FEDERAL INSTITUTE
FOR RISK ASSESSMENT

BfR
Bundesinstitut für Risikobewertung

Availability of Health and Environmental Data for High Tonnage Chemicals under REACH

Introduction to the Project

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Topics of Presentation

- Project objectives
- Introduction to the concept
- Overall results
- Summary/conclusion
- Announcement of detailed results

Project Objectives

- Overview on the completeness of selected data
- In REACH registration dossiers of high tonnage chemicals
- Examination of available data
- Estimation of data gaps
- Reviewing compliance with REACH requirements
- Obtain traceable and reproducible information

Project Concept

A screening method was developed for

- A standardised check
- Using decision trees
- Based on REACH Regulation Annexes VII – X
- Considering *phase-in* chemicals (≥ 1000 t/a)
- Dossiers of lead registrants & *opt-out* registrants

- 1932 dossiers (as of 7 March 2014)
- <60 min/dossier

1814 dossiers with (eco-) toxicological data,
118 dossiers without data (mainly UVCB)

Project Considered Endpoints

Human health

- Toxicity to reproduction/developmental toxicity
- Genetic toxicity
- Repeated dose toxicity

Environment

- Ecotoxicity: Aquatic toxicity
- Bioaccumulation
- Biotic degradation
- Abiotic degradation
- Environmental exposure

Project Concept

Decisions on the endpoints

'compliant' — **compliant** to REACH Annexes VII-X

'non-compliant' — **non-compliant** to REACH Annexes VII-X

'complex' — **not (yet) decided** due to waiving or
adaptation acc. to REACH Annexes VII-X,
Column 2 or Annex XI or
other (endpoint specific) reasons not assessable
due to time limitations

'testing proposal' — no further endpoint screening

Project Concept

Decisions on the **dossiers** based on endpoint decisions

'compliant ' dossier — **if all endpoints compliant**

'non-compliant ' dossier — **if at least one endpoint non-compliant**, others complex, compliant or testing proposal

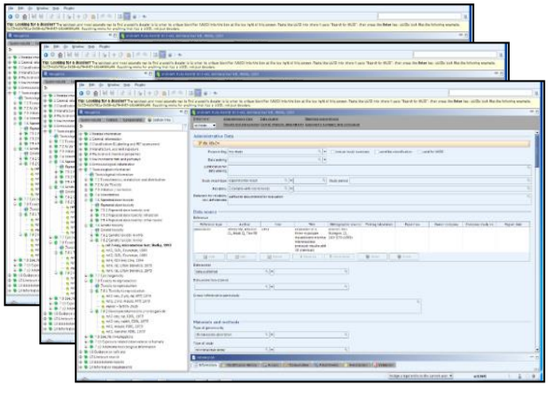
'complex' dossier — **at least one endpoint complex**, others compliant or testing proposal

Project Screening Procedure

Provided by ECHA

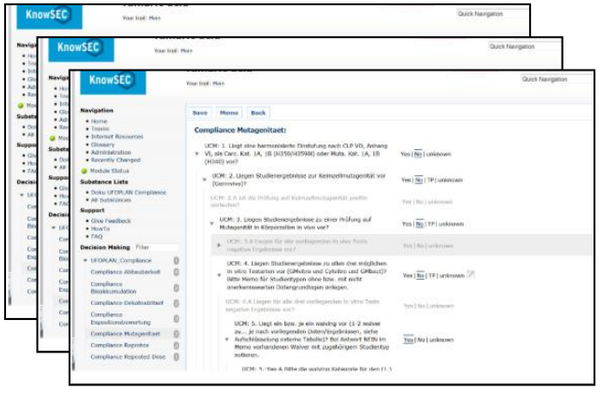
List of 1814 dossiers

Read-only access

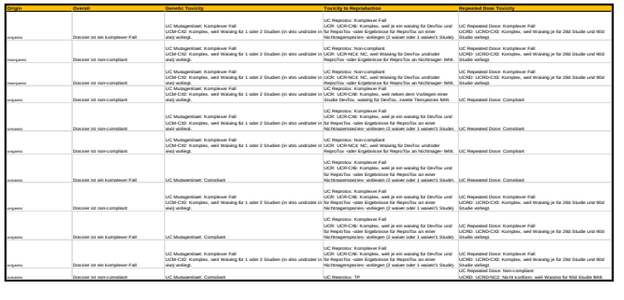


Registration dossiers (IUCLID)

