



# How to address systemic health effects with non-animal methods? Gaps, overlaps & research needs

Elisabet Berggren, Joint Research Centre, European Commission  
Workshop on the Commission roadmap towards phasing out animal testing for  
chemical safety assessments, Brussels, 11-12 December 2023

# Joint Research Centre

## Our purpose

The JRC provides independent, evidence-based knowledge and science, supporting EU policies to positively impact society.





# Directive 2010/63/EU on the protection of animals used for scientific purposes



European Union Reference Laboratory for alternatives to animal testing

mandate under the Directive:

- research & evaluation
- validation
- dissemination
- promotion



What are we doing at ECVAM?  
Watch what my colleague Raffaella is doing  
(<https://audiovisual.ec.europa.eu/en/video/I-230374?language=EN>)

# THE ECOSYSTEM OF CHEMICALS LEGISLATION

Vertical legislation:



Horizontal legislation:

CLP - all chemicals on the market (no information requirements)

REACH

Registration & Evaluation > 1 tonnes  
(information on systemic health effects +  
chemical safety report > 10 tonnes)  
Authorisation & Restriction based on concern

Downstream legislation

# GLOBALLY HARMONISED SYSTEM FOR CLASSIFICATION & LABELLING IMPLEMENTED THROUGH THE CLP REGULATION



Systemic  
health effects



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



- *endocrine disruption*
- *immunotoxicity*
- *neurotoxicity*



# Substances identified as endocrine disruptors at EU level\*

(complete list 108 substances)

25 substances with ED Health effects:

11 substances harmonised classified Repr. 1b

1 substance harmonised classified STOT RE 1

1 substance harmonised classified Asp. Tox. 1

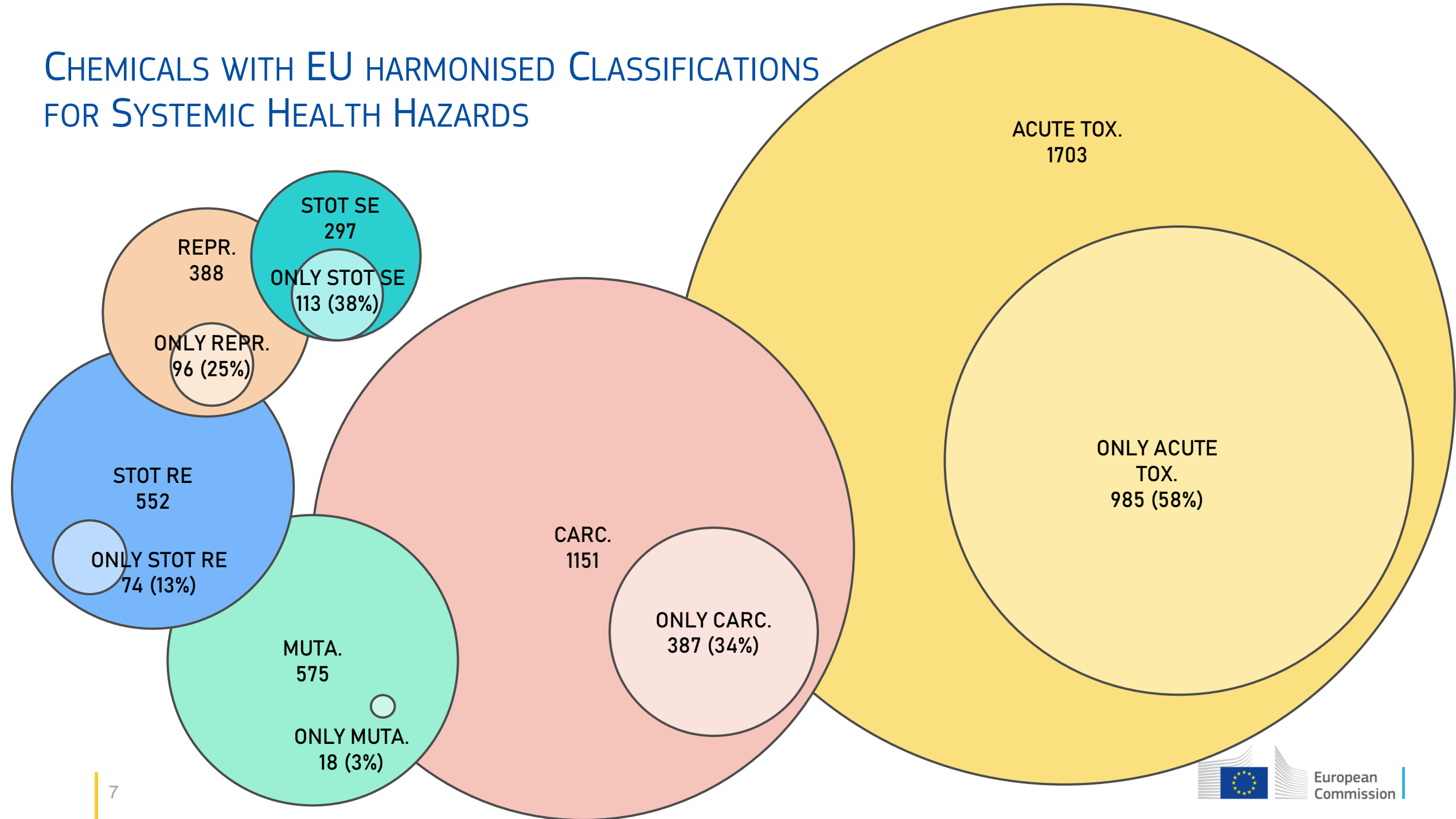
1 substance harmonised classified Aquatic acute & chronic 1, but without health class

