

# Occupational exposure to hazardous substances & risk management measures

## - Information obligations under REACH -

An assessment of data availability & supply chain communication in chemical safety reports and safety data sheets

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### Background and Aims

The European Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) requires manufacturers/importers of chemical substances upon registration ( $\geq 10$  tonnes per year) to (i) assess hazards and subsequent risks of substances, (ii) identify and implement necessary risk management measures (RMMs) and (iii) pass on relevant recommendations along the supply chain. Information of the Chemical Safety Assessment are summarised in the Chemical Safety Report (CSR) by the registrant whereas relevant information and recommendations are communicated via the safety data sheets (SDS) and the extended SDS (eSDS) to the downstream users. The information in these two documents, (i) CSR and (ii) SDS plus eSDS (= (e)SDS), is required to be consistent.

We investigate the fulfilment of information requirements with respect to availability and quality in CSR and (e)SDS and the consistency of the information and communication of risk and risk management between CSR and (e)SDS. The work presented here gives an overview of preliminary results of 50 datasets analysed.

### Methods

#### Assessment of availability and quality of information in the CSR:

- CSRs of registered substances in tonnage band of 100-1000 tonnes per year
- Inclusion criterion: Data provided until beginning of March 2017
- Data source: International Uniform Chemical Information Database Version 5 (IUCLID 5)

#### Investigation of translation of exposure information & RMMs from CSR to (e)SDS:

- Lead registrants contacted via standardised Email → asked to provide electronic copy (e)SDS

#### Simplified & harmonised data analysis:

- Development: Decision trees (example Fig.2) for assessment of data availability, quality and consistency:
  - Ranking of results using categories as shown in Fig.1; the highest ranking category possible in specific decision tree defines the final maximum overall ranking
- Systematic data collection, analysis and storage: Database in Microsoft Access
- Data analysis: R statistical software environment

