



# MISA-2 SELF-ASSESSMENT-TOOLS ENVIRONMENT General outcome and conclusions

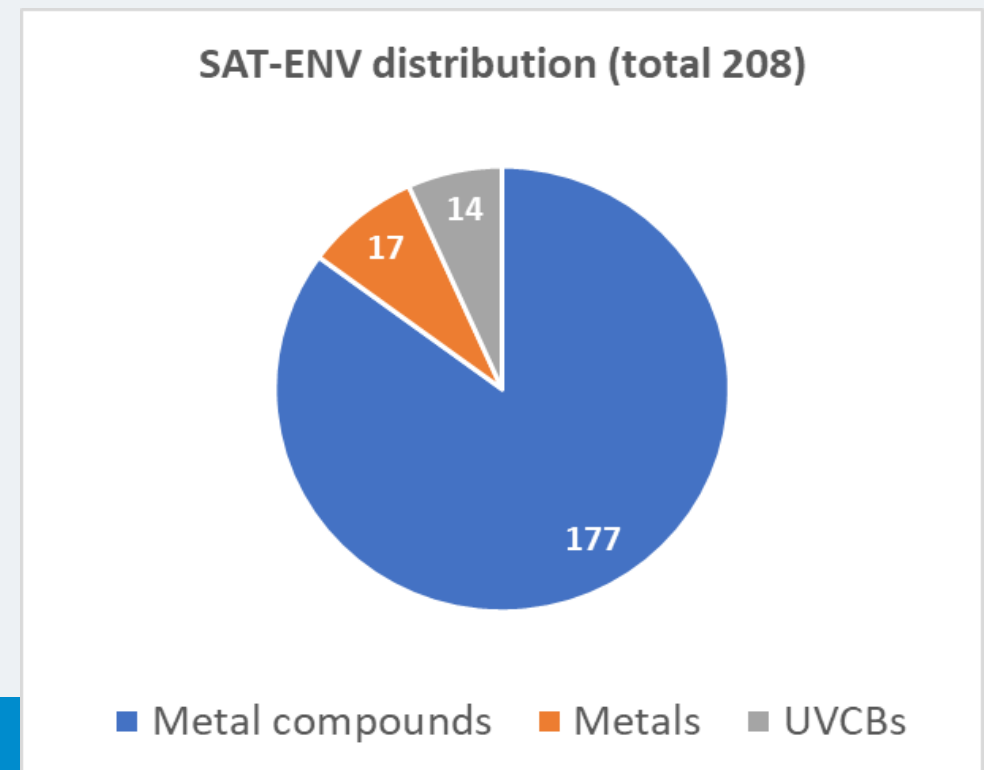
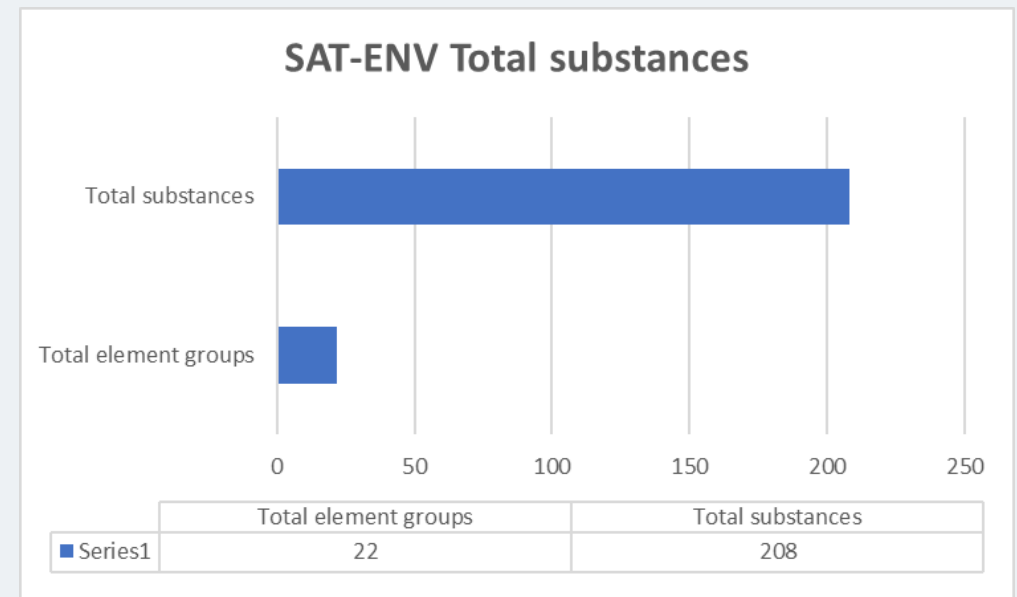
Eurometaux, 7 February 2019



