

From registration dossiers via safety
data sheets
to workplace risk assessment

Overview and preliminary results on REACH2SDS

August 24th, 2018: REACH Compliance – Workshop on data quality in registration dossiers, German Federal Institute for Risk Assessment (BfR), Berlin

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REACH2SDS

Aims & Objectives

Objectives:

- I. To assess the **availability of information** concerning workplace exposure, risk and risk management measures (RMMs) in the Chemical Safety Report (CSR) and extended safety data sheet (eSDS)
- II. To examine the **quality of information transfer** from CSR to the eSDS
- III. To study the **applicability of the given information** for workplace risk assessment

Key issue: Review of the communication of risk and RMMs throughout the supply chain of a representative number of registered substances (100 - 1,000 tpa)

→ Aims: Identification of information gaps and communication issues along the supply chain: **information availability vs. information needs**

- I. improve interface btw. REACH and occupational safety and health regulations
- II. supply consistent recommendations

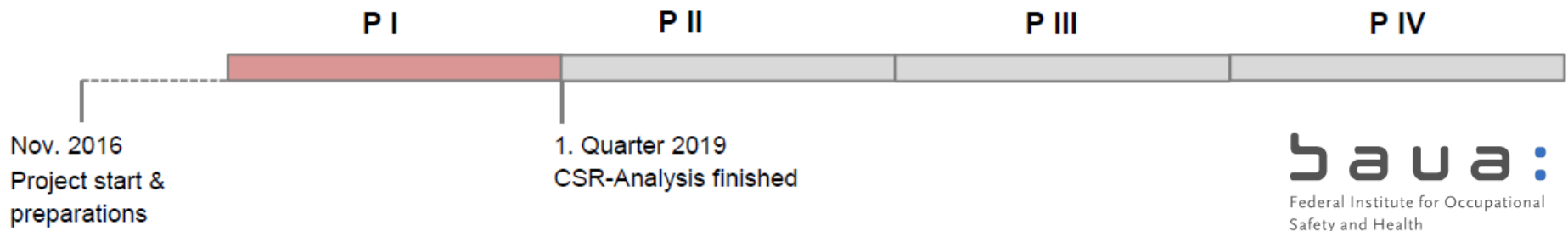
REACH2SDS WP I

The project comprises 4 work packages (WP I-IV):

WP I: Analysis of data availability and quality in CSRs for chemical substances registered under REACH

- I. 1690 lead dossiers for chemicals of the 100 – 1,000 tpa band
 - II. definition of markers: exposure assessment and recommended RMMs
 - III. development of decision trees
- Evaluation of information provided in CSRs and corresponding eSDS

➤ Cooperation with ECHA and BfR



REACH2SDS WP I

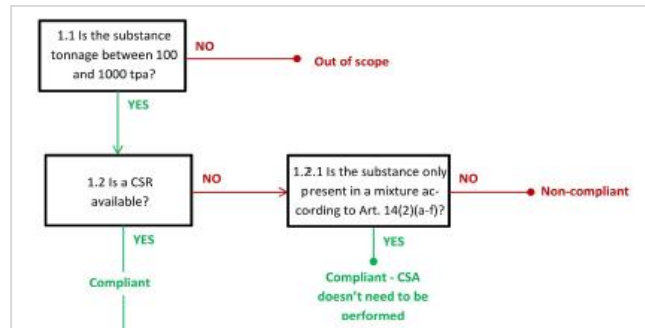
WP I: decision trees & result categories

- Evaluation of information provided in CSRs and corresponding eSDS
- Assignment to one of the three result categories:

compliant: fulfilling legal information requirements/ being within the boundaries of a model

non-compliant: not fulfilling legal information requirements/ out of model boundaries

