Aim and expectations: ECHA perspective

MISA Workshop
Brussels, 2 October 2018

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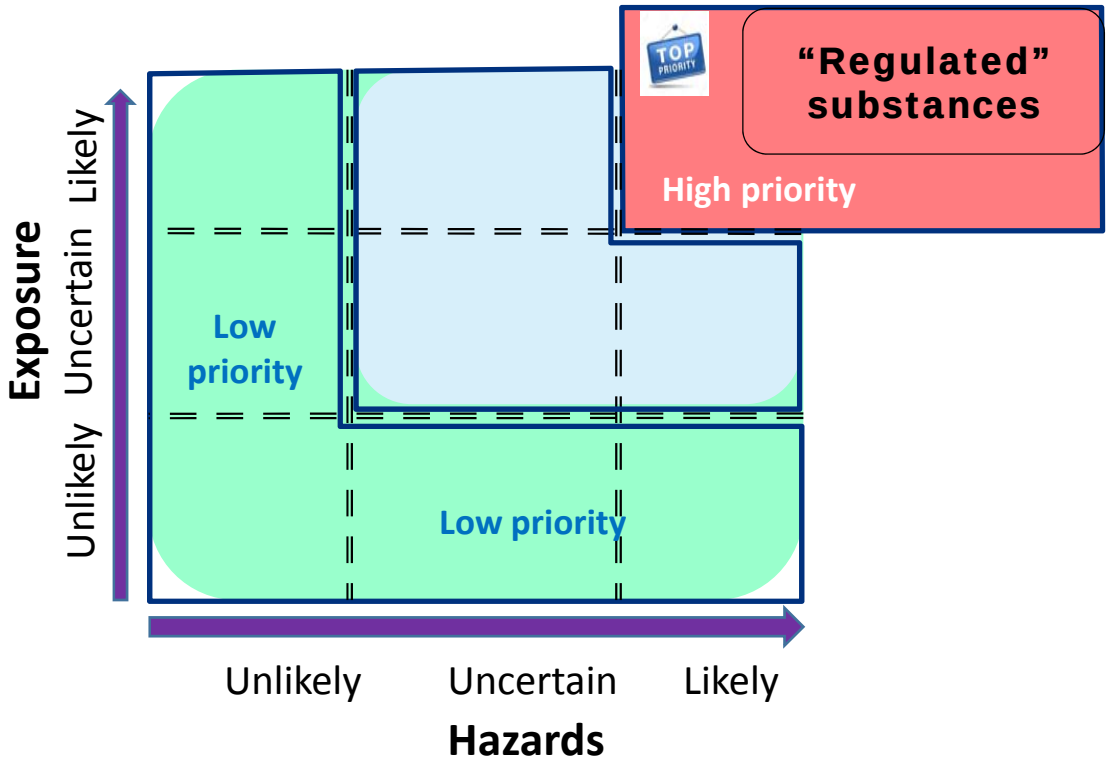
By 2020, for all substances > 100t

We want to know:

- Are they of (potential) concern?
- Do we need more (hazard) information?
- Do they need to be addressed through regulatory risk management action?

OR

- Can we safely put them aside as being <u>currently of low priority</u> for further work?