# SELF ASSESSMENT TOOL

## Environment: participation

- 45 SAT sets completed, covering about 200 substances
- Scope:
  - Annex VII / VIII / IX / X tests
  - Environmental Read Across
  - PNECs/ERVs
  - Environmental Classification
- Analysis of SAT, further exchanges with Consortia, some MSCs learnings

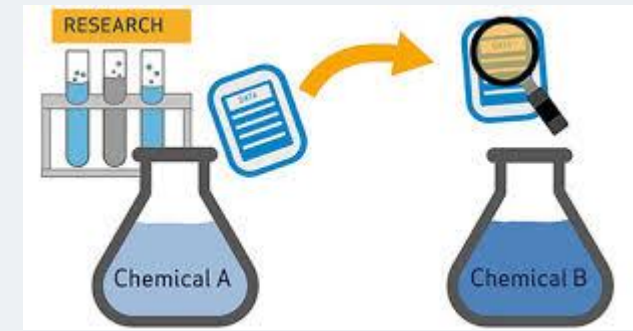


# MAIN OUTCOMES: ANNEX VII to X REQUIREMENTS

- Some of the waivers used are critical and require solid justifications which were not always available:
  - I. *“study does not need to be reported because substance is highly insoluble in water”*:
    - TD evidence needs to be available!
  - II. *“substance is unlikely to cross biological membranes”*
