

REMA Conference

Challenges of the European Commission's roadmap

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20 February 2025



Formerly called the Humane Society
of the United States and
Humane Society International

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Working together to create a better world for animals, tackling the root causes of animal cruelty and suffering to drive permanent change and create a better world for all animals around the globe



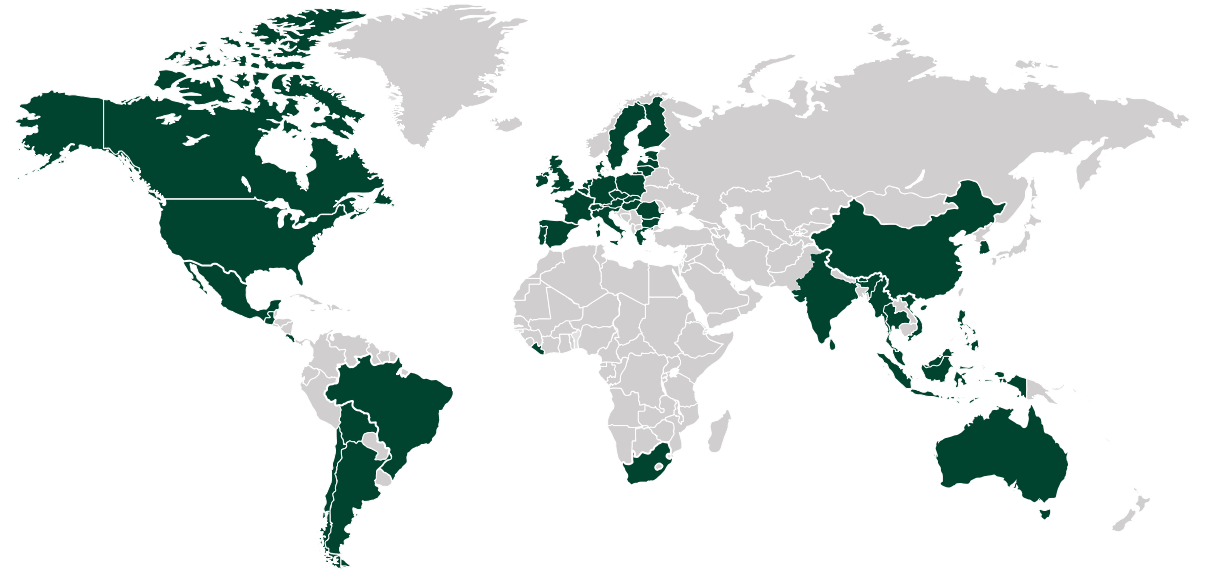
Humane
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**New name,
Same mission**