Anonymous data



KnowSEC Decision trees



Outcome

Screening results

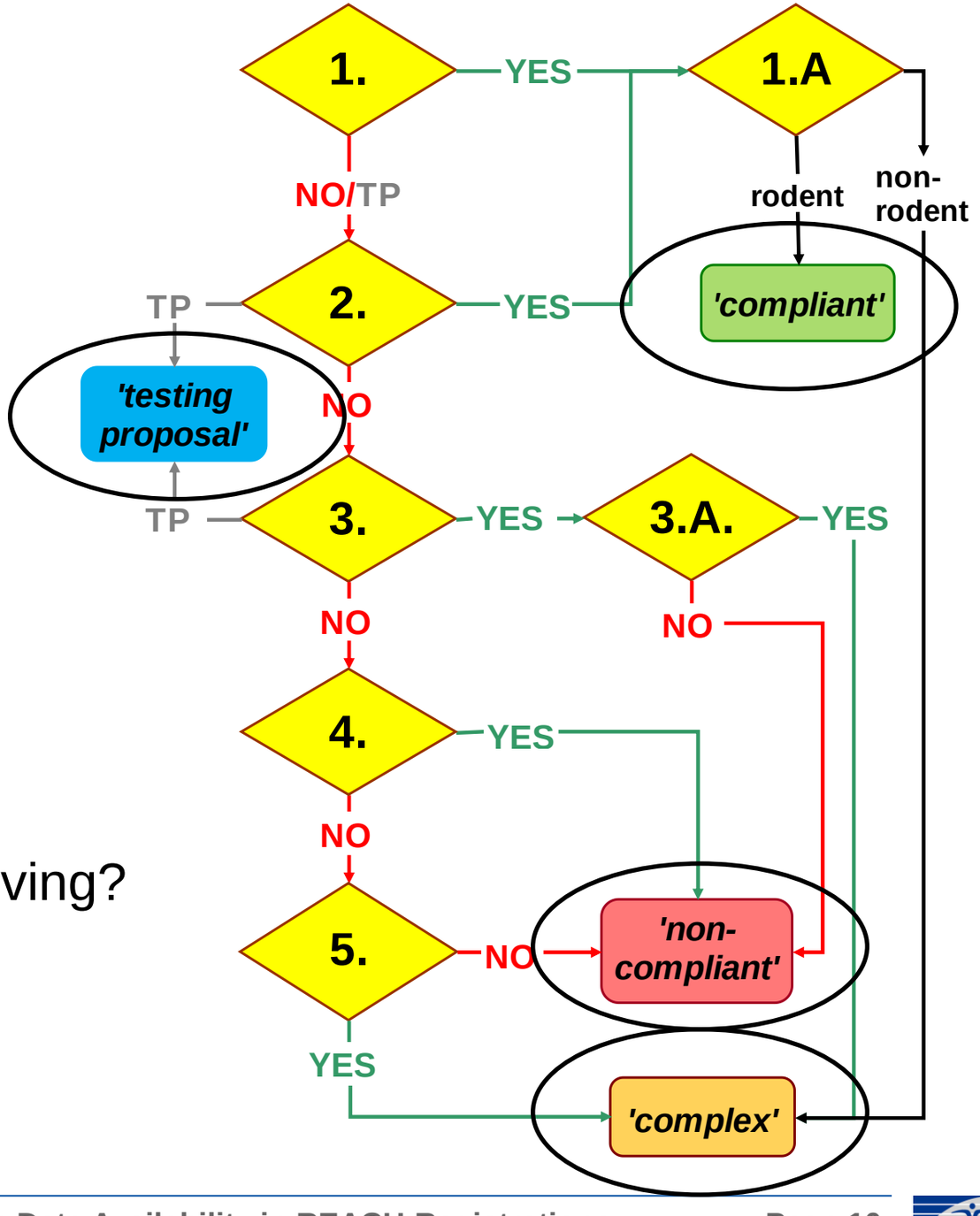
Project: Example on REACH Standard Information Requirements

Repeated dose toxicity for chemicals ≥ 1000 tpa

Annex VII	Annex VIII	Annex IX	Annex X
none	28 d-study, adaptations	28 d-study	
		90 d-study, adaptations	
			if required: chronic or other study