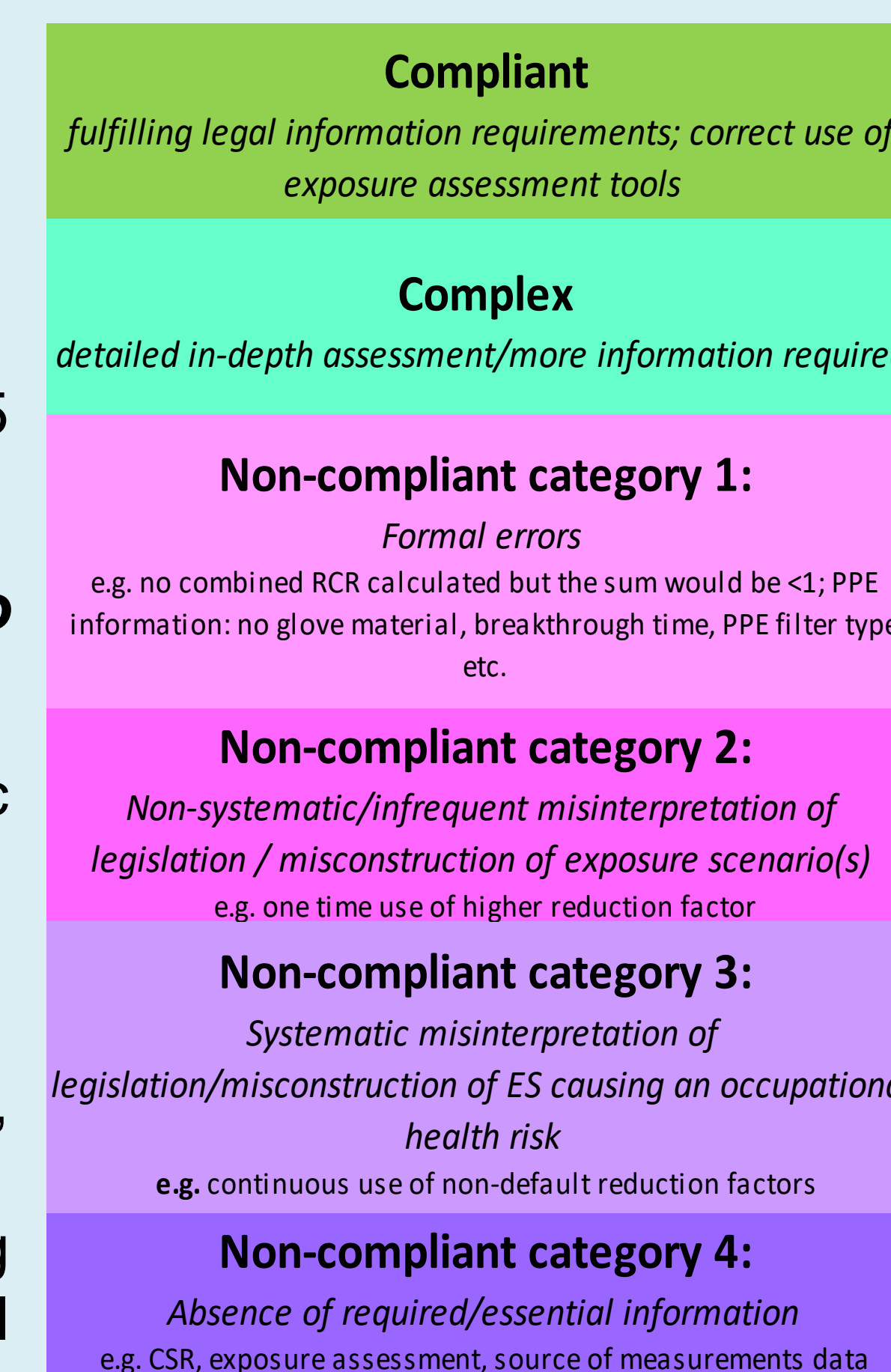


Figure 1: Ranking approach for result categories according to occupational safety & health risk level defined

