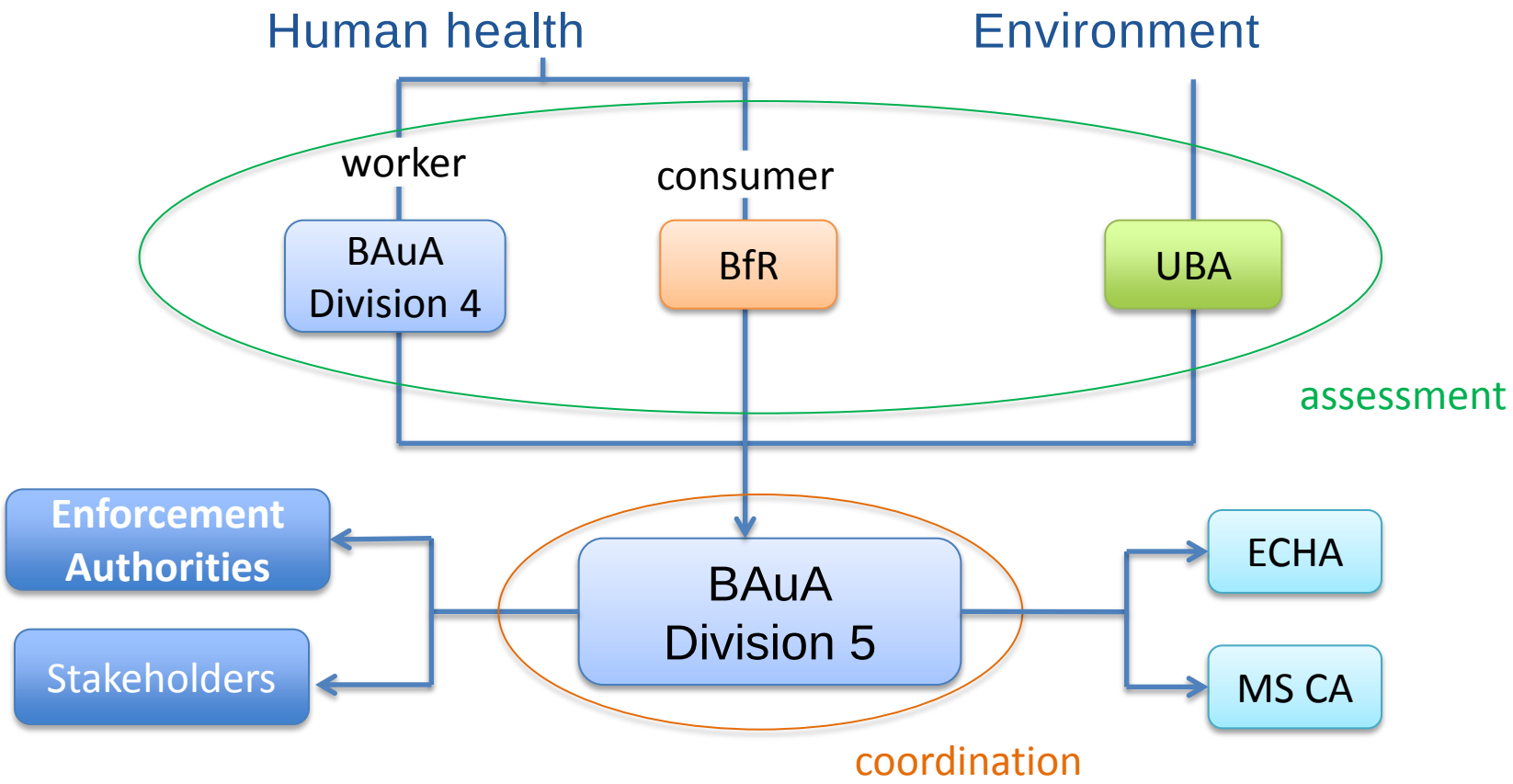
Idea of substance evaluation

- **Goal of Substance Evaluation :**
  - Substances shall be evaluated if there are grounds for considering that uses of the substance constitute a risk to the human health or the environment
- **Possible outcome of the substance evaluation**
  - No Risk
  - Risk
  - Not possible to clarify risk
    - Request for further information → (Draft) Decision
- **Support for improvement of registration dossiers**

