REACH registration dossiers as a source of exposure data

ECETOC workshop

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Celia Tanarro
European Chemicals Agency

Overview

- → Use and exposure information in registration dossier
- → Use of the information in ECHA processes
- → Use of the information upon request

REGISTRATION DOSSIER

Substance information, including:

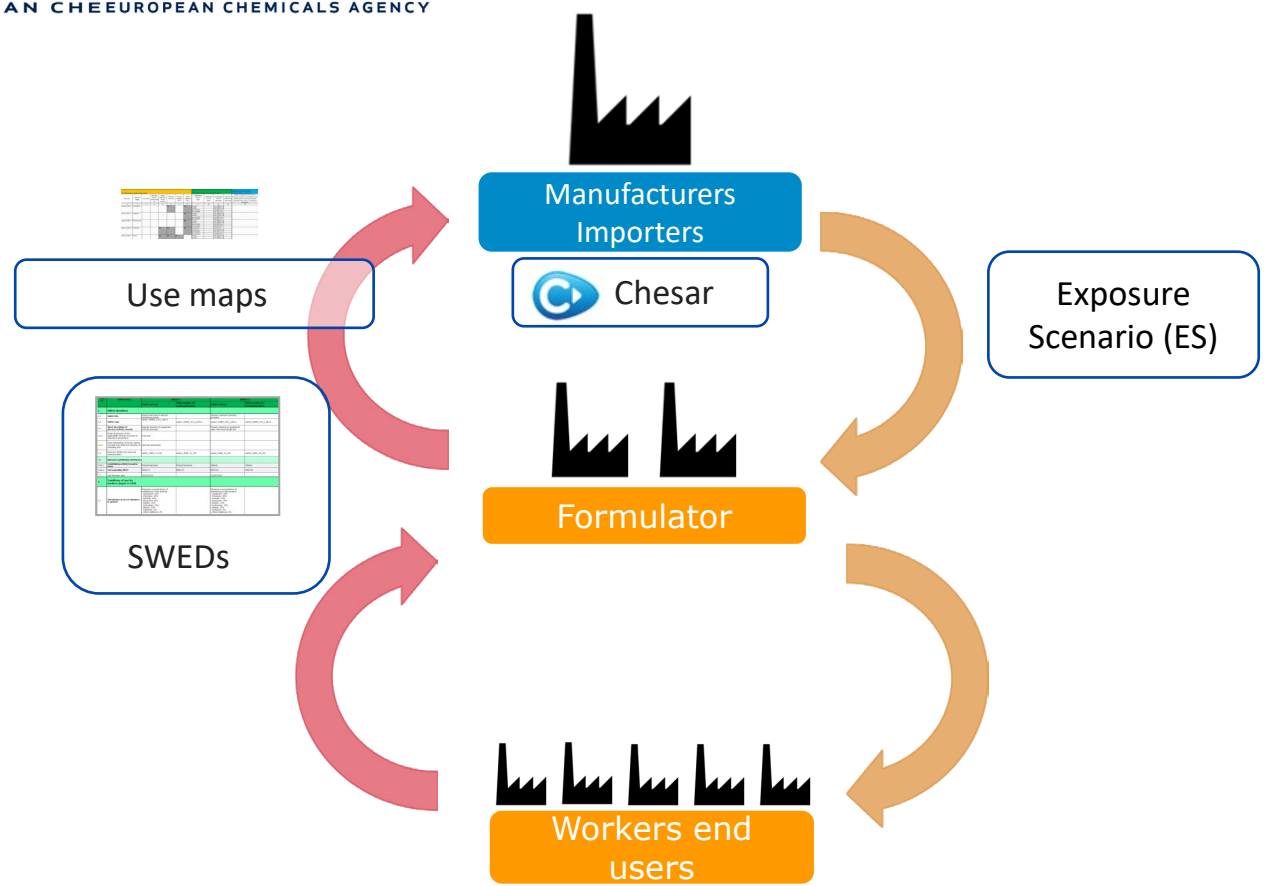
- Substance identity
- Classification and labelling
- Manufacture use and exposure
- Intrinsic properties

Chemical safety report
Incl.
Exposure/Risk Assessment

ECHA
Completness check (TCC)

ECHA
Dissemination

Supply chain
via SDS


Manufacturers
Importers
Chesar
Use maps
Exposure
Scenario (ES)
Formulator
SWEDs
Workers end
users

