

Role of prioritisation in chemicals legislation

Nordic seminar on Prioritization of
substances

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Main focus



1. Prioritisation within ECHA's Integrated Regulatory Strategy
2. How we work on groups of substances
3. Looking ahead

Prioritisation at several stages to achieve the high level goal

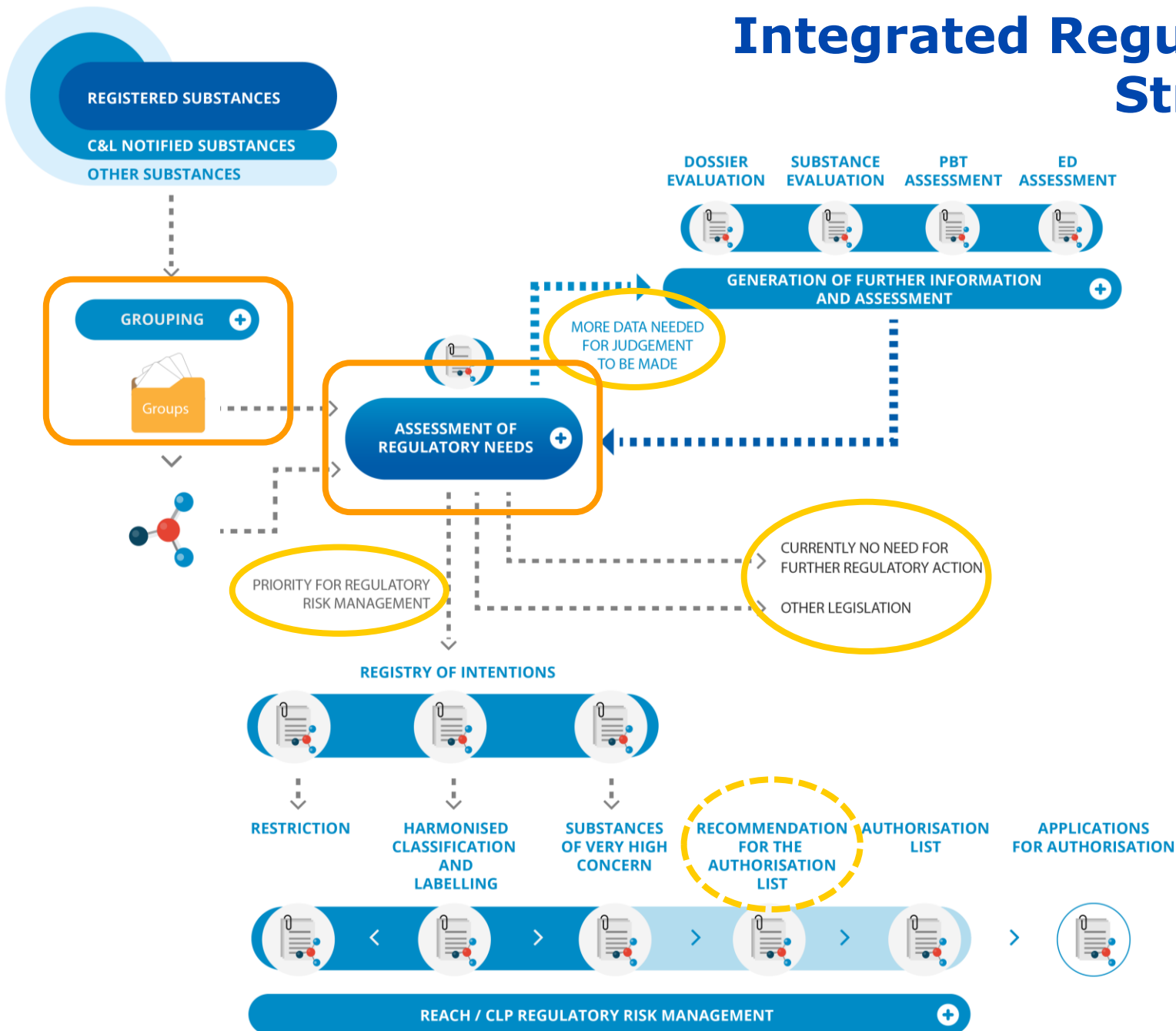


ECHA's Integrated Regulatory Strategy aims to accelerate identification of groups of substances of concern & regulatory action