complex: detailed analysis/ more information required



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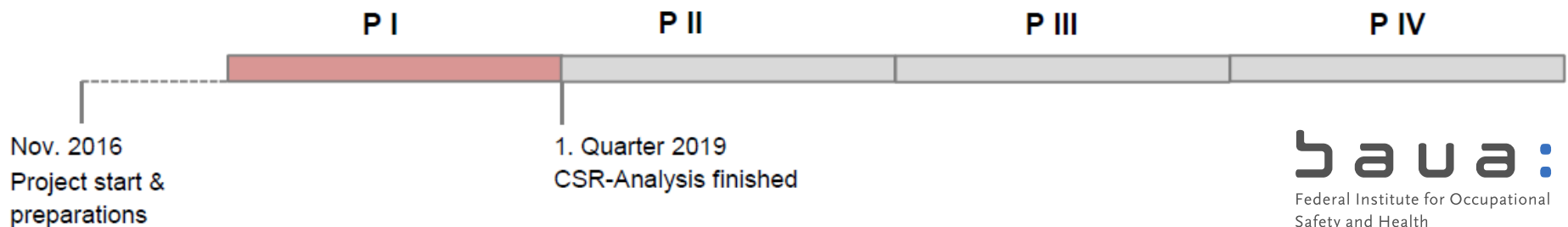
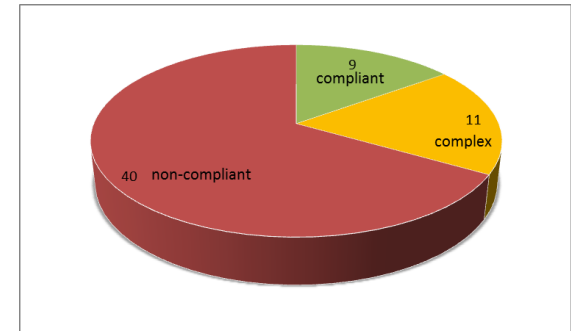
Nov. 2016
Project start &
preparations

1. Quarter 2019
CSR-Analysis finished

REACH2SDS WP I

WP I: preliminary results

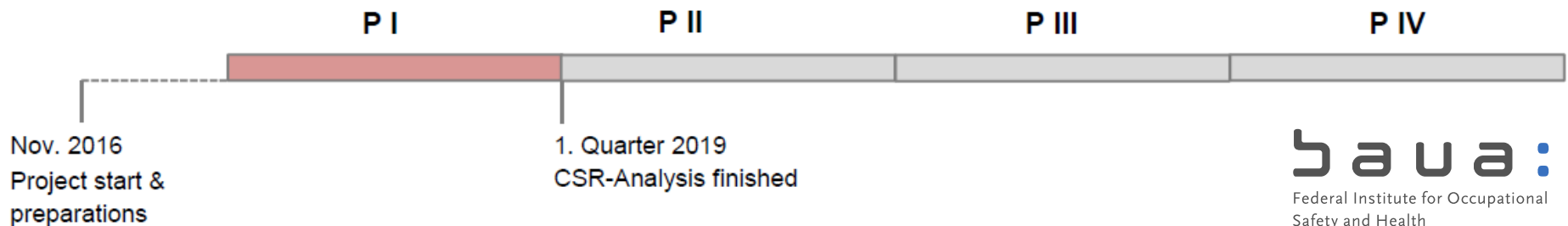
- 1690 lead dossiers
- To date: 229 analyses finished → result categories assigned
 - 159 substances not classified (= exposure assessment not required)
→ formal requirements fulfilled
 - 10 out of scope (e.g. other tonnage band)
 - **60** registration dossiers of interest with result



REACH2SDS WP I

WP I: preliminary results

- main reasons for **non-compliant** result category:
 - absence of details on personal protective equipment
 - absence of manufacturing processes for non-imported substances
 - absence of CSR
- main reasons for **complex** result category:
 - disregard of model limitations
 - use of inadequate reduction factors
 - discrepancies between the process and risk management measures

