CURRENT EU REQUIREMENTS FOR THE ASSESSMENT OF CHEMICALS

CHALLENGES IN REGULATORY ENDPOINTS AND OPPORTUNITIES FOR NEW APPROACH METHODOLOGIES

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

"CHALLENGING" REGULATORY ENDPOINTS DEFINED BY CLP CLASSIFICATION CRITERIA

Hazards:

- Physical
- Health
- Environmental

- systemic
- non-systemic

- acute toxicity
- carcinogenicity
- mutagenicity
- reproductive toxicity
- target organ toxicity

Current EU regulatory requirements for the assessment of chemicals and cosmetic products: challenges and opportunities for introducing new approach methodologies

Francesca Pistollato, Federica Madia, Raffaella Corvi, Sharon Munn, Elise Grignard, Alicia Paini, Andrew Worth, Anna Bal-Price, Pilar Prieto, Silvia Casati, Elisabet Berggren, Stephanie K Bopp & Valérie Zuang

Archives of Toxicology **95**, 1867–1897 (2021) https://doi.org/10.1007/s00204-021-03034-y

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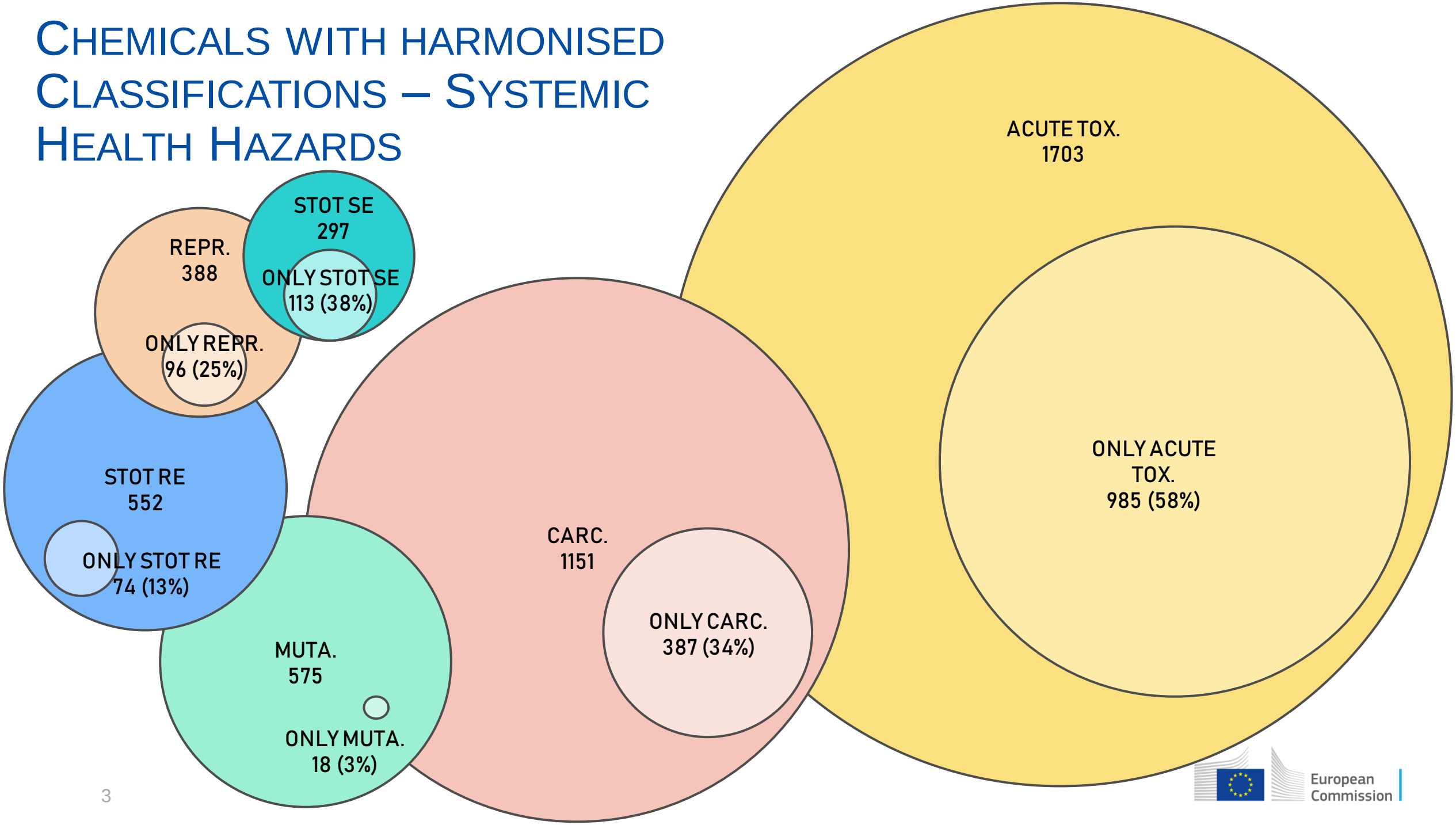
Chemicals with harmonised Classifications – Systemic Health Hazards



