

For our Environment

Information session on the new registration process

Quality observations on dossiers:

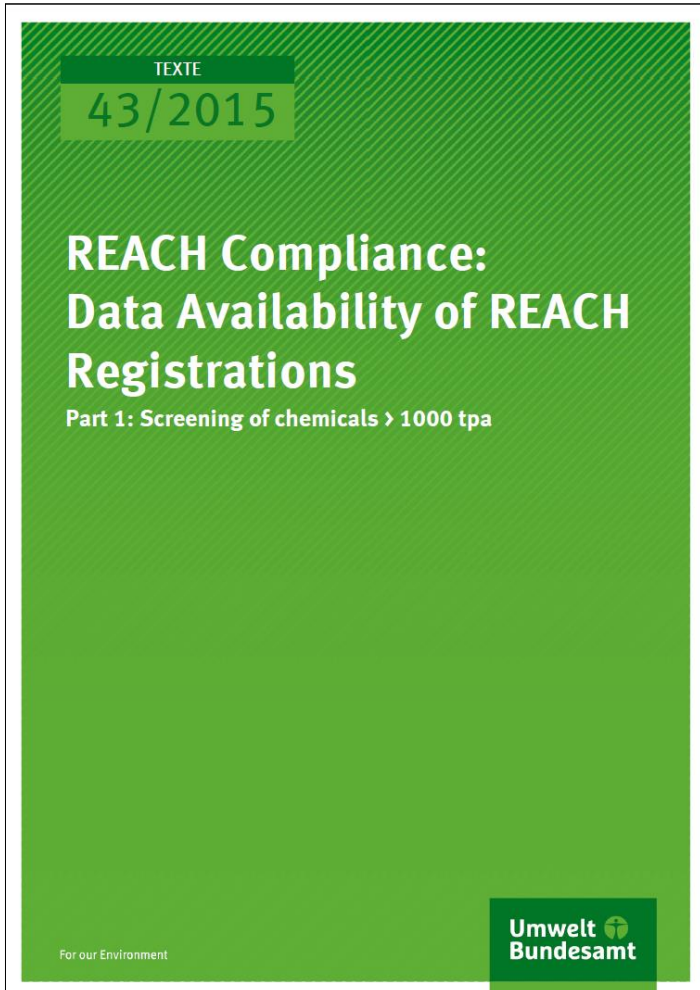
# Results from the German REACH-Compliance Project

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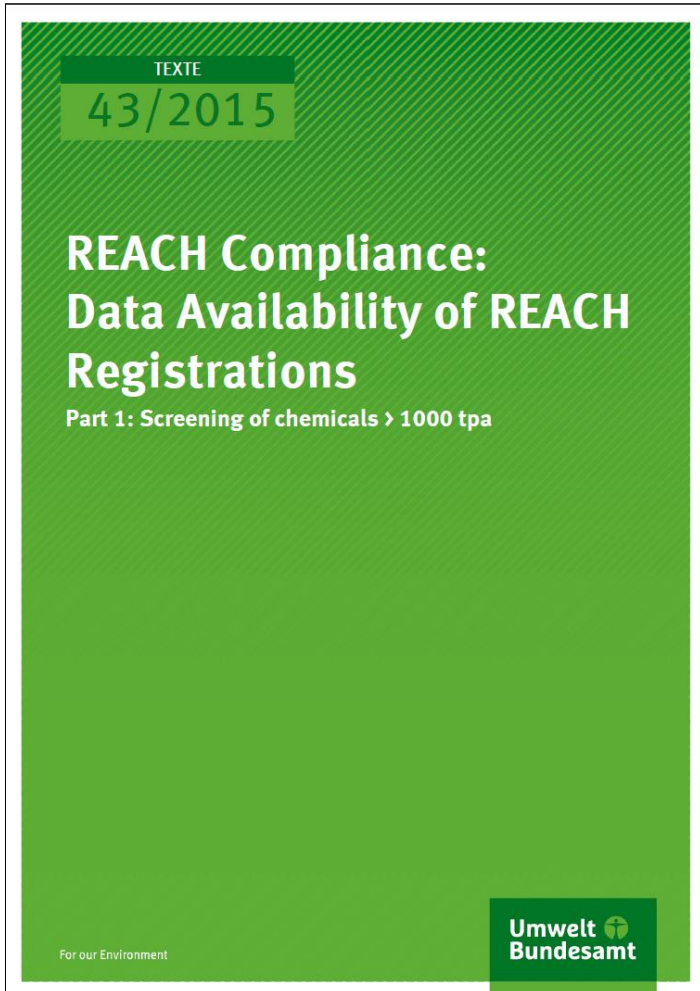
AbtL IV 2: Pharmaceuticals, Chemicals, Environmental Testing

