Austrian Agency for Health
and Food Safety

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Opportunities and Challenges

Session 2 – Stakeholder's perception on roadmap

- Paradigm shift requires *transfer of scientific knowledge* into the regulatory community
  - Roadmap can be the green light for initiatives
- Safety needed that new scientific frameworks deliver a *level of protection* equivalent to that of currently established methods
  - Mechanistic understanding of toxicity vs. holistic biodiversity protection
- *Trainings* can promote acceptance of non-animal approaches
  - Acknowledge strengths and gaps of established and new approaches
- *Agency collaborative structures* can provide engagement to accelerate implementation
  - Identify concrete areas for implementation and find harmonised solutions

Opportunities and **Challenges**

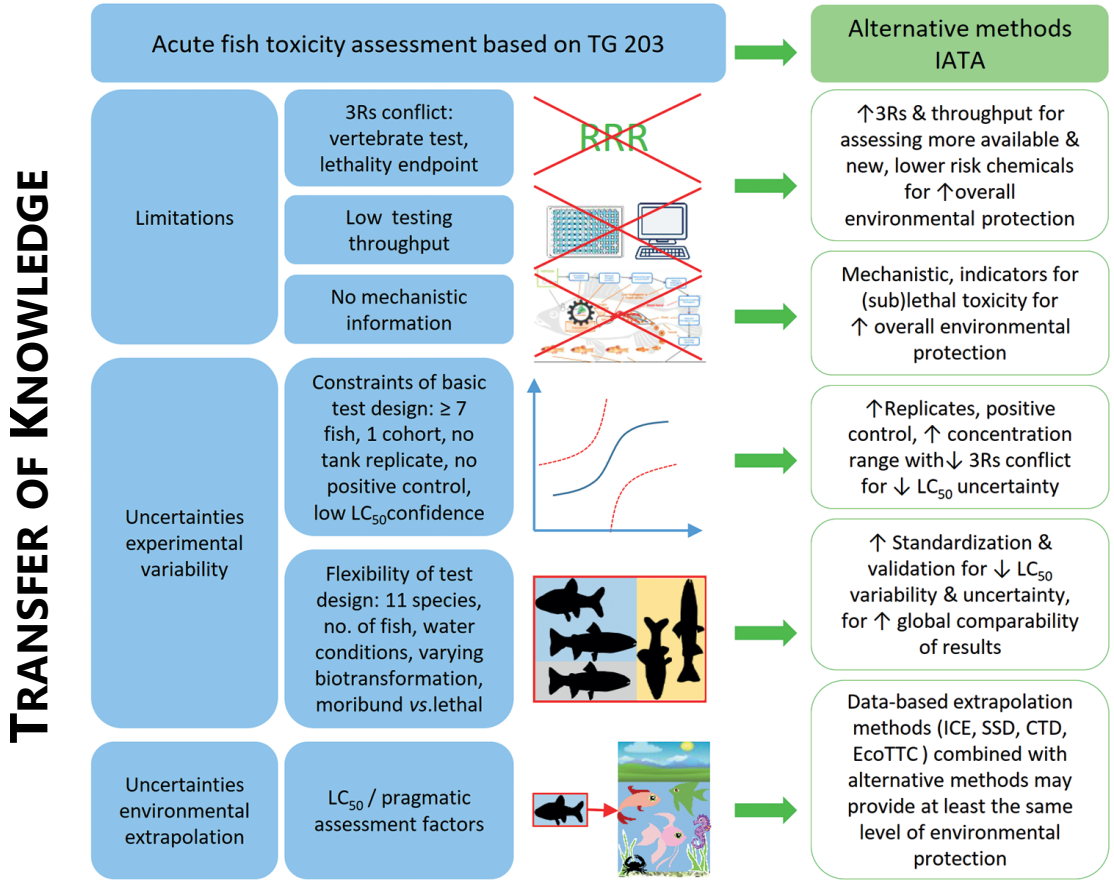
Session 2 – Stakeholder's perception on roadmap

- *Legal framework* provides the basis for all regulatory assessments
  - Regulations, directives, data requirements and guidance documents
- Implementation of new approaches require *adaptations* to increase confidence
  - Legal interpretation vs. regulatory convention
- *Lengthy revisions* of the legal framework hinders progress
  - Immediate adaptations/amendments needed to enable implementations

Opportunities and Challenges

Session 2 – Stakeholder's perception on roadmap

- **Acute toxicity to fish** - Concrete action proposal for reducing/replacing animal testing



Paparella et al., ALTEX (2021)

LEGAL BARRIERS/CHALLENGES

- Regulation 283/2013
  - Endpoint, species and test conditions defined
- EFSA Aquatic GD (2013)
  - Lack of concrete guidance

SOURCE OF LESSONS LEARNED: ED-GUIDANCE

- Trainings for regulators
- EFSA expert group
- Collection of case studies
- Annex to the GD for implementing XETA
- GD as a green light for initiatives

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Thank you for your attention!

Reference to figure on slide No. 4: Paparella, M., Scholz, S., Belanger, S., Braunbeck, T., Bicherel, P., Connors, K., Faßbender, C., Halder, M., Lillicrap, A., Liska, R., Schirmer, K., Stoddart, G., Thomas, P., & Walter-Rohde, S. (2021). Limitations and uncertainties of acute fish toxicity assessments can be reduced using alternative methods. *ALTEX - Alternatives to Animal Experimentation*, *38*(1), 20-32. https://doi.org/10.14573/altex.2006051, licensed under Creative Commons Attribution 4.0 International License.

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