Potential of screening data in prioritising chemicals for regulatory action

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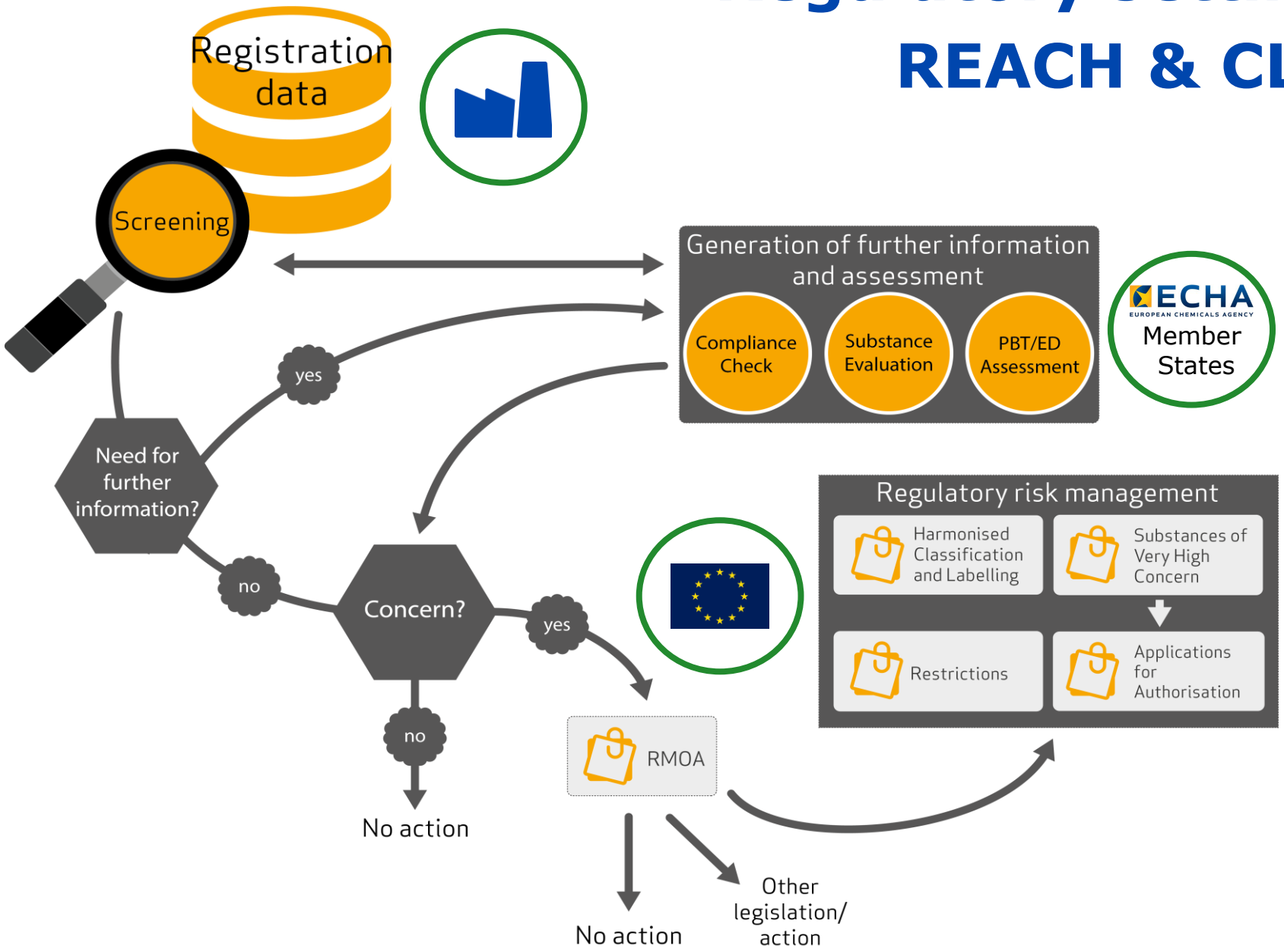
1. **Regulatory setting**

2. Exposure data under REACH

3. Potential of screening data in prioritisation

Regulatory setting REACH & CLP



Regulatory setting

- Integrated Regulatory Strategy
- World Summit for Sustainable Development 2020 goals
- Circular economy

Focus on substances that matter!

1. Regulatory setting

2. **Exposure data under REACH**

3. Potential of screening data in prioritisation

Role of exposure data (Industry)

Registration

- **Demonstrate control of risk** for registered uses of hazardous substances
- **Provide appropriate risk management advice** to users through safety data sheets

Authorisation

- Use monitoring data to **apply** for authorisation
- Demonstrate at single user level that **exposure controls work**

Role of exposure data (Authorities)

Screening

- Considers **exposure potential** (risk based system)
- Usually based on **use information** rather than exposure

Substance evaluation

Identification of substances as PBT/vPvB

- Measured occurrence can provide **additional evidence** on P & B
- Human/biota samples

Restriction

- Demonstrate **too high exposure/effectiveness of restriction**

Types of exposure information

- **Predicted exposure by models**
- **Measured data on substances**
  - Exposure at workplaces
  - Release from industrial sources, articles & construction materials
  - Occurrence in mixtures and articles, water, soil, sediment, biota, indoor air, human tissue
- **Type of measured data**
  - Long/short term monitoring
  - One-off surveys/tests
  - Non target screening
- **Owners**: Authorities or industry

1. Regulatory setting

2. Exposure data under REACH

3. **Potential of screening data in prioritisation**

Current directions in screening under REACH

- Sufficient data needed to prioritise and deprioritise substances
- More information needed especially on use and exposure

