General

New Approach Methodologies (NAMs)

What are they?

Advances in biology, computer science and other related fields are paving the way for major improvements in how we evaluate environmental and public health risks posed by chemicals.

New Approach Methodologies (NAMs) include but are not limited to, high throughput screening and other in vitro assays, omics and in silico computer modelling strategies (e.g. Artificial Intelligence (AI) and machine learning) for the evaluation of hazard and exposure in risk assessment.

NAMs include the best available science and are consistent with the reduction, refinement, and replacement (3Rs) of animal testing approaches.

What is being done?

To keep pace with these scientific and technological advances, we aim to use the best available cutting-edge scientific methodologies to incorporate additional tools into our regulatory risk assessment process to evaluate safety in food, consumer products and the environment more efficiently and without compromising quality.

Why?

This will enable us to provide improved risk assessments of chemicals and will help us to predict risk more rapidly, accurately, and efficiently leading to an increase consumer safety.

How?

The Food Standards Agency (FSA) and the Committee on Toxicity (COT) are developing a UK roadmap towards scientific acceptance and integration of these NAMs into safety and risk assessments for regulatory decision making.

What have we done so far?

- Scoping paper on NAMs [Environmental, health and safety alternative testing strategies:](#)

[Development of methods for potency estimation](#).

- Scoping paper on [Benchmark dose modelling in a UK chemical risk assessment framework](#).
- Organized three related workshops: [Exploring Dose Response](#); [Physiologically Based Pharmacokinetic (PBPK) Regulatory Workshop](#); and [Paving the way for the UK Roadmap: Development Validation and Regulatory Acceptance of New Approach Methodologies](#). These had worldwide participation with attendees from industry, academia and regulatory agencies covering a wide range of topics, which included but were not limited to modelling and simulation, artificial intelligence tools, dose response, legal, regulatory frameworks and sociotechnological factors.
- [A UK NAMs roadmap (Draft 3 Version)](#).
- Recruited a computational toxicology fellow and a PhD student to work on case studies and enhance partnerships.
- Participation at international working groups including Accelerating the Pace of Chemical Risk Assessment (APCRA) and Partnership for the Assessment of Risks from Chemicals (PARC).
- The FSA established a Cross Whitehall (X WH) Strategic Steering Group on NAMs called New Approaches to Chemical Risk Assessment in the Regulatory Space (NACRARS). The FSA lead with co-chairs and representatives from other government departments. The role of the group is to encourage discussion and partnerships that will be instrumental in creating confidence and reliance in the use of New Approach Methodologies in chemical risk assessment more widely. Furthermore, it will provide strategic steer towards integration and acceptance of NAMs across the wider space.