

Application of a science-driven approach to solve the needs of regulatory and industry communities in the implementation of NAM-supported read-across in regulatory dossiers

27-28 October 2021, virtual

WORKSHOP DESCRIPTION AND OBJECTIVES

It is a great pleasure for the EU-ToxRisk consortium to invite you to the upcoming EU-ToxRisk workshop on “*Application of a science-driven approach to solve the needs of regulatory and industry communities in the implementation of NAM-supported read-across in regulatory dossiers*”.

Background information: The EU-ToxRisk project aims to develop and implement new approach methodologies (NAMs) as an alternative approach for the safety testing of chemicals. The objective is to assess the application of NAMs as a tool to improve read-across, as well as in the context of ab initio chemical safety assessment. The final EU-ToxRisk advisory document targets the broader toxicology community and contains practical instructions on the application of NAM-supported read-across in different regulatory contexts. As such, it will allow to improve the quality of the submission of real read-across cases by registrants and increase the acceptance success rate of non-animal approaches.

Focus & main objective:

- To facilitate the discussion among stakeholders interested in the implementation of NAMs in RAX-based regulatory dossiers;
- To identify where the EU-ToxRisk NAM-supported Read-Across approach has successfully closed gaps for NAM-based RAX and where further resources should be focused;
- To mine and identify the gaps still negatively impacting the implementation of read-across for risk assessment’ and how to use new approaches to solve these issues across different frameworks.

Target group & Event format: experts from ECHA’s members of MSC (Member State Committee), European and national regulatory bodies, and industry representatives with experience in read-across and REACH framework.

Registration: [Zoom registration link](#)

Useful bibliography:

- Escher SE, Kamp H, Bennekou SH, et al. (2019) Towards grouping concepts based on new approach methodologies in chemical hazard assessment: the read-across approach of the EU-ToxRisk project. Arch Tox doi: 10.1007/s00204-019-02591-7
- Rovida C, Escher SE, Herzler M, et al. (2021) NAM-supported read-across: From case studies to regulatory guidance in safety assessment. ALTEX doi: 10.14573/altex.2010062
- Moné MJ, Pallocca G, Escher SE, et al. (2020) Setting the stage for next-generation risk assessment with non-animal approaches: the EU-ToxRisk project experience. Arch Toxicol. doi: 10.1007/s00204-020-02866-4.

PRELIMINARY AGENDA

Day 1 – Wed. 27 Oct		
Time	Topic	Speakers/Moderators
14:00	Opening of Day 1 workshop	Bob van de Water
Plenary session: introductory talks		
14:10	EU-ToxRisk NAM-supported Read-Across Advisory document	Hennicke Kamp
14:30	Presentation of the NAM-supported RAx Case I	tbc
14:50	Presentation of the NAM-supported RAx Case II	tbc
15:10	Break	
Breakout group session: industry and regulatory agencies representatives will discuss the presented cases in working groups.		
15:30	Breakout group of the industry representatives	Mod. Dinant Kroese Rap. Hennicke Kamp
	Breakout group of the regulatory agencies representatives	Mod. Susanne Hougaard Rap. Costanza Rovida
18:00	End of day 1 meeting	

Day 2 – Thu. 28 Oct		
Time	Topic	Speakers/Moderators
14:00	Opening of Day 2 workshop	
Plenary session: reporting on breakout session from Day 1		
14:10	Reporting from industry working group	Hennicke Kamp
14:40	Reporting from regulators working group	Costanza Rovida
15:10	Break	
15:30	Panel discussion	Bob van de Water
17:00	End of the workshop	