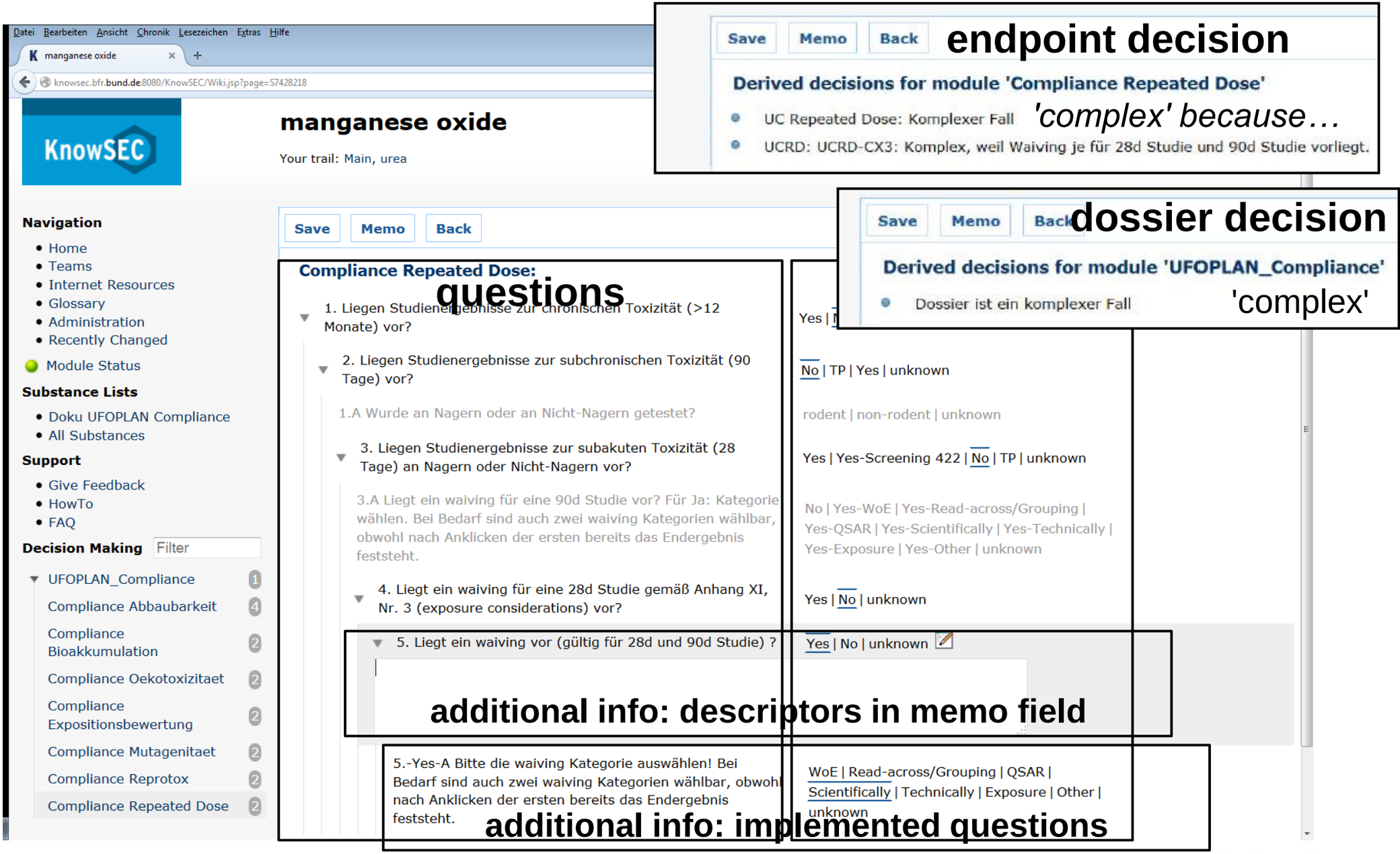
Project: Example Decision Tree - Repeated Dose Toxicity

1. Chronic study?
2. 90 d-study?
1.A Test with rodent?
3. 28 d-study
3.A Adaptation?
4. Exposure-based waiving?
5. Adaptation?