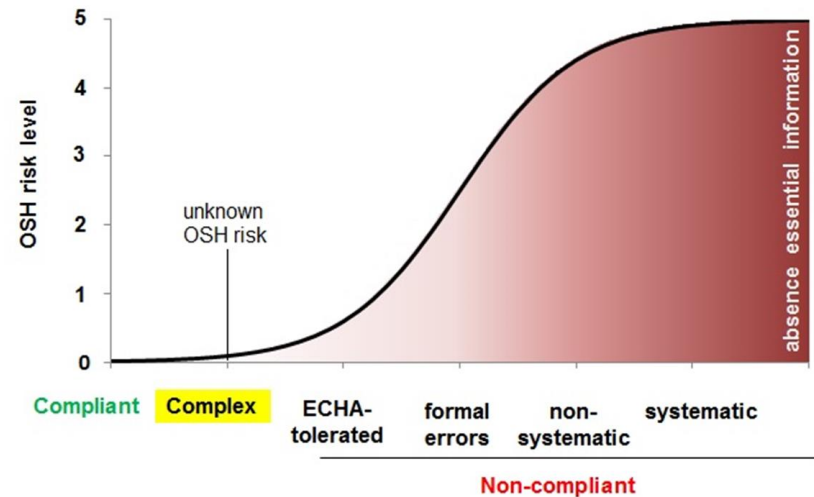


REACH2SDS WP I

WP I: preliminary results

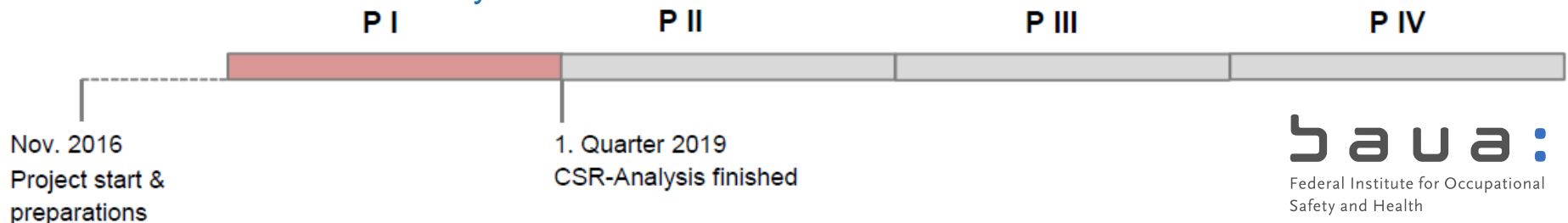
Identified issue: CSR analysis showed clear quality differences between the individual reports:

- the unweighted interpretation of the rather diverse markers might distort the conclusions drawn from the project
- therefore a **banding approach** is suggested to further characterise markers rated as non-compliant depending on the severity of the information gap for occupational safety and health



Next Steps

- transferring present results into the banding approach
- continue the CSR-analysis



REACH2SDS WP II

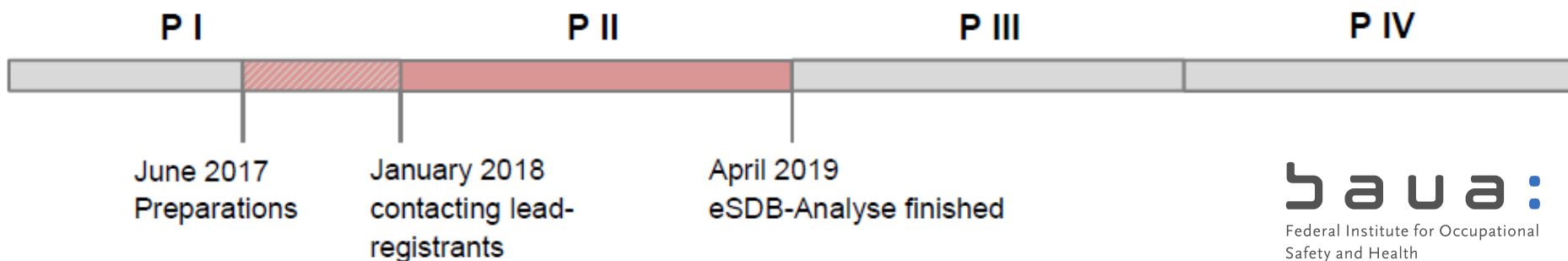
WP II:

Comparison of data availability and quality between registration dossier and eSDS

- definition of relevant eSDS-related markers
- development of decision trees

→ **Here we depend on the active support of the registrants: as many eSDS are not freely accessible our possibilities for analysis are limited. Therefore:**

