FEDERAL INSTITUTE FOR RISK ASSESSMENT

BfR
Bundesinstitut für Risikobewertung

Outlook

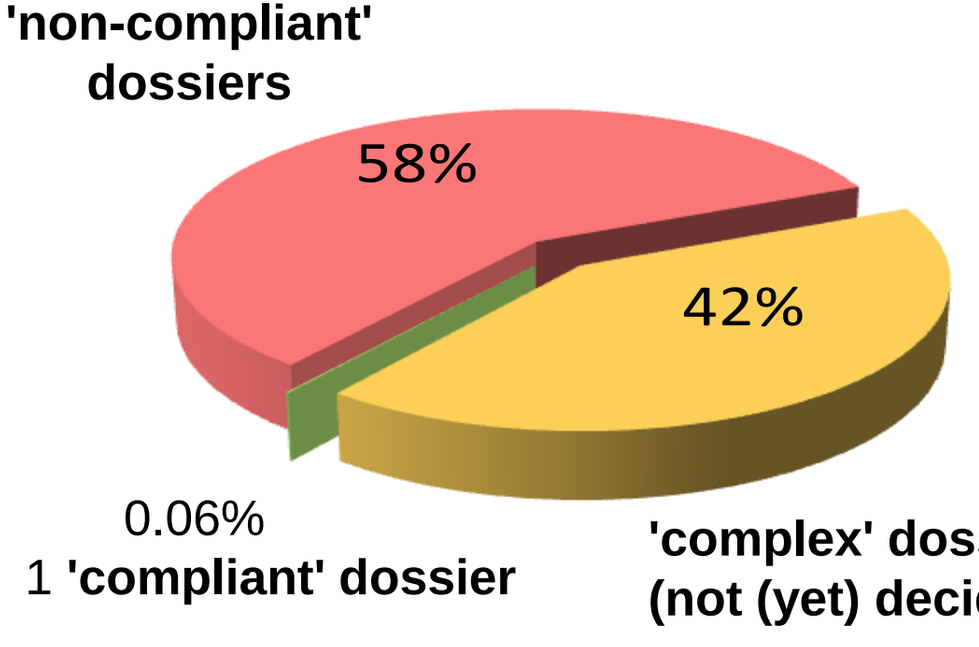
Agnes Schulte, Uta Herbst

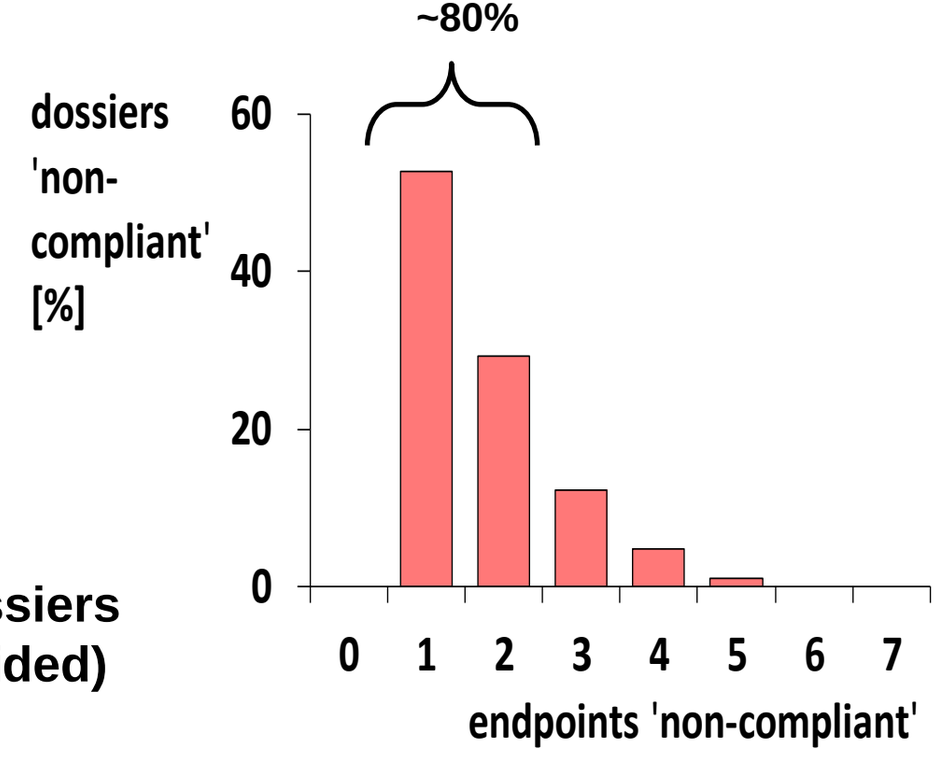
Data Availability in REACH Registrations: Results

