



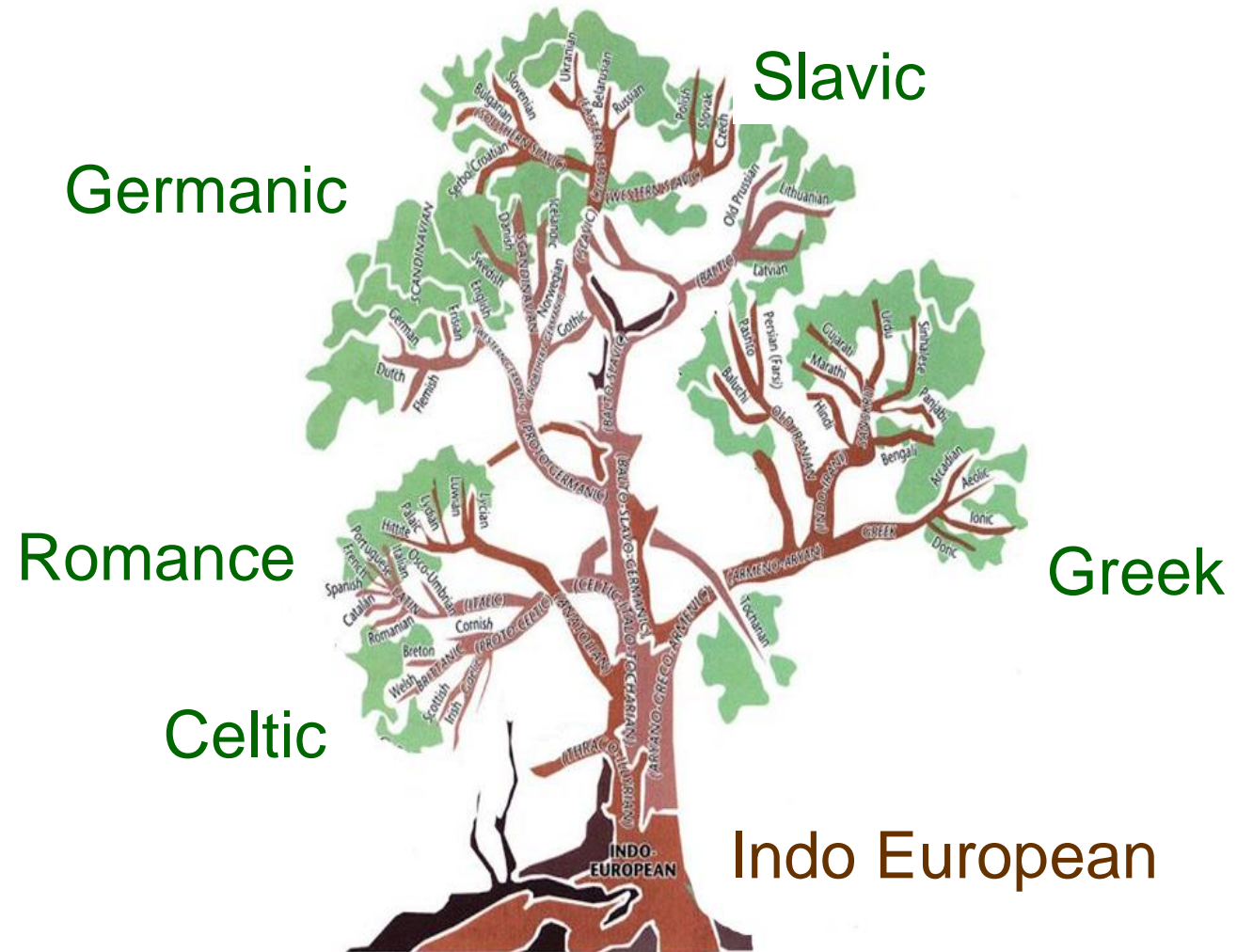
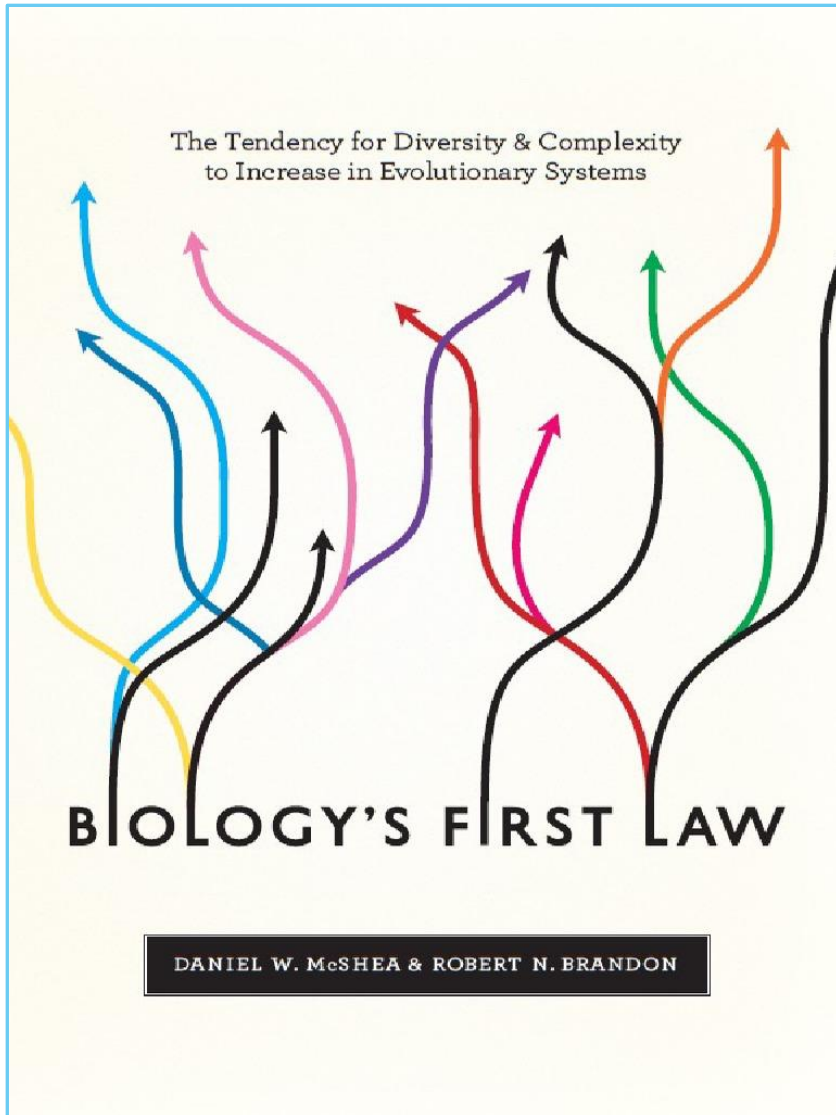
Innovating chemical safety assessment: What does “**Chemicals 2.0**” look like?