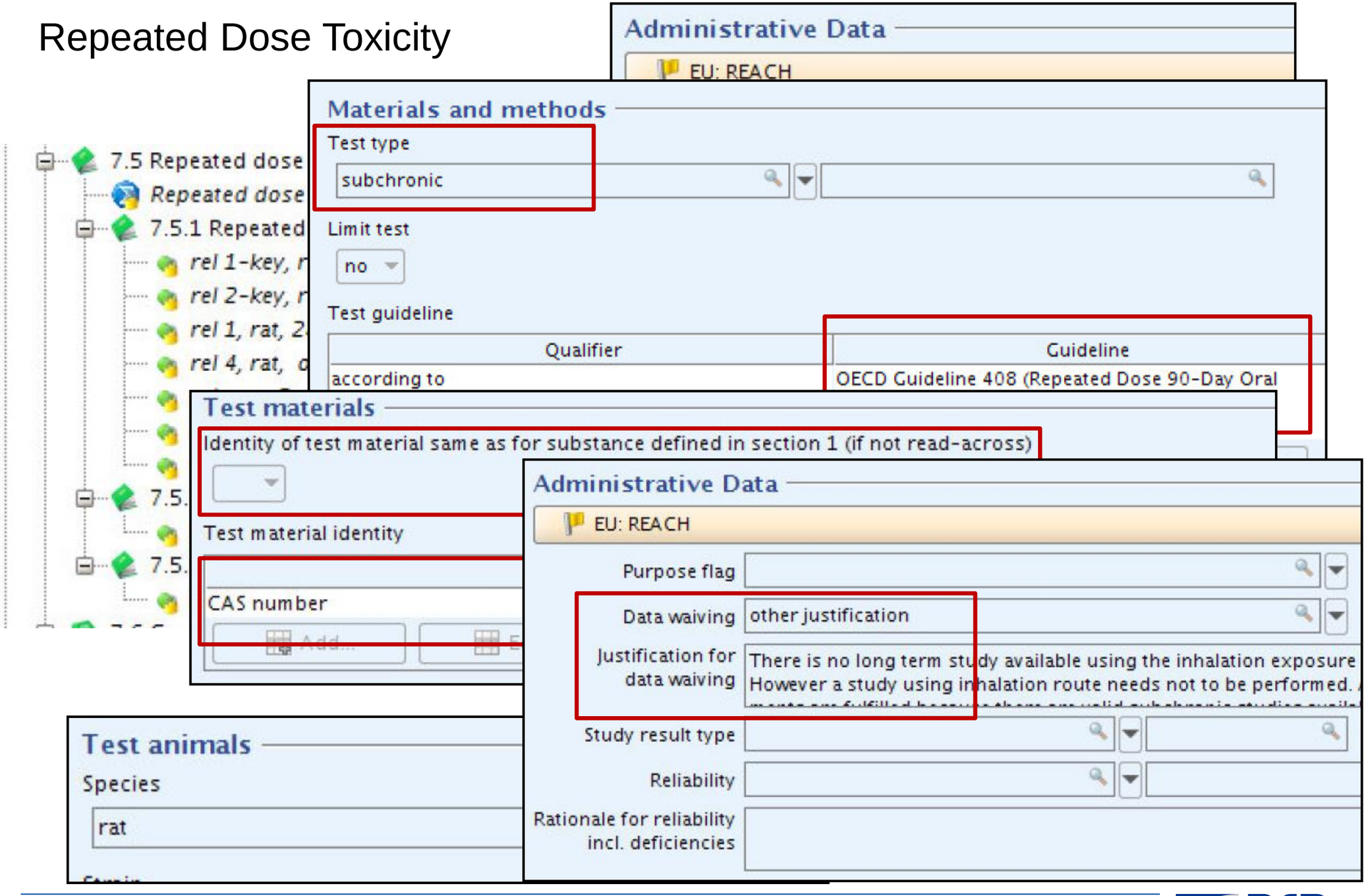
Project: KnowSEC-Software for Screening and Decision Making

