DRAFT AGENDA

Workshop on the Commission roadmap towards phasing out animal testing for chemical safety assessments

Brussels, Breydel 1, Auditorium (hybrid)

11 - 12 December 2023

Draft agenda

Session 1 – Introduction and setting the scene			
11 December, 9:00	5 min	Welcome and housekeeping	Georg Streck (EU Commission, DG GROW)
9:05	10 min	Welcome and opening	Kristin Schreiber (EU Commission, DG GROW)
9:15	10 min	Opening keynote speech	N.N. (European Parliament)
9:25	10 min	Introductory presentation: The roadmap towards phasing out animal testing for chemical safety assessments – Commission Communication, commitments, timeline	Georg Streck/Marco Fabbri (EU Commission, DG GROW)
9:35	10 min	Introductory presentation: Workshop on the roadmap towards phasing out animal testing for chemical safety assessments – Scope, aim and concept of the workshop	Katrin Schutte (EU Commission, DG ENV)
9:45	10 min	Main outcomes from ECHA NAM workshop and Key Areas of Regulatory Challenge report	Ofelia Bercaru (ECHA)
9:55	20 min	Towards phasing out regulatory animal testing, a perspective from European Food Safety Authority and the European Chemicals Agency	Andrea Terron (EFSA) and Tomasz Sobanski (ECHA)
10:15	15 min	Implementation of 3Rs at the EMA: current activities and future perspectives	Sonja Beken (EMA)
10:30	20 min	Coffee break	

10:50	10 min	PrecisionTox/ASPIS: Socio-technical barriers to the uptake of NAMs	Laura Holden (ASPIS)
11:00	10 min	Towards chemical safety assessments using solely non-animal methods: the PARC contribution	Mirjam Luijten (PARC)
11:10	15 min	NGO (animal welfare) perspective on the roadmap	Jay Ingram (Humane Society International)
11:25	15 min	Industry perspective on the roadmap	Katia Lacasse (CEFIC)
11:40	20 min	Q&A	
12:00	1 hour	Lunch break	
Session 2: How to replace animal testing for the concern of systemic human health effects?			
13:00	10 min	Introductory presentation: How to address systemic health effects with non-animal methods? - Gaps, overlaps and research needs	Elisabet Berggren (EU Commission, JRC)
13:10	10 min	Title TBC	Christophe Rousselle (ANSES, France) TBC
13:20	10 min	How are human health systemic effects covered when animal testing is not allowed?	Qasim Chaudhry (SCCS) (online)
13:30	10 min	Title TBC	Heli Hollnagel (CEFIC LRI)
13:40	10 min	Title TBC	Julia Baines (PETA)
13:50	10 min	An initiative towards a future solution: the EPAA Designathon	Carl Westmoreland (EPAA)
14:00	55 min	Panel discussion	Moderator: N.N.
14:55	20 min	Coffee break	
Session 3: How to replace animal testing for the concern of long-term aquatic toxicity?			
15:15	15 min	Introductory presentation: Long-term aquatic toxicity as area of concern – current regulatory status - differences between legislative areas	Georg Streck (EU Commission, DG GROW)

15:30	15 min	Introductory presentation: How to address long-term aquatic toxicity with non-animal methods? – Possibilities, gaps, parameters to be addressed	Adam Lillicrap (Norwegian Institute for Water Research)
15:45	15 min	NGRA for the aquatic environment and use of monitoring data	Stephanie Bopp (EU Commission, JRC)
16:00	15 min	Presentation by a MS authority on their view how to replace fish long-term toxicity testing	Gerd Maack (Environment Agency, UBA)
16:15	15 min	Feedback from the EPAA Partner Forum: Possibilities to address the area of long-term aquatic toxicity	José Vicente Tarazona Lafarga (Instituto de Salud Carlos III)
16:30	55 min	Panel discussion	Moderator: N.N.
17:25		Closing day 1	

Session 4: Enhancing the translation of non-animal methods into regulation			
Part 1 Setting the scene			
12 December, 9:00	10 min	Introductory presentation: What is meant by standardisation / validation / acceptance of methods? Legal certainty, demonstrability of compliance and enforcement, international acceptance and mutual acceptance of data	Katrin Schutte (EU Commission, DG ENV)
9:10	15 min	Different needs of legislative areas	N.N. (EU Commission, DG ENV, DG GROW, DG SANTE)
Part 2 Validation – how can it evolve			
9:25	10 min	Validation needs to evolve: Update of OECD GD 34 - How far do the principles of validation need to be addressed for a method to be considered valid?	Joao Barroso (EU Commission, JRC) (online)
9:35	10 min	OECD survey on operational and financial aspects of validation - preliminary results	Anne Gourmelon (OECD)
Part 3 Acceptance for regulatory use			

9:45	15 min	PARC's NGRAroute activity – towards a roadmap for implementing "Next-Generation Risk Assessment" (NGRA) as the default risk assessment approach in EU chemicals legislation	Matthias Herzler (German Federal Institute for Risk Assessment, BfR)
10:00	20 min	Coffee break	
10:20	10 min	Pathways to regulatory acceptance - Looking beyond validation	Andrew Worth (EU Commission, JRC) (online)
10:30	10 min	Experiences from the US-Roadmap to regulatory acceptance of non-animal methods	Nicole Kleinstreuer (NICEATM/ICCVAM) (online)
10:40	45 min	Panel discussion	Moderator: Miriam Jacobs (UK Health Security Agency)
Session 5: Next steps and closing remarks			
11:25	50 min	Panel discussion: • Take home messages from the sessions • What are the next steps to develop the roadmap? • Which topics necessary for the development of the roadmap require follow-up events?	Moderator: Gavin Maxwell (EPAA)
12:15	10 min	Closing keynote speech	N.N. (European Parliament)
12:25	5 min	Closing remarks	N.N. (EU Commission)
12 December, 12:30		End of the first part of the workshop	
12:30	1 hour	Lunch	

Second Part

"Guiding principles for NGRAroute - a roadmap proposal for implementing Next-Generation Risk Assessment (NGRA) in EU chemicals legislation"

Workshop session organised by the Partnership for the Assessment of Risks from Chemicals (PARC), Work Package 2 ("A common science-policy agenda")

13:30	3:30 hours	Interactive hands-on workshop discussing guiding principles for an NGRA framework as well as for NGRA-ready chemicals legislation drafted by PARC Task 2.2 ("Knowledge management and uptake into policy". These principles will help structure the further work towards the NGRAroute roadmap proposal. In interactive sessions, participants on-site as well as online will be asked for their input regarding the draft principles, as well as their views regarding important elements of such a roadmap. A detailed agenda and workshop materials will follow in due time.
17:00		Closing day 2