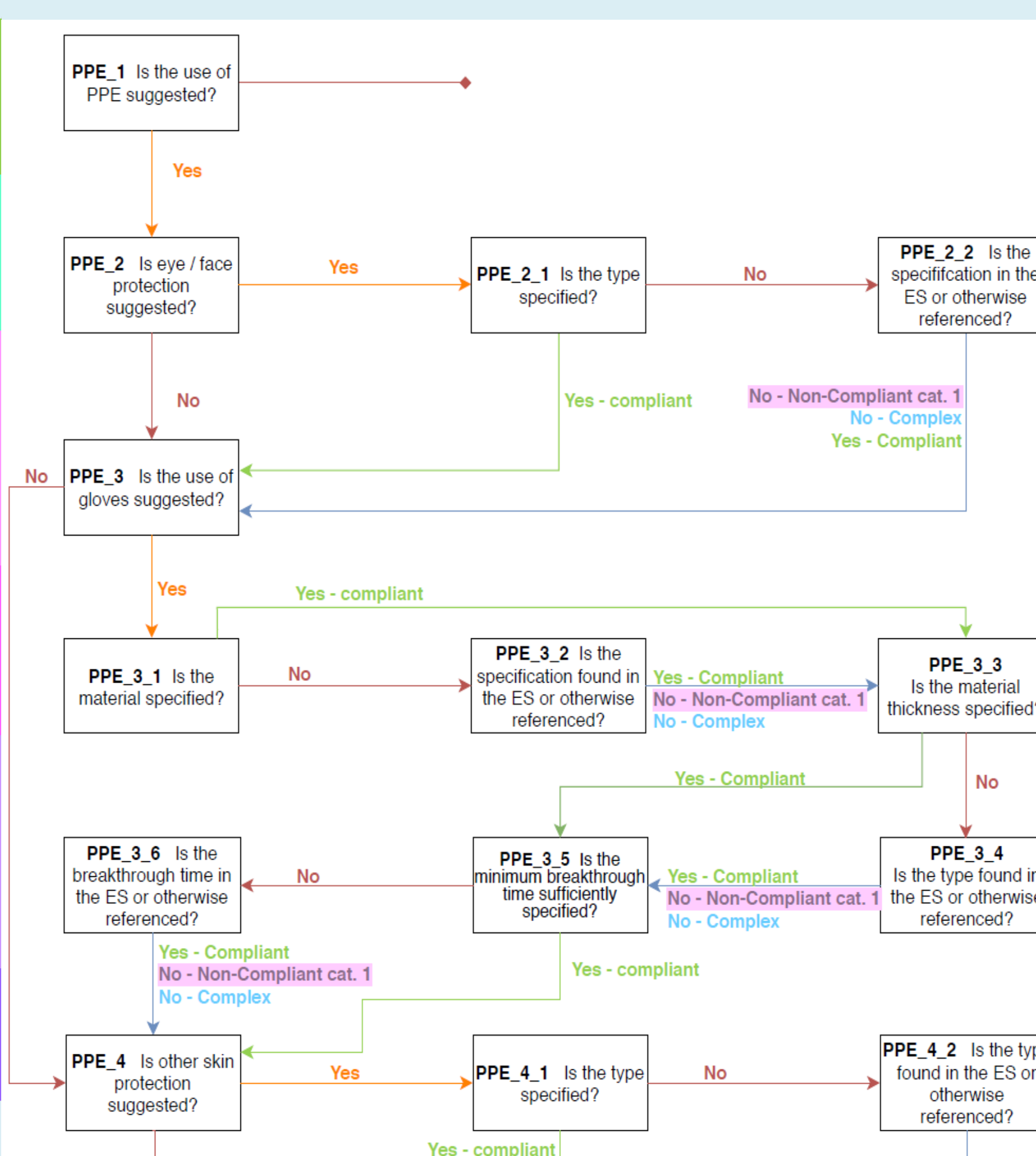


Figure 2: Example section of a decision tree with question logic on information on personal protective equipment (PPE)