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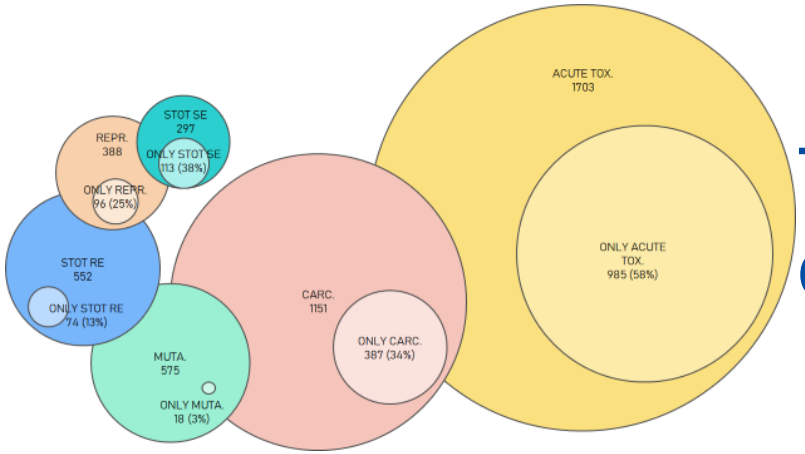
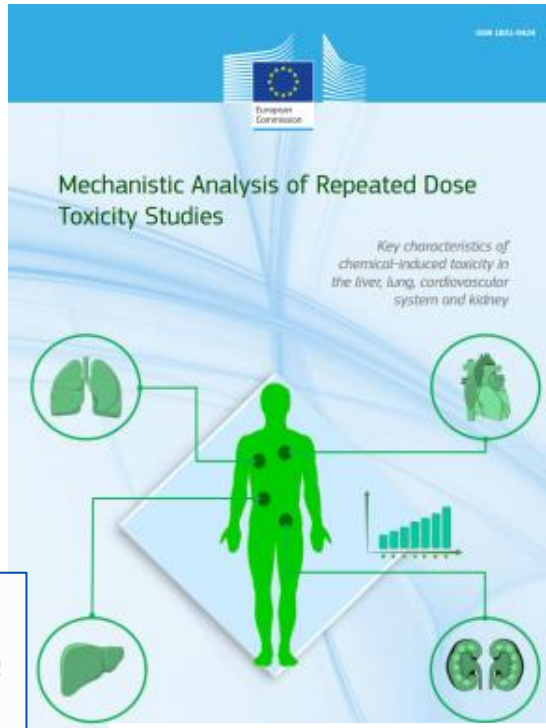


THE CHALLENGE OF UNDERSTANDING OVERLAPS & COMMON MECHANISMS

- Cost/benefit of new hazard classes: leading to better protection or already covered by an existing hazard class?
- Do we need new «smarter» classes to substitute old ones or include newly introduced hazards in existing ones?
- To what extent can new criteria be based on NAMs?



