

# Data availability of use and exposure information

REACH2SDS Online workshop

27 September 2021

Annika MÄLKIÄ  
European Chemicals Agency



# Introduction



# Registration: use and exposure data





## Use description

- Provided in section 3.5 of the technical dossier
  - Life-cycle stages and user groups
  - Occurrence of substance in product/article types used by consumers
  - Relevant activity at workplaces
  - Use pattern characteristic from environmental perspective
- Related to *identified uses* for the substance
  - Sets the scene for the chemical safety assessment
  - Does not reflect latest market situation
- Enables authorities to understand the use pattern and the exposure potential of the substance
  - Influences priority for regulatory action



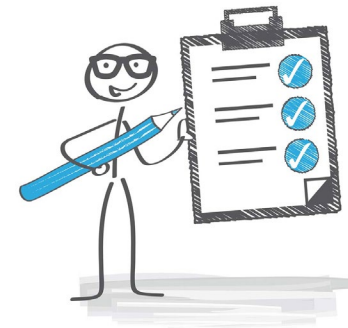
# Chemical safety assessment

- Important part of REACH registration process:
  - Characterises hazards and assesses how risks are controlled via operational conditions and risk management measures
- Required for all substances manufactured/imported at 10 tpa or more per registrant
- Consists of two steps:
  1. PC, ENV, HH hazard assessment and PBT assessment
  2. Exposure assessment and risk characterisation, if triggered by previous step (C&L, PBT)



## Chemical safety report (CSR)

- Documents the chemical safety assessment & demonstrates how the substance can be used safely
  - Declares use conditions are in place at own sites and communicated into the supply chain
- Contains the **exposure scenarios**: key source for safe use information to be communicated into the supply chain via eSDS
  - Support adaptations from information requirements
- Submitted to ECHA as an attachment to the REACH registration dossier; structure specified in REACH Annex I, but no electronic data format prescribed



## Completeness check

- Each registration dossier is completeness checked when submitted to ECHA
- In case of a completeness check failure, **4-month deadline** given to provide the missing information
- Initially, completeness check was an IT-based process, limited to technical dossier, but since 2016 it includes manual checks

<https://echa.europa.eu/technical-completeness-check>



## Completeness of CSR

- Presence of a CSR attachment automatically verified in the completeness check since 2009
- In 2016, manual checks of justifications when CSR not attached
- In 2021, checks of the CSR content introduced:
  - **First systematic view of the CSRs**



# Completeness checks of CSRs - first impressions





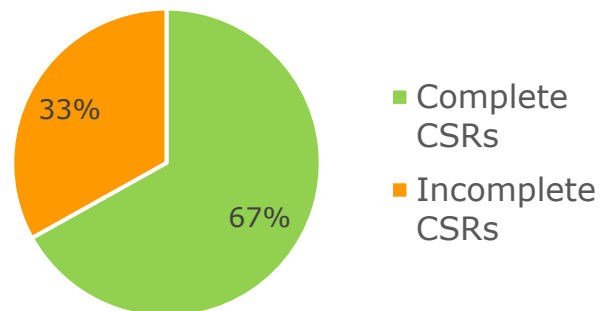
## Manual verification of CSRs

- Content of the CSR file is manually verified if:
  - The dossier is expected to contain a CSR and
  - The CSR is expected to contain exposure assessment and risk characterisation (based on REACH Article 14)
- CSR is checked for:
  - **Exposure scenarios** that correspond to the uses reported in the IUCLID dossier
  - **Contributing scenarios** that correspond to the contributing activities reported per use
  - Or, justifications for the omission of the above.