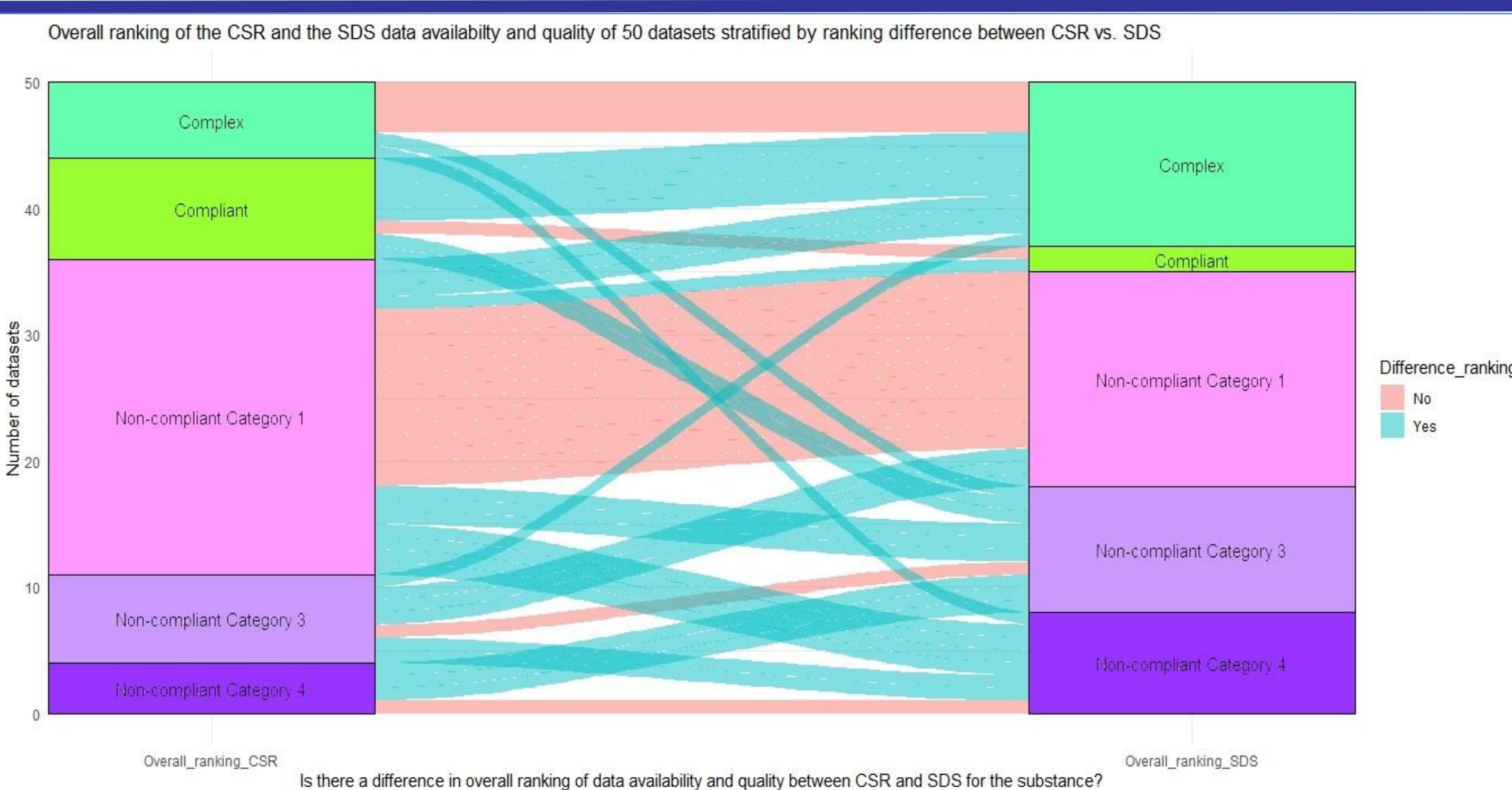


Figure 3: Overall ranking of 50 datasets stratified by difference in overall ranking between CSR and (e)SDS

The overall results of the assessment of 50 CSRs and their corresponding (e)SDS (Fig. 3) show:

- ~ 70% of CSRs: “Non-compliant” with 50% = “Category 1 non-compliance”
- ~ 70% of (e)SDS: “Non-compliant” with ~ 35% = “Category 1 non-compliance”
  - Main issue: Missing PPE information

Comparison of a specific CSR and its corresponding (e)SDS:

- Difference in the overall ranking outcome: in 58%
  - Further analysis needed as some of assessed information requirements triggering overall ranking decision were specific to CSR or (e)SDS.

For the majority of CSRs (Fig.3) shortcomings were identified. Common issues (for the rating non-compliant) included, but were not limited to:

- lack of information on PPE (Fig.5),
- issues with risk characterization ratio (RCR) calculation (12%), e.g. no combined RCR calculated and if it was calculated it was  $>1$ ,
- issues with use of exposure based adaptation (10%).

