REACh2SDS – Assessing the availability and quality of risk and risk management information in Chemical Safety Reports

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Background

The REACH-Regulation* requires chemical substances imported or placed on the EU market (>1 tpa) to be registered. For each substance (>1 tpa), the hazards, exposure assessment and risk characterisation have to be summarised in a Chemical Safety Report (**CSR**). For classified substances [1], the registrant is obliged to enable safe handling of the substance by communicating the necessary information to the downstream users in an extended safety data sheet (**eSDS**)

According to REACH, the information in these two documents (CSR and eSDS) is required to be consistent. So far, neither the fulfilment of information requirements concerning the communication of risk and risk management nor the consistency of the information between CSR and eSDS have been investigated systematically.

The first phase of the REACh2SDS project aims to assess the availability and quality of information on risk and risk management in the CSR of substances in the 100-1000 tpa band. The analysis of the risk communication along the supply chain will follow at a later stage with the assessment of the corresponding eSDS and the comparison of the two documents.

Preliminary conclusion & Outlook

The analysis of the CSR showed clear quality differences between the individual reports, e.g. due to the frequent absence or inadequate use of information. This caused an overall high occurrence of non-compliant or complex markers. However, 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 de-pending on the severity of the information gap for occupational safety and health (Fig. 1).

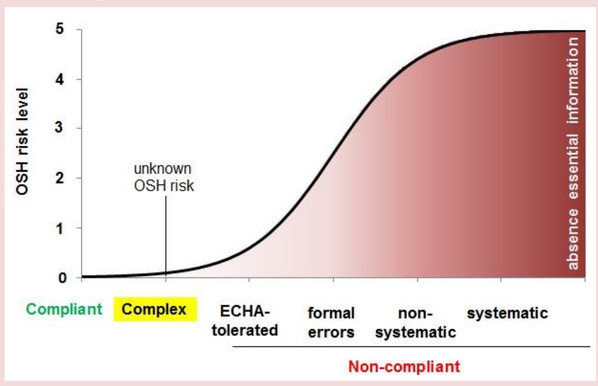


Fig. 1 Suggested bands

Method

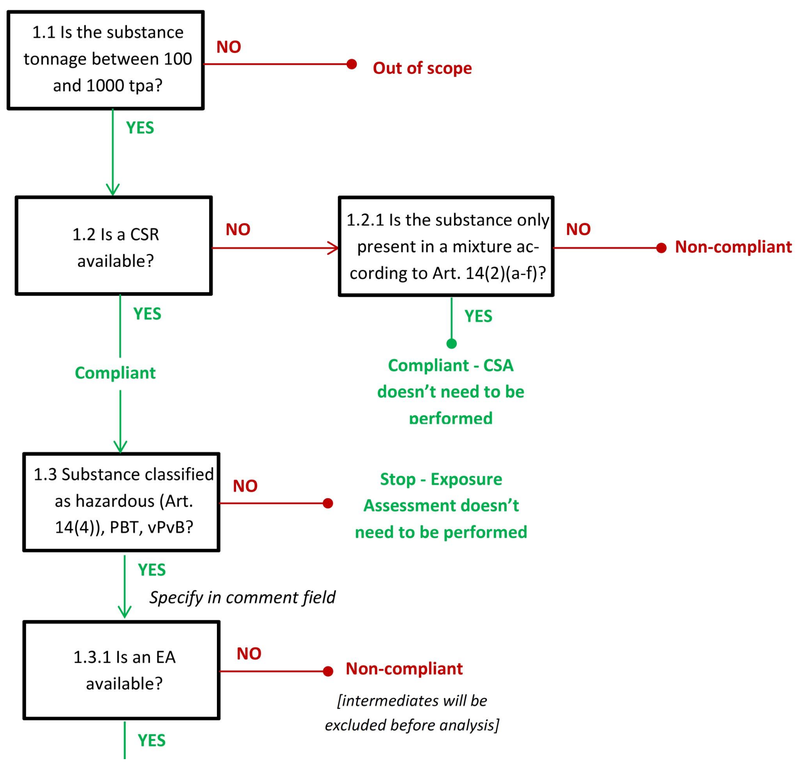
For the analysis of the CSR, markers of interest were identified based on (1) the legal requirements´ of the REACH-Regulation concerning exposure information and risk communication; (2) the limitations / boundaries of the most commonly used exposure estimation models (e.g. ECETOC TRA, Stoffenmanager, MEASE).

Five general decision trees were developed that cover 19 markers which are applicable to all CSRs of classified substances (example extract see Fig. 2). Twenty-one additional markers were defined for the use of the ECETOC TRA exposure estimation model (e.g. on the suitability of the model for the substance or the adequacy of reduction factors). For the use of other exposure estimation models or measurement data**, one more endpoint was defined.

All markers concluded in one of three result categories: **compliant** (fulfilling legal information requirements / being within the boundaries of a model), **non-compliant** (i.e. not fulfilling legal information requirements / out of boundaries), or **complex** (detailed analysis/more information required).

Exempted from the analysis were: Intermediates, inactive registrations, and substances with environmental classifi-cation only.

