

EN
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Answer given by Ms Roswall
on behalf of the European Commission
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In 2022, 33 029 skin sensitisation tests were conducted on animals constituting a reduction of 12.2 % compared to 2018 and 12.5% compared to 2021.

Based on ALURES¹ data, most guinea pig sensitisation assays occur in the medical devices (MD) sector. Testing requirements for these are governed by the International Organization for Standardization standards, and the relevant standard 10993-10:2021² still lists guinea pig assays next to the local lymph node assay (LLNA) and non-animal methods.

Member States are expected to urge manufacturers to validate the LLNA or other alternatives for specific needs such as MD. Manufacturers should prioritise application of Defined Approaches for skin sensitisation. These consist of a combination of non-animal methods and a defined algorithm to interpret results and are described in the Organisation for Economic Co-operation and Development Guideline 497³. These approaches have superior performance compared to the LLNA in predicting human responses.

Member States require regular reporting on progress made with alternatives, or to limit the project authorisation period for animal tests. If validation of the alternative fails, use of animals should continue to be allowed. The Commission collaborates closely with Member States to remind them of the obligations⁴ under Directive 2010/63⁵ to ask product-specific qualification of recognised alternatives.

The European Partnership for Alternative Approaches to Animal Testing⁶ has invited the MD industry to join initiatives such as the skin sensitisation project to share knowledge and accelerate qualification of non-animal methods also by MD manufacturers.

The Commission will publish a Roadmap on phasing out animal testing which covers MD legislation.

¹ https://environment.ec.europa.eu/topics/chemicals/animals-science/statistics-and-non-technical-project-summaries_en.

² Biological evaluation of medical devices – Part 10: Tests for skin sensitisation.

³ https://www.oecd.org/en/publications/guideline-no-497-defined-approaches-on-skin-sensitisation_b92879a4-en.html.

⁴ E.g., during bi-annual meetings.

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://single-market-economy.ec.europa.eu/sectors/chemicals/european-partnership-alternative-approaches-animal-testing_en.