doi:10.2760/824535

Integration of data across toxicity endpoints for improved safety assessment of chemicals: the example of carcinogenicity assessment

Federica Madia, Gelsomina Pillo, Andrew Worth, Raffaella Corvi & Pilar Prieto

Archives of Toxicology **95**, 1971–1993 (2021) https://doi.org/10.1007/s00204-021-03035-x

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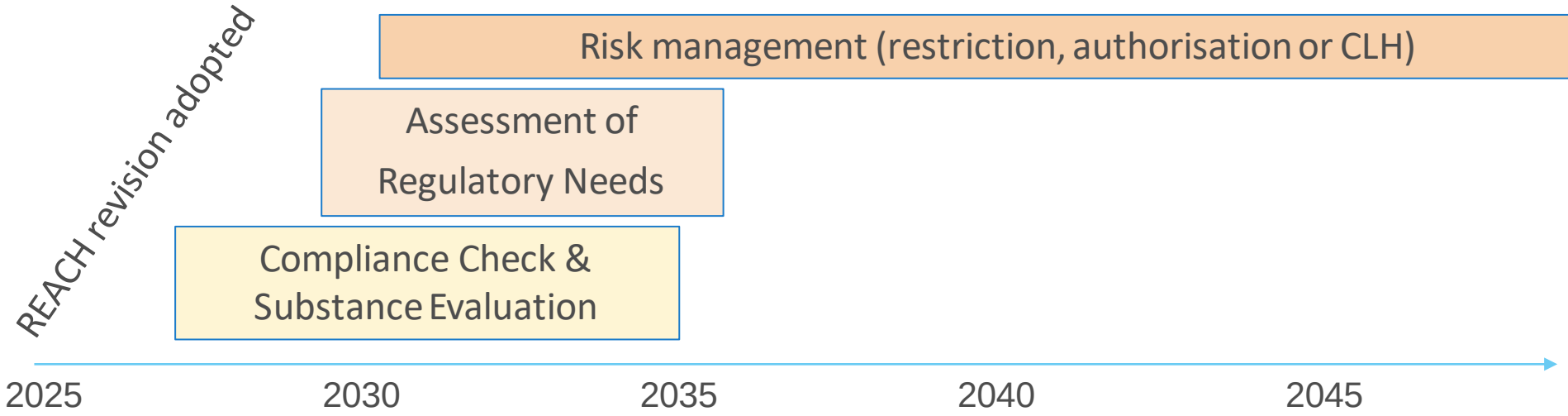
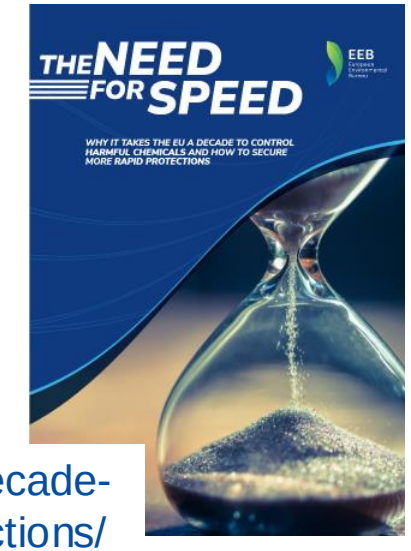
Problems experienced when introducing NAMs under the REACH Information Requirements

- NAMs not sufficiently validated or standardised (OECD TG required?)
- Perception of “less safe” & higher uncertainty
- NAMs used to trigger additional animal testing rather than reduce animal use
- NAMs for systemic toxicity – not 1-to-1 replacement, need for IATA
- Standalone NAMs not able provide legal certainty for Classification & Labelling (C&L) (not identifying adverse systemic health effects and environmental hazards)

FOCUSSING ON REACH INFORMATION REQUIREMENTS

14,000 registered chemicals in scope for extended Standard Information Requirements





https://eeb.org/library/the-need-for-speed-why-it-takes-the-eu-a-decade-to-control-harmful-chemicals-and-how-to-secure-more-rapid-protections/

