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Implementing NAMs

Challenges and opportunities in the Regulatory context

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Regulatory acceptance & data availability

Regulatory agencies require assurance that NAMs can produce reliable and accurate results that are equivalent to traditional animal testing methods.

Challenge

The regulatory acceptance of NAMs varies across different regions, with some agencies incorporating them into their guidelines and others still evaluating their reliability and relevance.

Developing new NAMs without the input of Regulators might need to the tools not being accepted or fit for purpose.

Proposal

Multistakeholder platform to define scientific and regulatory needs to move forward, collaborate in the development phase, obtain feedback, and provide faster access to data and scientific evidence can help build confidence in NAMs and accelerate regulatory acceptance.

Develop a framework to incorporate NAMs into chemical legislation¹

Cooperation between regions, the US, Canada, OECD in order to build scientific confidence in NAMS.

¹Framework for chemical safety assessment incorporating new approach methodologies
<https://www.ecetoc.org/publication/a-framework-for-chemical-safety-assessment-incorporating-new-approach-methodologies-within-reach/>

The long-term investment in new approach methodologies (NAMs) is beginning to result in an emerging consensus of how to use information from in silico, in vitro and targeted in vivo sources to assess the safety of chemicals.



ECETOC Framework

Incorporates in silico, in vitro and in vivo methods designed to meet the requirements of REACH

- Both hazard and exposure can be assessed using a tiered approach.
- The outputs from each tier are classification categories, safe doses, and risk assessments, and progress through the tiers depends on the output from previous tiers.
- Results show a more conservative than parallel assessments based on conventional studies
- Allows a transparent and phased introduction of NAMs in chemical safety assessment
- Enables science-based safety decisions which provide the same level of public health protection using fewer animals, taking less time and using less expert resource
- It would also allow new methods to be incorporated as they develop through continuous selective evolution rather than periodic revolution.

Validation & Standardisation

There is a growing need to expedite the validation process to keep pace with the demand for new approach methodologies

Challenge

- Rigorous validation studies are required to assess sensitivity, specificity, and reproducibility.
- Standardisation of NAMs is required to ensure consistency in quality of data.
- Both processes are complex and slow.

Proposal

- Develop international collaborations to establish standardization protocols and validation strategies.
- Identify the most promising NAMs and prioritize their development and validation.
- Create a repository of available test and applicability scope.

Cost and Resource Constraints

Capacity building and accessibility will be key to ensure a smooth staged transition to new approach methodologies

Challenge

- Implementing NAMs can be costly and require significant resources, which may not be readily available or affordable for all actors involved
- Contract Research organisations need time and resources to modify their installations and implement NAMs. Capacity might be limited.

Proposal

- Staged implementation, starting with readily available methodologies, incorporate transitional periods and review progress.
- Developing cost-effective NAMs and increasing the availability of infrastructure and resources for NAMs can make them more accessible.

Conclusions

- NAMs offer numerous opportunities for reducing animal testing and improving the efficiency of regulatory testing.
- Several challenges must be overcome, including validation and standardization, regulatory acceptance, and cost and resource constraints.
- Developing international collaborations, engaging with regulators, academia, industry and NGOs, and optimizing NAMs workflows and data management systems can help overcome these challenges and foster the development and adoption of NAMs.
- The continuous improvement of the predictive power and specificity of NAMs, as well as the enhancement of their efficiency and speed, can further advance their potential and increase their reliability and relevance for regulatory purposes.

Thank you.