## The German REACH-Compliance Project



- Based on an initiative of Federal Ministry of Environment
- Cooperation between the German agencies UBA and BfR (BfR as contractor)
- Project employees at BfR: 3 (2 experts on human health, 1 expert for environment)
- Duration: 1 year

## The German REACH-Compliance Project



- Manual check of 1.932 registration dossiers from 2010
- Check for 7 regulatory important endpoints
- Duration of check: 5 months
- Categorisation of endpoints and overall dossiers

English report is available

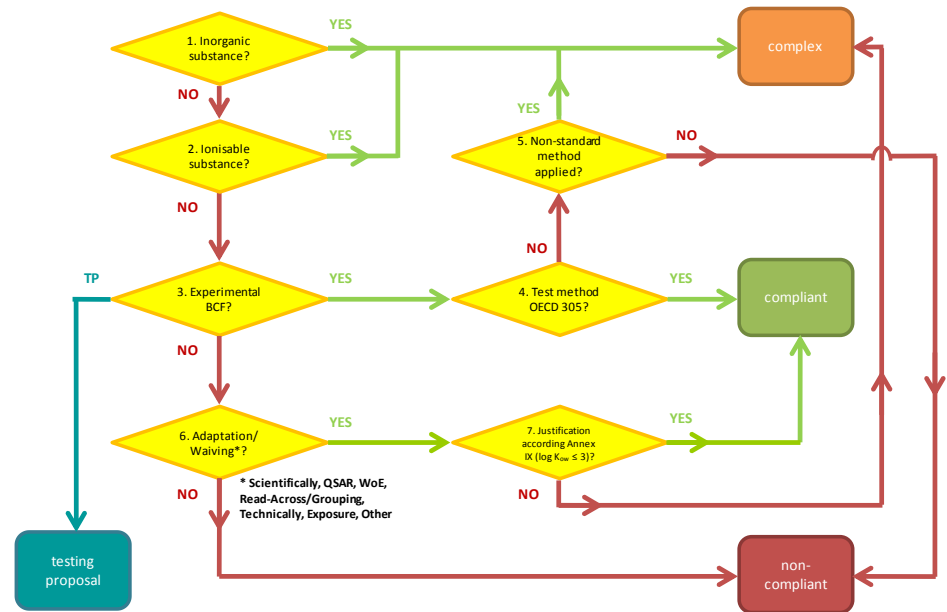
[http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte\\_43\\_2015\\_reach\\_compliance\\_data\\_availability\\_of\\_reach\\_registrations\\_0.pdf](http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_43_2015_reach_compliance_data_availability_of_reach_registrations_0.pdf)

## Exact definition of categories

- **“Compliant”**: In compliance with the REACH standard information requirements according to the screening criteria of this project
- **“Non-compliant”**: In non-compliance with ...
- **“Complex”**: No conclusion regarding compliance or non-compliance could be made as a result of the screening
- **“Testing proposal”**: A testing proposal is provided by the registrant in order to comply with the REACH information requirements