EPAA Annual Conference 2022

*Presented by Andrew Worth
Developed in collaboration with Elisabet Berggren
European Commission Joint Research Centre (JRC)*

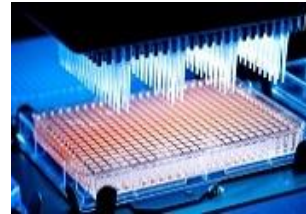
Disclaimer: this presentation is a thought starter developed by the JRC authors and does not necessarily represent a Commission position

Complexity and diversity in evolutionary systems



Issues raised when introducing NAMs into REACH

- NAMs not sufficiently validated or standardised
- Perception of “less safe” & more uncertain
- NAMs used to trigger additional animal testing rather than reduce animal use
- NAMs for systemic toxicity – not 1-to-1 replacement, need integrated approaches
- Standalone NAMs not sufficient for Classification & Labelling (C&L)



“Chemicals 2.0” – What do we want to achieve?



Objectives

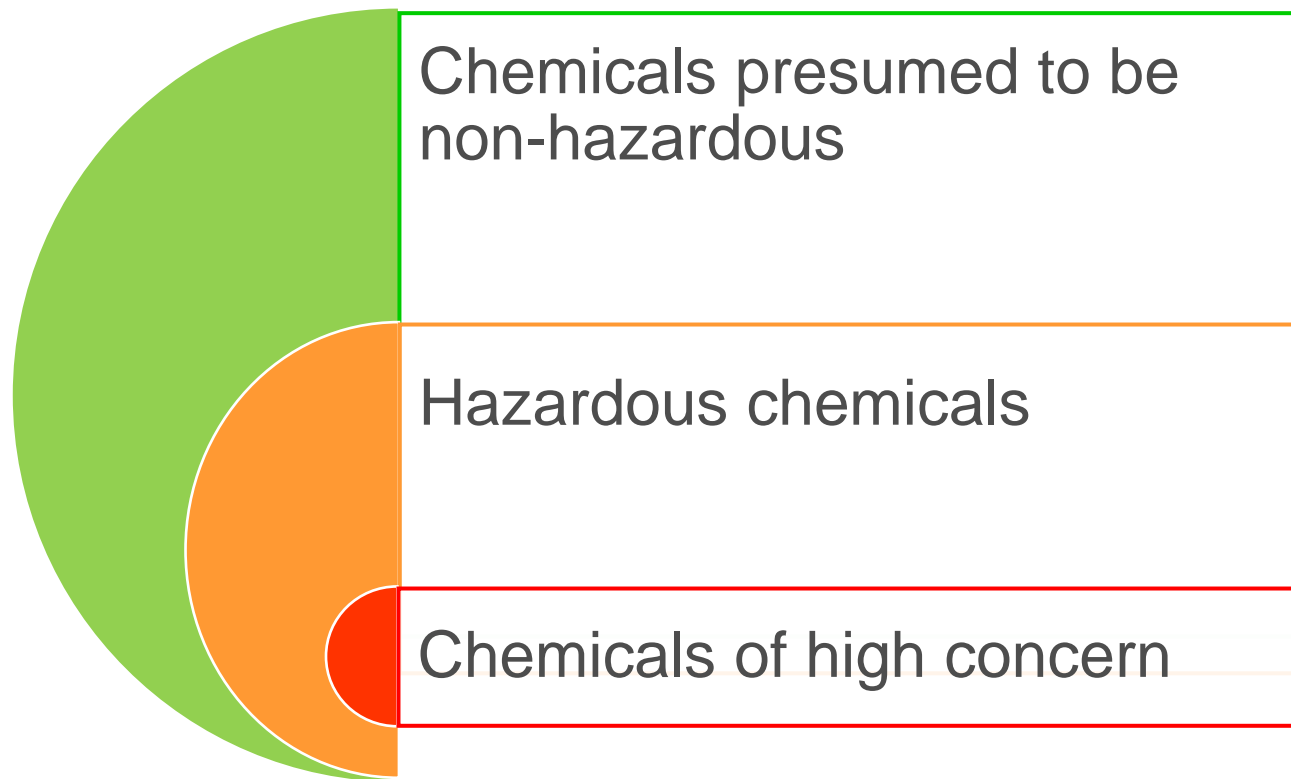
- consider all chemicals & evaluate them according to concern
- minimise animal testing during “phase-out” period
- eventual aim of complete replacement

Design specifications of a future regulatory system for chemicals



- Applicable to all substances on the market
- Provides an equivalent level of protection (same risk management decisions)
- Provides regulatory certainty and guides innovation
- Risk management is based on NAMs and exposure considerations
- Current C&L conclusions are maintained (unless challenged)
- Additional NAM-based C&L conclusions result in higher level of overall protection

Principle of equivalent protection: Make the same decisions, not necessarily the same predictions