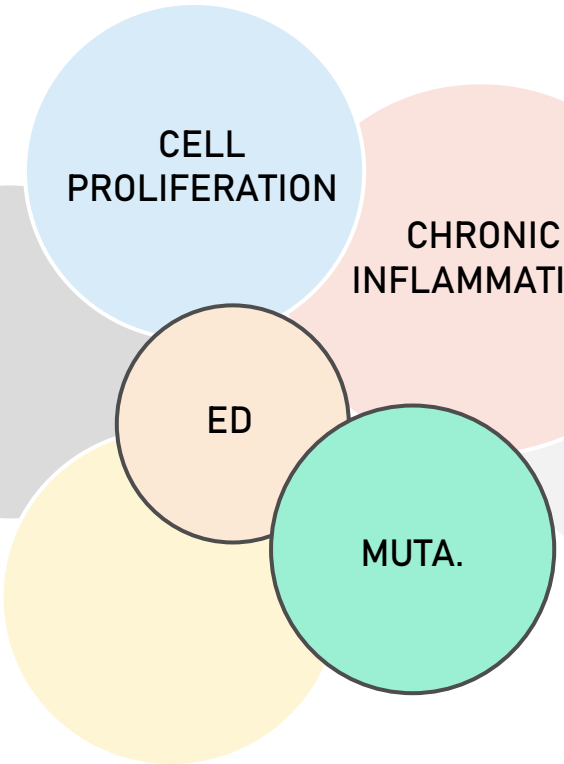
11 substances without harmonised classification,

9 with similar structure to other EDs on the list + 2 REACH registered substances with no self-classification

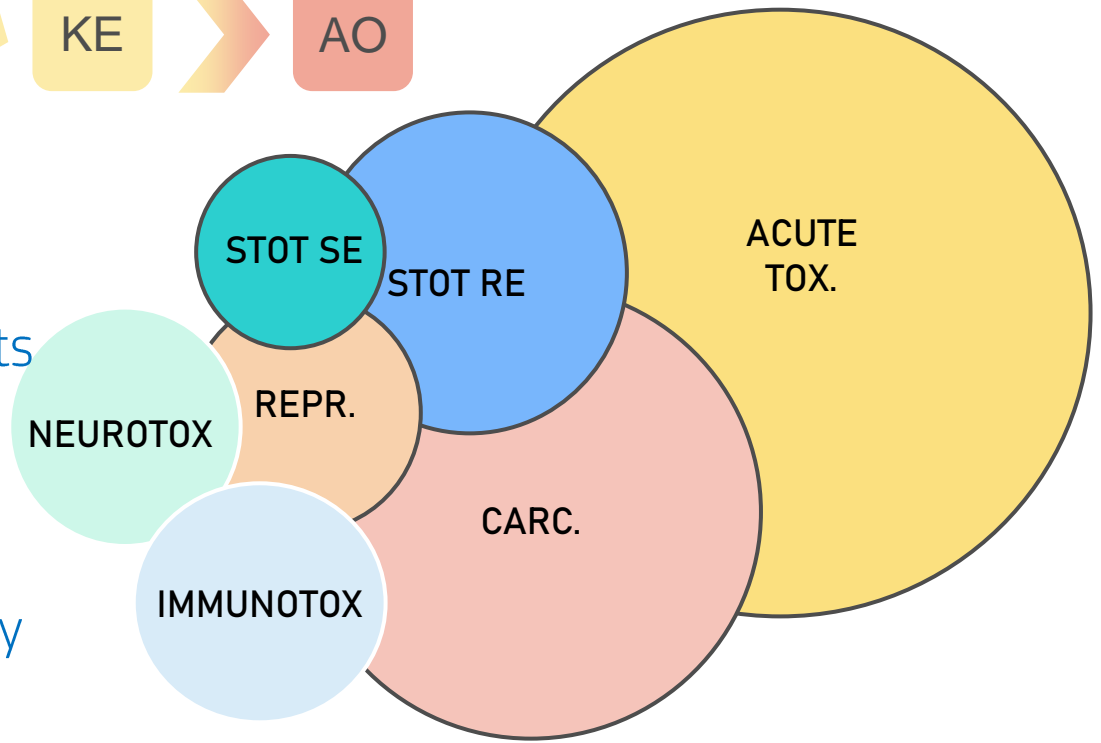
\* <https://edlists.org/the-ed-lists/list-i-substances-identified-as-endocrine-disruptors-by-the-eu>

