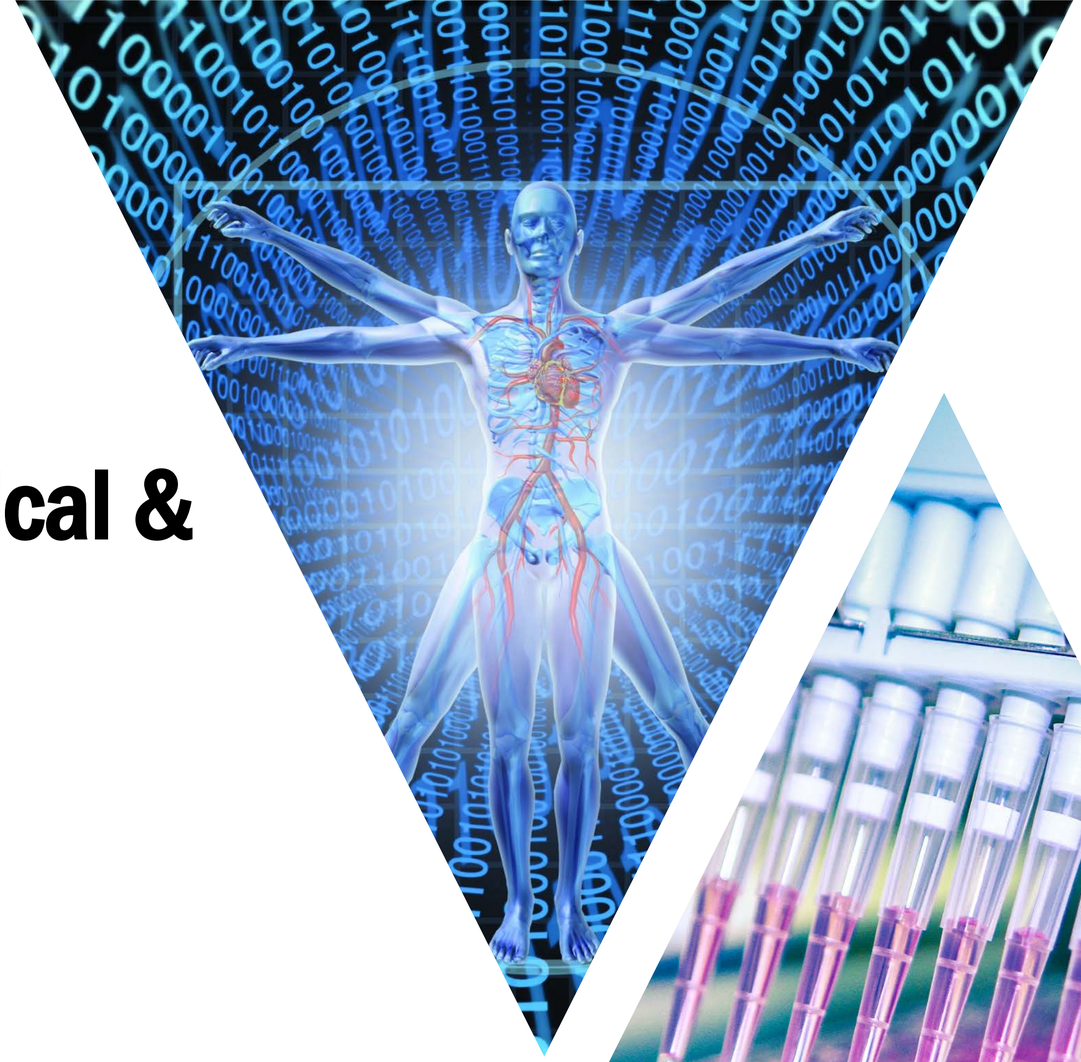
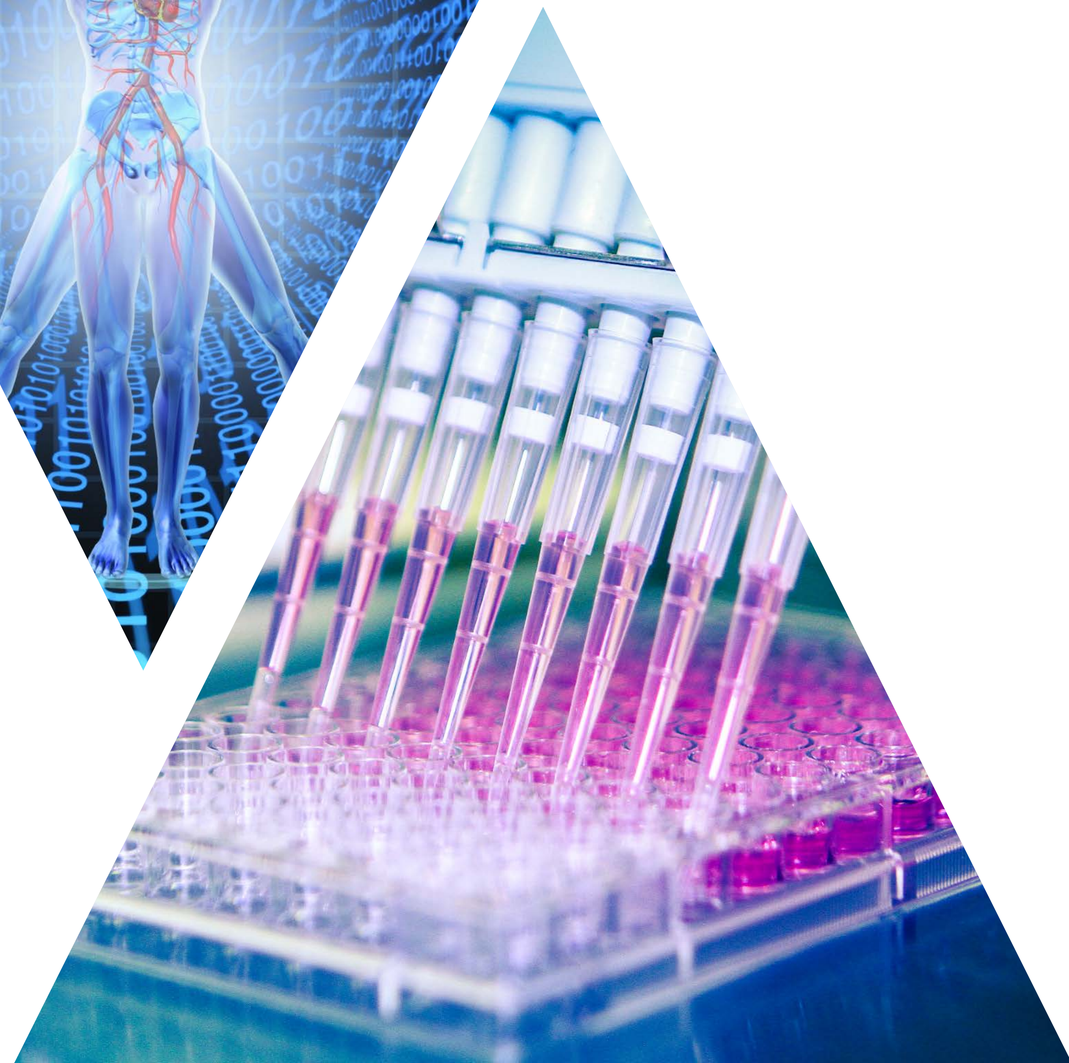
NAMs for Improved Chemical & Product Safety Assessment