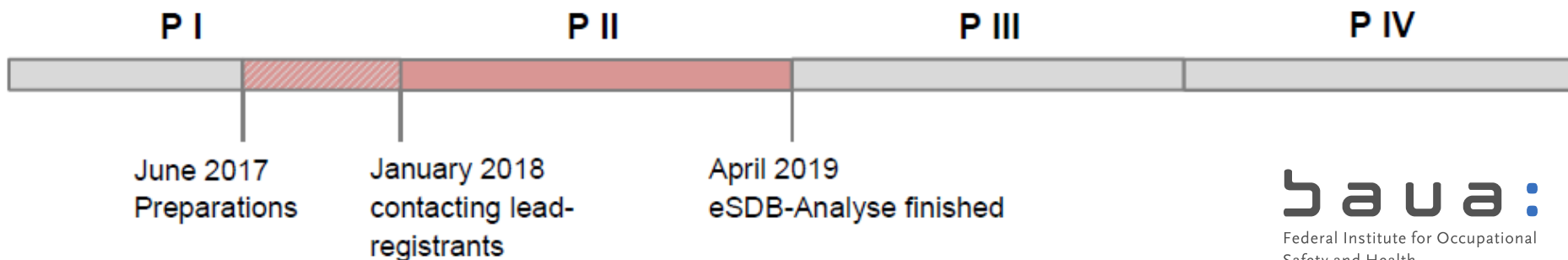
- contacted the lead registrants and enquired the eSDS
- to maximise the value of this enquiry a questionnaire was developed



REACH2SDS WP II

WP II: Questionnaire

1. **Introduction:** role of the respondent within the REACH process
2. **Development / Compilation of the eSDS:** which tools and information are used, who is responsible
3. **Communication:** use for business-internal risk assessment, how is the eSDS and changes communicated to the downstream users
4. **Quality Management:** is accuracy and completeness of eSDS checked, consistency check with CSR
5. **Personal views:** impact of eSDS, effort compiling it, its use for the downstream user
6. **Personal views:** changes to make ES / eSDS useful tools
7. **Information on the company:** employees, in which country



REACH2SDS WP II

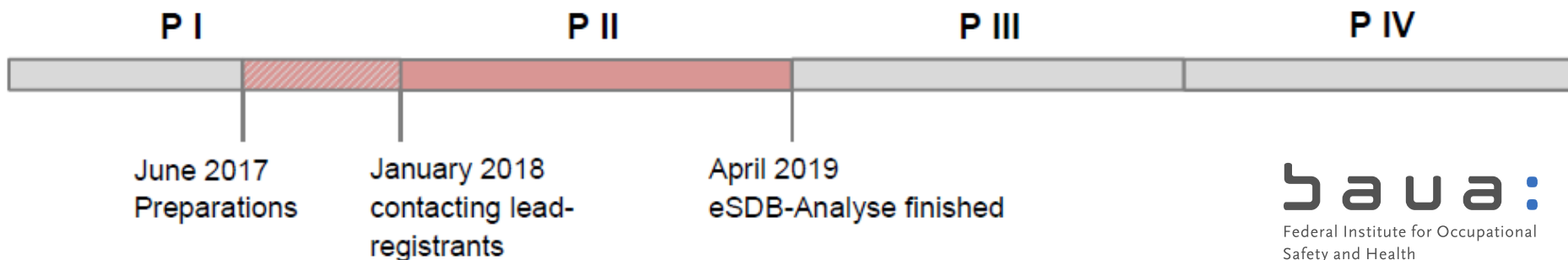
WP II: Questionnaire – preliminary results

Majority of respondents:

- regards eSDS compilation and communication as useful
- does not use any other tools for risk communication to downstream users
- regards eSDS as not suitable for workplace risk assessment

But:

- uses results/ outcomes from internal workplace risk assessment for CSR compilation
- even more use the eSDS internally for communication of risk and RMM