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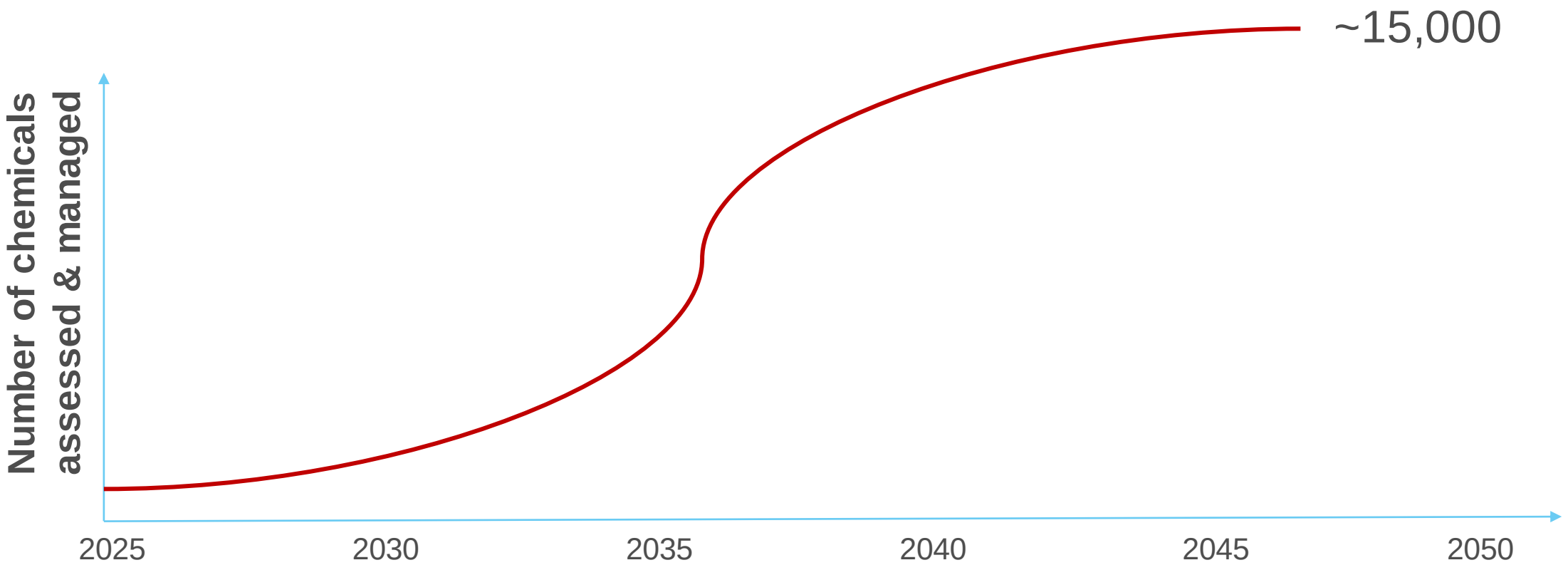
CHEMICALS ASSESSED & MANAGED LARGELY BASED ON ANIMAL TESTING THROUGH REACH AND SECTORIAL CHEMICALS LEGISLATION



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~ 100 000 chemicals
on the market

~ 22 600 chemicals
with a use over
1 tonne per year

~ 4 700 chemicals
with a use over
100 tonnes per year
prioritised in
hazard characterisation
and evaluation

RISKS

HAZARDS

EXPOSURES

~ 500 chemicals
extensively characterised for
their hazards and exposures

~ 10 000 chemicals
fairly well characterised for
a subset of their hazards and exposures

~ 20 000 chemicals
with limited characterisation for
their hazards and exposures

~ 70 000 chemicals
with poor characterisation for
their hazards and exposures

https://www.eea.europa.eu/soer

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Design a future regulatory system based on NAMs

