

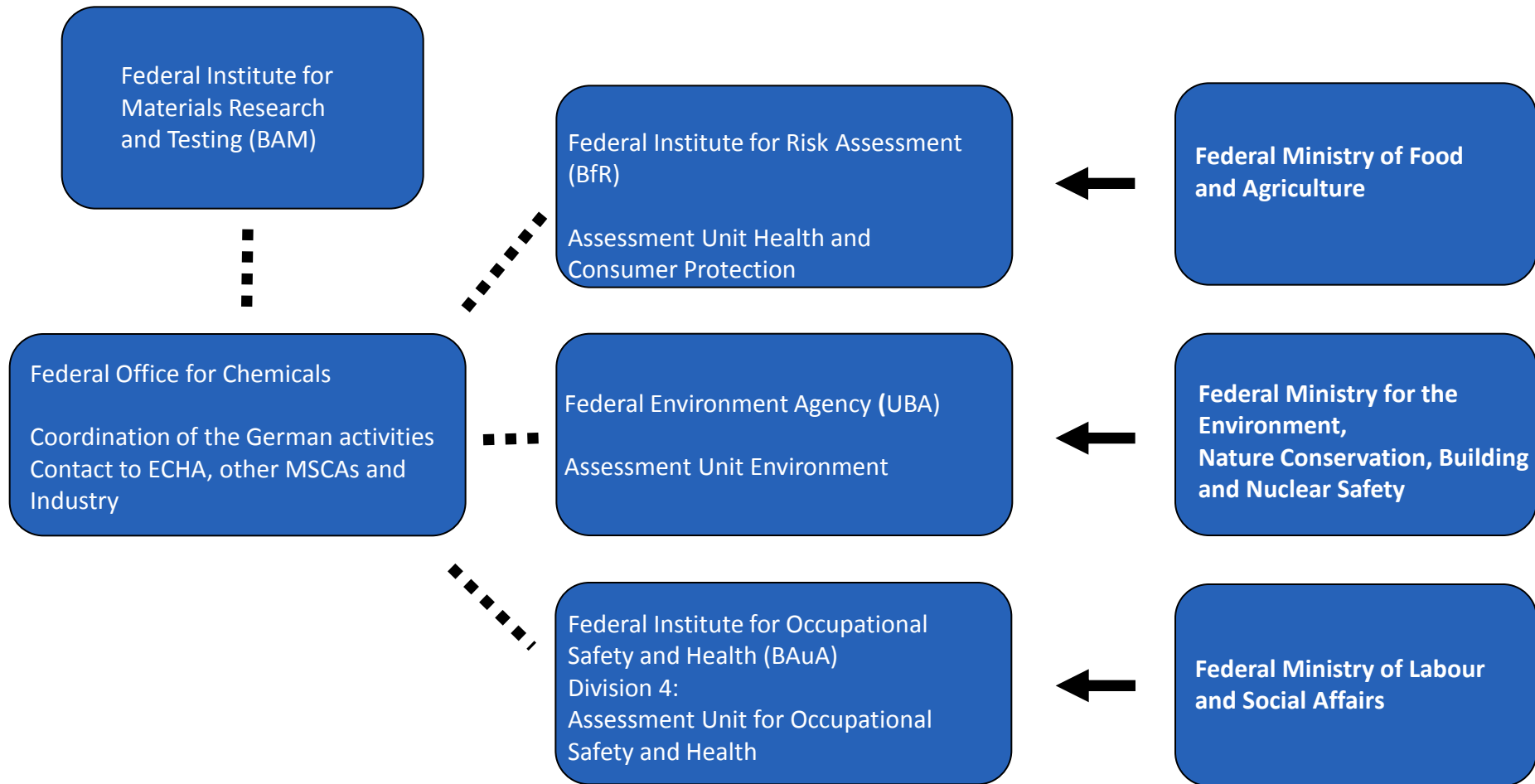
How authorities make use of the information from registration

Example(s) from authorities where information provided/not provided lead to decision on which regulatory risk management pathway to take.