Implemented decision tree



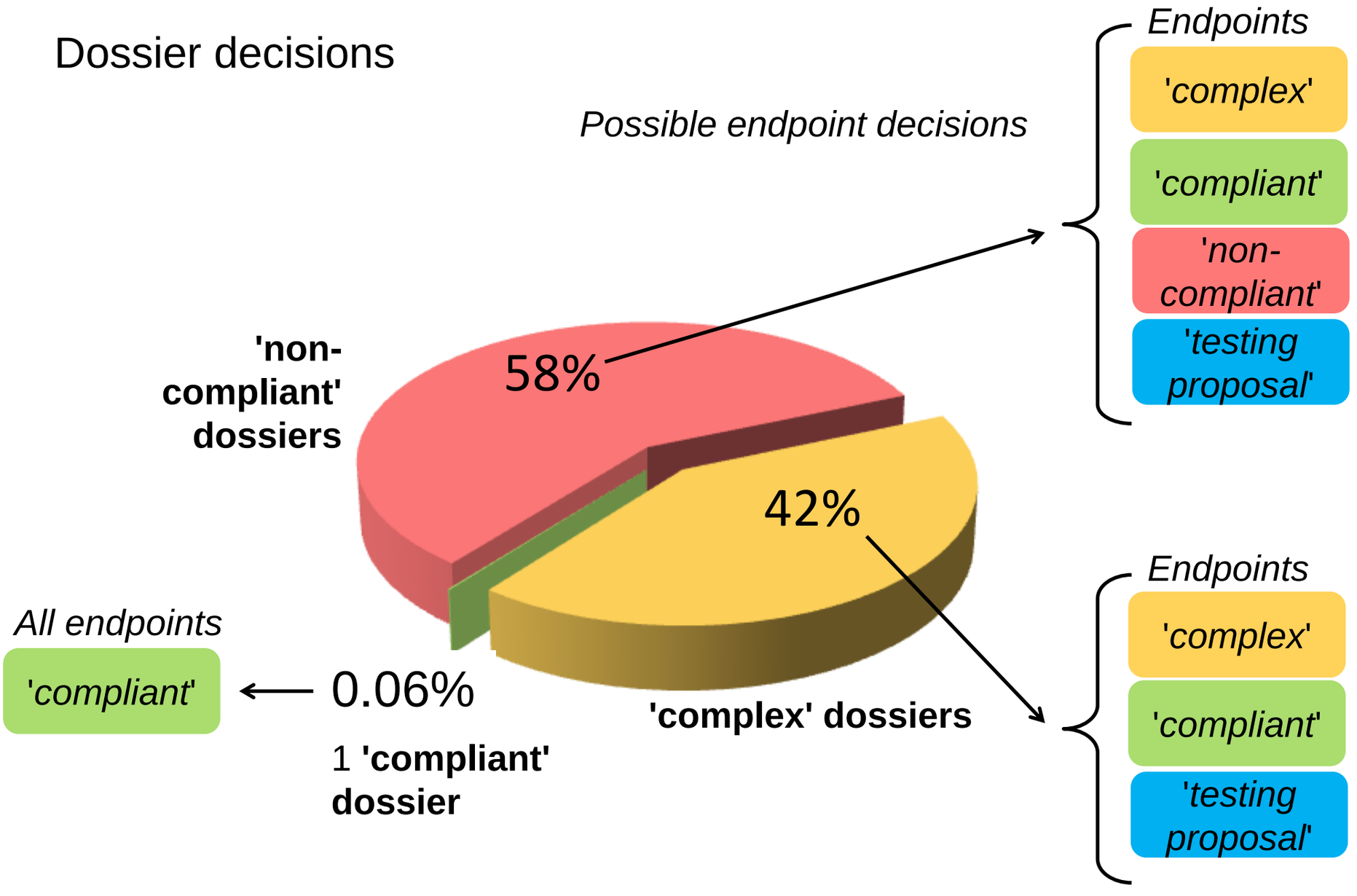
Project: Example on IUCLID Dossier Screening