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

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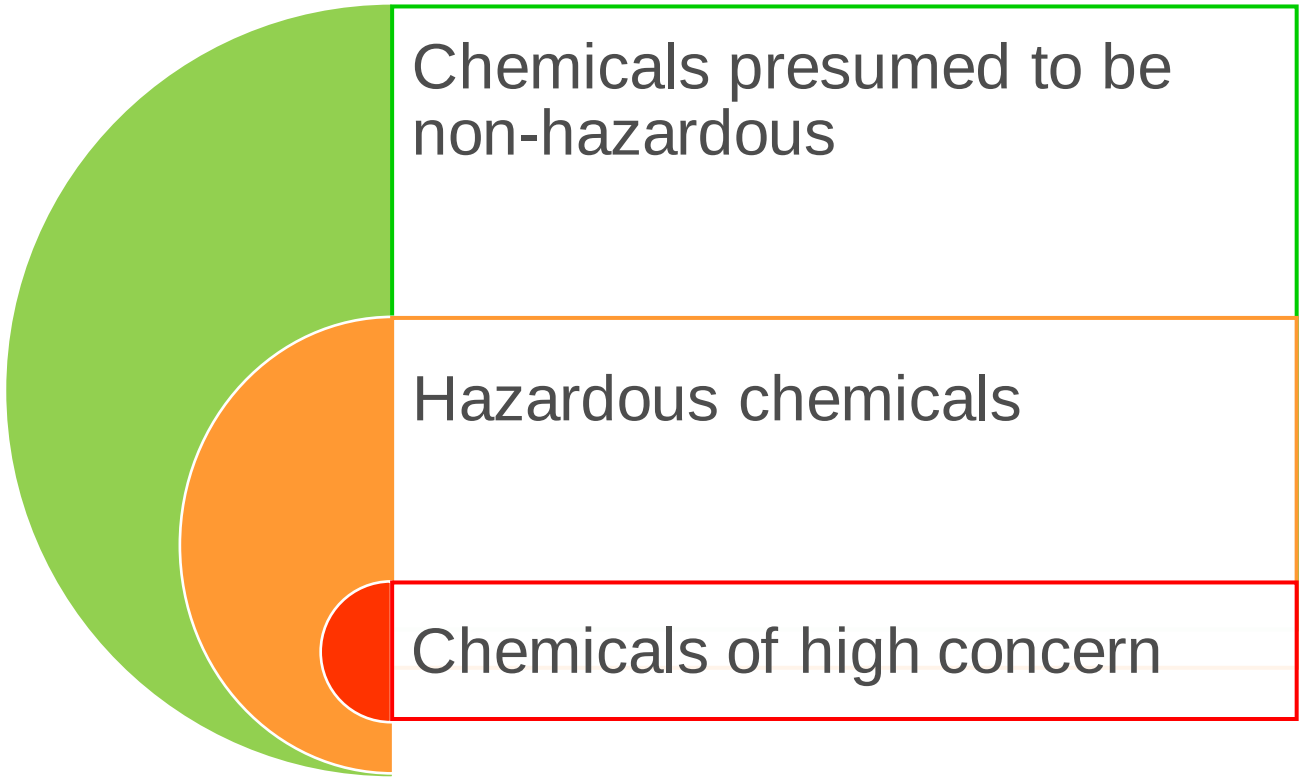
Principle of equivalent protection: Make the same decisions, not necessarily the same predictions