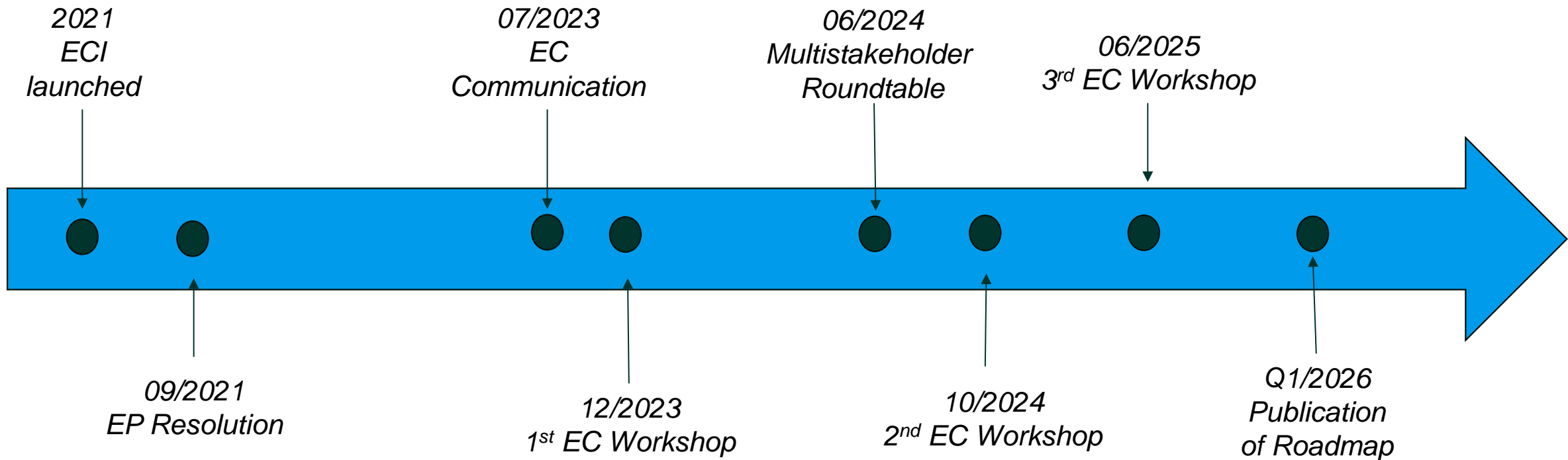
Humane World for Animals

Multi-disciplinary team of research and toxicology, corporate, regulatory and public affairs, science communication and advocacy professionals...

... improving the lives of animals in over 50 countries.



EC Roadmap path



Regulatory Transformation



- Actively contributing to the phase-out of animal testing in chemical assessments in the EU
- Investigating the scientific and regulatory readiness of non-animal methods (NAMs) of hazard and safety assessment and their potential to replace in vivo animal tests, whilst providing the same or superior protection to human health and the environment.

Animal-Free Safety Assessment

- AFSA Master Class: (re-)education to build capacity and confidence in NAMs and NGRA



The Stakeholders' perspective & expectations

The Roadmap represents a significant moment in a regulatory and societal paradigm shift

Transitional steps needed to facilitate a new EU regulatory system with five key identified areas:

- **Scientific development**
- **Validation**
- **Change management**
- **Policy development**
- **Regulatory Implementation**

Expected Deliverables to achieve ultimate goal

- Concrete action plan to accelerate the phase out of animal testing
- Build a structure to create confidence for NAMs, including funding and validation
- Establish indicators to monitor the progress
- Define organisational structure to activate policy changes

EU goals and expectations



Chemicals Strategy for Sustainability objectives

“safety testing and chemical risk assessment need to innovate in order to reduce dependency on animal testing but also to improve the quality, efficiency and speed of chemical hazard and risk assessments”

REGULATION (EC) No 1907/2006 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Article 25 (1)

“In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests”

Article 13 (2)

“These methods shall be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved. The Commission, following consultation with relevant stakeholders, shall, as soon as possible, make a proposal, if appropriate, to amend the Commission Regulation on test methods adopted in accordance with the procedure referred to in Article 133”

Challenges and Concerns

- ☐ NAMs do not fit in the current regulatory needs, no incentive to change the latter
- ☐ 15 Legislative pieces identified
 - REACH, currently under Revision, will not benefit from the work of the Roadmap
- ☐ Stakeholders are occasionally involved in the Change Management discussion but not part of the working group team
- ☐ Collaboration of the Commission and the Member States could be strengthened

Challenges and Concerns

- ☐ Risk of mismatch between ECI expectations and current EC ambition
- ☐ Not clear implementation plan, needed for impact and future-proofing effort
- ☐ Not enough incentive for industry and regulators to change the way of testing for safety assessment
- ☐ Far from fulfilling the request of EU citizens and EU Green Deal

Hope, Opportunities and Solutions

The Roadmap opens the path to;

- ✓ Advanced chemical safety assessments
- ✓ Regulatory advancement
- ✓ Building trust in NAMs
- ✓ Saving several animals



Proposed actions and solutions

- Establish more proactive involvement of MSs
- Include education and raising awareness for NAMs
- Provide clear messaging to regulatory and industry to demonstrate the benefit from the transition to NAM-based Risk Assessment
- Evaluate regulatory needs which are fit to advanced technology
- Propose funding and further research to prioritize methods for further development and validation



Thank you