

REACH2SDS - Adequate data in REACH exposure scenarios for successful workplace risk assessment

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Background and aims

One key objective of the European chemicals regulation REACH (EC) No 1907/2006 is to advance the protection of human health and the environment from the risks posed by chemicals by improving the communication of relevant recommendations along the supply chain. A key element to achieve the communication of information on safe handling and use of hazardous substances is the safety data sheet (SDS). For registered substances of tonnages above or equal to 10 tonnes per year, exposure scenarios (ES) from the Chemical Safety Report (CSR), including risk management measures (RMM) and operational conditions, must be attached to the SDS as an annex, the extended SDS (eSDS).

The project REACH2SDS¹ analyses availability and quality of information and its transfer between registration dossier and SDS and eSDS for chemical substances with regard to their usability for workplace risk assessment. In order to examine the usability for risk assessment at the workplace, the RMM of the SDS are compared with the results of the Easy-to-use Workplace Control Scheme for Hazardous Substances (EMKG).

Methods

Tool

EMKG-Software²

- Control banding tool by the German Federal Institute for Occupational Safety and Health (BAuA)
- Tool input: four initial parameters from the SDS and three worksite specific variables (Fig. 1).
- Tool output: one of four Control Strategy Levels (CSL) → 42 Control Guidance Sheets³ (summarized in Tab. 1) in format of two-page checklists with RMM

eSDS examination

- Worksite specific variables: conservative assumptions as real-world workplace conditions not known (Example Tab. 2).
- Check, if necessary information in eSDS was available and appropriate?
- Assessment using EMKG

Comparing RMM with EMKG results

- Examination of usability for risk assessment at workplace:

Comparison of EMKG output (Control Guidance Sheets³) describing suitable protective measures with RMM in main body of the SDS as well as the eSDS (ES).