→ Innovate
→ Use without restriction

→ Restrict via concentration limits
→ Demonstrate safe use

→ Ban for some or all uses

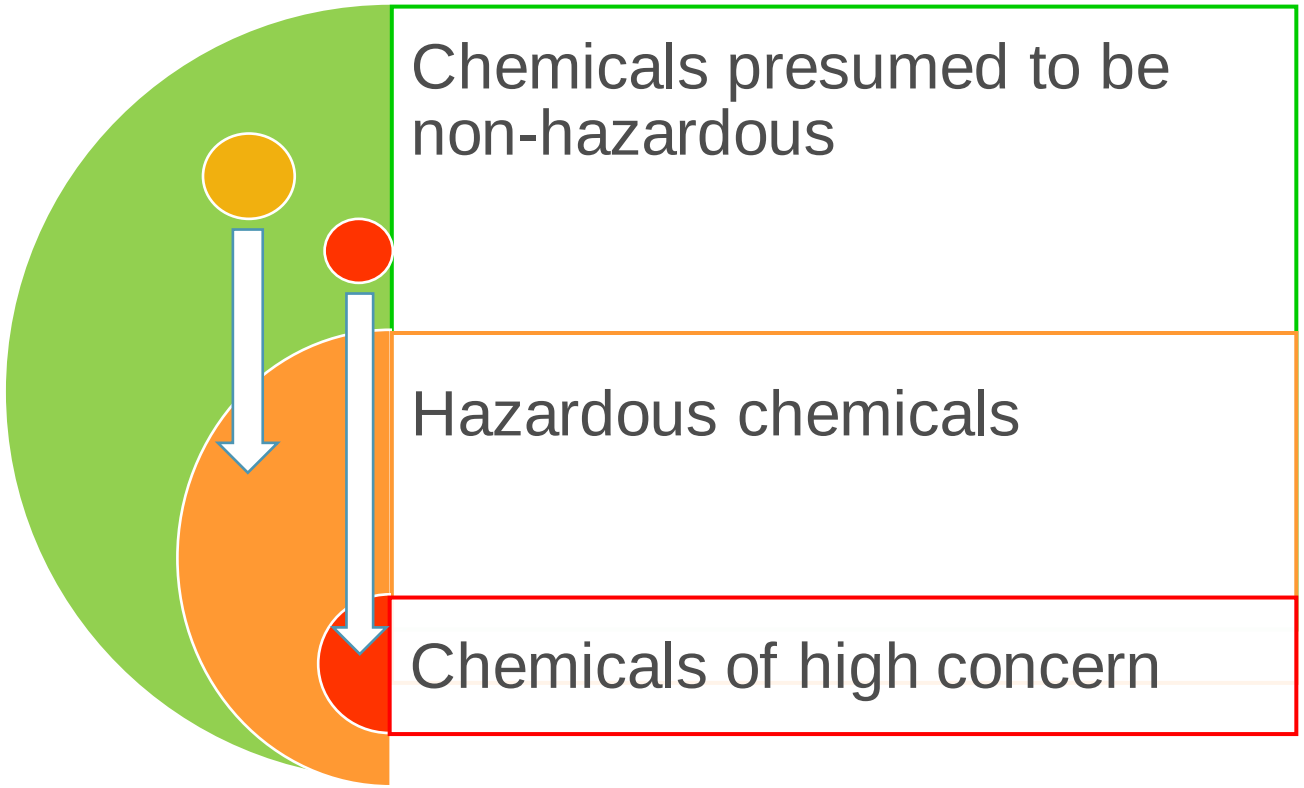
DEVELOPING A NEW CLASSIFICATION SCHEME

- A generic risk matrix is developed to assign chemicals to groups 1-3 (low, medium & high concern)
- Existing data for already classified chemicals (high & medium concern) are used to calibrate the classification scheme resulting in **equivalent protection**

		Activity (NAM-based toxicodynamics)		
		High	**Medium**	**Low**
Potential Systemic Availability (NAM-based toxicokinetics, based on ADME properties)	**High**	H	H	M
	Medium	H	M	L
	Low	M	L	L

NAMs capture chemicals currently treated as green, but based on no or limited information

- Application of the new classification scheme to chemicals in the current low concern group will result in some additional classifications and thus an **overall higher level of protection**