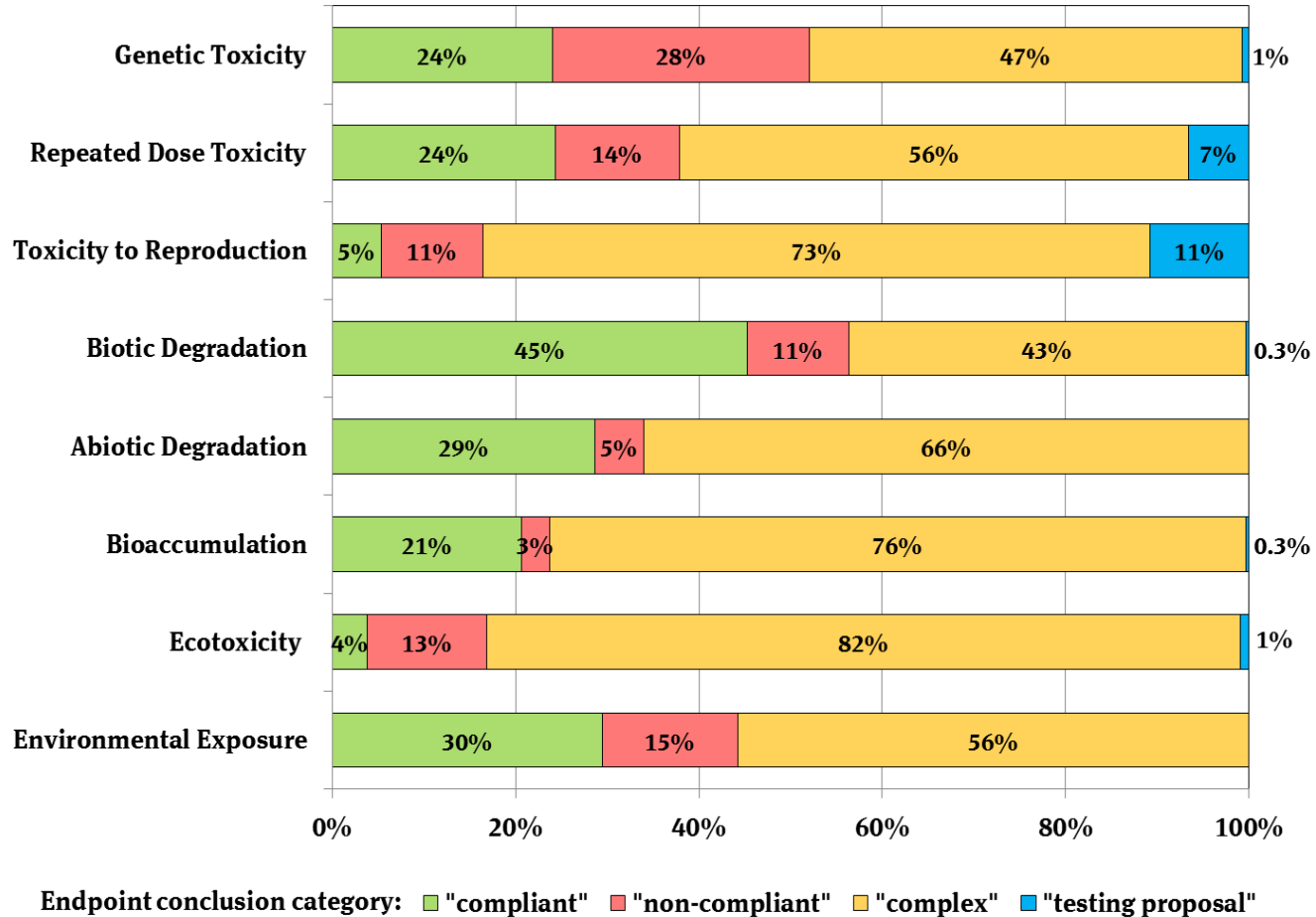
## How to evaluate consistently in a project of this scale?