Outline

- **Organisation of REACH activities in Germany**
- **Screening process**
- **Certain examples of decision processes**
- **Criteria for (de-)prioritisation**

Organisation of REACH activities in Germany



Substance screening process in Germany

Substance selection

- via individual prioritisation
- via IT-based preselection by ECHA (“short lists”)

Risk based selection criteria

- Potential hazard (e.g. C& L)
- Potential exposure (use description, tonnage, release)

Target specific substance screening

- Worker
- Consumer
- Environment

Phase I: IT based prioritisation

Substance prioritisation based on the preselection by ECHA (“short lists”)

Selection criteria:

- (Potential) hazard (C&L)
- Non hazard criteria
- High tonnage
- Wide dispersive use
- Identified consumer use (SU 21, PC in scope of REACH)
- Article service life (for consumers)
- professional uses (for workers)



Phase II: Manual Screening

Issues, to be checked

Data quality



- Clear description of the identified uses
- Exposure scenario for each identified use of the life cycle
- Tonnage per use to characterise the extent of certain uses
- Exposure estimates, DNEL, RCR
- Documentation of determinants / operational conditions
- Used exposure model / tool (Tier of the exposure estimate)
- Convincing justification for exposure based waiving
- Convincing justification for SCC
- Clear RMMs



Phase II: Manual Screening





















**Quality of the
exposure
assessment**

Issues, taken into account

- Exposure relevant substance properties (e.g. dustiness, vapour pressure, log K_{ow})
- Additional Information (e.g. measurements, monitoring)

Experiences during the SEV 2012-2014

Substance	A	B	C	D	E
Are identified uses congruent to the public information on the market?					
Are all identified uses and exposures described via ES in the CSR?					
Appropriateness of exposure models & defaults			-		
Transparency and reproducibility of exposure estimates			-		
Risks associated with data gaps	NO	YES	YES	YES	YES

Information exchange process, example I

Goal:

Clarification of open questions (missing / unclear consumer ES) with the lead registrant during the process of substance evaluation

Result:

In consequence, the registrants provided the missing information and no further requirements were necessary

In conclusion:

Clear description of the uses and the possibility to execute a proper exposure assessment led to de-prioritisation of the substance

→ currently no further regulatory risk management necessary

Information exchange process, example II

Goal:

Clarification of open questions with respect to some uses of the concerned substance indicating that these uses occurred in (partly) open systems, or exposure may occur during interruption of processes.

→ **potential exposure risk of these uses needed to be clarified .**

Result:

The concerned registrants gave explanations of the selection process for uses and accordingly exposure scenarios to be included in the registration dossier. It became clear that the registrants have a different comprehension than the ECHA Guidance Documents of the meaning of “professional uses” at workplaces.

After the communication the registrants described the relevant uses with potential exposure to workers whereby the working activities became more clear for the eMSCA.

Information exchange process, example II

In conclusion:

- Provided data suggested that the occupational exposure risk is in an acceptable range
- Based on this convincing information the eMSCA came to the result, that there are no professional uses which could lead to unacceptable occupational exposure
- Conclusion that the initial concern was clarified.

→ No need for further activities

Summary environment – triggers for (de-)prioritisation

For prioritisation: Information on:

- **uses: wide spread uses take place outdoor**
- **uses: wide spread use of consumer products with direct and indirect emission to environment, e.g. substances in sunscreen, cosmetics**
- **sector of use: uses in branches where water contact is expected, e. g. washing of textile in consumer uses with release of textile dyings**

For de-prioritisation: Information on:

- **subsequent life cycle step: is the substance formulated in a mixture which is consumed in the next life cycle step, e.g. burned (pigment for fuel)**
- **technical function: is the substance consumed during process, e. g. substance is used as an polymerization initiator, vulcanization accelerator**
- **uses: wide spread uses take place indoor with no emission to environment**

Summary worker/consumer – triggers for (de-)prioritisation

Prioritisation

- Widespread use
- High potential release
- Poor quality of the registration dossier)



De-prioritisation

- Clear description of uses
- Product description
- Proper exposure assessment
- Clear description of RMM
- Monitoring data
- Measurements (concentration, migration)

Thank you for your attention

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