



DEVELOPMENT OF INTEGRATED APPROACHES TO TESTING AND ASSESSMENT AT OECD

Joint Cefic LRI /Cosmetics Europe/EPAA workshop

23-24 April 2015



Promoting the regulatory use of alternative test methods

- The OECD is actively working towards the adoption of methods to replace animal tests where possible, or to refine existing tests to reduce the number of animals used and minimise suffering.
- A number of OECD Test Guidelines are already based on non- animal tests, including but not limited to skin corrosion/irritation, phototoxicity and skin absorption, eye damage/irritation, genotoxicity and endocrine disruption

SCA1

Slide 2

SCA1

CASATI Silvia (JRC-ISPRA); 20/04/2015

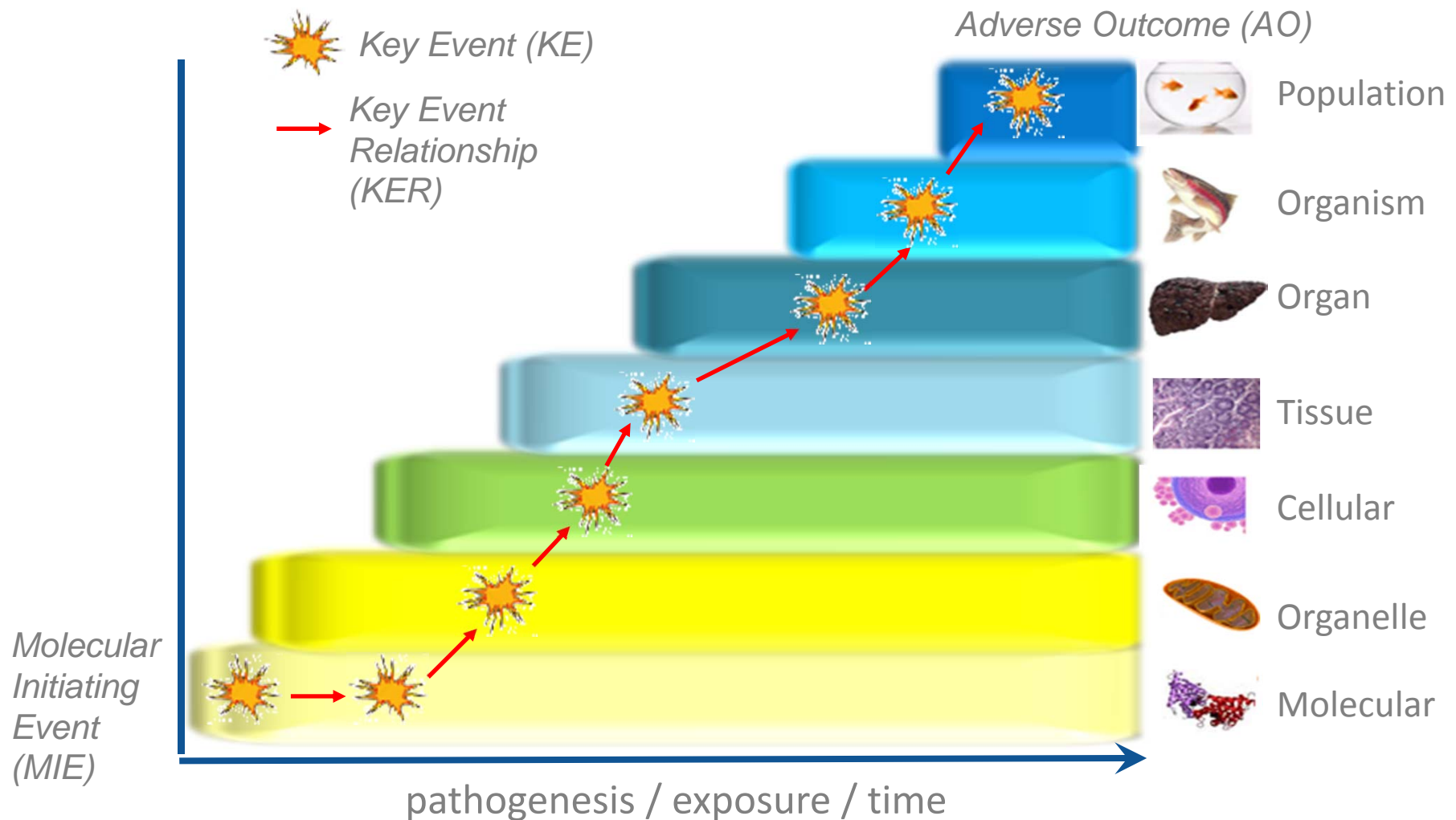
Animal test doesn't tell us the mechanism

To be comfortable to use alternative methods for complex endpoints, developmental or reproductive toxicity, we have to know

How toxicity is brought about at the molecular level resulting in an effect at organ or organism level

If we understand the mechanism and mode, we understand toxicology, predict it and justify predictions

Adverse outcome pathway Framework for predictive toxicology





Need for scientific framework

The **Adverse Outcome Pathway** is an **objective** and **systematic mechanistic based** framework that provides the **biological context** to facilitate the interpretation of results from alternative test and non-test approaches in predicting an adverse effect and facilitates their application in regulatory decision-making.