- Systematic and independent evaluation → employ decision trees
- Use strict criteria for categorisation based on
  - legal text of regulation
  - guidance documents
  - newest scientific results
  - what would be used by agency (e.g. in Substance Evaluation)



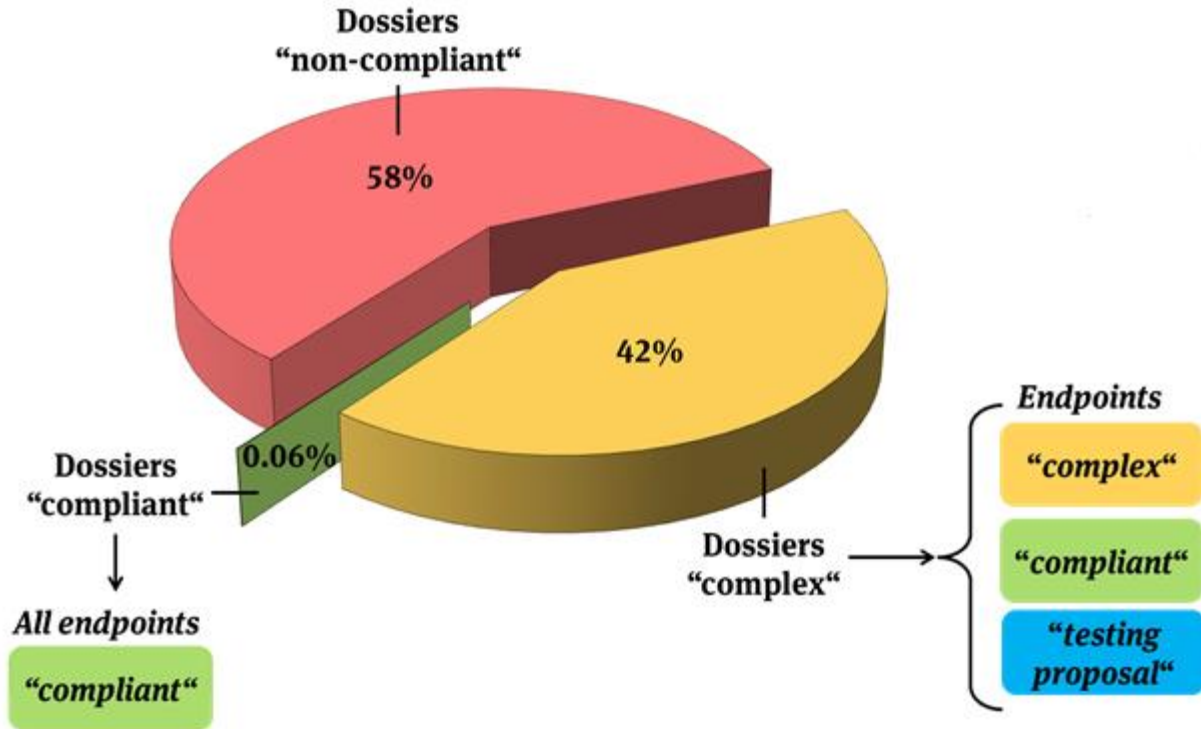
Source: project report

## Overview of results for the individual endpoints



Source: project report

## Overview of results for the overall dossiers



Source: project report

## Quality observations from this project

- High quality data in registration dossiers is
  - needed for all further REACH processes
  - in the interest of all stakeholders to guarantee a level playing field
  - but still not guaranteed even for the dossiers of high volume substances submitted 2010
- Often encountered issues include e.g.
  - inconsistent use of testing materials
  - use of unacceptable studies
  - Missing justification and documentation when adapting or waiving standard data requirements



## Ideas, suggestions and recommendations based on our observations

### **ECHA:**

- Strong commitment on Dossier Evaluation to guarantee high quality of dossiers needed
- focus on endpoints that are relevant for regulation and where systematic problems have been shown
- check possibility to implement ideas from the project in larger scale

### **Registrants:**

- Use generated data on the dossiers to improve them
- Use project observations on issues that are problematic or complex for future registrations

### **Member States:**

- Support industry in their registration obligations especially with regard to SMEs and the registration deadline in 2018

