NAMs for Improved Chemical & Product Safety Assessment

AN EDUCATION & TRAINING OPPORTUNITY
HSI represents the largest force for animal protection globally, active on the ground in >60 countries across Europe, the Americas, Asia & Africa.

Our science team brings together experts in human & environmental toxicology, risk assessment, biomedicine, law and public policy, etc.

Working with regulatory authorities, industry, policy-makers, academia and public interest stakeholders.

Accredited stakeholder of ECHA, EFSA, CARACAL, EURL-ECVAM, OECD Test Guidelines & AOP development programmes & other governmental advisory bodies on chemical safety (e.g. US EPA).
New Approach Methods (NAMs)

- Any technology, methodology, approach, or combination thereof that can be used to provide information on chemical hazard and risk assessment that avoids the use of intact animals.*

- In a broad context, NAMs include in silico approaches, in chemico and in vitro assays, as well as the inclusion of information from the exposure of chemicals in the context of hazard assessment. They also include a variety of new testing tools, such as “high-throughput screening” and “high-content methods” e.g. genomics, proteomics, metabolomics; as well as some “conventional” methods that aim to improve understanding of toxic effects, either through improving toxicokinetic or toxicodynamic knowledge for substances.#

*US EPA – Strategic plan to promote the development and implementation of alternative test methods within the TSCA program. 2018
Next-Generation Risk Assessment (NGRA)

How the risk assessment should be conducted

1. Following an appropriate appraisal of existing information
2. Using a tiered, iterative approach
3. Using robust and relevant methods and approaches

Goal of risk assessment

- Human relevant
- Exposure-led
- Hypothesis driven
- Designed to prevent harm

How the risk assessment should be documented

- Identifying and characterizing sources of uncertainty
- Transparent and explicit about logic of overall approach

SEURAT* Decision Framework

* SAFETY EVALUATION ULTIMELY REPLACING ANIMAL TESTING (EU FP7 RESEARCH FLAGSHIP)

(Gavin Maxwell, Paul Carmichael, Unilever. 2019)
The AFSA Collaboration works to accelerate global adoption of a modern, species-relevant approach to safety assessment that will better protect people and our planet, and hasten the replacement of animal testing.

5 AFSA workstreams

- Pathway-Based Toxicology
- Non-Animal Cosmetic Safety Assessment & Legislative Reform
- Chemical Read-Across
- Vaccine Global Regulatory Harmonization
- Alternatives Database (refactored AltTox.org)
Non-animal cosmetic safety assessment

Supporting innovation without new animal testing

- Risk-based safety decisions through integration of scientific evidence from multiple sources
- Exposure-led, product & use-specific, iterative safety decision frameworks
- Sharing of relevant case studies from multiple stakeholders

Developing & disseminating a global training program in next-generation risk assessment (NGRA)

- Support regional capacity-building to achieve long-term acceptance & implementation of legislative measures
- Address the needs of regulatory & regulated communities, CROs & other stakeholders
SCOPE

→ Exposure, hazard & risk decision-making approaches without the use of animals
→ Regulatory & non-regulatory decisions
→ Collaboration between industry, consultants, CROs, regulators
→ Development of frameworks & case studies

Target audiences:
Regulators and industry assessors, including SMEs, safety and regulatory compliance consultants, academic researchers and students
Training modules in development

1. **Problem formulation** (hypothesis generation)
2. **Consumer exposure** (use habits, exposure routes, etc.)
3. **Predictive chemistry** (read-across, Q/SAR, etc.)
4. **Exposure-based waiving** (TTC)
5. **Internal exposure** (PBPK, IVIVE)
6. **In vitro assay synthesis** (IATA, defined approaches)
7. **Integration into risk assessment** (WoE, MoS determination, etc.)
8. **History of safe use**
Dissemination channels

→ Lectures & small group trainings
→ Webinars
→ Videos
→ 1-pagers
→ Continuing education sessions
→ Symposia
→ AFSA website (coming soon)
Companies whose aims are aligned with those of AFSA are invited to join the collaboration.

Authorities are invited to provide input in terms of training content (priority modules, anything we’ve overlooked?) & discuss channels for dissemination.

Companies are invited to contribute existing training material for specific AFSA modules, or assist in the creation of new material.

Partner companies are invited to discuss legislative language with HSI & affiliates with a view to global harmonisation.
Thank you!

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