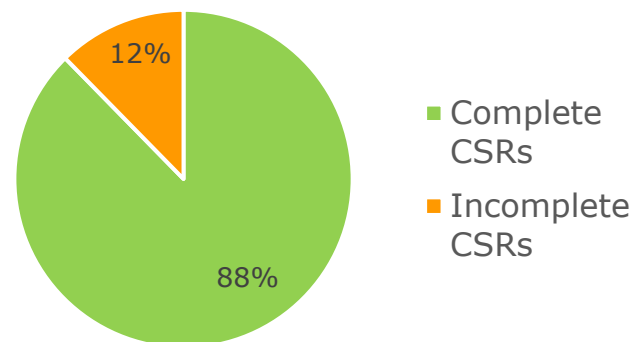


## First six months of operation

- **1 160** CSRs checked
  - 776 CSR found complete (67%)
  - 384 CSRs found incomplete (33%)



- **235** requested updates
  - 206 complete (88%)
  - 29 rejected (12%)





## **Finding: CSR does not match use information in IUCLID**

- Uses and contributing activities in IUCLID do not have corresponding exposure scenarios in the CSR
  - CSR not maintained (updated) with IUCLID dossier
  - CSR does not match registrant's uses
- Use description in the dossier is not clear
  - Duplicate use records
  - Use descriptors conflict with life cycle stage
- **Consequences:**
  - CSR missing exposure assessments



## Finding: CSR structure unclear

- Exposure assessment and risk characterisation are not following a structure driven by ES titles (as foreseen in Annex I of REACH)
- Various life cycle stages and user groups combined in one exposure scenario (does not follow IUCLID format)
- Consequences:
  - CSR difficult to understand
  - Unclear assessment coverage
  - Problems with generating use-specific ES for the supply chain



## **Finding: challenges with jointly maintained information**

- Hazard information and C&L normally provided jointly by the “lead” registrant;
- Use-information provided separately by each registrant
- CSR can be provided jointly in the “lead” dossier, or separately by each registrant
- Frequent observation: joint and separate parts of the dossiers do not match.



## Finding: Article service life not assessed (1/2)

- Under REACH, *article service life* refers to the life-cycle stage following the use of a substance (as such or in mixture).
- For example
  - Additives having been incorporated into plastic or rubber articles
  - Substances in dried coatings having been applied to surfaces of buildings, vehicles, furniture, packages



## **Finding: Article service life not assessed (2/2)**

- Exposure scenarios for the article service life are often missing in the CSR, although the use has been reported in the IUCLID dossier
- Also, exposure scenarios omitted with high level argumentation that substance reacts upon use and is not present anymore in the article
  - Registrants need to understand how their substances react and document this in the CSR.
  - Residual parent and transformation products to be addressed.
  - Clearer assessment framework and methodology needed for service life.

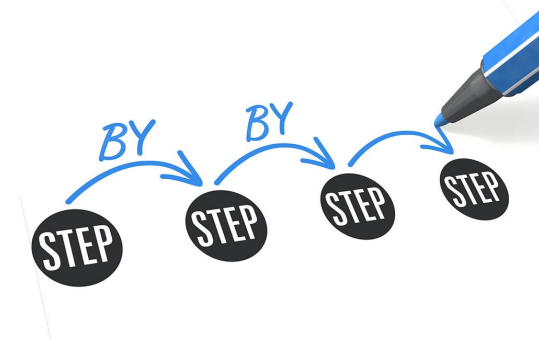


# Conclusions



## **CSR completeness check provides...**

- A systematic check of the last remaining part of the registration dossier
- The possibility to feed back to registrants on the CSR content
- A useful overview of areas where assessment methodology and advice needs further attention



## Learnings so far...

- Registrants need to review uses & make sure the CSR matches
- CSR structure is important pre-requisite to be able to generate meaningful exposure scenarios – Chesar a great help
- Communication among registrants of same substance is needed to make sure CSRs are based on latest hazard and use information
- The assessment of the Service life stage requires attention both by authorities (methodology, guidance) and industry (clear documentation)

# Thank you!

Subscribe to our news at  
[echa.europa.eu/subscribe](https://echa.europa.eu/subscribe)

Follow us on Twitter  
[@EU\\_ECHA](https://twitter.com/EU_ECHA)

Follow us on Facebook  
[Facebook.com/EUECHA](https://Facebook.com/EUECHA)