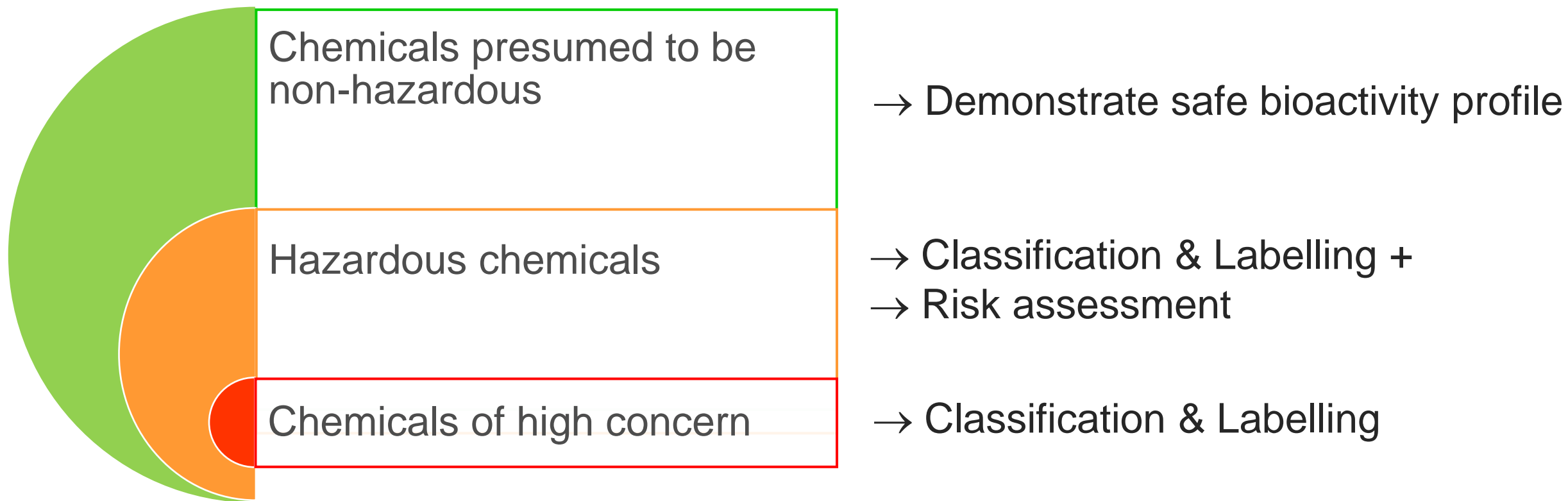


→ Innovate
→ Use without restriction

→ Restrict via concentration limits
→ Demonstrate safe use

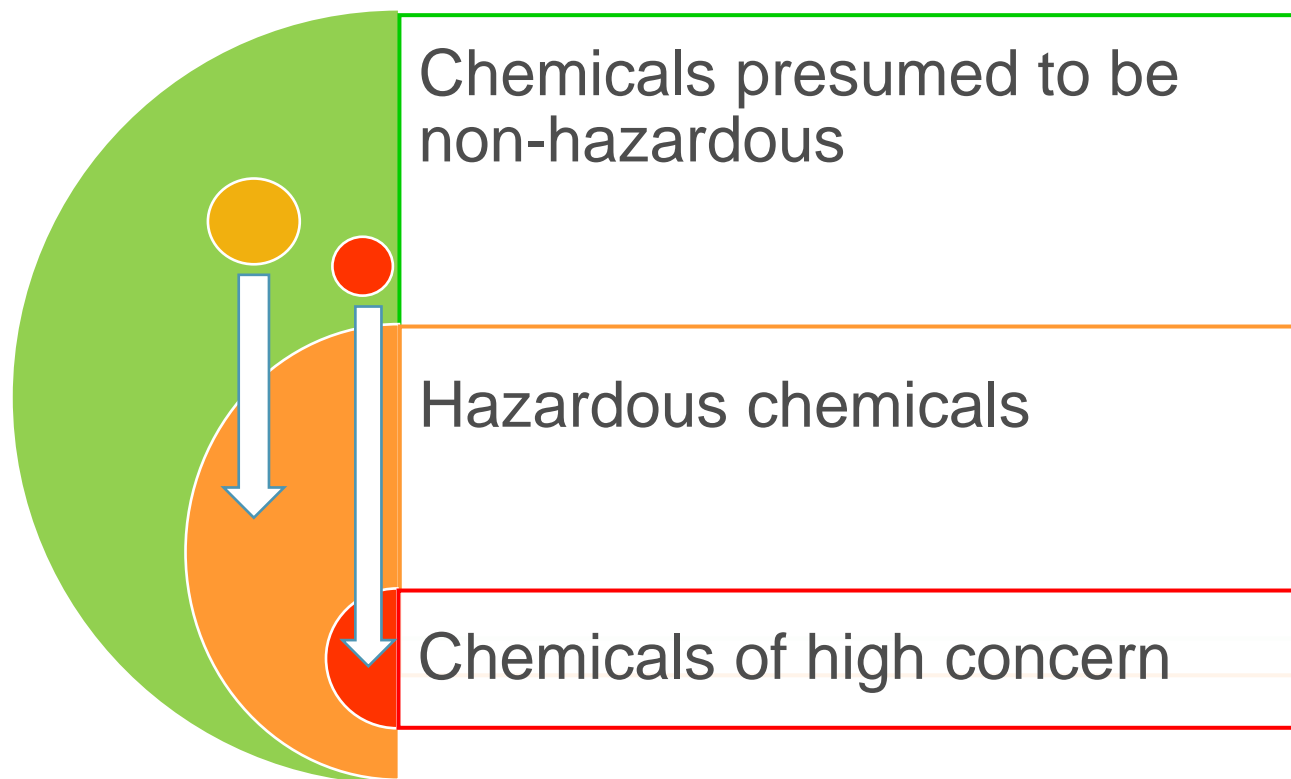
→ Ban for some or all uses

Developing a new NAM-based classification system



The fraction of chemicals covered by each group is calibrated to at least **keep current protection level**