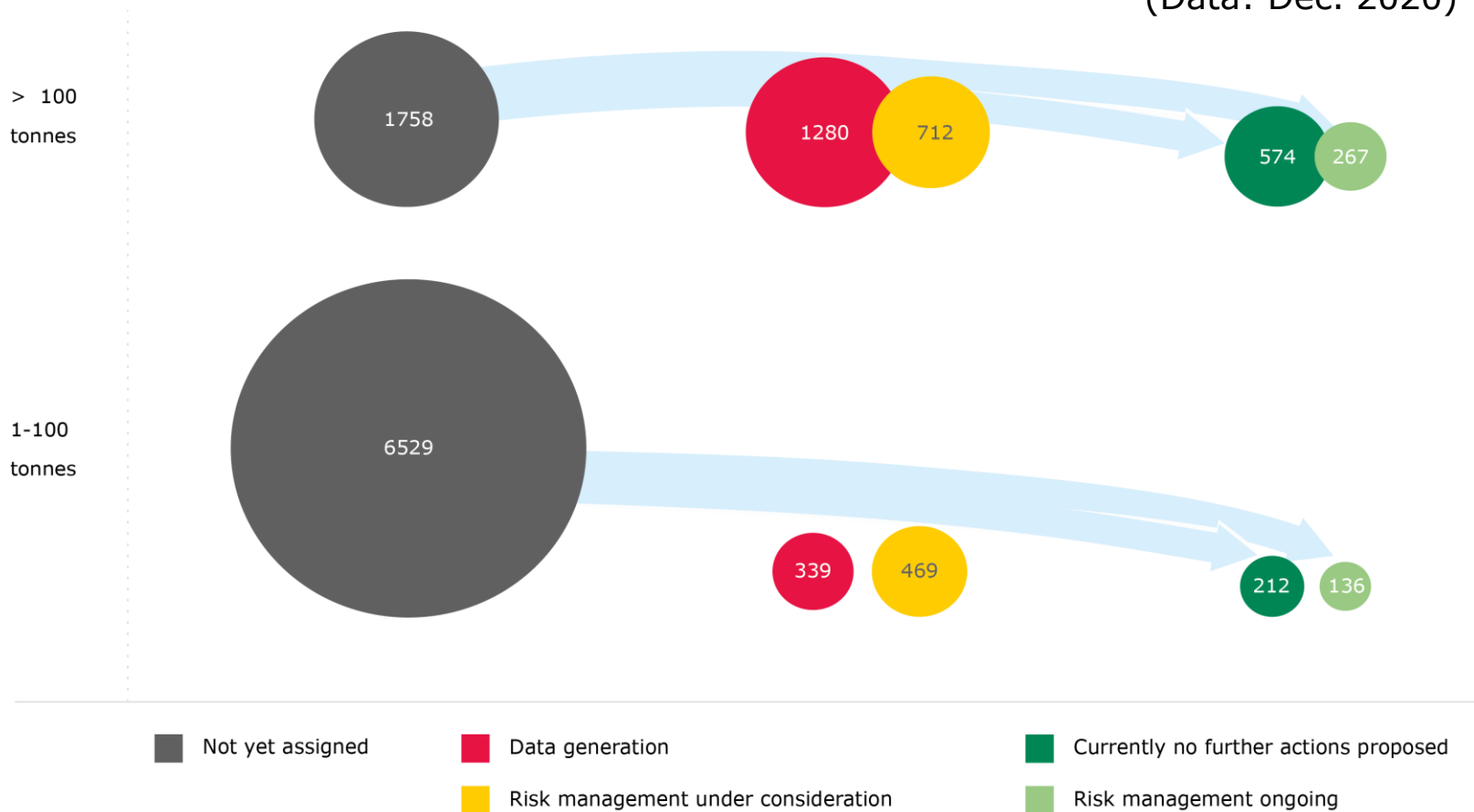
Its goal is to clarify by 2027 which registered substances are high priority for regulatory risk management or data generation, and which are currently a low priority for further regulatory action

Integrated Regulatory Strategy



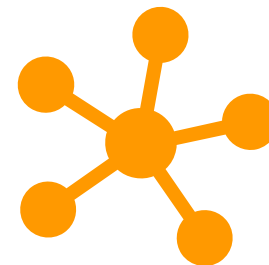
Universe of registered substances

(Data: Dec. 2020)



Why & how we work on groups of substances





Why we work on groups?