First project on all lead and opt-out dossiers of the high tonnage band

- Significant data gaps in many registration dossiers
- Majority of dossiers with lack of data for 1-2 endpoints
- ‚Complex' endpoints with deviations from standard requirements

Likely that the percentage of non-compliant dossiers will increase





Compliance to REACH Annexes is essential

Standard informations legally binding minimum requirements (REACH Art. 10)

Essential for a **safe use of chemicals**

>1000 tpa substances:
The level of exposure and distribution increases with the production volume

Data gaps are unacceptable

- For responsible Registrants and in the supply chain
- For the responsible bodies like ECHA and Enforcement bodies
- For the Member States

Joint efforts of all parties needed

To improve data availability and data quality for all substances on the EU market

Compliance to REACH Annexes is essential

Registrant

To identify potential hazards for men and environment

To assess potential risks

Member States

To identify substances of high concern

To initiate risk management measures
(restriction, authorisation or substitution)

To evaluate substances, if concern on potential risks

To propose harmonised classification on dangerous properties

Project versus Compliance Check acc. Art. 41

Project REACH Data Availability in REACH registrations

- Screening on data availability in 1814 dossiers >1000 tpa
- Targets at higher tier endpoints only (Annex IX +X)
- Broad examination on the availability of data/studies
- Updated registrations since March 2014 not considered
- In depth analysis of ‚complex' cases still needed

To note!

This project is **not** comparable with a Compliance Check by ECHA

But: Consistencies expected for
‚non-compliant' endpoints and ‚compliant' endpoints

Concordance to ECHA decisions in a selection of Compliance Checks

Project outcome: Benefits for the German Authorities

Project results serve the German Authorities

- To select substances for regulatory measures under REACH
- To prioritise substances for immediate and long-term actions

Cooperation with ECHA and Member States

- Outcome table delivered to ECHA
- Open to share results with by Member States
- Co-operation with the Stockholm University on a project on hazard assessment

Project outcome to support ECHA

ECHA

- Will feed the project outcome into their IT-screening activities and their new compliance check strategy

- May consider to prioritise the least compliant dossiers for compliance check (Proposal to include118 (UVCB) dossiers without toxicological data)

Thereby the project outcome
can be integrated into ECHA‘s Multi-Annual Work Programme

ECHA may consider communication and feedback to registrants

- Inform all registrants with non-compliant dossiers to conduct updates (actions beyond the formal Compliance Check)

- Workshops/Conferences for registrants
  (e.g. Training for Registration Deadline 2018)

Project outcome: Possible impact at Community level

Commission for consideration

- Observation that Compliance Check on 5% of registration dossiers/tonnage band is not sufficient to ensure data quality