# CHEMICALS WITH EU HARMONISED CLASSIFICATIONS FOR SYSTEMIC HEALTH HAZARDS



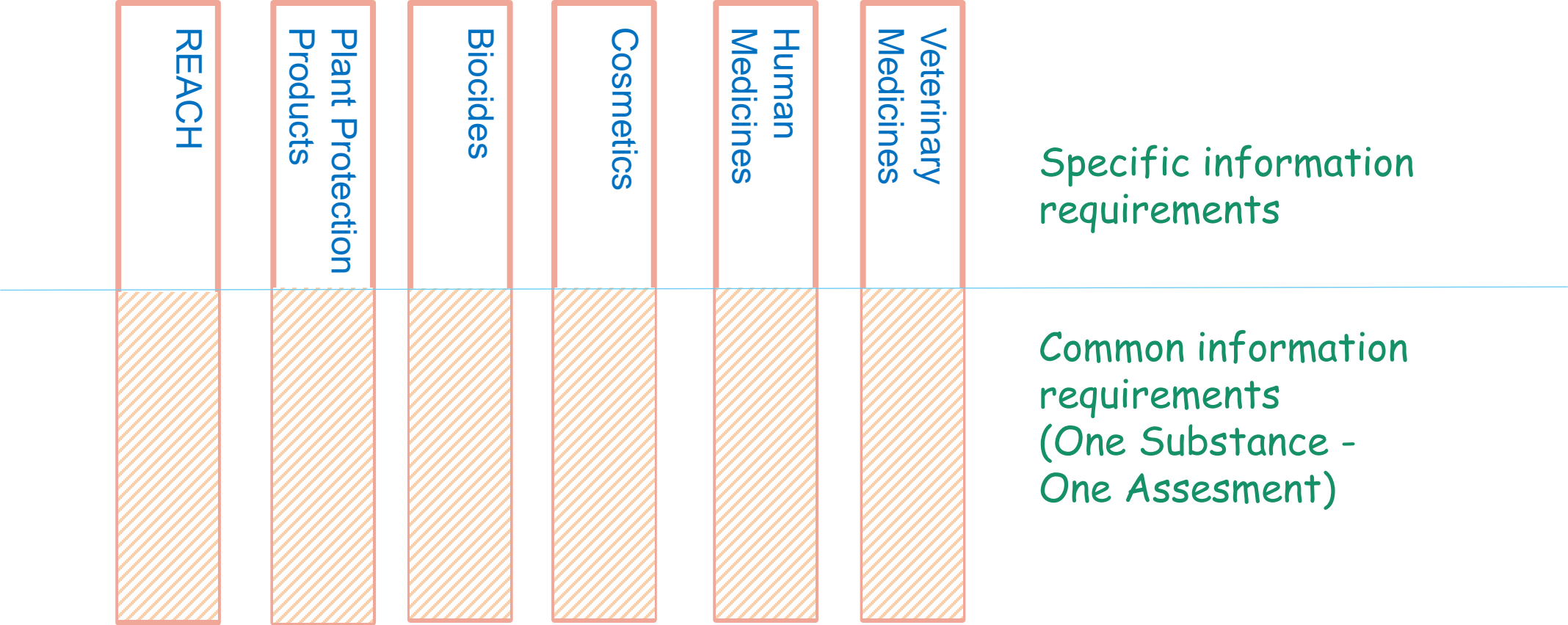


- Identify intermediate effects leading to adverse outcome
- Stop predicting adverse outcome
- Avoid redundancy & identify gaps upstream
- Keep current protection levels