AOPs helps to organise and analysing all the available relevant data on a given substance or group of substances coupled with mechanistic information where possible, tailored to the toxicity profile of the chemical in question.

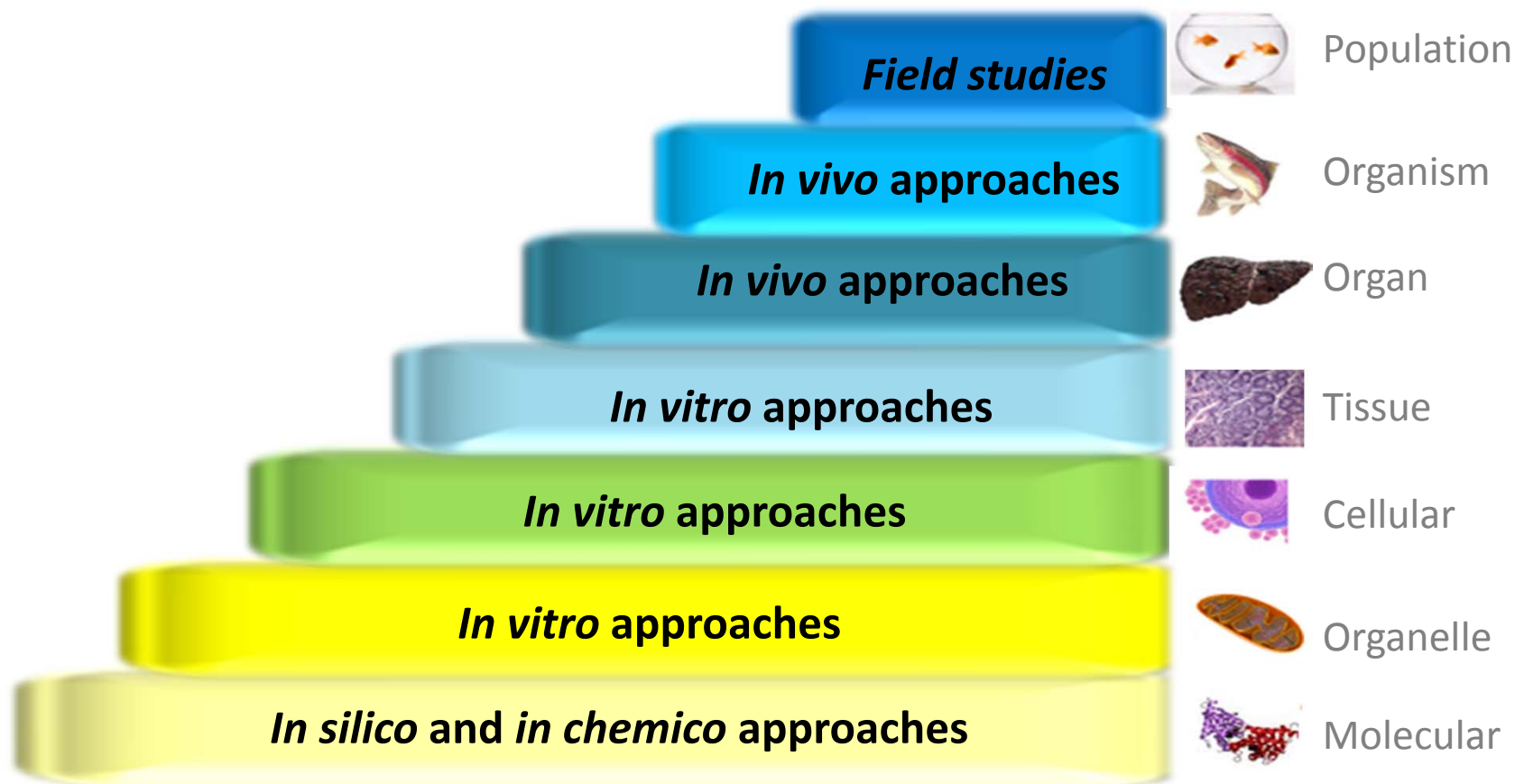




Integrated Approach to **Testing** and **Assessment** (IATA)

