



**HUMANE SOCIETY
INTERNATIONAL**

EUROPE

Destination animal-free



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

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Roadmap requirements

What an EU roadmap can & should deliver

“Nuts & bolts”

- Defined milestones
- Action plan
 - What can be achieved now?
 - Clear links to ultimate goal
- How to phase-out redundant tests
- Include educational & support mechanisms

Philosophy

- Challenge existing frameworks & assumptions
- Focus must shift from apical endpoints to health protection goals
- Embracing specific solutions to solve specific problems
- Cross-sector/government alignment to address regulatory intersections

Regulatory & social paradigm shift

Embracing disruption

- Acknowledge & address scale & impact of disruption
- Minimise impact to maximise gains
- Regulatory & societal shift

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Common language

Why the language we use matters

NAMs = **non-animal** methods

- If we are to ultimately phase-out animal testing, we cannot be distracted from our ambition by dilution of meaning

Health protection goals & one-health

- Enables holistic protection of human health & environment

Avoid unhelpful comparisons and defeatist language

“Cosmetics are easy, using NAMs for pesticides are much more difficult”

“One cannot replicate a whole system using NAMs”

Embrace “specific solutions to specific problems”

Applicability domains

Important to understand test boundaries

Narrow domain not necessarily a weakness of method

Validation

Can unvalidated methods be useful in certain circumstances?

Are we sacrificing useful tools for the sake of the current paradigm?

OSOA

Tailor-made solutions to offer better protection



Safe spaces

- Spaces needed for free exchange of ideas, approaches, data, etc.
 - Open dialogue between industry & regulatory agencies
- Requires sufficient level of expertise across both industry & regulatory stakeholders
 - Intra-agency committees staffed by NAMs experts

Learning from others

- Identify and integrate best practice
 - Use the best available science to inform milestones to position the EU as a world leader in regulatory safety assessment without animals
 - Concretely apply principles and practices from international partnerships (e.g. APCRA) and policy precedent (e.g. S Korea & Canada) to EU legislative frameworks
 - Risk-based prioritisation
 - Generation of case studies
 - For authorisation/restriction
 - For providing legal certainty
- Transparency
 - Number of animals commissioned for studies
 - Demonstration of a truly “last resort”

Workshop deliverables & next steps

- Milestones for:
 - Removal of requirement for redundant/duplicative tests
 - Fully phasing-out animal testing in chemical safety assessments
 - Addressing regulatory intersectional inconsistencies
- Establish mechanism to monitor progress
- Commitment to transforming validation process/acceptance
- Open, transparent, and inclusive roadmap building
- Alignment on common language
 - Non-animal methods
 - Health protection goals



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Thank you

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