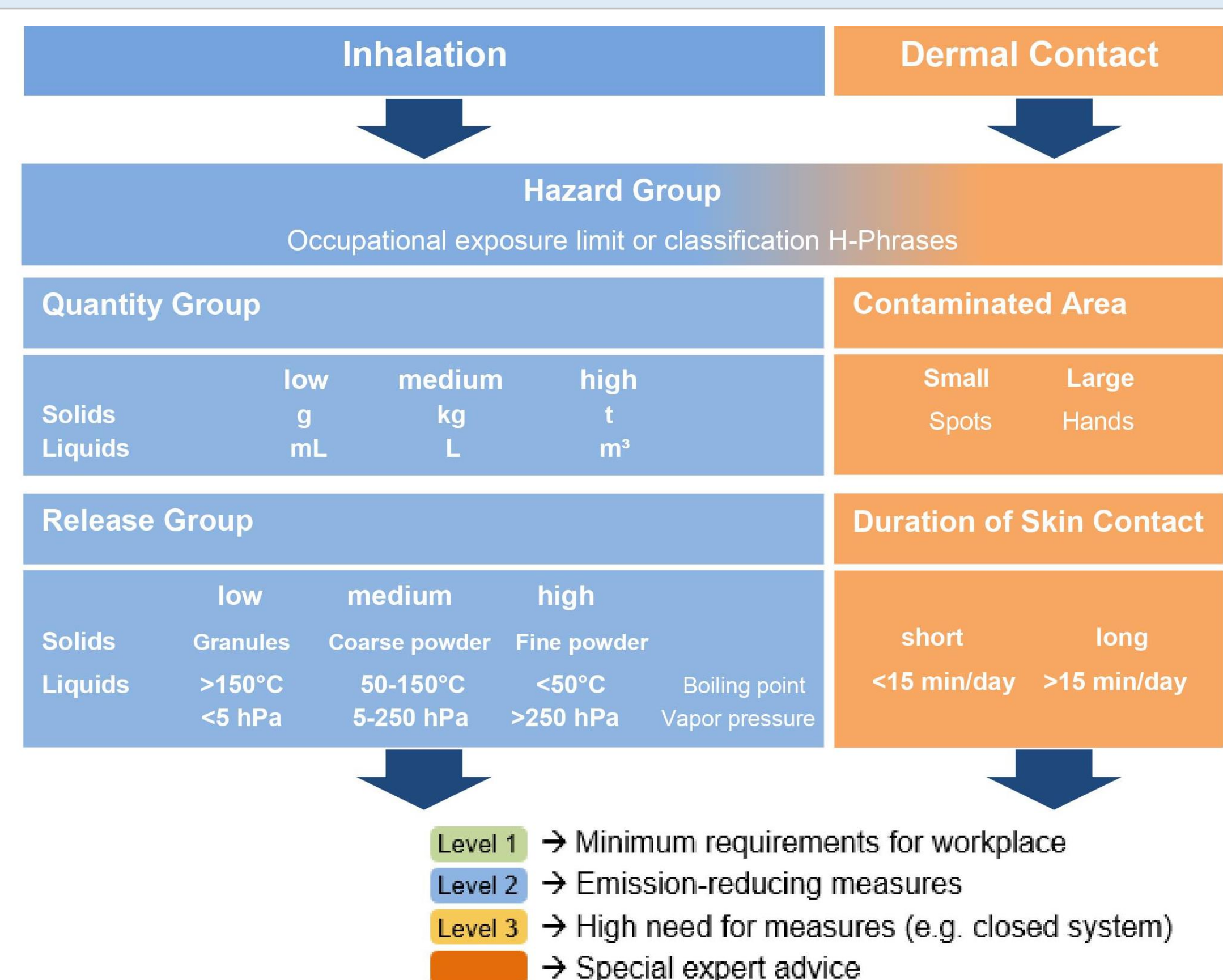


Figure 1: Overview on tool input to determine the Control Strategy Levels for the hazard groups "Inhalation" and "Dermal Contact".

Table 1: Summarized Control Guidance Sheets⁴ for comparison with the RMM.

CSL	Number of Control Guidance Sheets	Recommended protective measure(s)
1	100	Free ventilation
	La-101	Handling and storage
	110	Organisational and hygiene measures "Inhalation"
2	120	Organisational and hygiene measures "Skin"
	200	Local exhaust ventilation
	201, 203	Fume cupboard / exhaust cabinet
	204, 205, 206, 208, 210, 211, 212, 213, 214, 215, 217	Filling systems and special systems
	240	Dust workplace (principles)
3	250	Extended need for "skin" measures
	300	Closed system
	305, 306, 307, 308, 310, 312	Filling systems

Table 2: Extract of the standardised input for the EMKG with the process category (PROC)⁴, which describe the use of a substance, the estimated quantity range and dermal exposure estimation for PROC 15.

PROC	Industrial quantity range	Professional quantity range	Input for dermal exposure
15: Use as laboratory reagent	kg or L; g or mL	kg or L; g or mL	Small affected area with more than 15 min of exposure

Methods continued

For this comparison, it was checked:

- if the information provided in the Control Guidance Sheets and RMM matched,
- whether the required RMM were missing or less RMM would have been sufficient to achieve safe levels at the workspace
- or if the Control Guidance Sheet and RMM are only consistent up to a certain quantity range.

For the data analysis Microsoft Excel⁵ and R Studio⁶ were used.

Preliminary results & discussion

EMKG Input & Limitations

So far a total of 47 eSDSs have been considered for the risk assessment using EMKG, of which only 41 could be used for the input due to missing or incorrect information → eSDS could not be entered into EMKG if important data such as boiling temperature or vapor pressure were missing or physical state in SDS and eSDS (ES) did not match.

690 ES were included in these 41 eSDSs of which only **454 ES** (~66%) could be used for risk assessment and comparison in the end → In most cases the ES could not be considered because the concentration of the substance in the ES no longer corresponded to a pure substance.

Comparison of RMM with EMKG results

- ~52% of the examined ES were consistent,
- while ~48% were inconsistent (Fig. 2).
- For ~46% of the consistent results, less measures would have been sufficient,
- while only ~13% of the inconsistent results would have been consistent for lower quantity ranges (Fig. 2).

Reasons for inconsistency

ES classified in CSL 3:

- ~73% of all inconsistent results were based on lack of RMM "Closed System".

ES classified in CSL 2:

- ~21% lacked RMM for local exhaust ventilation
- ~6% lacked RMM local exhaust ventilation in connection with missing requirement for protective gloves.

Discussion

Preliminary results show that about 50% of the RMM from eSDS were not consistent with the recommended protective measures of the EMKG. These inconsistencies may effect the risk assessment of the employers and may complicate the employer's duty to implement appropriate RMM to protect employees working with hazardous substances.

It is also noted that, although conservative assumptions with respect to the tool input were made, for about half of the consistent results, less RMM would have been sufficient. In the future, this issue will be examined more thoroughly within the scope of this project.

Conclusion

Our preliminary results indicate that the communication of appropriate RMM is currently not working as expected. Future Work within the scope of the project, will include putting the results presented into perspective with the assessment conducted in a different work package of the project focusing on information availability and quality and consistence between CSR and the corresponding eSDS.