Use and exposure information in registration dossier

→ Information on uses (used as proxy for exposure):
- use name
- user group (e.g. workers, consumers)
- life cycle stage (e.g. manufacture, industrial sites)
- tonnage
- use descriptors (e.g. PC, PROCs, ERCs, ACs))

→ Information on exposure (CSR):
- conditions of safe use (%, RMM etc)
- quantification of exposure (where relevant):
  - Exposure estimates based mainly on Tier 1 tool
  - Tier 2 tools and measured data used less often

Uses of registration use and exposure information

→ Use of information for ECHA's activities
- Dossier/ substance evaluation: assessment of exposure-based adaptations
- Screening assessment under Assessment of Regulatory Needs (ARN)
- Prioritisation of SVHCs for authorisation
- Development of dossier, e.g. restriction, OEL

→ Use of information upon request. Case example :

- The case of impact assessment of Mixture Assessment Factor (MAF)

Use and exposure information for ECHA activities

Exposure based adaptations

→ Omission of tests (standard information requirements)

- Rigorous and thorough exposure assessment demonstrating absence of or no significant exposure.
  - Exposure estimates being well below derived no effect level (DNEL), when relevant and suitable DNEL is available.
- All uses under strictly controlled conditions.
- Lack of release from an article
  - SCC in the production of the article and waste management
  - Likelihood of exposure of to workers, general population or envi is negligible

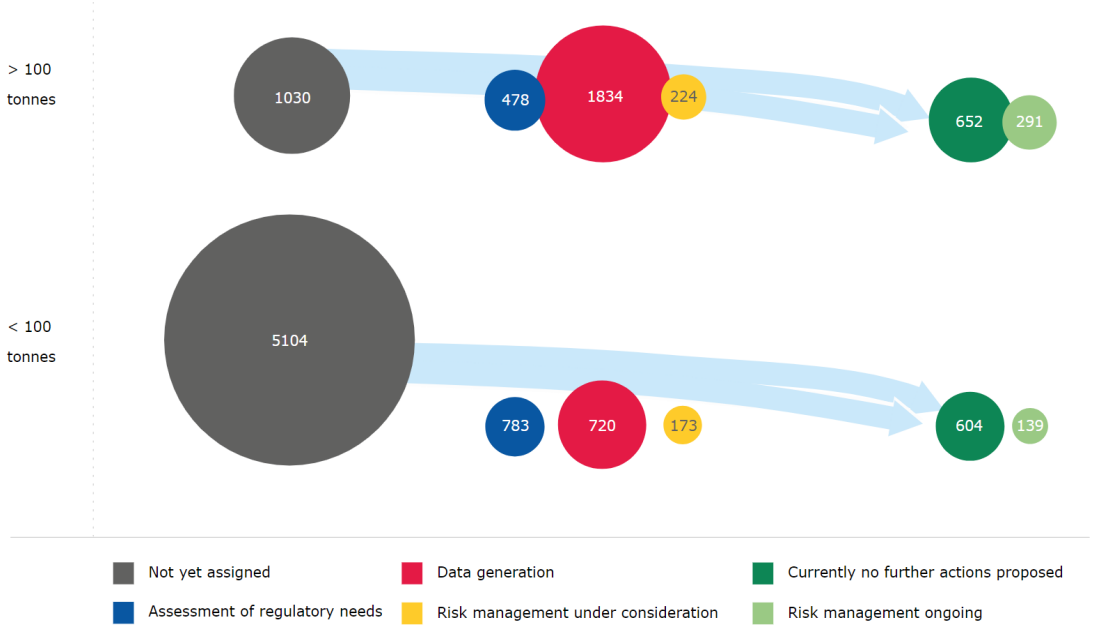
→ For column 2: no widespread uses, nor long-term and frequent exposure etc (e.g. Carc, 90 days study)

This requires a **thorough documentation and demonstration of exposure assessment of uses reported <u>normally</u> in the CSR or in additional documentation.**

ECHA
EUROPEAN CHEMICALS AGENCY

ECHA screening strategy

Screening strategy aims at clearing the chemical universe whilst identifying candidates for risk management



Every registered substance mapped to one regulatory 'pool'
based on planned, ongoing or concluded regulatory actions

As for Dec22

Use information as proxy for exposure

- → ARN for (group of) substances is based on stepwise approach with first hazard profile assessment and exposure considerations as a second layer to support the need/priority for action.
- → Use information (use name, user group, life cycle stage, product category used, tonnage) is used as a proxy for exposure
- → Combination of hazard(s) identified, life cycles relevant, and **likelihood exposure** will be assessed to conclude on best way forward for the group
- → Results of the assessment are transparent and published on ECHA website (https://echa.europa.eu/assessment-regulatory-needs)

Information to determine whether exposure is significant

→ Indicators of significant exposure:

- High aggregated tonnage
- Many sites
- Many uses of applications
- Certain PCs or TFs indicate high exposure/ release potential. For instance, PC35 (washing and cleaning) for environment and PC 9 (Paints coatings) for human health) or TF “solvents”.