  - III. *“Substance and its degradation products decompose rapidly”*
  - IV. *“The study does not need to be conducted because relevant exposure to the environment can be excluded”*
  - V. *“Testing is waived because technically not possible”*



# MAIN OUTCOMES: READ ACROSS



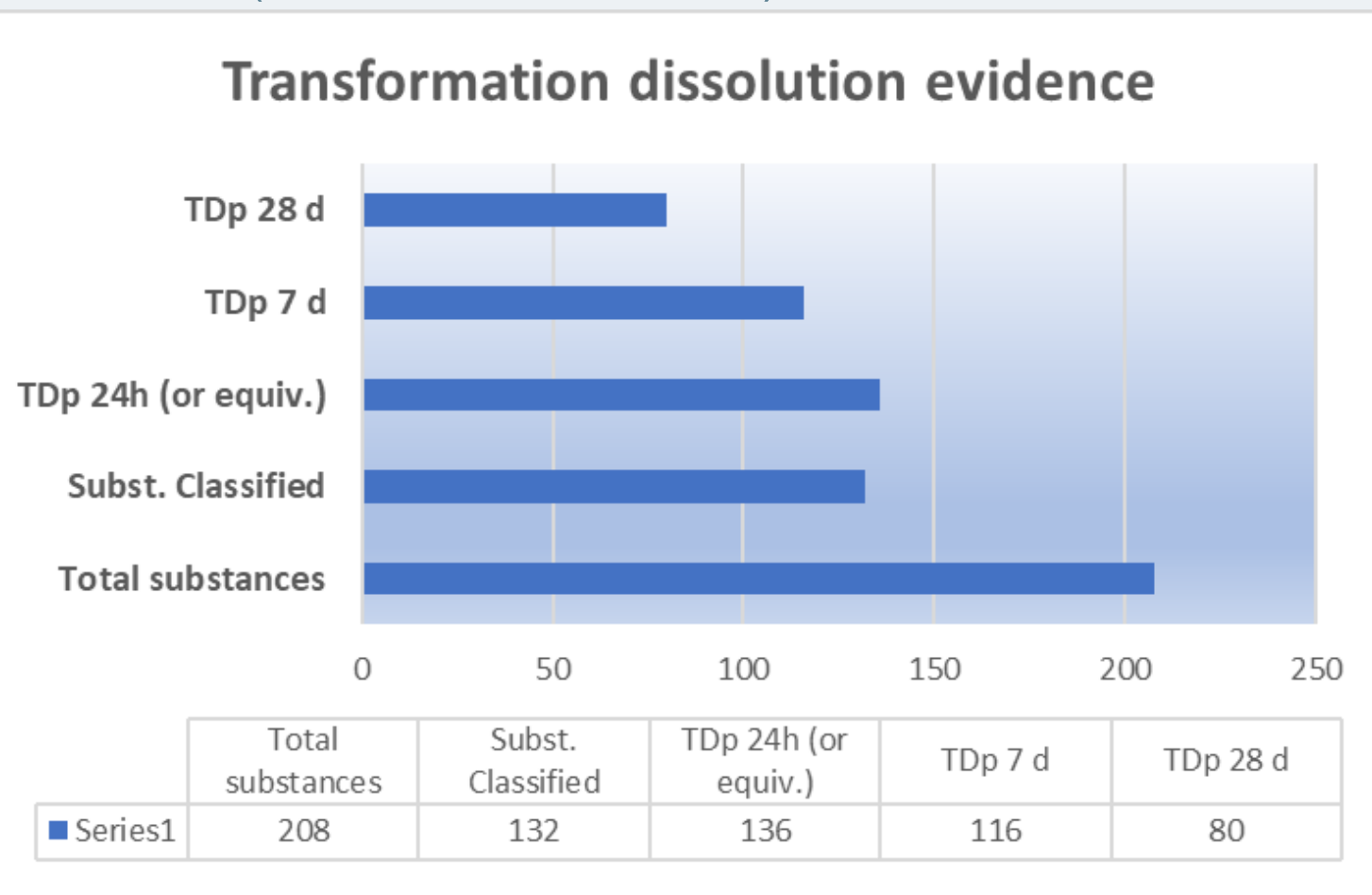
- Reporting **read-across**: the link to / justification using RAAF is still lacking in several Registrations
- The **counter-ion** effect: not systematically checked for or reported
  - (more valid for substances with higher NOECs, EC50)
- **Assessment entities** were generally not considered as relevant tools for reporting ion effect