Your registration dossiers are vital…

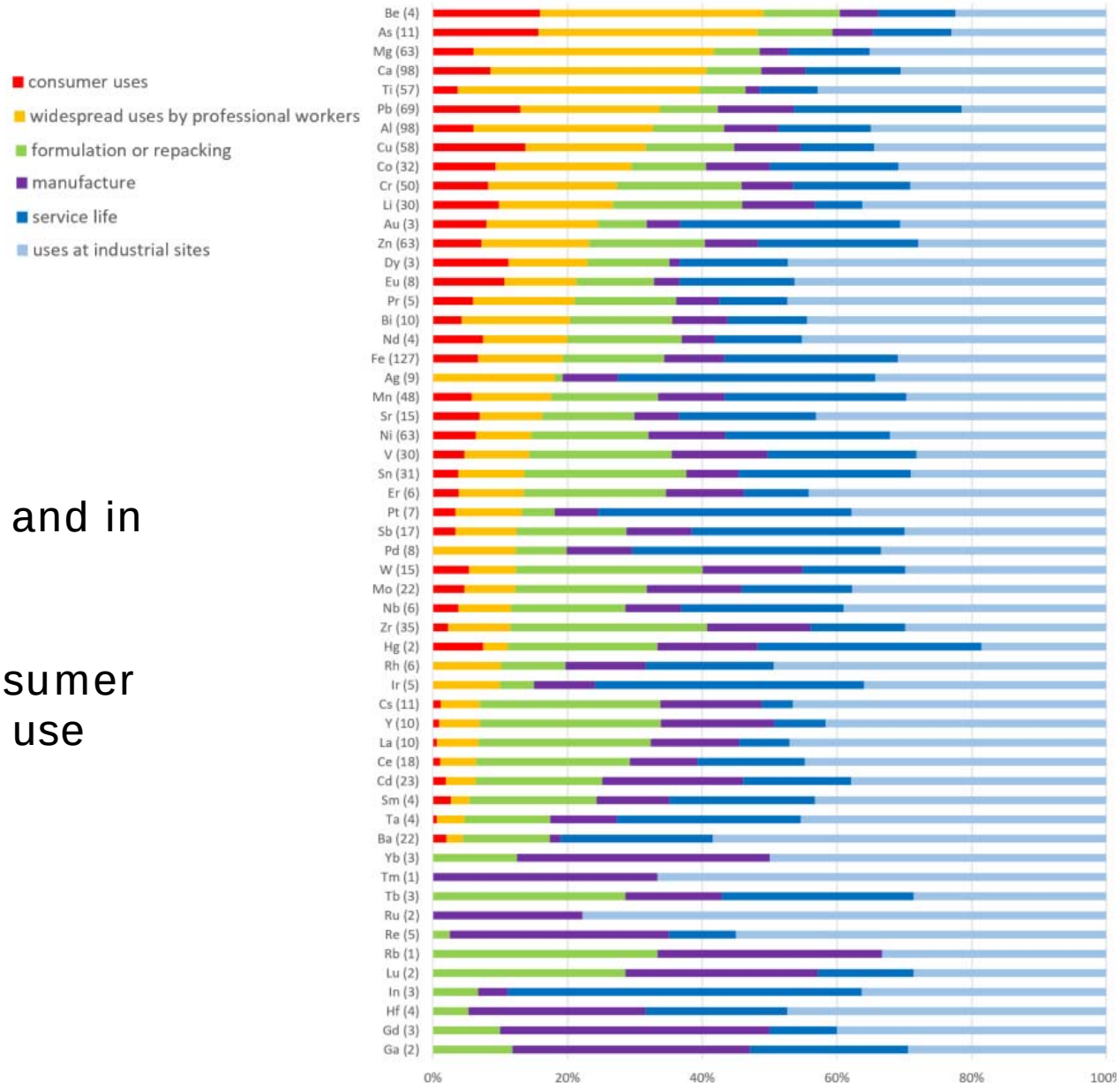
They demonstrate that:

- You know your portfolio
- All necessary information is available
- The chemical safety assessment is appropriate and convincing
- Your customers are informed adequately on how to safely use your substance

➢ Provide confidence to your clients, stakeholders and the general public, that that you take your corporate social responsibility seriously

Use patterns

- Mostly industrial and in articles
- But for some considerable consumer and professional use