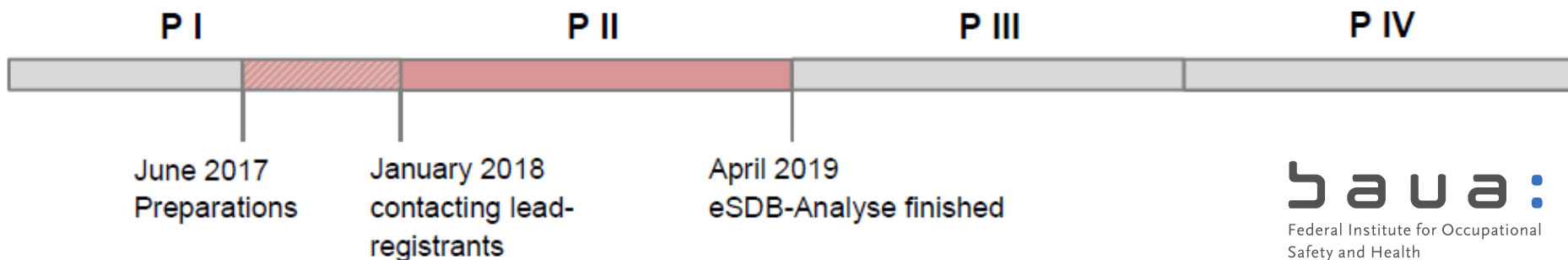


REACH2SDS WP II

WP II: Questionnaire – preliminary results

Free text fields were used to large extent, suggestions to improve the format included:

- increase standardisation/ harmonisation; obligatory format
- shorter; distribute information throughout core SDS
- less scientific; more applicability to different education levels



REACH2SDS WP III

WP III:

Evaluation of data available in the eSDS to enable a reliable workplace risk assessment

- Comparison eSDS ⇔ CSR in the context of workplace risk assessment
- **Consistency check of RMM communicated through the eSDS by use of the EMKG**
- The consistency of recommended RMMs with a control-banding approach-associated protection level will be assessed using the **‘Easy-to-use workplace control scheme for hazardous substances’** (EMKG)

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January 2019
Preparation EMKG

November 2019
adaptability test finished

REACH2SDS WP IV

WP IV: Workshop

The information obtained in Parts I-III will be used to develop strategies addressing identified challenges to improve the communication throughout the supply chain.

→ the identified problems and developed strategies will be communicated to and discussed with the relevant stakeholders in a workshop (planned for 2020)

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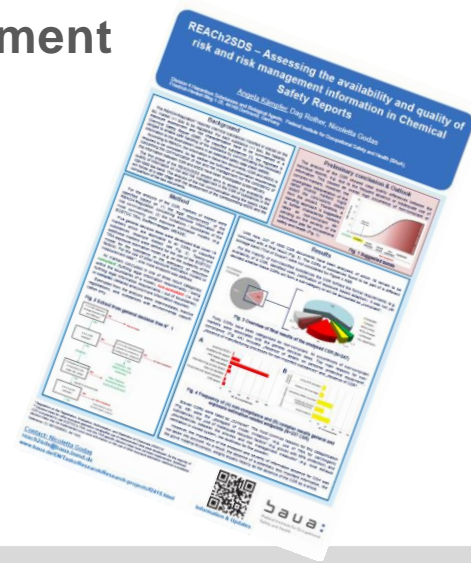
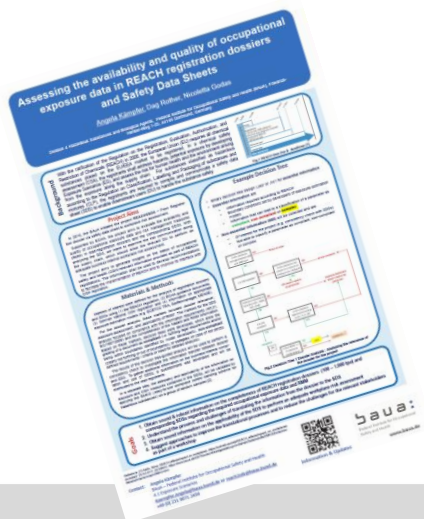
P IV

January 2020
Evaluation, strategy & tools

Spring/Sommer 2021
final report & project
ending

Summary

- REACh2SDS evaluates:
 - the data availability on workplace exposure and on RMM for registered substances
 - how this data is communicated in the supply chain via eSDS
 - how this data can be used for workplace risk assessment



Closing remarks

- **Good and reliable information** at the beginning of the supply chain are **essential for a well-functioning chemicals legislation and safe workplaces!**

Not only for REACH but also for all related legal areas that use this data as a basis for their risk-based action!

Thanks for your attention!

REACH2SDS

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