

EN

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Answer given by Ms Roswall
on behalf of the European Commission
(30.7.2025)

1. In 2022, two Member States (the Netherlands and France) reported dog testing in procedures in the framework of industrial chemicals legislation. The Netherlands responded upon clarification request that the data was incorrect and that instead it should have been reported under plant protection product legislation. Commission Regulation (EU) No 283/2013 on data requirements for active substances used in plant protection products¹ requires a 90-day toxicity study that includes non-rodent species which is usually a dog. France confirmed the data were correctly reported in relation to chemicals: it had been a dose range finding study, preliminary to a 90-day toxicity study as per Organisation for Economic Cooperation and Development Test No 409², which may be required by authorities outside the EU³ to obtain marketing authorisation.

Member State-specific additional information may in some cases be found in Section V of the EU summary report on the statistics on the use of animals in the EU⁴.

2. Directive 2010/63/EU regulates the use of animals for scientific purposes in the EU⁵ and requires the use of alternative non-animal methods for testing to satisfy legislation when these are recognised by the legislation of the Union. However, it does not prohibit the use of animals when testing for non-EU purposes when no equivalent data requirements exist in the EU.

3. The use of dogs may be necessary in some cases to ascertain, before proceeding to clinical trials involving humans, the safety of medicinal products. The use of alternative test methods is however actively encouraged by the European Medicines Agency⁶.

¹ Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, OJ L 93, 3.4.2013, p. 1–84.

² https://www.oecd.org/en/publications/1998/09/test-no-409-repeated-dose-90-day-oral-toxicity-study-in-non-rodents_g1gh2933.html.

³ e.g., US Environmental Protection Agency and Brazil.

⁴ https://environment.ec.europa.eu/topics/chemicals/animals-science_en#implementation.

⁵ 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.

⁶ <https://www.ema.europa.eu/en/homepage>.