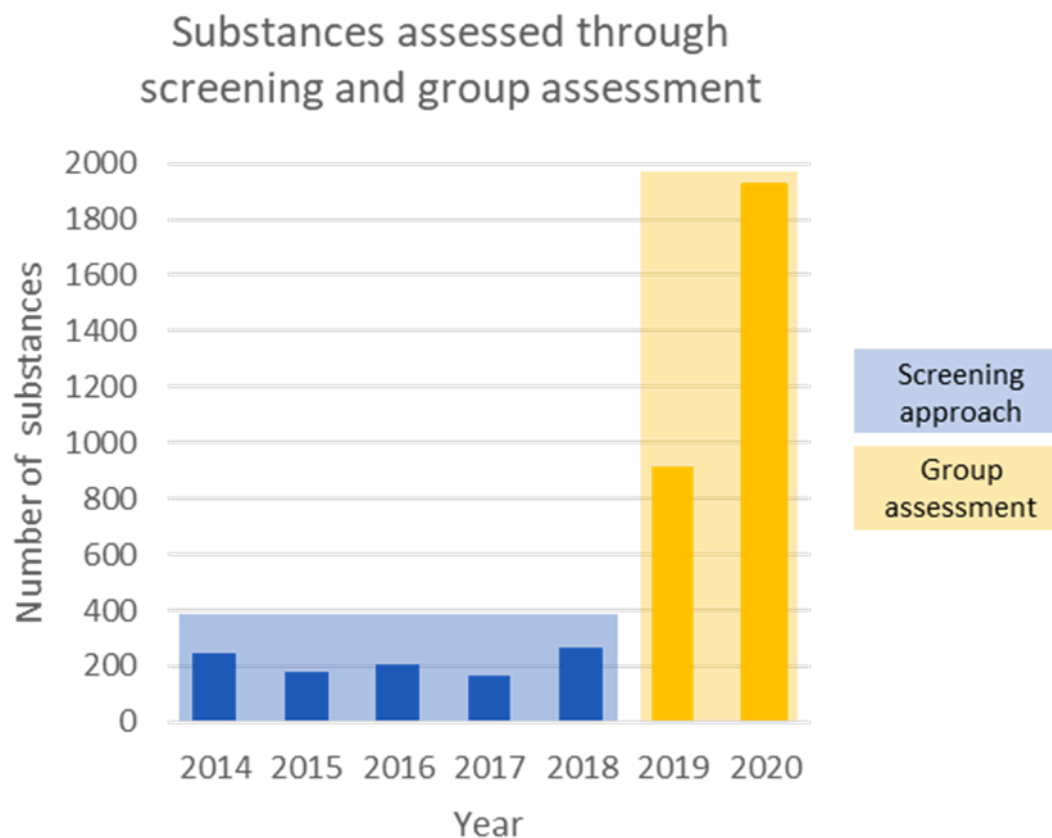
For many substances of (potential) concern, relevant regulatory actions are already ongoing – on the substance itself / on related substances