→ **Work with groups of substances**

→ **Pilot to assess potential of non-target screening data**

Non-target screening data in prioritisation

Pilot with Norman in 2017

- Assessing added value of occurrence data

Data

- Non-target screening data from Black Sea

Substances of interest

- Within scope of REACH
- Not yet regulated

Data availability through non-target screening

- REACH registered: **~12 000 substances** (in 2017)
  - Many UVCBs (substances of unknown/variable composition, complex reaction products & biological materials) or multiconstituents

- Suspect list exchange: **14 633 substances**
  - Only 33% REACH registered

Pilot with data from Black Sea

Analysed samples: ~ 86

- Biota, water and sediment

Analysed substances: 777

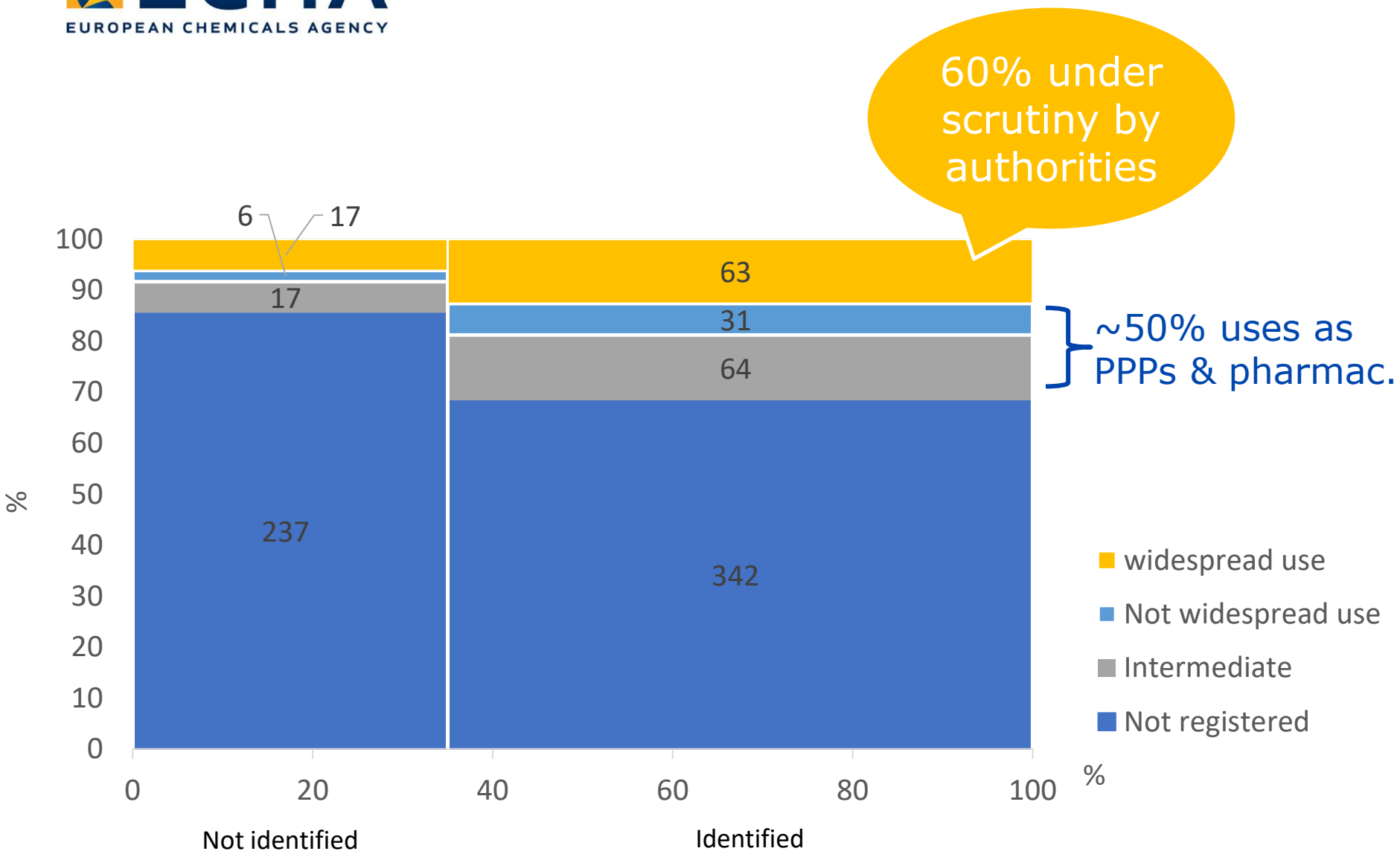
- 25% REACH registered

Detected substances: 500

- 32% REACH registered

Non-detected substances: 277

- 14% REACH registered


60% under scrutiny by authorities
6
17
17
237
63
31
64
342
~50% uses as PPPs & pharmac.
widespread use
Not widespread use
Intermediate
Not registered
%
100
90
80
70
60
50
40
30
20
10
0
0
20
40
60
80
100
%
Not identified
Identified

Conclusions

Potential in NTS data

In order for ECHA to use NTS data in its screening, the data needs to be

- On substances relevant for REACH
- Reliable
- EU-wide/spatially and temporally representative
- Centrally available

Particular challenges

- Competence required in a regulatory setting
  - Understanding the applicability domain & limitations of non-target screening data
  - Expertise to assess underlying study designs & analysis
- Link needed between detected chemical structures and REACH-substances placed on the market