AN EDUCATION & TRAINING OPPORTUNITY





HUMANE SOCIETY INTERNATIONAL

AFSA
ANIMAL-FREE SAFETY ASSESSMENT COLLABORATION

ADVANCING

HUMAN-PREDICTIVE

APPROACHES IN TOXICOLOGY

& BIOMEDICAL RESEARCH

WORLDWIDE

About HSI

- 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)

HUMANE SOCIETY INTERNATIONAL

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

ECHA – New Approach methodologies in regulatory science – Proceedings of a scientific workshop. 2016

Next-Generation Risk Assessment (NGRA)

How the risk assessment should be conducted

Following an appropriate appraisal of existing information

Using as tiered, iterative approach

Using robust and relevant methods and approaches

Goal of risk assessment

Human relevant

Exposure-led

Hypothesis driven

Designed to prevent harm

Identifying and characterizing sources of uncertainty

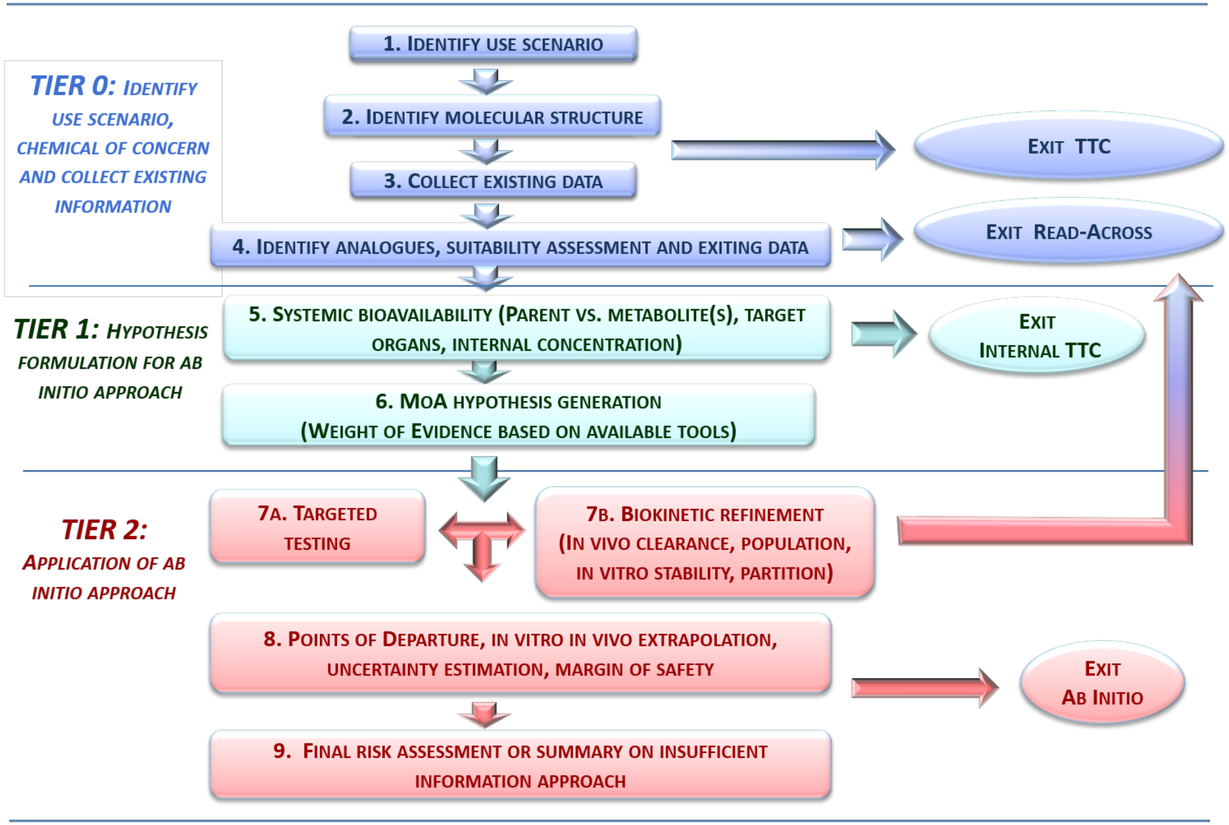
Transparent and explicit about logic of overall approach

How the risk assessment should be documented

Dent et al. 2018. Principles underpinning the use of new methodologies in the risk assessment of cosmetic ingredients. Computational Toxicology 7:20-26.

SEURAT* Decision Framework

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



- Read across
- Exposure-based waiving
- In silico tools
- Metabolism and metabolite identification
- Physiologically-based kinetic modelling
- In chemico assays
- 'Omics
- Reporter gene assays
- In vitro pharmacological profiling
- 3D culture systems
- Organ-on-chip
- Pathways modelling
- Human studies

(Gavin Maxwell, Paul Carmichael, Unilever. 2019)

AFSA

ANIMAL-FREE SAFETY ASSESSMENT COLLABORATION

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 Databas
(refactored AltTox.or