### Preliminary results & discussion

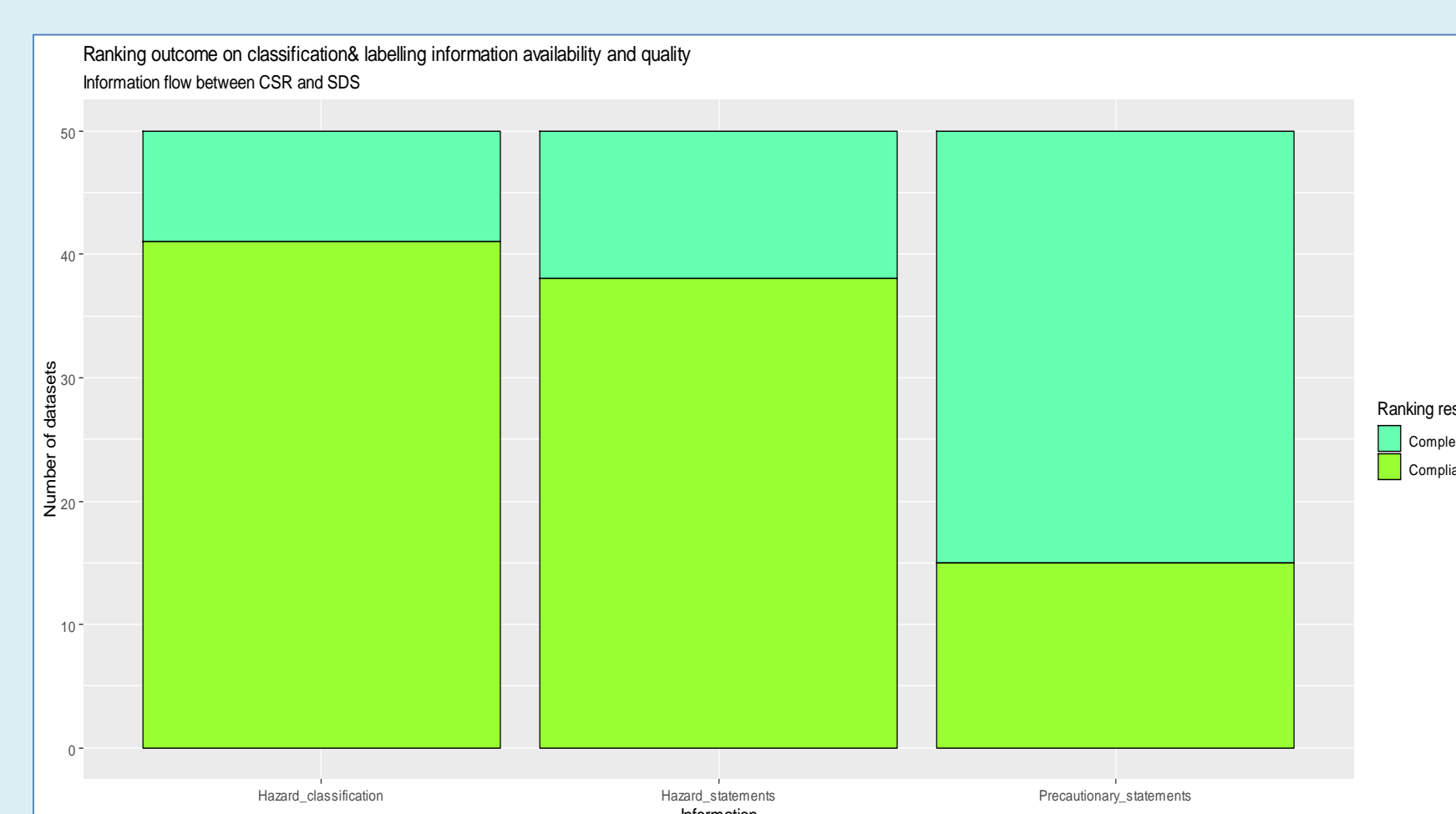


Figure 4: Ranking on questions on classification & labelling information

For the majority of (e)SDS (Fig.3) common issues included:

- lack of information on PPE (Fig.5),
- issues with risk characterization ratio (RCR) calculation (8%), i.e. RCR  $> 1$  or national occupational exposure limit not considered in risk assessment in eSDS scenarios.

Another issue identified is the information flow with respect to differences in classification and hazard and precautionary statements between CSR and SDS indicated by the ranking result of “complex” (Fig. 4). It has to be noted that the number of datasets assessed pose a limitation and might not be representative.

A comparison of PPE information availability between CSR and (e)SDS (Fig.5) showed that in (e)SDS information on all types of PPE assessed was provided at a higher percentage at a compliant level compared to CSRs. A common issue are information on glove thickness and their breakthrough time.



Figure 5: Comparison of PPE information availability between CSR and (e)SDS

### Conclusions

The analysis of the CSRs and the (e)SDS showed clear differences of information availability and quality between the individual reports, e.g. due to the absence or inadequate use of information. Furthermore our preliminary results suggest that there are information gaps and inconsistencies in communicating information along the supply chain between CSR and (e)SDS highlighting the need for strategies to address these issues.

The high occurrence of information gaps with respect to specific information requirements, such as PPE and RCR calculation, indicates that stricter guidance on how to assess and provide that information correctly is needed.

A workshop involving stakeholders is planned as a future milestone within the scope of this project to discuss and subsequently evaluate the issues identified with the aim to strengthen the mutual understanding of the different actors in the supply chain with respect to their differing and specific needs.