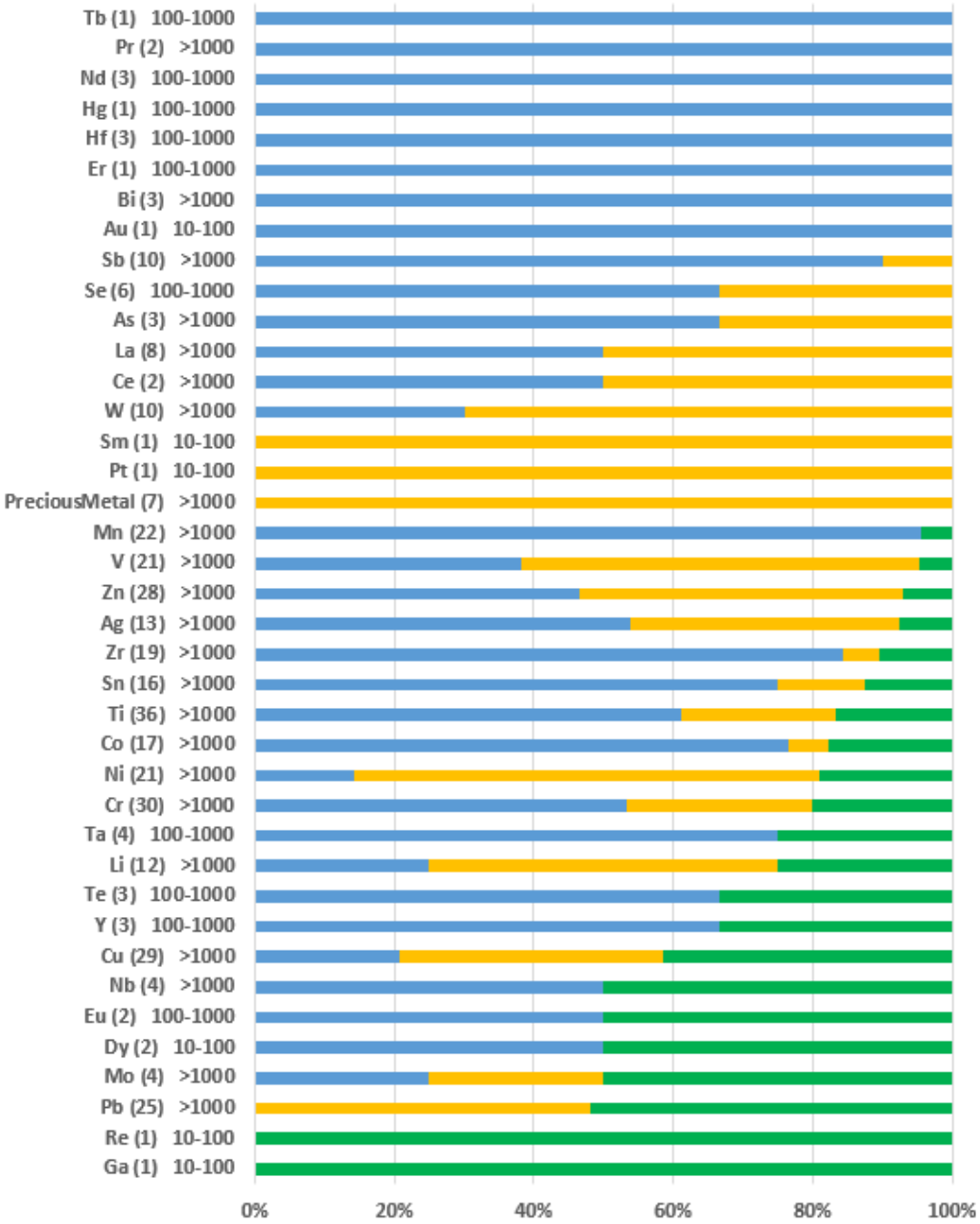
MISA offers good perspectives

Progress so far gives confidence:

- Signed framework for cooperation
- Preparedness to commit
- Potential of the approach is recognised
- Good number of substances covered
- Scientific issues are on the agenda
- Workshops and discussions are planned
- Self assessments

Priorities

- Use of waivers and adaptations
- A closer look at quality is useful
- Give starting point for improvement