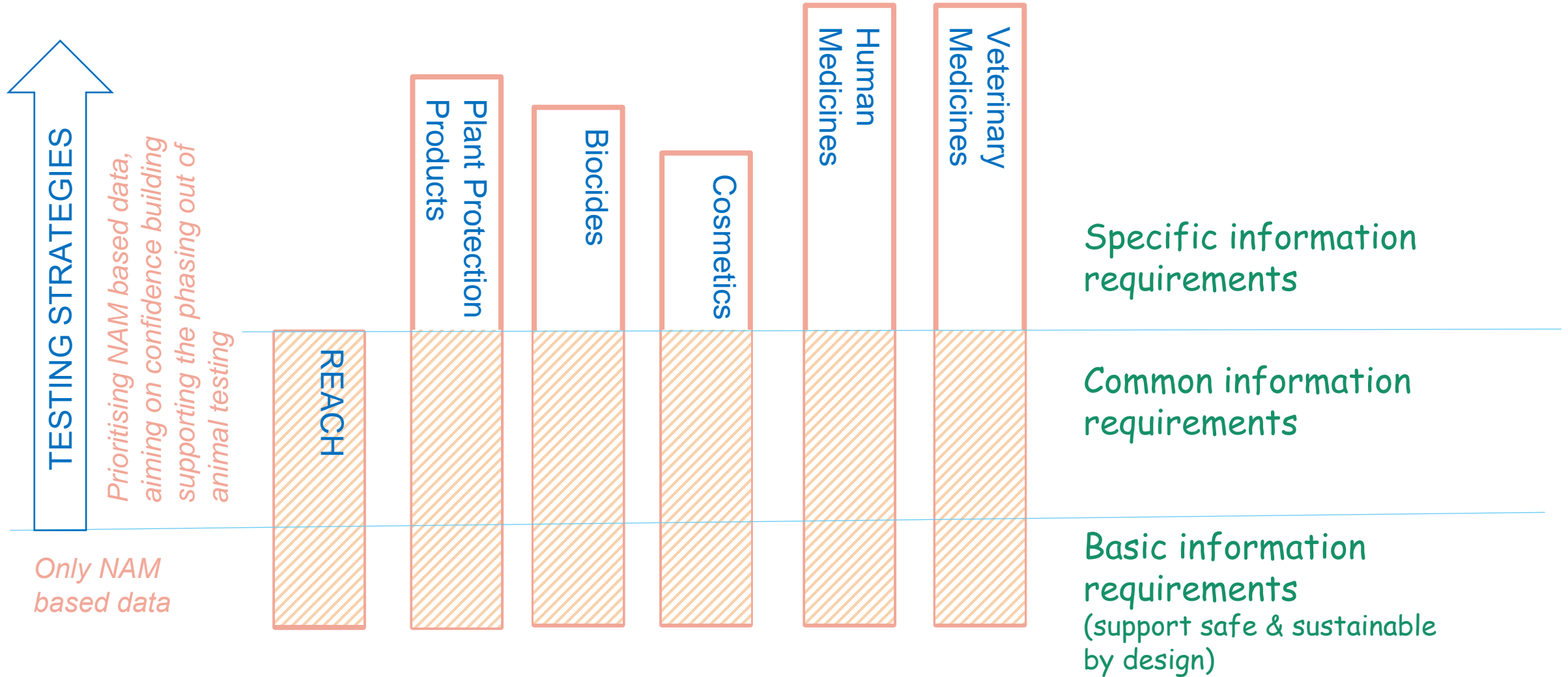




# Information Requirements for Systemic Health Effects



# Information Requirements for Systemic Health Effects



# Thank you



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## Session 2: How to replace animal testing for the concern of systemic human health effects?

Introductory presentation: How to address systemic health effects with non-animal methods? - Gaps, overlaps and research needs

Elisabet Berggren  
(EU Commission, JRC)

A national risk assessor's perspective to move towards the assessment of systemic health effects using non-animal methods

Christophe Rousselle  
(ANSES, France)

How are human health systemic effects covered when animal testing is not allowed?

Qasim Chaudhry (SCCS)  
(online)

What does it take to start reducing systemic animal testing now, and to phase it out soon?

Heli Hollnagel (CEFIC LRI)

Paving the way towards a One-Health approach to chemical risk assessment

Julia Baines (PETA)

An initiative towards a future solution: the EPAA Designathon

Carl Westmoreland (EPAA)

**Panel discussion**