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## **EPAA Partners Forum 2023**

13-14 November 2023, Brussels, Belgium



The European Partnership for Alternative Approaches to Animal Testing

## Use of Alternatives to Animal Testing for Environmental Safety Assessment

The EPAA Partners Forum (PF) on the "Use of Alternatives to Animal Testing for Environmental Safety Assessment" was organised from 13-14 November 2023. This Partners Forum was hosted by Cefic (association member of EPAA) at their premises, organised in partnership with ECETOC and ICCS, and gathered 32 participants in person and 29 online.

The objective of this year's PF was to perform a strategic, cross-sector review of the use of Alternatives to Animal Testing-based frameworks for Environmental Safety Assessment in the European Regulatory context, to capture learnings and identify opportunities for cross-sector industry - regulator dialogue, scientific gaps and research challenges.

On day 1, participants heard the perspective of the regulators and industry users from the various sectors. Day 2 included short presentations by important scientific research organisations on their environmental safety programme, and moderated discussions that aimed at identifying the remaining scientific gaps and research needs.

Five priority areas of common interest have been identified:

Fish acute toxicity

- · Alternatives to fish bioaccumulation
- · Fish chronic toxicity
- Endocrine disruption assessment, covering all modalities
- New Systems-based approach to Environmental Safety Assessment

The first two are ready for short-term actions, aiming at getting confidence in the regulatory use of the available OECD TGs on alternative methods, including the identification of applicability domains and guidance/decision-trees for integrating different lines of evidence. Case studies under the OECD IATA programme could facilitate a global regulatory uptake.

A dual approach was suggested for addressing fish chronic toxicity. In the short-term, the focus should be on waiving options, exploring lines of evidence that, alone or in combination, could provide sufficient confidence for concluding that further fish testing is not needed. The second phase should focus on the application of 3Rs in those cases that fish chronic information is needed. In addition to replacement, reduction options, such as screening or combination of bioaccumulation/TK and omics-based toxicity assessments, could be considered when fish testing is still needed.



Endocrine disruption is a very relevant but complex area, with increased regulatory interest particularly in the EU. This represents a challenge but also an opportunity for implementing mechanistic non-animal methods, as well as for integrating human and environmental safety assessments. It requires a step-by-step approach with a continuous dialogue to ensure that the technical developments would address the regulatory needs.

Additional opportunities for across-sector collaboration were identified in the area of exposure (exposure driven prioritisation, TK and internal/external exposure assessments for QIVIVE and use of monitoring data); testing and assessment of complex and difficult to test substances; QSAR and read-across; use of mechanistic information for safety assessment, or integration of human and environmental expertise and cooperation with academic organisations, among others.

It was also agreed that these challenges offer an excellent opportunity for mapping the Environmental Safety Assessment processes and improving the links with the protection goals. The long-term aspiration is a new system-based approach, linking prospective and retrospective assessments and providing connectivity between the chemical legislation and the policies covering the overall protection of biodiversity and ecosystems. Materialising this aspiration requires specific actions to be run in parallel with those described above.

In addition to facilitating the identification of cross-sector priority actions, the EPAA is also in a unique position to help with their implementation. The proposed actions will be discussed next with the PF Organising team and presented for discussion to the EPAA Steering Committee.

The main findings from the PF will be reported and published as an open access publication in a peer-reviewed journal.

## **About EPAA**

EPAA is a Public-Private Partnership across seven industry sectors and between European Commission and Industry stakeholders. Launched in 2005, it gathers 38 companies, 8 European trade federations and 5 Directorates-General of the European Commission.

Further information is available on: <a href="https://ec.europa.eu/growth/sectors/chemicals/european-partnership-alternative-approaches-animal-testing\_en">https://ec.europa.eu/growth/sectors/chemicals/european-partnership-alternative-approaches-animal-testing\_en</a>



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