

Hazard Assessment for Chemicals – Industry perspective

ECHA Workshop on NAMs



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Our needs

Improving acceptance and confidence in New Approach Methodologies



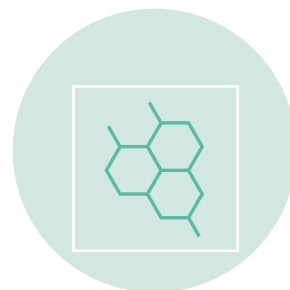
Agreement on a framework for the current application of NAMs



Internationally harmonised application of NAM methodologies and Mutual acceptance of data



Long-term vision for a new hazard and safety paradigm, and a roadmap towards it



Better uses & exposure information governing registered substances



Time to improve acceptance and confidence

Action 1: Build confidence by agreement on a **framework** for the current application of NAMs ensuring equal or higher protection levels

Why?

Ability to use the 'Best Available Science' for assessing product safety

Building experience in using the NAMs, and avoid triggering more animal testing

Enabling activities:

- Allow the use of NAMs in the current regulatory schemes for Weight of Evidence and read-across approaches, as well as new hazard classes and lower tonnage bands.
- Establish a science discussion platform to share and discuss learnings, interpretations, experiences
- Evolve the development of NAMs for screening purposes to designing NAMs fit for classification and substance safety decisions.
- Define domain of validity and acceptance of outcome
- Develop a different fit for purpose validation paradigm to speed up fit for purpose NAM frameworks for integrated hypothesis driven testing approaches



Time to improve acceptance and confidence

Action 2: Develop the long-term vision of the new hazard and safety paradigm, and agree on a **roadmap** towards it



Why:



All stakeholders (regulators, industry, academia, NGOs) should agree on what is achievable within the next two decades, identify (regulatory) needs and milestones and start embarking on the transition path

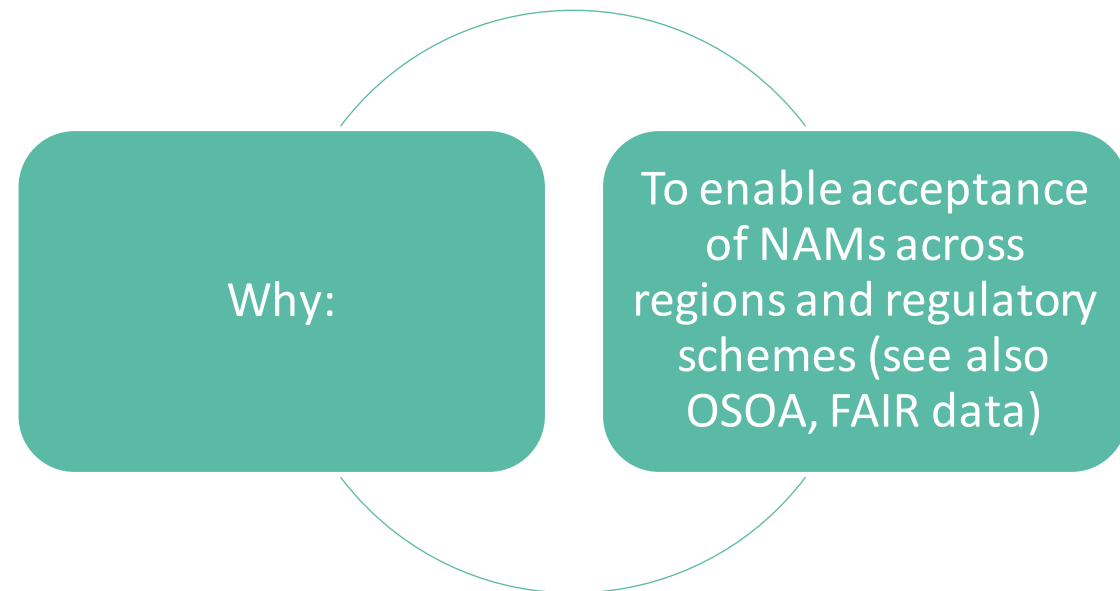
Enabling activities:

- Mapping of the required changes to the regulatory frameworks on medium/long term (e.g. GHS modernisation) to reflect progress on NAMs
- Development of a standardized framework to apply quantitative *in vivo* to *in vitro* extrapolation for deriving human reference values from a combination/selection of bioactivity data
- Define capacity building/training needs, support to SMEs, laboratory availabilities and potentials for innovation



Time to improve acceptance and confidence

Action 3: Ensure the **internationally harmonised** application of NAM methodologies and Mutual acceptance of data (MAD)



Enabling activities:

- Develop a robust system of data reporting and data sharing for NAMs
- Define workable and straight forward Weight-of-evidence approaches for data interpretation
- Multi-stakeholder platform



Time to improve acceptance and confidence

Action 4: Improve uses & exposure information governing registered substances

Why?



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Critical for the objective of improving the protection level as refined exposure metrics can help target testing needs

Enabling activities (based on EPAA Partner forum):

- Development of QIVIVE approaches to extrapolate from NAM data to in vivo benchmarks
- Progress the development and use of Bioavailability and Thresholds of Toxicological Concern (TTC) concepts for exposure-based adaptations
- Improved use of aggregate exposure estimates, and human biomonitoring data



Thank you.

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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 1.2 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