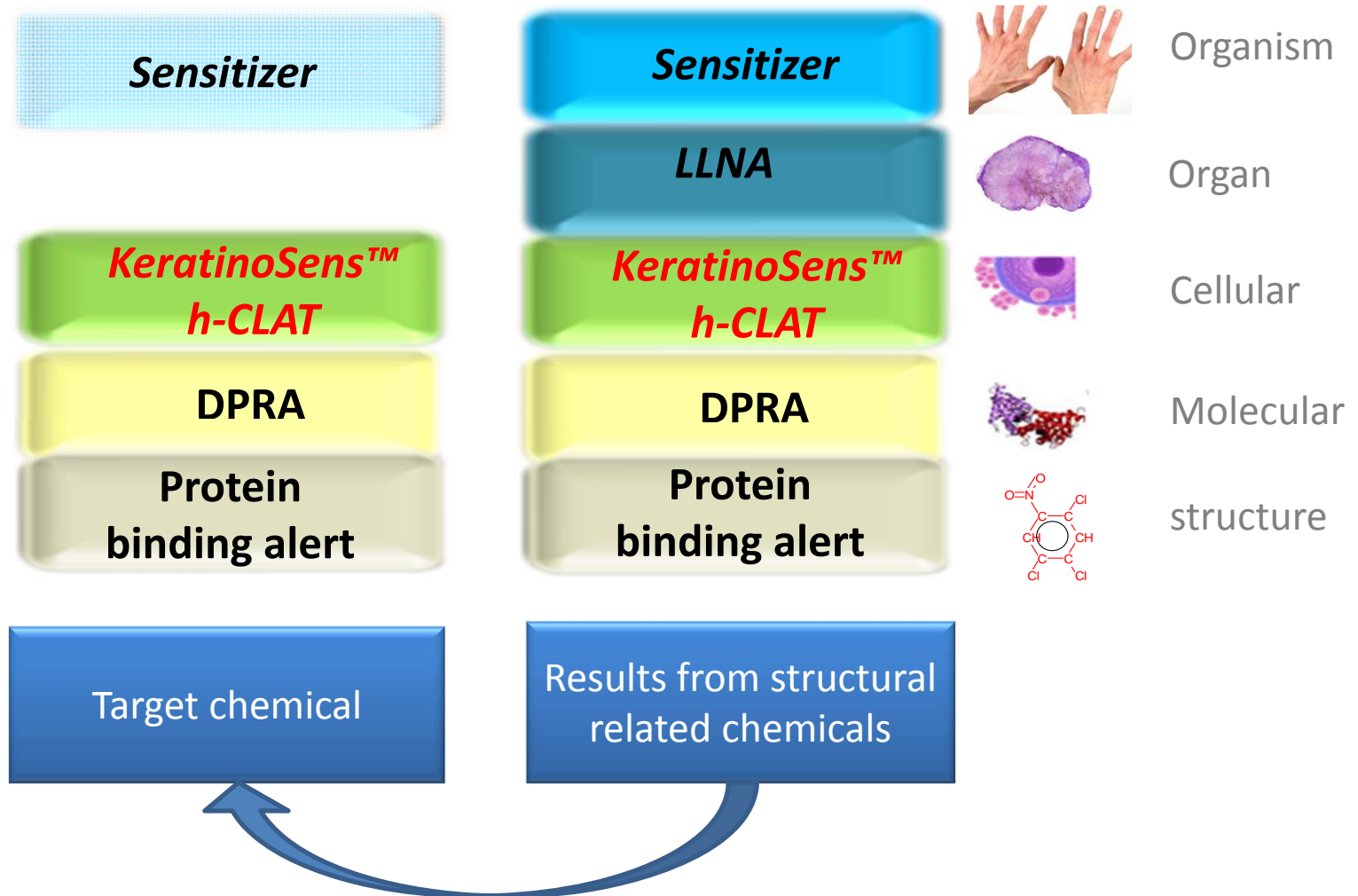
Structured approaches used for chemical or group of chemicals, **that strategically integrate and weight all relevant data** and **guide the targeted generation of new data where required (hypothesis driven)** to inform regulatory decisions regarding the hazard identification (potential), hazard characterisation (potency) and/or safety assessment (potential/potency and exposure).

The AOP concept can be used as a framework for the development of Integrated approaches to testing and assessment (IATA)



Development of Integrated approaches to testing and assessment

Read-across based on mechanistic understanding





Integrated Approach to Testing and Assessment (IATA)

- The degree to which an IATA needs to be populated by a full complement of information will be dependent on the ultimate purpose it is being used for.
- Thus flexibility is foreseen in the construction of IATA depending on the regulatory need and tailored to the substance(s) under consideration.
- However, there is also a need to provide regulators with some degree of consistency and understanding of the assumptions on which the IATA is based

Need for Guidance on reporting, evaluation and application of IATA



CHALLENGES

- Multiple IATA solutions may be possible, but not necessarily represent an optimum solution
- A common approach to IATA ensure consistency in how information from alternative methods is used in regulatory decision-making process.
- Allow sharing of assessments between countries and avoid duplicative efforts





Goal for harmonisation of IATA

- Long-term goal:
Increase harmonisation of IATAs, where possible and needed
- Short/medium term goal:
Harmonise testing strategies, where needed by regulators (depending on the regulatory application), especially where they involve alternative Test Guidelines