Repeated Dose Toxicity



Overall Results

Project Overall Results

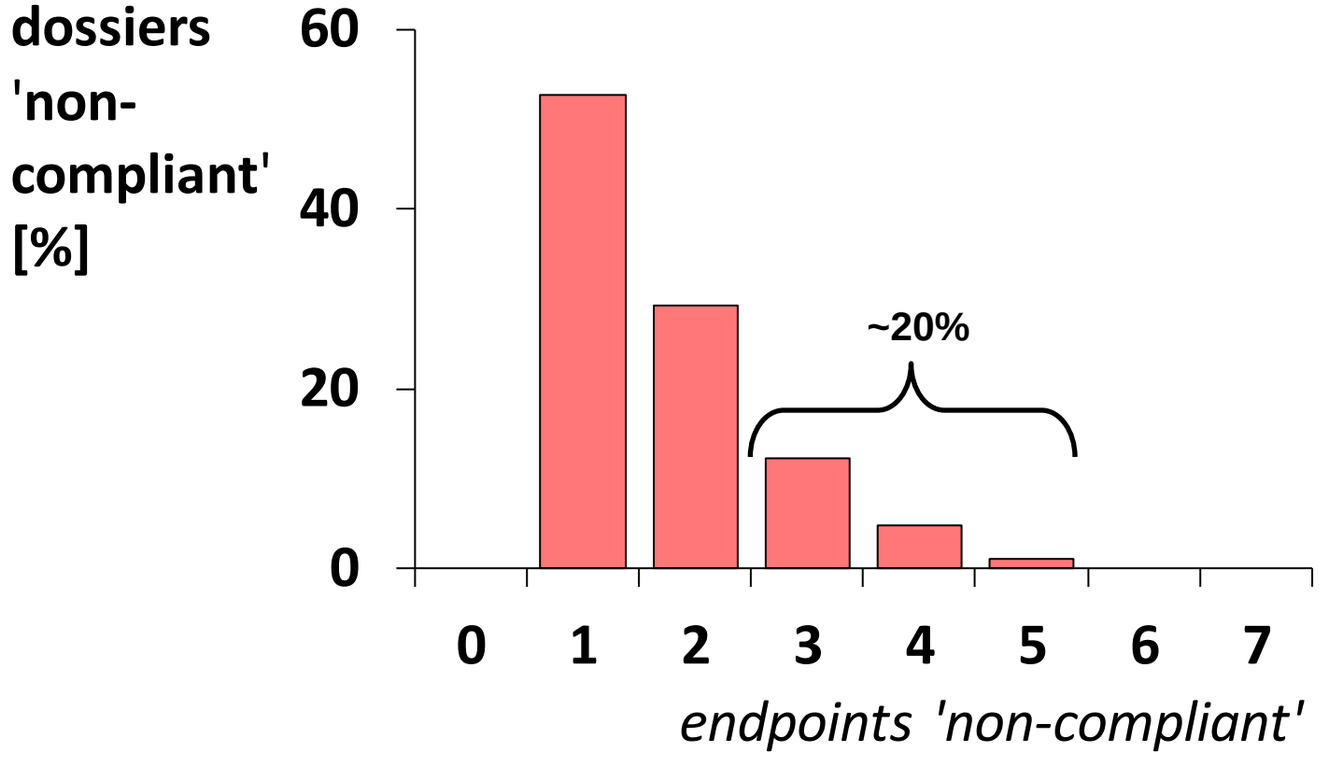


Total dossiers: 1814

Project Overall Results

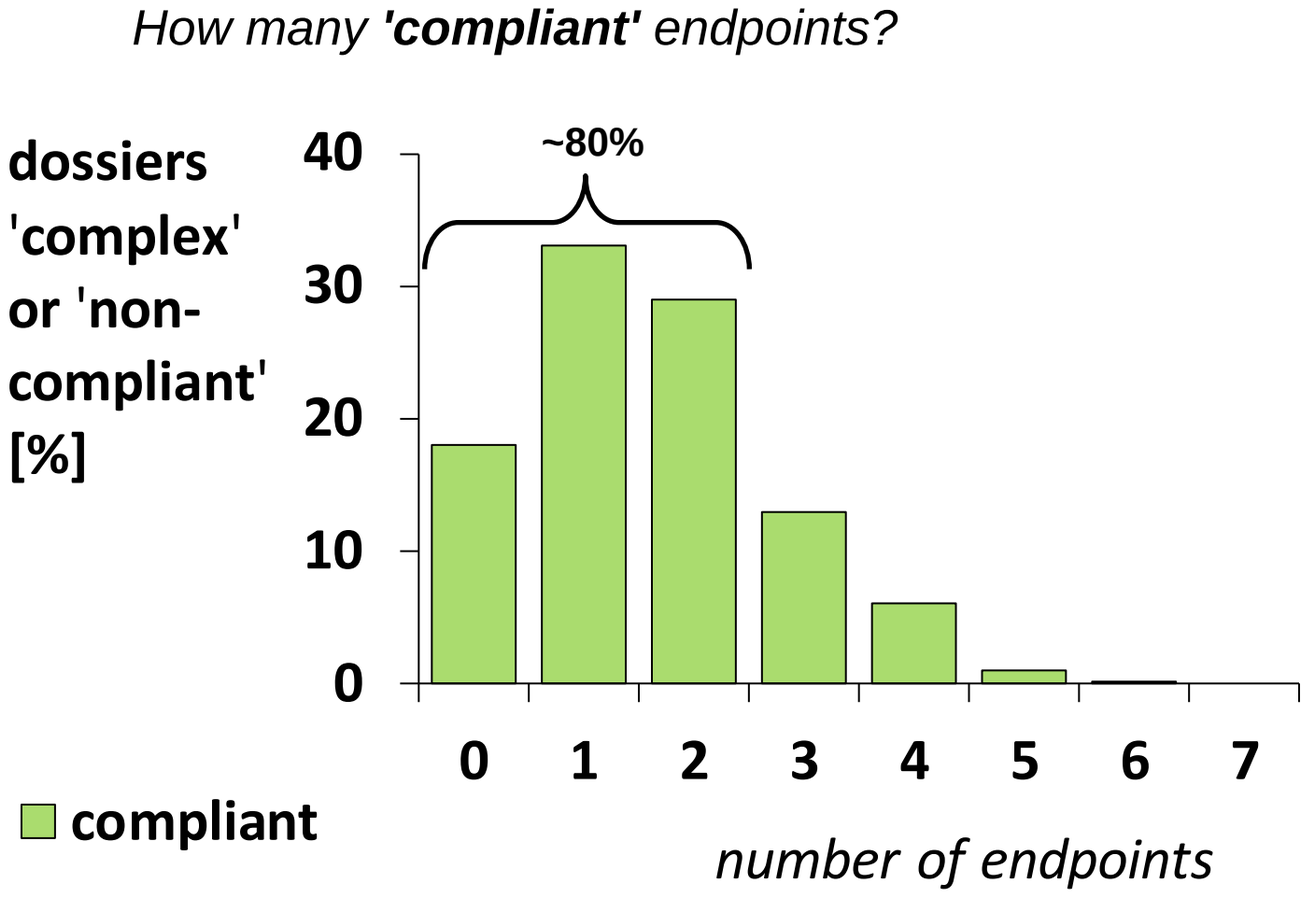
58% (1043) 'non-compliant' dossiers

How many ***'non-compliant'*** *endpoints?*



Project Overall Results

All dossiers except the 'compliant' dossier: 1814 - 1 = 1813



Project Overall Results

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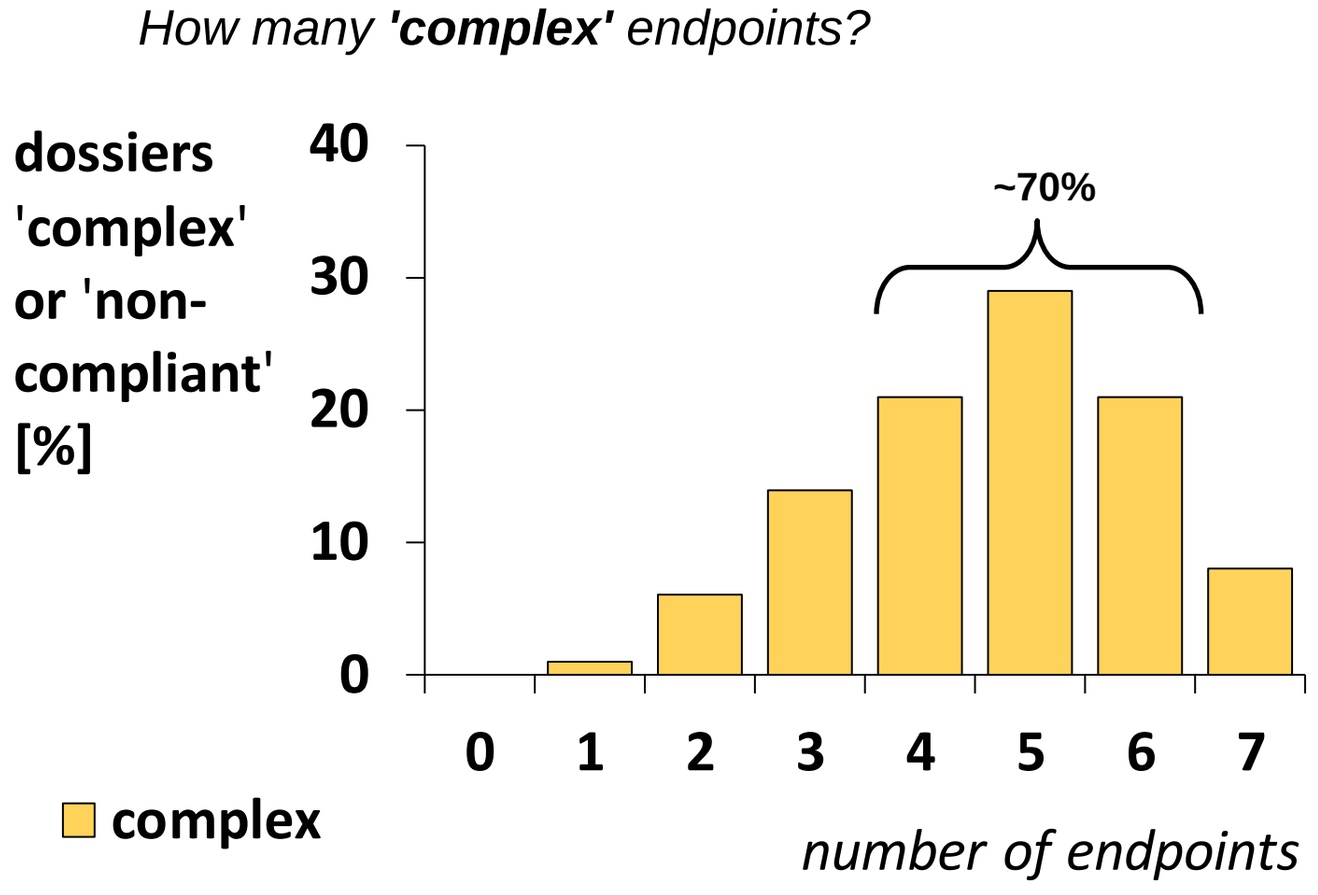
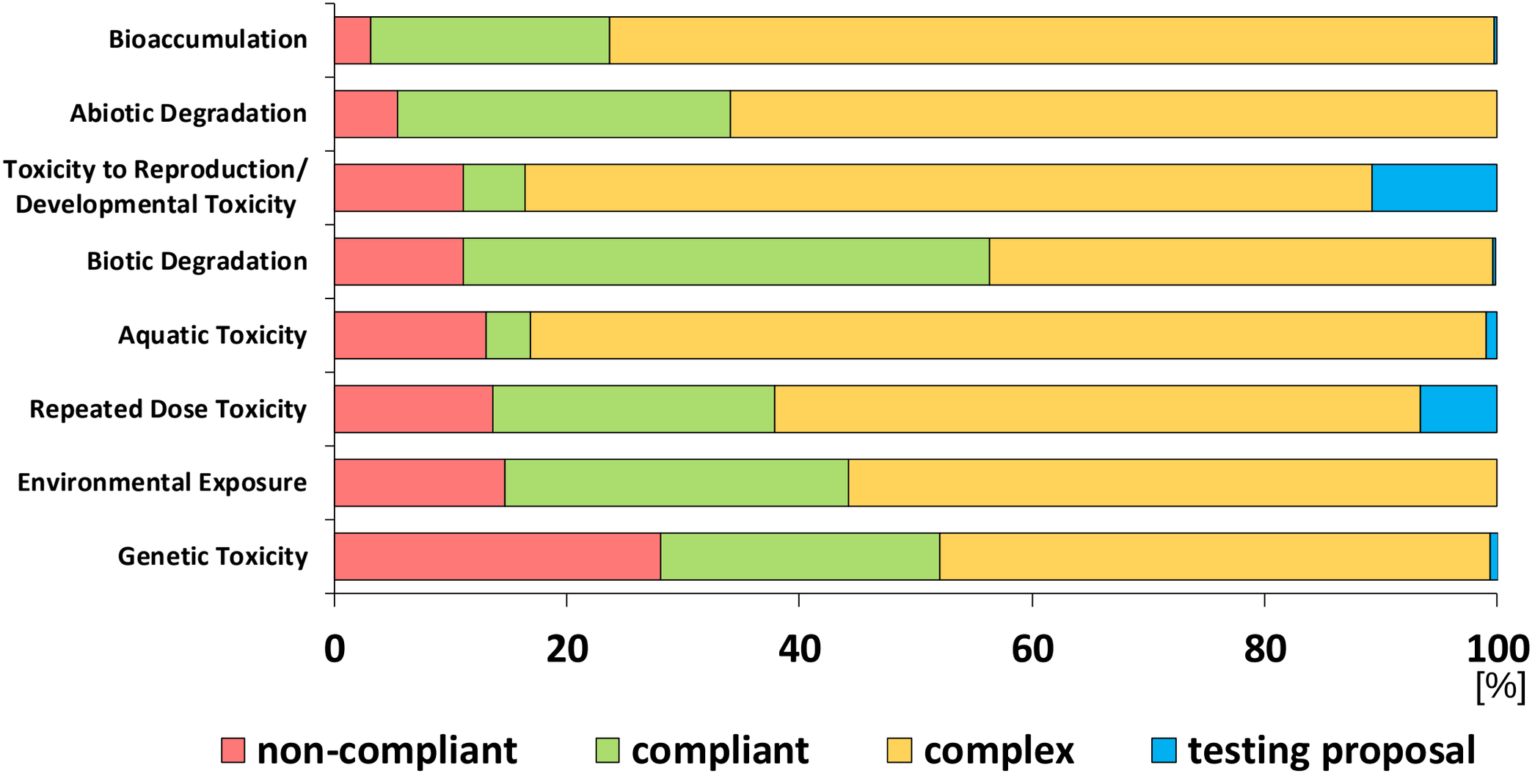


Project Overall Results

Endpoint decisions overview [%]

Sorted by 'non-compliant', ascending



Total dossiers: 1814

Project Summary of Overall Results

- In 58% of dossiers at least one 'non-compliant' endpoint
- ~20% of 'non-compliant' dossiers were 'non-compliant' for 3-5 endpoints
- Only 1 dossier with 'compliant' data in all endpoints
- ~ 80% of dossiers were 'compliant' in only up to 2 endpoints
- ~ 70% of dossiers were 'complex' in 4-6 endpoints
- Endpoints were mostly 'complex' due to adaptations/waiving of standard requirements or other reasons not assessable. Plausibility examined in single cases.
- Differences between endpoints

Project Conclusions from Overall Results

- ✓ Overview on the availability of data in REACH registration dossiers of high tonnage chemicals was achieved
- ✓ Data gaps were detected

Follow-up actions

- Further examination of 'complex' endpoints

Project: Further Results

Next presentations on

- Results on human health endpoints
- Results on environmental endpoints

- Single case analysis of complex cases

  (read-across/grouping approaches excluded)

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Thank you for your attention

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