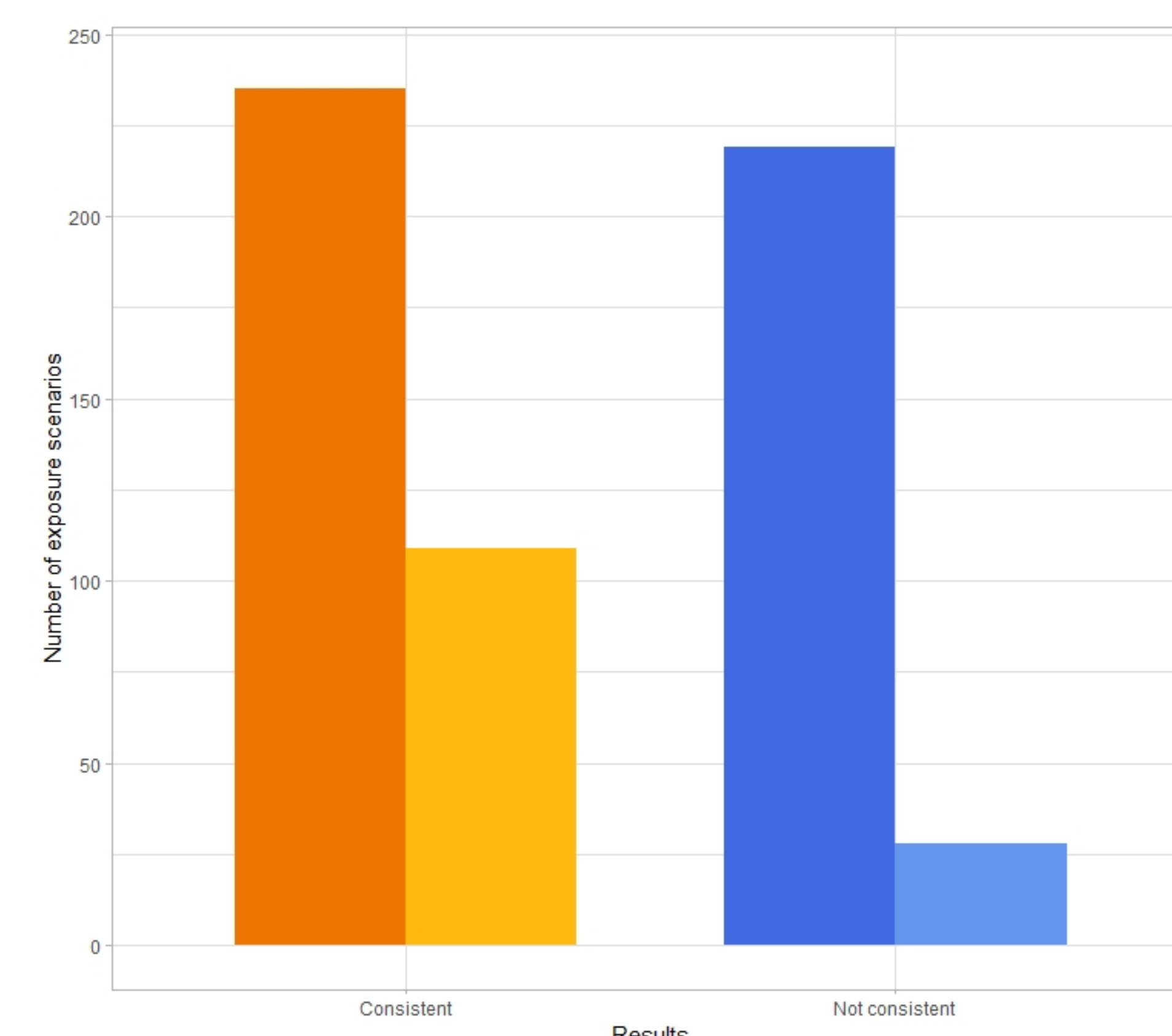


Figure 2: Comparison of Control Strategy Levels (EMKG) with recommended RMM (eSDS).



¹BAuA (2020): From registration dossier via safety data sheet to workplace risk assessment - data availability and quality between REACH and occupational safety (REACH2SDS). <https://www.baua.de/EN/Tasks/Research/Research-projects/f2415.html>

²BAuA (2020): Easy-to-use Workplace Control Scheme for Hazardous Substances (EMKG). Version 0.21.0. 23.12.2019; Download: www.baua.de/emkg

³BAuA (2020): Control Guidance Sheets for the Easy-to-use Workplace Control Scheme for Hazardous Substances (EMKG). <https://www.baua.de/EN/Topics/Work-design/Hazardous-substances/EMKG/EMKG-control-guidance-sheets.html>

⁴ECHA (2015): Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.12: Use description. Version 3.0 https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

⁵Microsoft Corporation (2018). Microsoft Excel. Version 16.0. Download: <https://office.microsoft.com/excel>

⁶RStudio Team (2015). RStudio: Integrated Development Environment for R. Boston, MA. Version 1.2.1335. Download: <http://www.rstudio.com/>