REACH processes in DE



Selection of CoRAP Substances

- **REACH Article 44:**
  - Risk-based approach
  - Criteria: -hazard information
    - exposure information
    - tonnage
- **ECHA and MSCAs developed criteria**
  - http://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf
- **Screening of registered substances**

Selection of CoRAP Substances by German Authorities/ Concern

- Results of screening
- National screening
- Other Activities (SVHC, research activities)

- Substances suggested for CoRAP based on an initial concern (e.g. environment)
- Evaluation of the substance (not focused on the initial concern)

Substance Evaluation in Germany

- **SEV starts with CoRAP update**
  - ECHA provides aggregated dossiers
  - Cursory assessment for further concern(s)
  - Information of Industry (letter to lead registrant)
- **SEV to be finalized after ~8,5 month**
  - Meeting with industry (if necessary)
- **Merging of the results**
- **Consistency screening by ECHA**

Finalisation of SEV within latest 12 month

Contact between eMS CA and registrants

- **DE CA informs lead registrants about the start of the SEV after publication of CoRAP-update**
  - Information about contact point
  - Industry should install a contact point
  - Information about the process
- **One meeting with industry preferred (if necessary)**
  - Results are not discussed during the year of evaluation
  - Explanation of the process, clarification of questions

Contact between eMS CA and registrants

- **Meetings with registrants took place in most cases so far**
  - Too early in the process in the first year – better in the second year (month 4-5)
  - Industry was willing to cooperate (e.g. submission of further documents)

- **Dossier updates:**
  - Not necessary for SEv
  - If necessary: early information of eMS appreciated

Contact between eMS CA and registrants during decision making process

- **DE informs lead registrant about finalisation of the SeV and about the result (draft decision or not)**
- **Draft decision sent to registrants by ECHA**
- **30 day period for commenting:**
    - CA can answer questions
    - No discussion of the draft decision
    - Formal process of decision making – comments to be sent to ECHA
- **eMS decides about further process (decision making with MSs and ECHA)**

Experience with SEv in DE

- **2012 : 5 substances evaluated by Germany**
  - Initial concerns for environment, human health, PC properties, formation of critical degradation products
  - Additional concerns noted for some substances
  - 5 draft decisions (four final decisions sent to registrants, one not agreed in MSC)
- **2013: 7 substances evaluated by Germany (one late SEv)**
  - Initial concerns for environment, human health, RCR, exposure
  - Additional concerns noted for some substances
  - 3 (4) draft decisions - sent to registrants, 3 SEV ended with clarifications of the risks (SEV finalized)
- **2014: 7 substances to be evaluated by DE**
  - Initial concerns for environment, human health

Lessons learned

what went well:

- Discussions with national experts with different expertise within relatively short timeframes
- Good cooperation with industry
  - Voluntary and quick submission of further information (e.g. full study reports)
- Cooperation with ECHA (consistency screening)

Lessons learned

- **Room for improvement:**
  - Timing within MS
  - Updates of registration dossiers late in the process
  - Questions of confidentiality
    - noticed very late
    - low experience
  - Meeting in decision making phase may cause misunderstandings

Advice to industry

Read ECHA leaflet

„Substance evaluation under REACH - Tips for Registrants and Downstream Users“

http://echa.europa.eu/documents/10162/13628/sub_eval_under_reach_leaflet_en.pdf

- Check (draft) CoRAP
- Prepare participation in SEV (Contact eMSCA, coordinate with other registrants, Update the dossier, if needed)
- Coordinate comments during formal decision making process
- Provide the requested information
- Follow the conclusions

Advice to industry – DE perspective

- **Coordinate early within the SIEF**
  - CA cannot contact all registrants
  - Prepare for quick responses if questions occur
- **Wait until CA contacts you**
- **Inclusion of a substance into CoRAP is no reason for dossier update**
  - quality of registration dossiers should always be good
- **Be aware of timelines in the decision making process**

Thanks for your attention

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