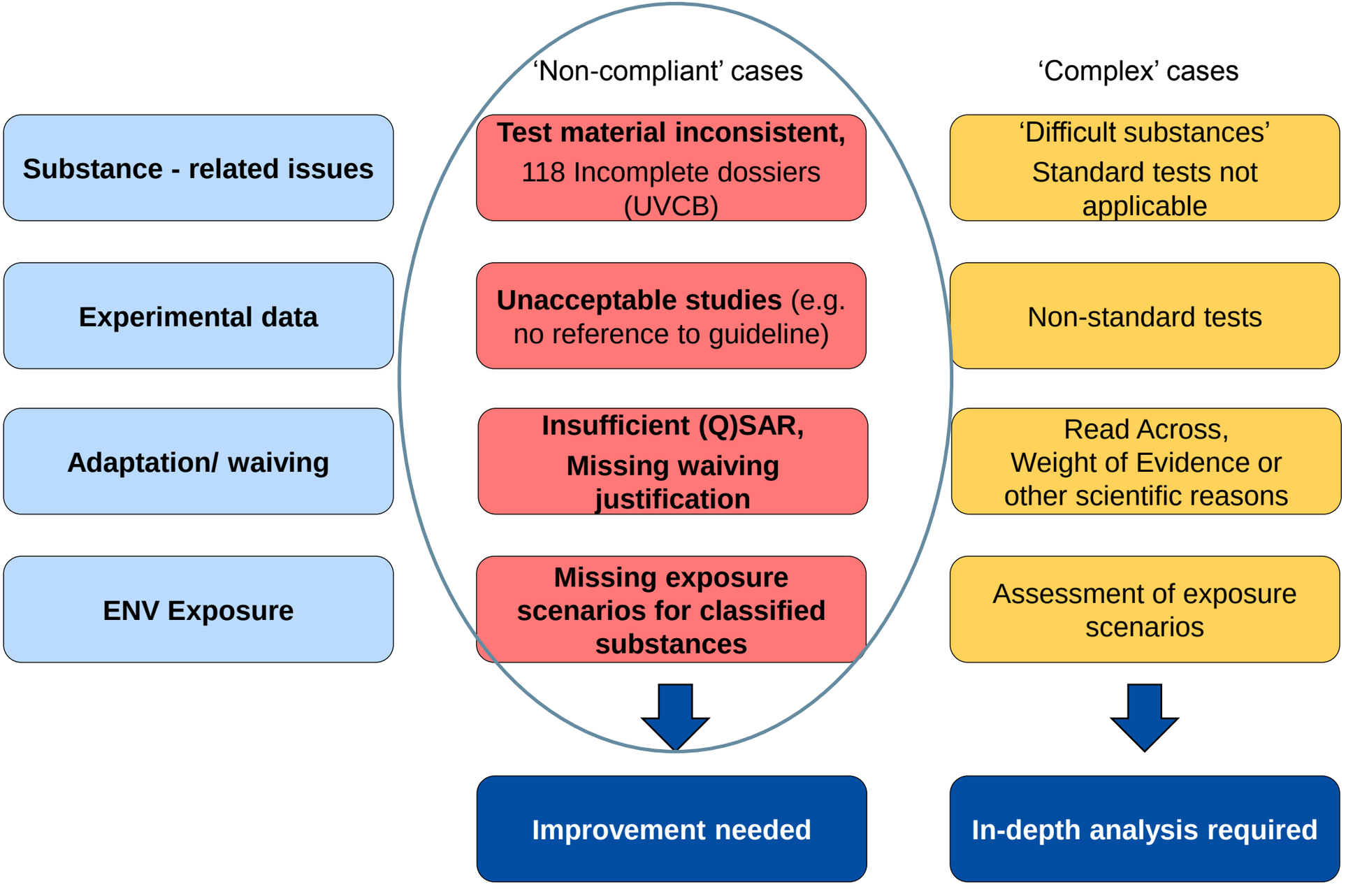
- 5% Level needs revision?
  Art. 41.7 ‚*Commission may take a decision to vary the percentage*‘

- Improving the quality of REACH registrations
  Dec 2014 Letter on priority issues of 8 Member States to EU Commissioners Vella and Bienkowska