Benefits

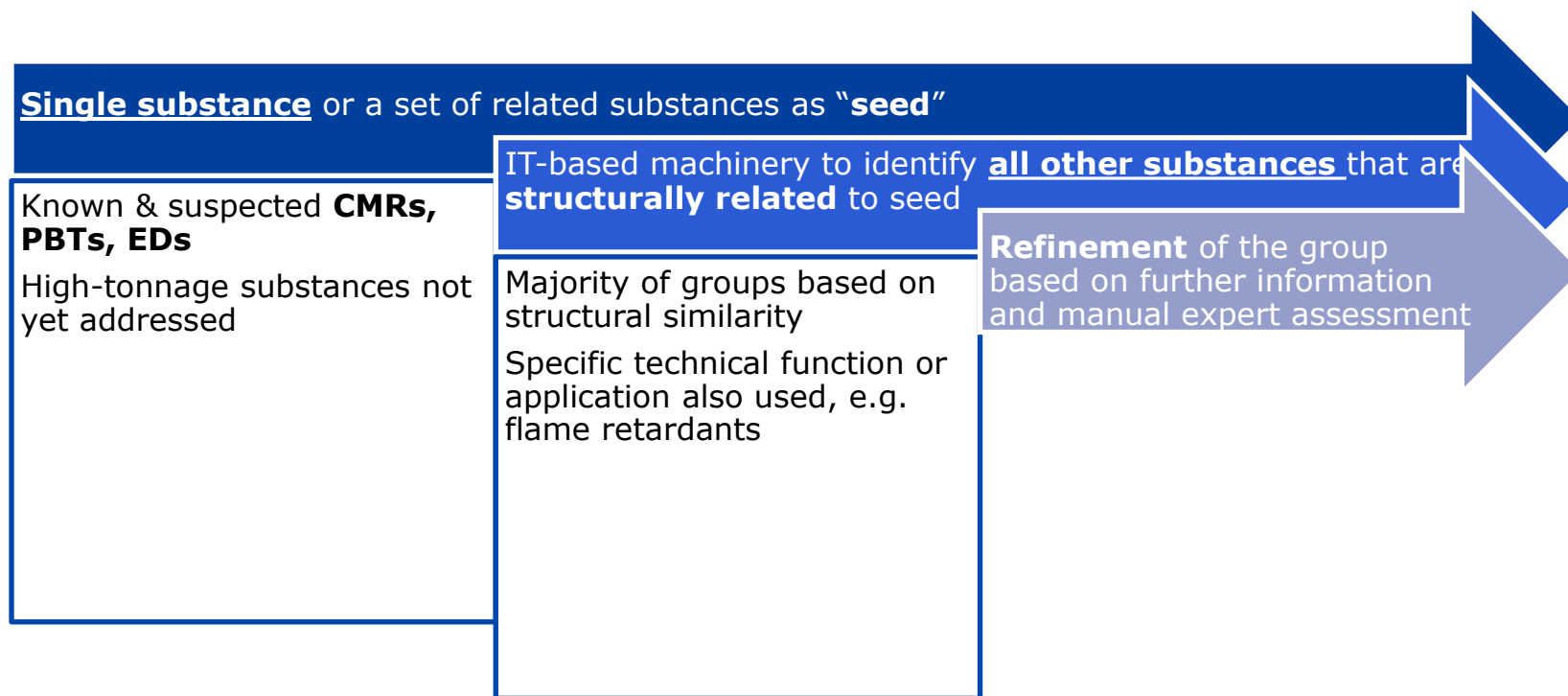
- Treats related substances **consistently**
- **Targets** the right substances at the right time
- **Pools** information which may allow faster action – despite data gaps
- Increases **predictability** of authorities' actions
- Supports **informed substitutions** or avoids regrettable substitutions