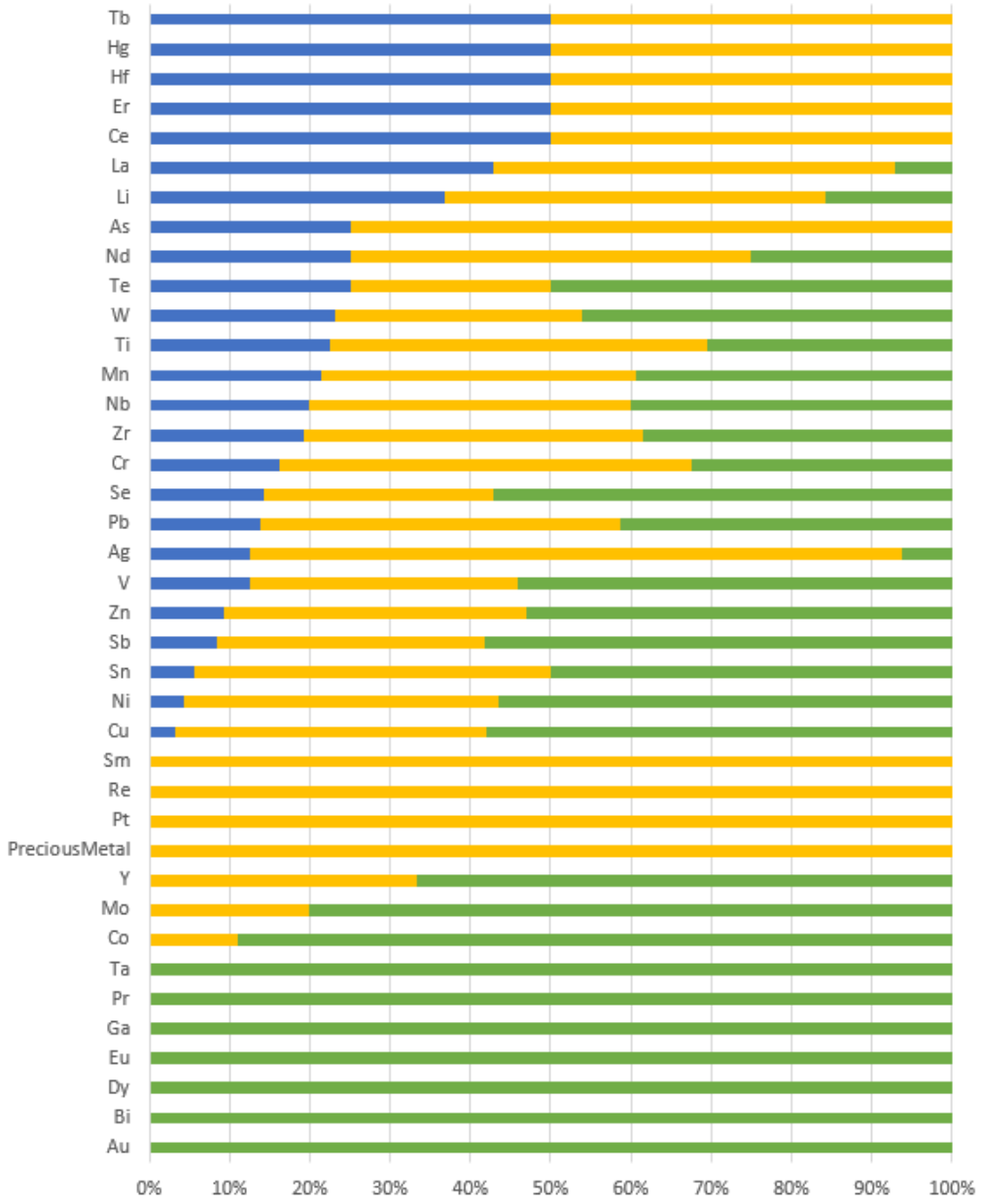
Reprotoxicity

Metal (dossiers) tonnage band

- Data waiver
- Adaptation
- Key study

Updates

- A good moment to check where updates are needed
- Reach review: updates need attention
- Registrations are completed



What it means for this workshop…

- SAT as a starting point
  - Overview of what is available in the dossiers
  - For the key endpoints
  - Description of the read across
- Gives indications where work may be needed
- Makes clear where questions exist

During the workshop …

The aim is to support improvement of dossiers

- Present examples and approaches
- Industry perspective and ECHA experience
- Discussion on open questions

- Relate examples to your own dossiers
- Share good practices

No ‘approval’

At the end of the workshop…

- How to build solid read across justification
- Questions on EOGRTS and route of exposure addressed; Questions on mutagenicity collected
- Sufficient input for a work plan
  - Improved justifications
  - Additional data generation
- Overview of open questions

After the workshop…

Industry

- Complete the workplan (and start the work)
- Participate in or follow work on other MISA priorities

ECHA

- Response to open questions where possible
- Follow and contribute to other MISA priorities
- Continues work on integrated regulatory strategy

ECHA
EUROPEAN CHEMICALS AGENCY

Thank you!

