(English version)

Question for written answer E-001391/25
to the Commission
Tilly Metz (Verts/ALE)
(4 April 2025)

Subject: Compliance with Directive 2010/63/EU for antibody production methods

In 2022, 477 632 uses of animals were recorded for routine production purposes, including for antibody production, despite the availability of a validated non-animal method recommended by the European Centre for the Validation of Alternative Methods (ECVAM). Of particular concern is the fact that 49 309 uses involved the ascites method, which ECVAM has strongly discouraged since 1998. France accounted for 97% of these uses and has reported a 34% increase since 2021.

Given that directive 2010/63/EU requires the use of non-animal methods where they are available:

1. What steps is the Commission taking to ensure that the Member States comply with this requirement?

2. Will the Commission initiate infringement proceedings against countries such as France, where there is a persistent failure to transition to non-animal methods?

Submitted: 4.4.2025

Question for written answer E-001392/25
to the Commission
Tilly Metz (Verts/ALE)
(4 April 2025)

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?

Submitted: 4.4.2025

Joint answer given by Ms Roswall on behalf of the European Commission
(30 July 2025)

Directive 2010/63/EU ([1]) provides a harmonised legal framework for the protection of animals used for scientific purposes. In accordance with its Article 2, the directive applies where animals are used or intended to be used in procedures or bred specifically so that their organs or tissues may be used for scientific purposes. Article 1(5) enumerates practices not covered by the directive.

In some cases, alternative (non-animal) methods may be unsuitable for specific applications. For biological products, a product-specific validation is required before their use can be accepted, which may partly account for a continued use of animals.

Under the directive a Member State competent authority may authorise a project only when no alternatives are available to achieve its results ([2]).

([1]) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276, 20.10.2010, p. 33-79.
([2]) Article 13.

Each project has a named person ([3]) to ensure uptake of new alternatives should these become recognised by EU legislation after the project was authorised. The directive has been transposed into national legislation of the Member States primarily responsible for its enforcement.

Commission Implementing Decision 2020/569/EU ([4]) specifies the format and content of statistical information on the use of animals that Member States have to submit. Data on uses for botulinum toxin products are not required to be detailed.

The Commission supports the development of alternatives to animal testing through the Horizon Europe Framework Programme for research and innovation (2021-2027) ([5]).

Progress in developing, validating and adopting alternatives is ongoing. The 2022 statistical report on animal use for scientific purposes ([6]) highlights significant decrease in regulatory uses, including a 40% reduction in batch potency testing over the past five years.

([3]) Article 40(2)(b).

([4]) Commission Implementing Decision (EU) 2020/569 of 16 April 2020 establishing a common format and information content for the submission of the information to be reported by Member States pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes and repealing Commission Implementing Decision 2012/707/EU (notified under document C(2020) 2179), OJ L 129, 24.4.2020, p. 16-50.

([5]) https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en.

([6]) https://circabc.europa.eu/ui/group/8ee3c69a-bccb-4f22-89ca-277e35de7c63/library/051e5787-7746-46cf-8a0d-310f84fd1900/details?download=true.