Applying the new NAM-based classification system



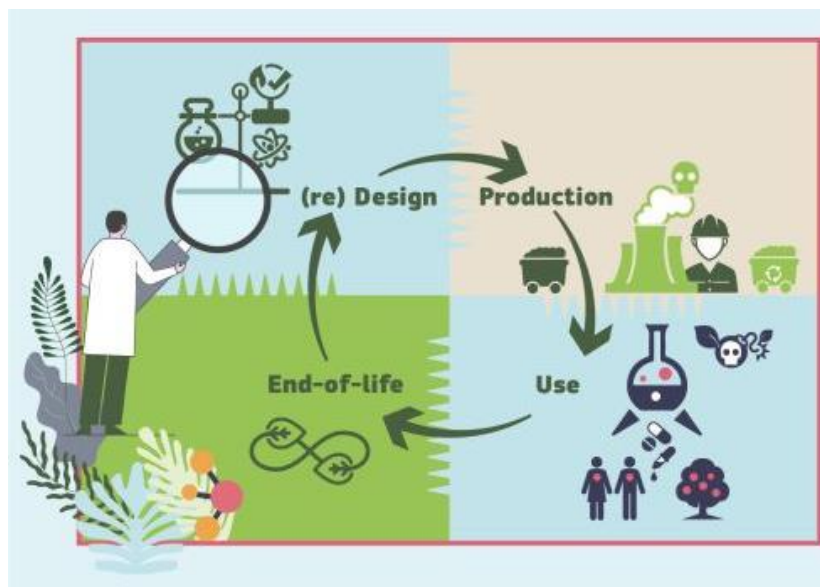
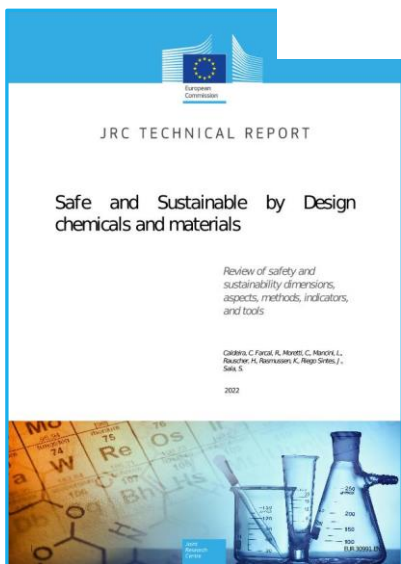
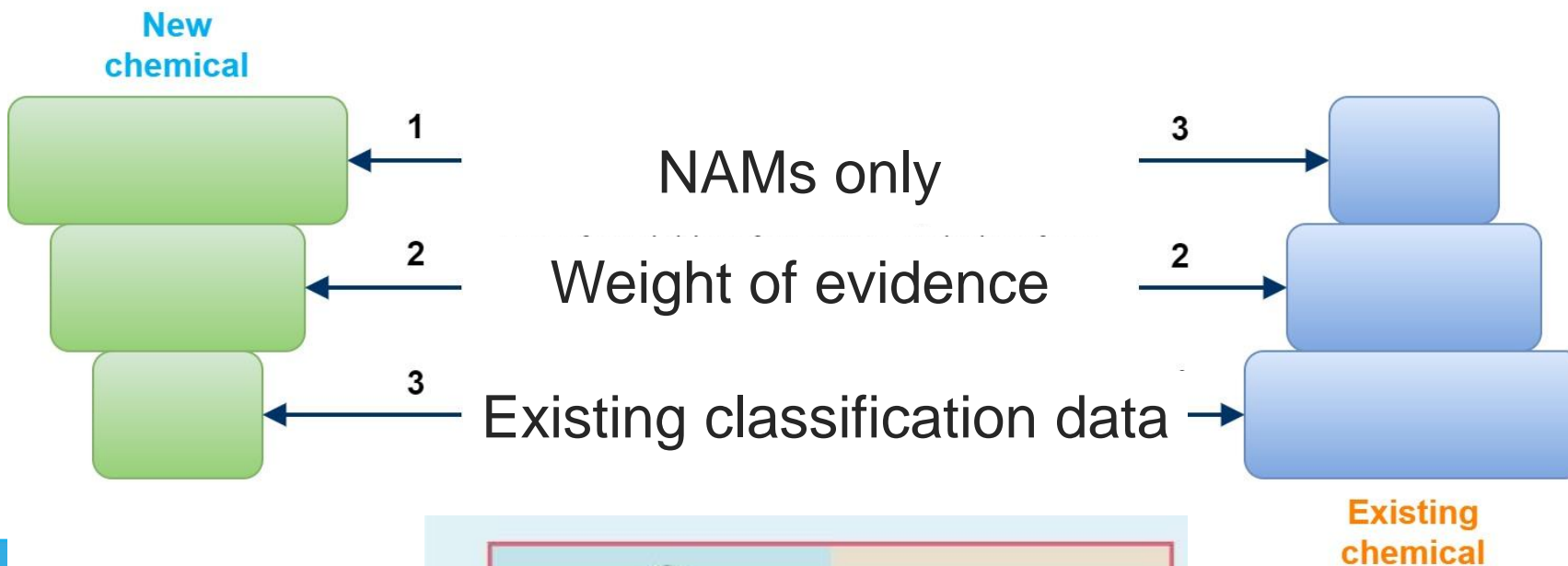
- Innovate
- Use without restriction

- Restrict via concentration limits
- Demonstrate safe use

- Ban for some or all uses

Additional classifications result in overall
higher level of protection

Enabling Safe and Sustainable by Design



Additional considerations

- **Less is more** – optimal combinations of a limited number of NAMs
- **NAMs for C&L** – constrained, regulatory certainty
- **NAMs for Risk Assessment** – flexible, companies develop bespoke solutions
- **Multiple pathways to acceptance**
- **Common roadmap** to create confidence together



Thank you



© European Union 2020

Unless otherwise noted the reuse of this presentation is authorised under the [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/) license. For any use or reproduction of elements that are not owned by the EU, permission may need to be sought directly from the respective right holders.