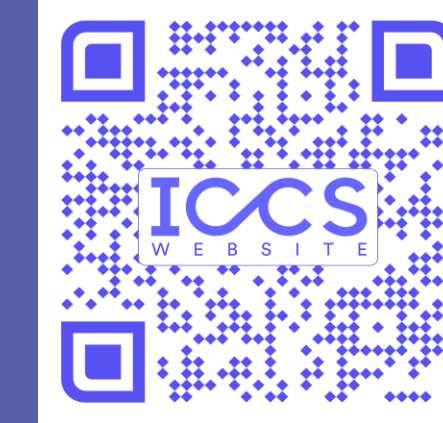




Chronic Fish Toxicity Case Studies toward a Best Practice Guidance Document

Adriana Wigh¹, Noémie De Croze², Takahiro Suzuki³, Stephanie Kennedy⁴, Markus Hecker⁵, Ryan Heisler⁶, Amelie Ott⁶

¹Henkel, ²L'Oréal, ³Kao, ⁴ToxStrategies, ⁵University of Saskatchewan, ⁶ICCS

Background

- Chronic fish toxicity data are essential for aquatic safety assessments and required under regulatory frameworks such as **EU REACH**.
- Traditional *in vivo* studies rely heavily on animal testing, are resource- and time-intensive, and provide limited biological coverage.
- Alignment with the **EU Commission's Roadmap to Phase Out Animal Testing** and **ECHA's KARC 2025 priorities** increases the need for New Approach Methodologies (NAMs).
- There is growing momentum to incorporate **NAMs** into **Next Generation Risk Assessment (NGRA)** for chronic aquatic toxicity.

Project Overview

- ICCS is leading a collaborative project to evaluate the applicability of NAMs for chronic fish toxicity, focusing on cosmetic ingredients.
- Multiple case studies will be used to explore how NAM-derived evidence can meet standard information requirements under regulatory frameworks (e.g., CLP, REACH)
- Outputs will feed into an ICCS best practice guidance to support regulatory and industry safety assessors.

Draft Best Practice Guidance Framework for Use of NAMs to Inform Chronic Fish Toxicity Assessments

Required Considerations: ☐ Optional Considerations: ☐

1. Problem Formulation and Scoping

What is the decision context? · What resources are available for the assessment?
What is the required timing? · What is the definition for new approach method? · What species coverage is the aim of the assessment?

2. Define Substance, Collect Existing Exposure Data

Substance Characteristics

Read Across

Estimate External Exposure

Bioaccumulation (BCF/BAF/Kow)

Persistence (Biodegradation)

Mobility

Environmental Occurrence, Emissions

Is external exposure relevant to trigger need for chronic fish toxicity evaluation?

Exit to Step 5

Yes, or Unknown

Estimate Internal Exposure

Absorption

Distribution

Metabolism

Elimination

Is internal exposure relevant to trigger need for chronic fish toxicity evaluation?

Exit to Step 5

Yes, or Unknown

3. Gather Existing Hazard Data

In silico

In vitro

In vivo

Mechanistic

Read Across

4. Map Hazard Data to Chronic Fish Toxicity Outcomes, Evaluate Lines of Evidence, and Weight of Evidence

Chronic Fish Toxicity Outcomes

Growth

Development

Reproduction

Survival

Endocrine Disruption

Behavior

Other

For each LOE evaluate sufficiency, reliability, and adequacy

Integrate Available Data, Consider Potential MOA(s), and Weigh Evidence

5. Uncertainty Assessment and Conclusion

Conclude on Hazard

Conclude on Risk

Can a conclusion be made based on overall confidence level?

Yes

No

Generate data and iterate as data gaps are filled

Tiered Approach towards a BPG

Step 1

Identify data gaps in current chronic fish toxicity assessments

Step 2

Develop NAM-based strategies and evidence to support chemical safety assessments and regulatory dossiers

Step 3

Progress toward full environmental NGRA implementation for chronic aquatic toxicity

Collaboration and Alignment

The project is aligned with case studies from other international initiatives to ensure:

- Cross-fertilization of scientific approaches
- Harmonization of data integration and assessment strategies

Joint efforts aim to contribute to future OECD Integrated Approaches to Testing and Assessment (IATAs) for chronic aquatic toxicity.

CHRONIC FISH CASE STUDIES

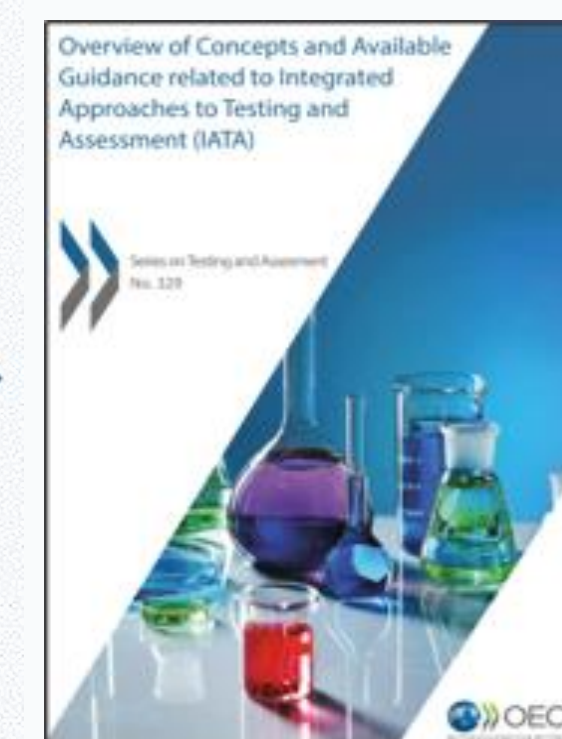
4 examples (TBD)
Data rich and data poor
Different chemistries...

Herbicide Specific MOA – (e.g., neurotoxicant)
Non-specific MOA (e.g., surfactant)

3 cosmetic ingredients (TBD) towards BestPractice Guidance (BPG)

TOOLS
DATA
APPROACHES

Coordination across management:
• M. Embry, J. Krzykwa (HESI Global)
• A. Ott, R. Heisler, A. Wigh (ICCS)
• L. Wilmut, H. Laue (ECETOC)



Expected Outcomes and Impact

- Invite discussion and collaboration
- Advance regulatory acceptance of NAMs and NGRA frameworks for environmental safety
- Ultimately strengthen environmental protection using modern, animal-free scientific approaches