# MAIN OUTCOMES: TRANSFORMATION DISSOLUTION (TD)

**TD data are** typically performed for Metals & Sparingly Soluble Metal Compounds (SSMCs):

I. TD data are almost always available (for metals & SSMCs)

➤ but *not* always included in registration file



# MAIN OUTCOMES: TRANSFORMATION DISSOLUTION (TD)

- **Transformation Dissolution (TD)** is typically performed for metals or Sparingly Soluble Metal Compounds (SSMCs):
  - II. Some **WAF testing** reported to demonstrate toxicity (for ERV & PNEC)
    - Normally not allowed (lack of particle size/surface and pH impact)
  - III. No (or not reported) **TD 24h** test while the “metal ion is ecotoxic”
    - means that SSMCs get classified as Chronic 4 ( )
  - IV. Extrapolation of 28 d TD from 7 d TD data for **complex substances**
    - could lead to the risk of selective/sequential dissolution
  - V. When the **surrogate approach** is used in absence of Chronic ecotox data
    - TD testing at 10 and/or 100 mg/l is relevant/required (not always done)



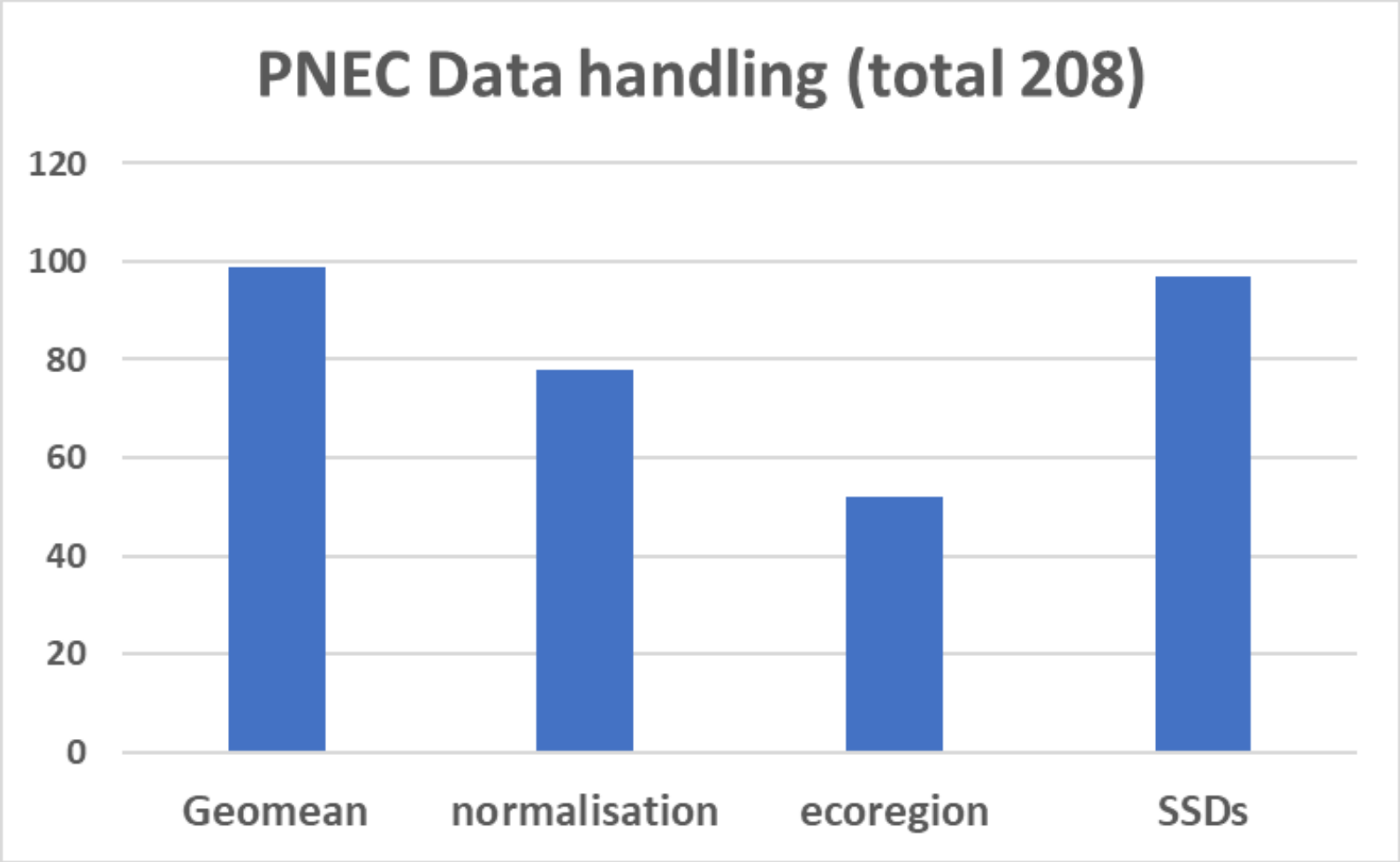
# MAIN OUTCOMES: ERVs DERIVATION

- **Geomean** use:
  - Sometimes used from “2” on instead of “4 studies” under “similar conditions”
  - Not always clear what conditions are/are not “similar”
- Data sets with **low Klimisch score** not always included in Registration dossier:
  - Lacking transparency on what evidence was **screened but not used**
- ERVs are:
  - Generally based upon **Standard Species** for data rich substances
  - Generally *all good quality existing evidence* is used (before deciding for the need for additional tests) for data poor substances
- Can **mesocosm evidence** be used to define the ERV for classification or PNEC?



