

Question for written answer E-001392/2025
to the Commission
Rule 144
Tilly Metz (Verts/ALE)

Subject: Continued use of batch potency tests on animals despite accepted non-animal alternatives

In 2022, 452 699 batch potency tests were conducted in the EU, accounting for 5 % of all animal experiments and 41 % of those carried out for regulatory purposes. Of these, 152 642 tests were performed on mice to comply with human medicines legislation, with a significant proportion likely to be botulinum toxin batch tests, despite the availability of accepted non-animal alternatives.

In view of the above:

1. Can the Commission explain why such a large number of batch potency tests continue to be conducted in the EU, and can the Commission provide a list of the products for which these tests are required and explain what is being done to reduce the use of animals in routine batch testing?
2. What proportion of these tests were conducted specifically for botulinum toxin products?
3. What measures is the Commission taking to ensure that Member States comply with Directive 2010/63/EU by eliminating the use of animals where validated alternatives exist?

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