Fig. 2 Extract from general decision tree N° 1



Results

Until now, 247 of 1690 CSR documents have been analysed, of which 18 remain to be concluded with a final result (Fig. 3). The CSRs of substances found to be part of a different tonnage band ("Out of Scope") were not considered for Figure 4 A&B.

For the majority of non-classified substances the CSR fulfilled the formal requirements (e.g. availability of a CSR, identified uses, justification of exposure based adaption). It was not yet decided whether these CSRs will form a sub-category or will be accounted as „compliant".

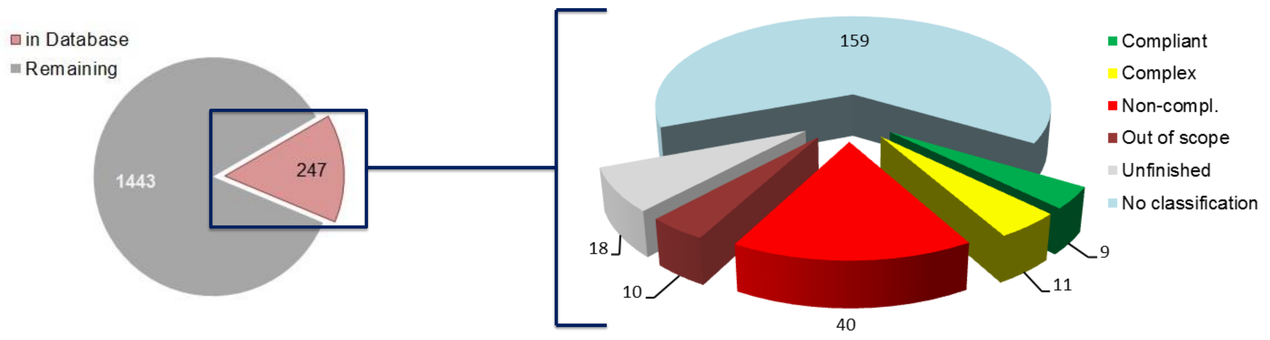


Fig. 3 Overview of final results of the analysed CSR (N=247)

Forty CSRs have been categorised as non-compliant. All occurrences of non-compliant markers were associated with the general decision trees. The main reasons for non-compliance (Fig. 4A) included „Absence of details on personal protective equipment", „Absence of manufacturing processes for non-imported substances" and „Absence of CSR".

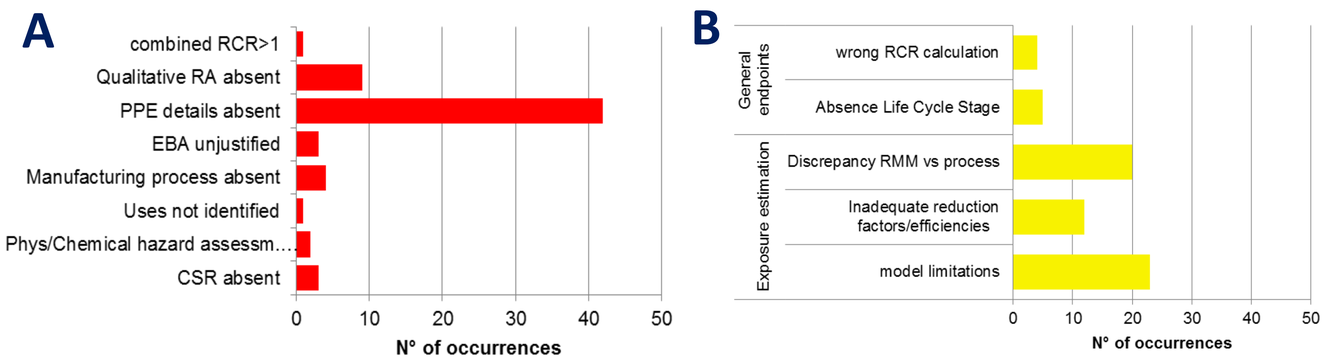


Fig. 4 Frequency of (A) non-compliance and (B) complex results general and exposure estimation-related endpoints (N=237 CSR)

Eleven CSRs were rated as „Complex". The most common reasons for this categorisation (Fig. 4B) were the „disregard of model limitations" (e.g. use of TRA for carcinogenic substances), the „use of inadequate reduction factors" (e.g. gloves with 99% protection), and „discrepancies between the process and risk management measures" (e.g. local exhaust ventilation in closed system, low dustiness for fine powder).

However, the importance of the endpoint and severity of information absence for OSH was not taken into account. As a result, the absence of a potentially less important information, like the glove material thickness, weighs equally heavily as the absence of the CSR as a whole.

** Regulation on the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH)*
*** Decision trees for other exposure estimation models/the use of measurement data were developed. As the majority of CSR is expected to use ECETOC's TRA, only the TRA-specific decision trees have yet been implemented. Additional decision trees may be implemented once more information on the use of other exposure estimation methods is available.*

Reference: [1] 1907/2006/EC, Art 14(4)

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www.baua.de/EN/Tasks/Research/Research-projects/f2415.html

Information & Updates

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