→ *Preparatory work to support REACH & CLP processes*

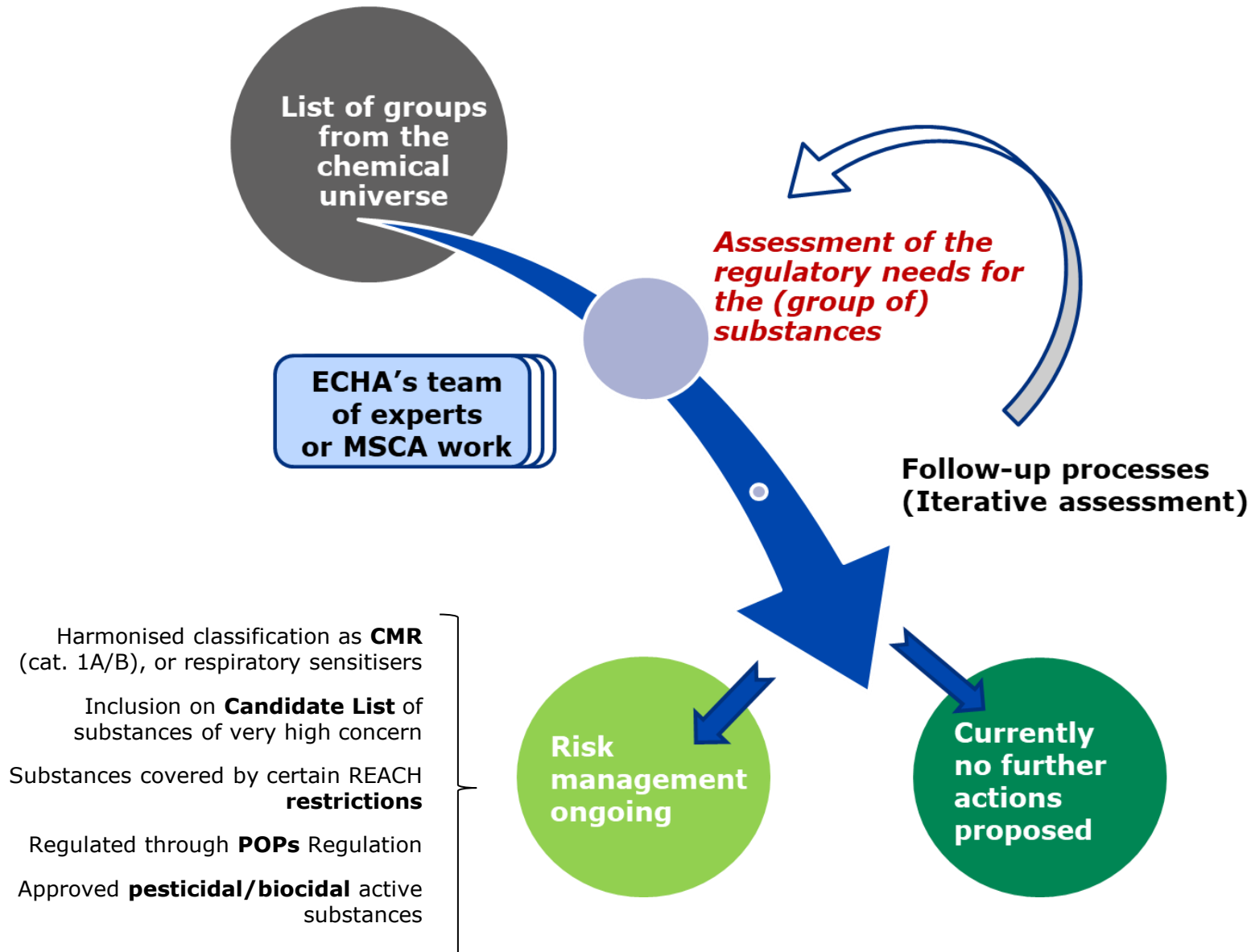
Assessment output increased ten-fold



Forming groups for regulatory scrutiny



Work on groups



Iterative assessment of regulatory needs

- Assessment of regulatory needs
 - Hazards
 - Uses/exposure
 - Group boundaries (and need for subgrouping)
 - Potential for substitution
 - Immediate action & expected further regulatory actions for whole group, subgroup or individual substances
- Usually data generation or “currently no action” proposed as immediate action – in some cases, risk management is already possible
- In depth of assessment and knowledge on substances will increase in further iterations

Foreseen regulatory needs

Plan for the longer-term regulatory risk management measures – beyond next action

EU regulatory risk management foreseen for ~20 % substances assessed in groups during 2019-2020

Most common actions planned were harmonised classification, restriction & authorisation

- In most cases, data generation & confirmation of hazard needed before regulatory risk management can be initiated

Longer-term regulatory need may be revised

Looking ahead



Prioritisation approach development



ECHA's **grouping approach** can **be applied wider** than only for REACH & CLP purposes



Collaboration with European Food Safety Authority (EFSA) on prioritising **substances with potential plasticiser** use in different food contact materials



Prioritisation also ongoing for substances under the **Drinking water Directive**

- European Positive Lists of substances authorised in manufacture of materials in contact with drinking water

More information

- Integrated regulatory strategy [Infographic](#)
- Publication of **assessments of regulatory needs**
 - Report on expected regulatory needs & proposed immediate actions for all substances in a group
 - Increased transparency & predictability
 - Published from end of 2021
- Annual [IRS Report](#)
 - Progress in identifying & addressing substances of concern
 - Chemical universe
 - Statistics, case studies



Thank you!

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