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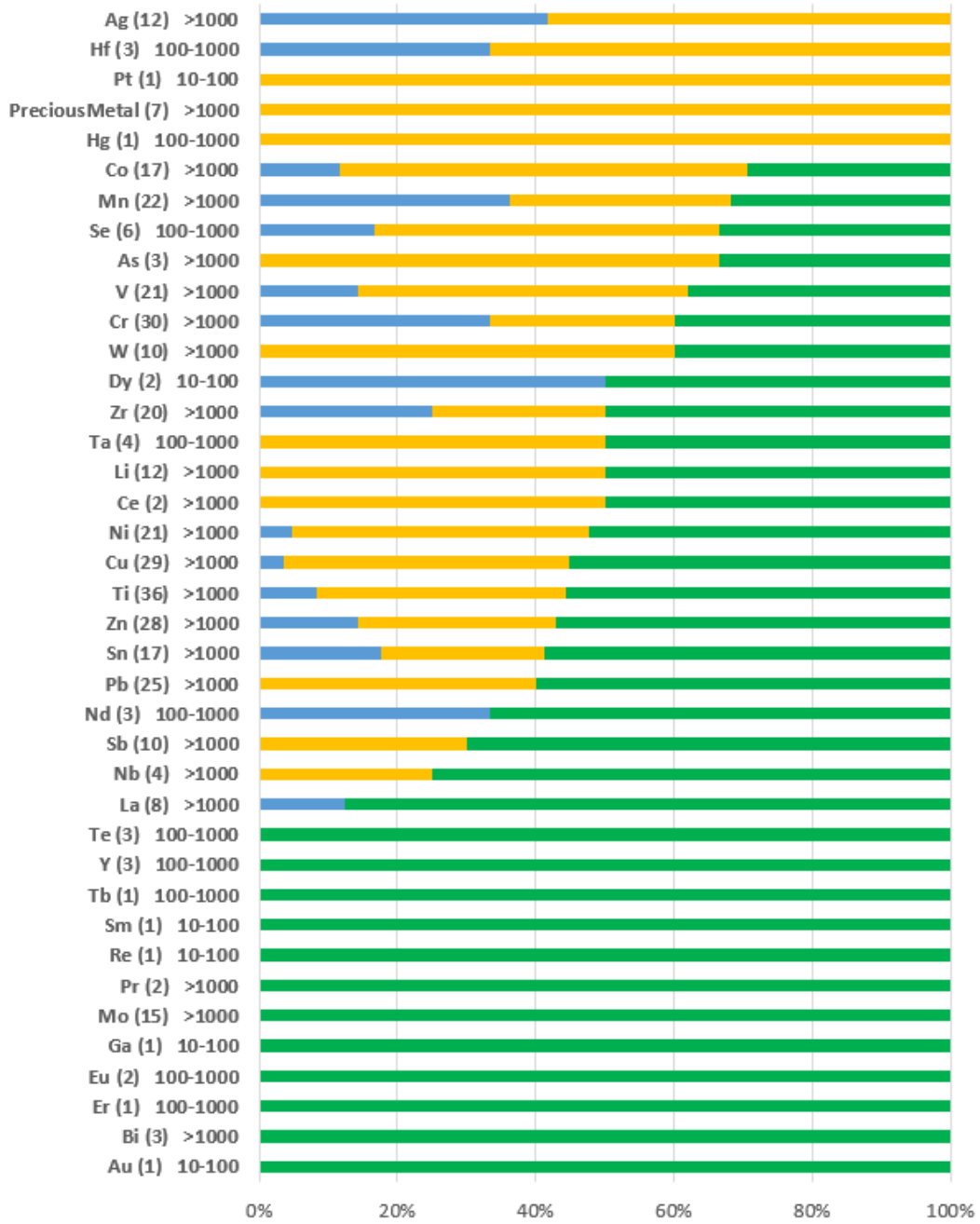
Data availability – Mutagenicity



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