

Question for written answer E-002468/2025
to the Commission
Rule 144
Jutta Paulus (Verts/ALE)

Subject: Use of non-protected organisms and NAMs in REACH: implications for animal testing policy

In the context of chemical safety assessment, new approach methodologies (NAMs) contribute to the improved understanding of mechanism-based toxicity. To enhance confidence in the extrapolation of mechanistic effects observed in NAMs to adverse effects at the individual or population level for regulatory purposes, research often uses organisms and life stages that are not considered as protected animals under Directive 2010/63/EU, such as whole-organism invertebrates (e.g. *Daphnia*, nematodes, *Drosophila*) and early life stages of aquatic vertebrates (e.g. zebrafish and frog embryos). These are crucial for the medium-term replacement of animal tests.

1. In the light of the revision of the REACH Regulation ((EC) No 1907/2006) and the Commission's roadmap to phase out animal testing for chemical safety assessments, can the Commission say to what extent it will implement NAMs for chemical safety assessment in order to simplify REACH and fulfil its stated goal of employing animal testing only as a last resort?
2. Does the Commission agree that the use of organisms and life stages that are not considered as protected animals under Directive 2010/63/EU is crucial for the medium-term replacement of animal testing?
3. Does it intend to change the scope of protected animals under Directive 2010/63/EU to also include non-vertebrate animals beyond cephalopods, and early life stages of all vertebrates other than mammals?

Submitted: 18.6.2025