

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



Dr. Heli M. Hollnagel

Dow Europe, Chair of the Cefic Long Range Initiative



# Timeline View and Resulting Options for the Shorter Term



**Continue with REACH Standard Information Requirements for the next ~10 years.**

Animal testing will decrease thereafter as existing chemicals will have been tested.

NAM will be applied as SIR to few innovation chemicals.



SIR: Standard Information Requirement

# Timeline View and Resulting Options for the Shorter Term



**Continue with REACH Standard Information Requirements for the next ~10 years.**

Animal testing will decrease thereafter as existing chemicals will have been tested.

NAM will be applied as SIR to few innovation chemicals.



Reduce

- 1) imminent peak in animal testing
- 2) uncertainty in human protection

via **exposure-driven decisions on higher tier testing**

Precedence:  
EU product regulations  
REACH Ecotox (tonnage)

- Where we are not confident in exposure knowledge, policy should improve that knowledge, not sacrifice animals instead
- Augmenting regulation to increase exposure management is faster than developing and validating new experimental methods



# Facing the Barriers for the Longer Term

## Reducing Uncertainties and Increasing Confidence (Effects Side)

### Coverage

(How much can we know, and do we have to know?)

- Most NAMs do not detect adverse effects. Realistically, we will never be able to predict 100% of all effects detected in animal models or in humans, to fit the current CLP-based chemical management framework. Shift in mindset (and regulations) required.
- Particularly for human health, the current tonnage-based approach of REACH is highly untargeted: Major opportunity to reduce uncertainty in protection
- Reduction of uncertainties in NGRA achievable by a focus on covering the most frequent/most impactful target tissues and effects with quantitative NAM read-outs



# Facing the Barriers for the Longer Term

## Reducing Uncertainties and Increasing Confidence (Effects Side)

### Coverage

(How much can we know, and do we have to know?)

- Most NAMs do not detect adverse effects. Realistically, we will never be able to predict 100% of all effects detected in animal models or in humans, to fit the current CLP-based chemical management framework. Shift in mindset (and regulations) required.
- Particularly for human health, the current tonnage-based approach of REACH is highly untargeted: Major opportunity to reduce uncertainty in protection
- Reduction of uncertainties in NGRA achievable by a focus on covering the most frequent/most impactful target tissues and effects with quantitative NAM read-outs

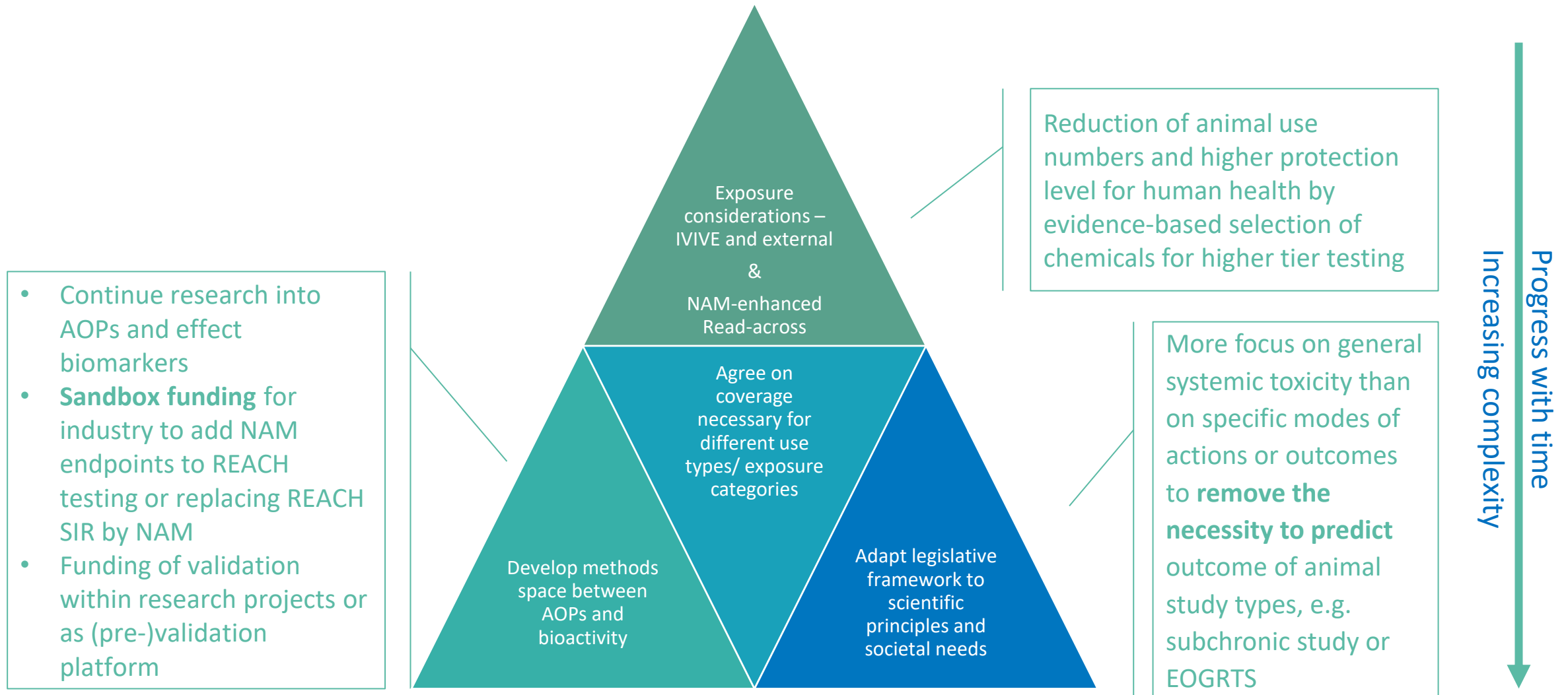
Mechanistic knowledge creates trust. But we will probably never know and be able to test all human AOP events

Improve linkage of effect biomarkers for tissue injury with mechanistic key events to increase confidence?!

Animal methods hardly offer mechanistic insights, but detect effects to tissues



# Hierarchy of Actions to Decrease Animal Testing in a Step-wise Approach



Vision: Protection of humans by effect characterisation via a quantitative in vitro battery and interpretation model covering a majority of relevant effects



# Thank you.

**Contact:**

Katherine Santizio  
Product Stewardship  
[kas@cefic.be](mailto:kas@cefic.be)



**About Cefic**

Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies across Europe, which provide 1.1 million jobs and account for 15% of world chemicals production. Cefic members form one of the most active networks of the business community, complemented by partnerships with industry associations representing various sectors in the value chain. A full list of our members is available on the Cefic website. Cefic is an active member of the International Council of Chemical Associations (ICCA), which represents chemical manufacturers and producers all over the world and seeks to strengthen existing cooperation with global organisations such as UNEP and the OECD to improve chemicals management worldwide