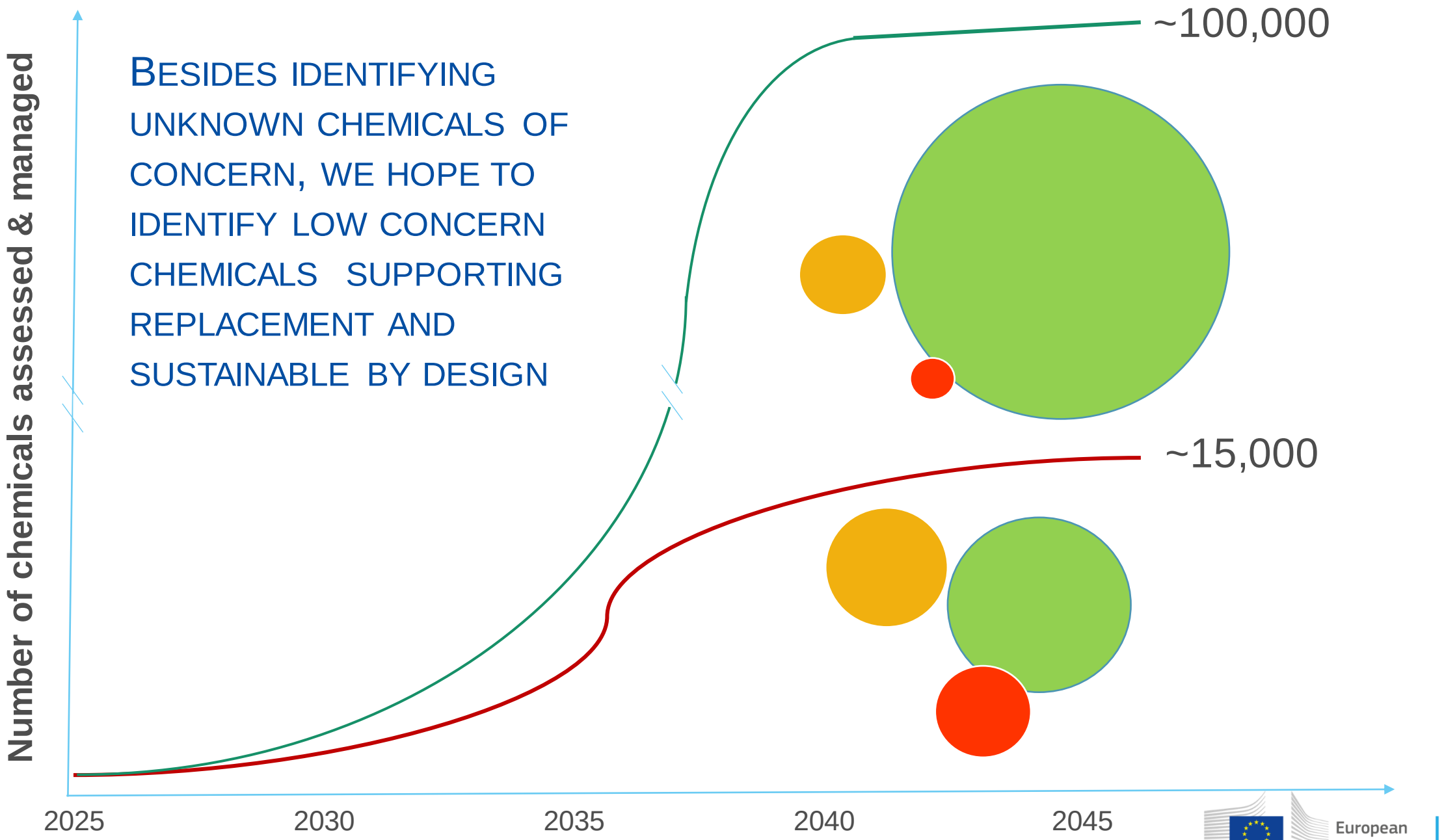


→ Demonstrate safe activity/systemic availability profile

→ Classification & Labelling +
→ Risk assessment

→ Classification & Labelling

BESIDES IDENTIFYING UNKNOWN CHEMICALS OF CONCERN, WE HOPE TO IDENTIFY LOW CONCERN CHEMICALS SUPPORTING REPLACEMENT AND SUSTAINABLE BY DESIGN