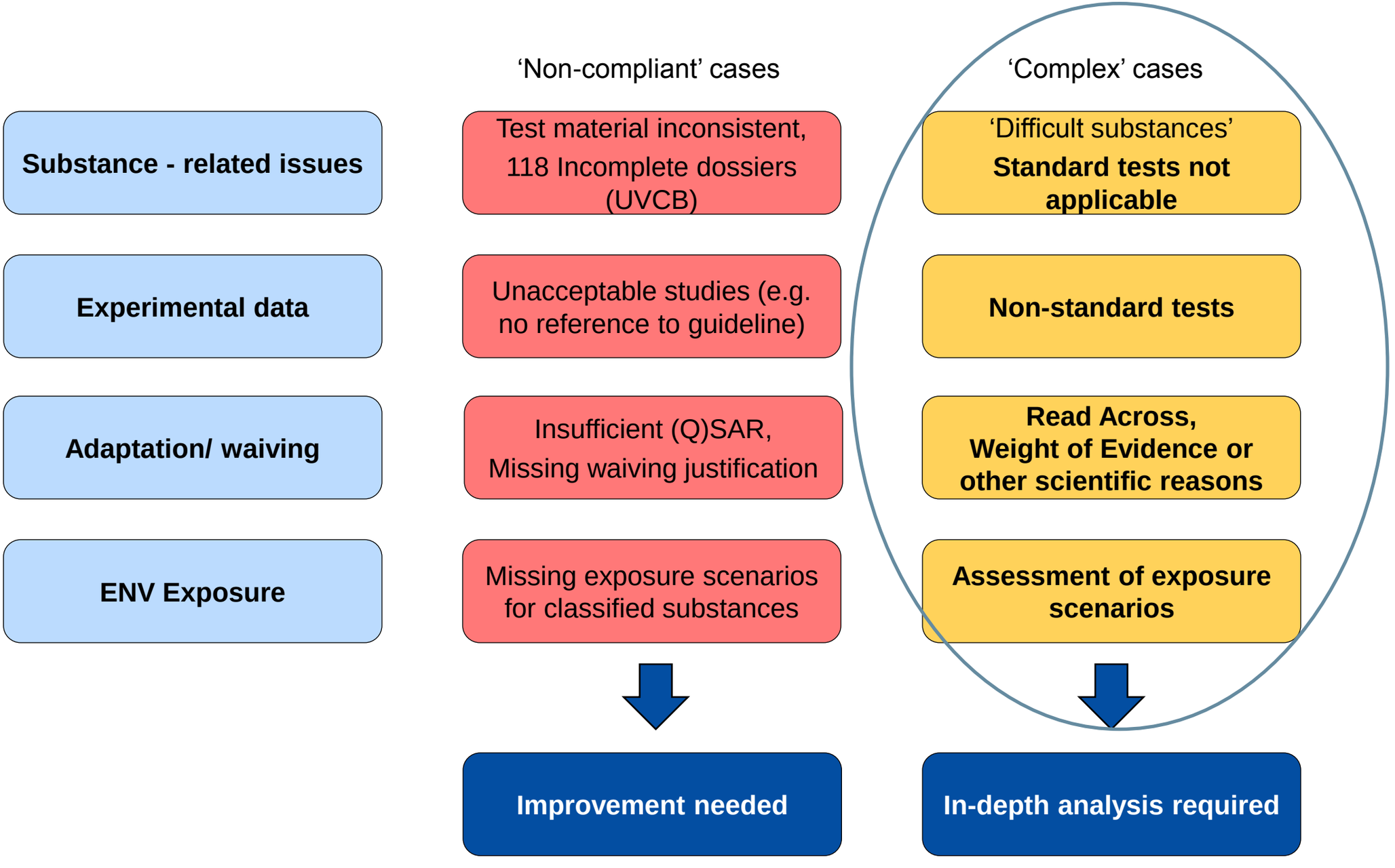
- Proposal to engage & enable ECHA to conduct compliance checks on more/most/all lead registration dossiers for substances >1000 tpa?

All stakeholders
to take joint efforts to improve the quality of registrations

Project outcome: Take home message for registrants



Project outcome: Follow-up



Project follow-up

Final project report by 31 March 2015

Will be published

Follow-up Project

April 2015 – March 2016

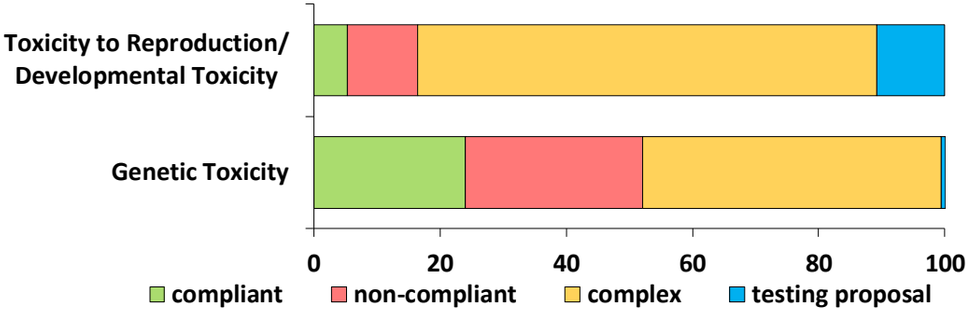
In depth assessment on

Test material & registered substance

‚Complex' endpoints –

- Adaptations/waiver - Further categorisation
- Adequacy of deviations and justifications

Estimate on animal studies for reproductive toxicity/mutagenicity



Will not include single case analysis of read across and grouping

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Thank you for your attention

Agnes Schulte

Federal Institute for Risk Assessment

Max-Dohrn-Str. 8-10 ● 10589 Berlin, GERMANY

Tel. +49 30 - 184 12 - 0 ● Fax +49 30 - 184 12 - 47 41

bfr@bfr.bund.de ● www.bfr.bund.de