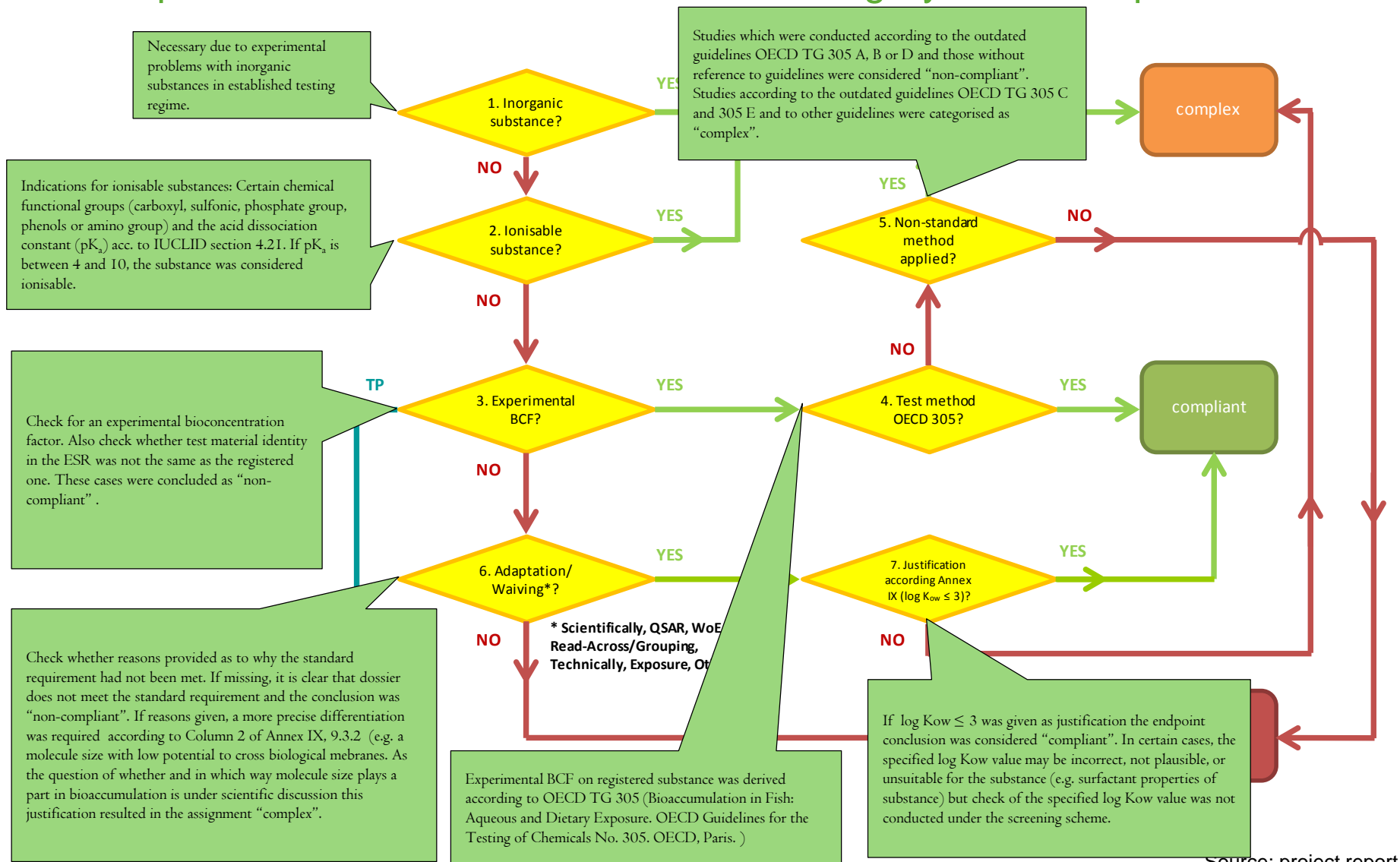
# Thank you for your kind attention!

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## Backup: What constitutes which decision category? An example.



Source: project report