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

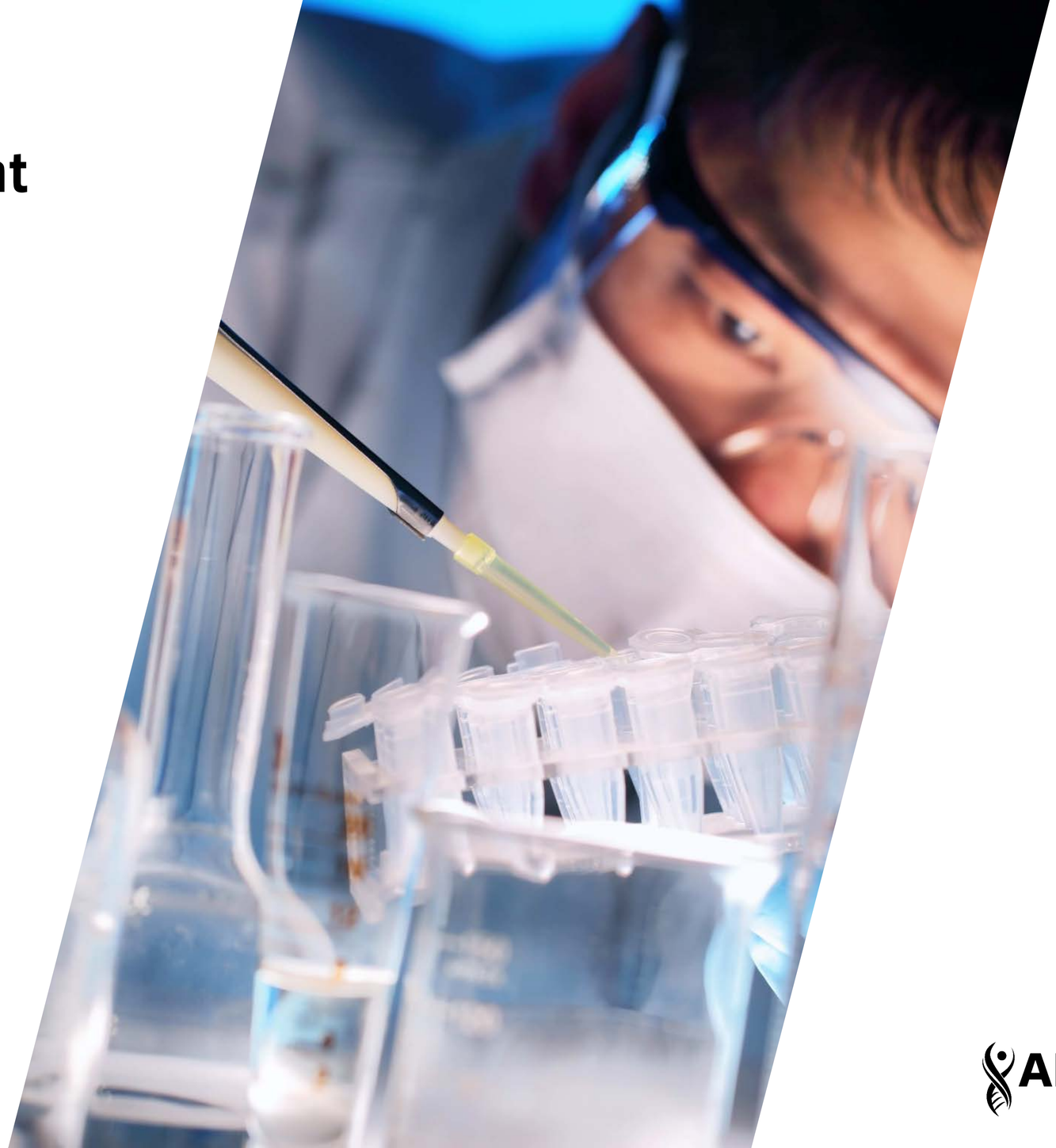
→ Development of frameworks & case studies

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

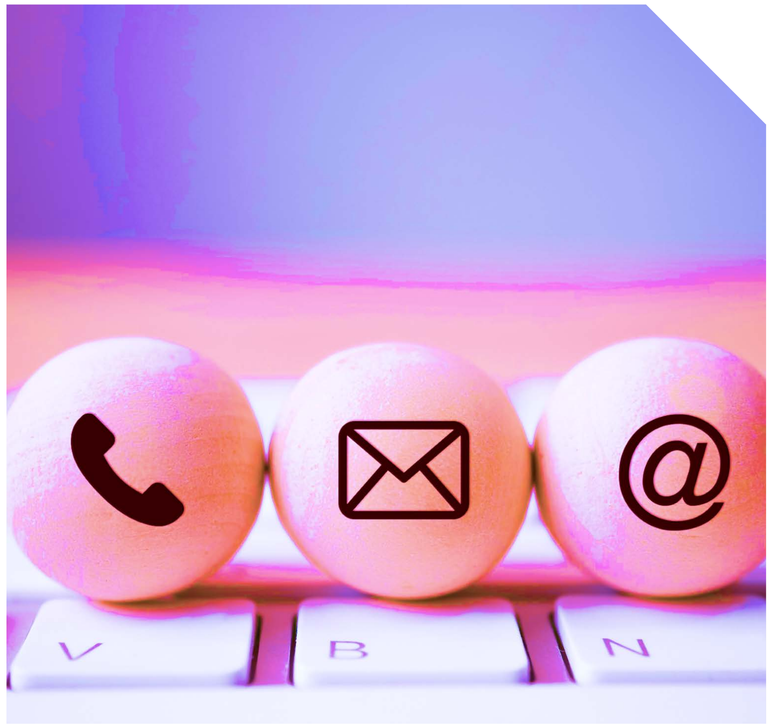
- Lectures & small group trainings
- Webinars
- Videos
- 1-pagers
- Continuing education sessions
- Symposia
- AFSA website (coming soon)

- **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!

Lidia Ceriani, MSc
Regulatory Science Advisor
lceriani@hsi.org
hsi.org

HUMANE SOCIETY INTERNATIONAL