# Main outcomes: PNECs derivation

Data handling: a wide set of tools used on the more data rich files

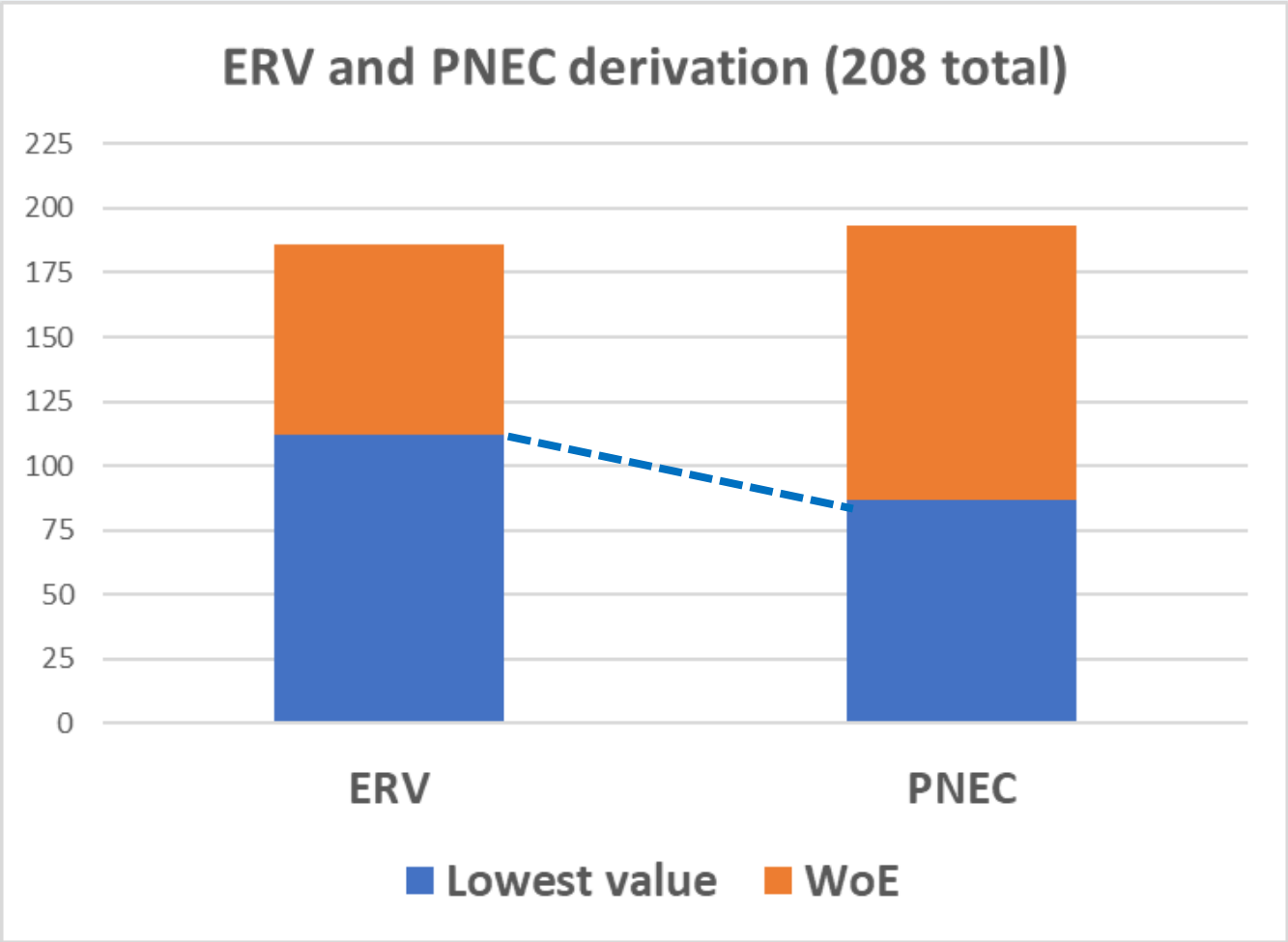


# Main outcomes: PNECs derivation

- Depending on data availability:
  - Data rich substances: typically both standard and non-standard species used (often very broad spectrum of species > 25)
  - Data poor: usually only standard species considered (available)
- Geomean:
  - Broadly applied for “similar conditions” (may require some more explanation)
- Normalisation:
  - Justification of parameter choices is sometimes missing in the Registration file
- Ecoregion approaches used in several data rich files
  - based on standard scenario's (ex ESR)
- Assessment Factors selection for SSD derivation:
  - Often but not always well justified