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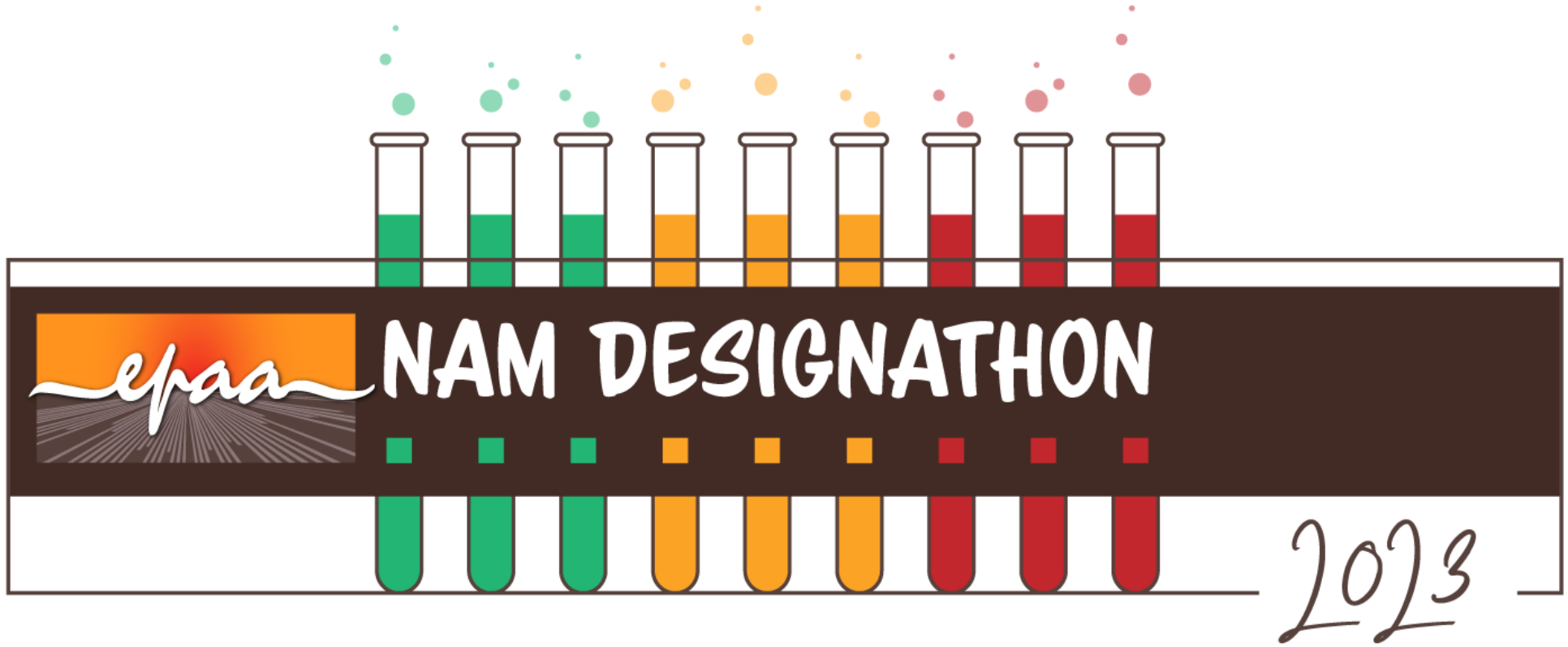
epaa
NAM DESIGNATHON
2023

The EPAA invites the submission of **NAM-based solutions** to inform the development of a future classification system for systemic toxicity of human health.

There will be no winning solution

Instead, in this pilot phase, the aim will be to compare and contrast the different solutions and co-create!

31 May – 1 June	LAUNCH
Early July 2023	Orientation webinar(s) for all
1 August 2023	Deadline to register interest for pilot phase*
31 December 2023	Deadline to submit pilot phase solutions
January 2024	EPAA team plan workshop based on submitted solutions
End February/early March 2024	Workshop to discuss pilot phase solutions with submitters

*At registration participants receive **REFERENCE LIST OF CHEMICALS** & reporting template/guidance.

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Thank you

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