→ All analysis mainly based on information (potentially) present in registration technical dossier in **IUCLID**

→ CSR information hardly used at this stage

Information to determine whether exposure is significant

ECHA regularly assesses the substances from the Candidate List to determine which ones should be included in the Authorisation List as a priority.

→ Art. 58(3): Priority should normally be given to substances with

- PBT/vPvB properties, or
- **Wide dispersive use,** or
- **High volumes**

→ Other aspects to be considered ("further considerations")

→ Approach developed by ECHA (2014) and updated (2020)

Aim of prioritisation:

Include the more relevant substances before the less relevant substances in Authorisation List

See the agreed prioritisation approach

1. Prioritisation - scoring system

Inherent property	Score
Carc/ Muta/Repro	1
ED, or subst. of equiv. concern as SVHCs	7
PBT, vPvB	13
PBT/ vPvB and (at least) one other SVHC property	15

Volume	Score
no volume	0
< 10 t/y	3
10- <100 t/y	6
100- <1 000 t/y	9
1 000- <10 000 t/y	12
≥ 10 000 t/y	15

WDU	Score
no use	0
IND	5
PROF	10
CONS	15
Refinement possible , e.g. for use in articles with non-neglible release	

V ≥ 10 t/y→ 2
V < 10 t/y→ 1

ASL

Total score: 1 – 45

Information preparing dossiers (OEL/ Restriction): uses

→ General information on substance(s) uses
- Often can be gathered from the registration dossiers (at least partly). However:
  - Substances not registered (e.g. generated on site such as welding fumes nitrosamines)
  - Information not available in registrations needs to be gathered via reports, literature searches etc

→ Tonnages
- Available in registration for the registered substances and uses

Information preparing dossiers: exposure information (i)

→ For OELs
- Identify the current uses of the substance(s) in the EU and the description of typical exposure levels in occupational settings
- Identification of high exposure sector/activities
- Identification of background levels in the general population

→ For restriction
- Less standard information, depends on the scope of the restriction
- E.g. can require occupational, consumer and or environmental exposure information including use of biomonitoring data
- The uses under scope are normally narrower than for an OEL report

Information preparing dossiers: exposure information (i)

Information in the CSR will normally be insufficient, used when:

→ There is limited information available outside of the dossier

→ Reliable/Measured data or tier 2 modelling data are available

Normally would need to be complemented with:

→ Measured data from literature / databases / reports etc

→ Biomonitoring data from workers and/or general population

→ Modelling specific scenarios within the scope of a restriction

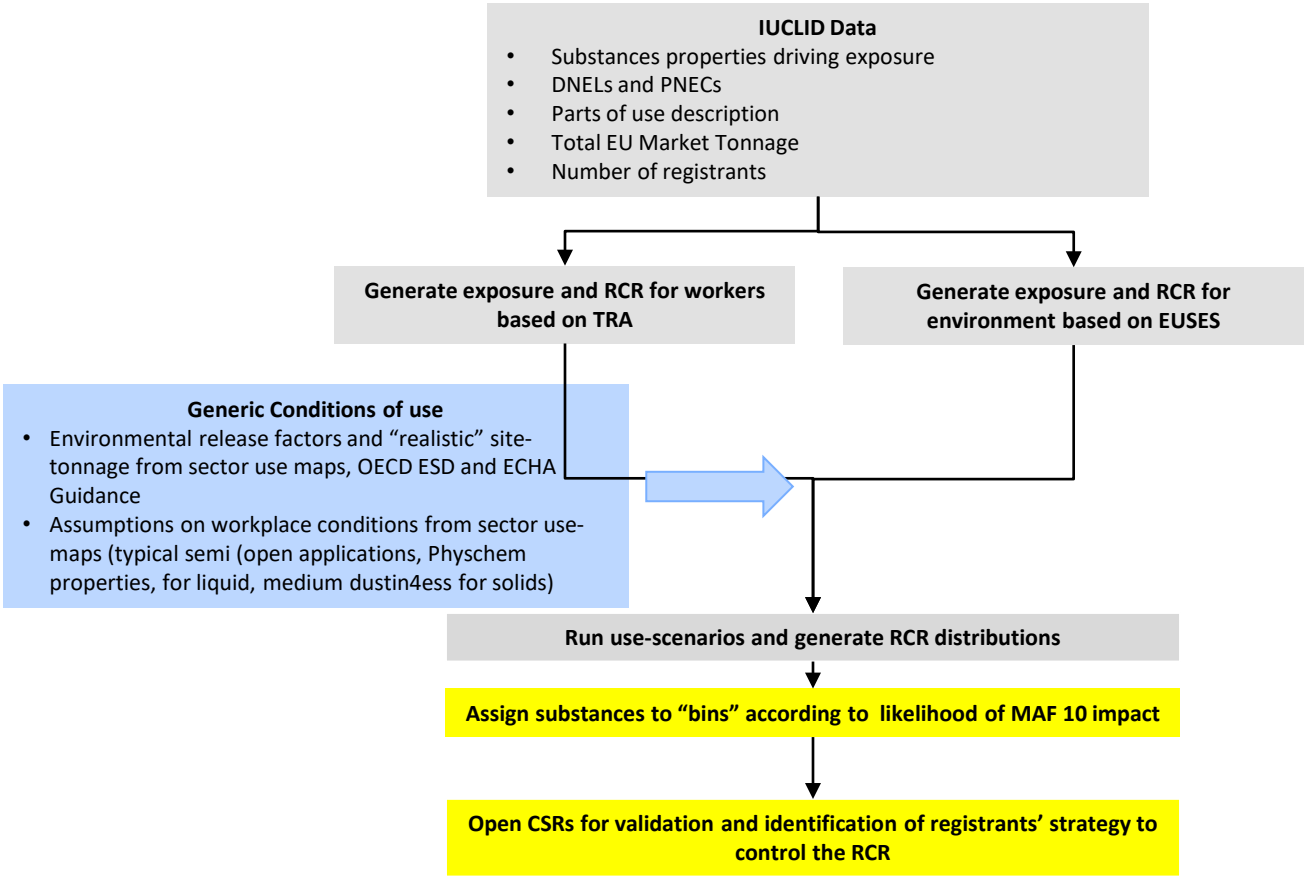
Use of information upon request: example (MAF)

Landscape for a MAF introduction

Chemical Strategy for Sustainability (CSS) on mixtures

- → Focus on unintentional mixtures: unintentional mixtures needs to be taken into account and integrated more generally into chemical risk assessments
- → For REACH it means to assess how to best introduce in REACH (a) mixture assessment factor(s) for the chemical safety assessment of substances
- → Analysis of possible impact of the MAF on Chemical Safety Assessment and quantitative risk characterisation (COM study)
  - ➢ Here the focus is on the methodology, i.e. use of data in IUCLID and scenarios to help evaluating the impact of MAF

The simulation tool



Basic scenario for environmental exposure assessment

	Use group/type	Daily amount per site (kg)	release factor to water
1	Formulation of mixtures	450	0.001
2	Industrial use, low water contact	50	0.003
3	Industrial, water-based processing into/onto article matrix (ERC 5); 90% onsite RMM	100	0.02
4	Widespread use down the drain products	Total tonnage divided by no of registrants; conversion to 10,000 consumers	1
5	Widespread use in coatings, adhesives, inks or functional fluids (motor oil, break fluids, …)		0.05
6	Widespread service life		0.03

Basic scenario for worker exposure assessment

	Product types	Activity	TRA Exposure banding by Volatility	Conc % in product	Ventila-tion	Dermal Protection	RPE
Widespread professional use (liquid)	adhesive coatings inks	PROC10 8h/d	Inhalation (by vapour pressure): 500, 100, 25 ppm dermal: 27.43 mg/kg d	100	1-3 ACH No LEV	no	no
Widespread professional use (solid)	adhesive coatings inks	PROC10 8h/d	Inhalation (medium dustiness): 5 mg/m3 dermal: 27.43 mg/kg d	100	1-3 ACH No LEV	no	no

Presentation of results

→ The results were presented in terms of impact of the MAF factor. Four categories were defined:

- RCR <0.1 (no impact)
- RCR <1
- RCR<10
- RCR>10 (high impact)

→ Percentage of substance in each of the categories was presented

Thank you

celia.tanarro@echa.europa.eu

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