# Main outcomes: ERV and PNEC assessment

- Lowest value approach more used for ERV while WoE more for PNEC



# Main outcomes: Environmental classification(1)

## Metallic forms

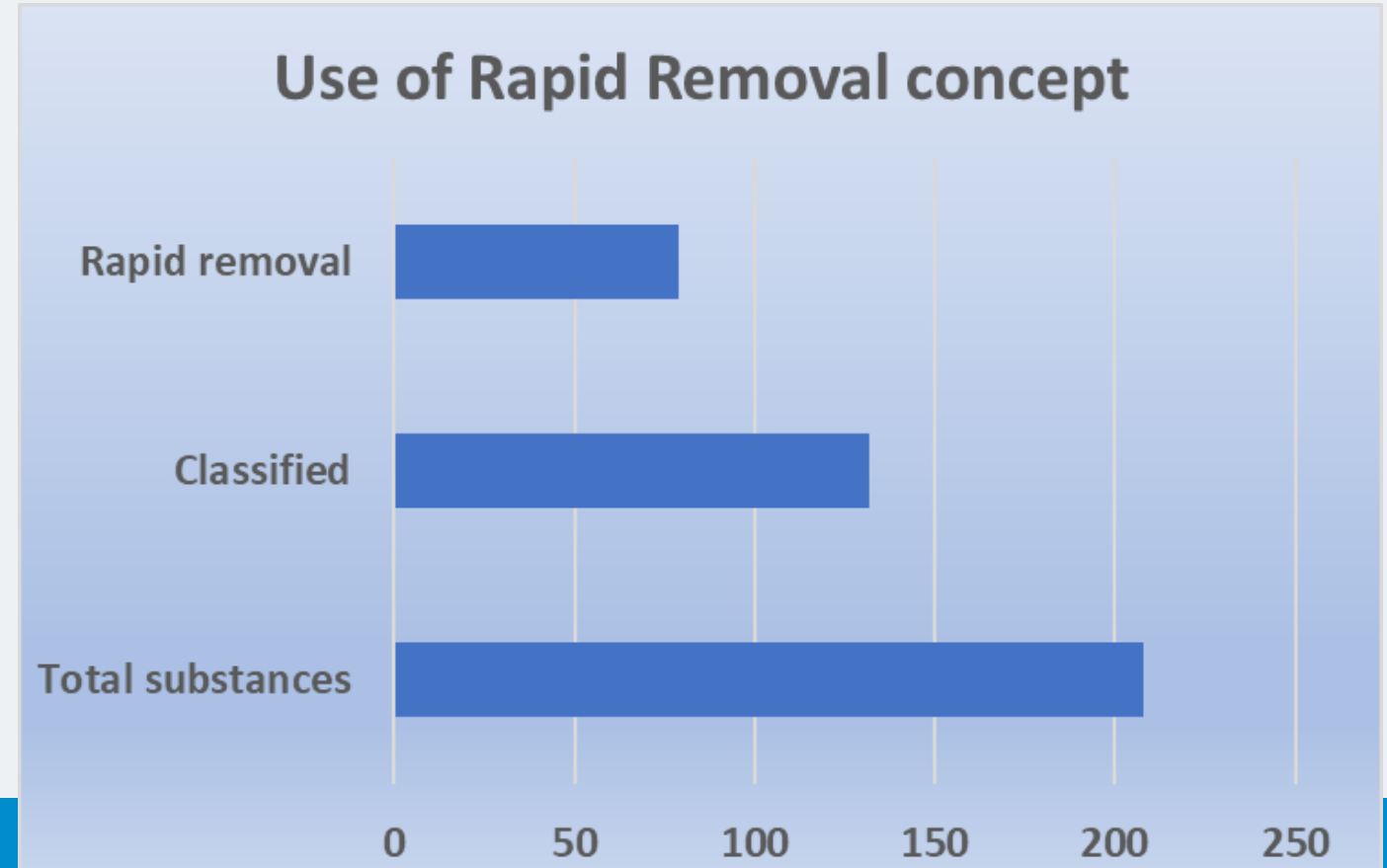
- A double entry (powder vs. massive) requires justification:
  - Of: different dissolution rate, normal use not leading to significant powder release, massive and powder produced by different (special) processes:
  - However, proper justification is lacking in Registration dossier in almost all cases, although known to the registrants
- Justification for selection of the powdery material used for TD testing:
  - Reporting rationale for the sampling selection on the finest relevant powder on the market is often lacking in Registration dossier, while not necessarily unknown



# Main outcomes: Environmental classification (2)

## Rapid Removal concept

- It is applied in quite some Registration dossiers (79 of 208 substances)
- Its use is motivated
- *Approaches could not be checked for consistency*



# ENVIRONMENTAL FATE

- Environmental fate was not investigated in the SATs
- Evidence shows that:
  - the BCF *reference value identification approach varies*\* between metals (\* exposure best as close to NOEC)
  - Bio-magnification: Limited –included- evidence shows:
    - the use of a high default causing Risk Identification for data-rich substances
    - Nevertheless, standard approaches were used in most cases

# THANK YOU

Federica Iaccino and Hugo Waeterschoot

