

EN

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Answer given by Mr Sinkevičius  
on behalf of the European Commission  
(16.7.2020)

Of the 20,686 uses of rabbits in 2017 to satisfy non-EU regulatory requirements, 9,703 were for pyrogenicity testing, 108 for testing eye irritation/corrosion and 483 for testing skin irritation/corrosion.

Directive 2010/63/EU<sup>1</sup> does not distinguish between tests to satisfy EU and non-EU regulatory requirements. Once a method/a testing strategy providing the necessary information, not entailing the use of a live animal, is recognised under the legislation of the Union, an animal procedure can no longer be used. The Directive has been transposed into national legislation and Member States are responsible for its enforcement.

In some cases, like for skin/eye corrosion/irritation, alternative methods have limitations as to the effects they can predict making them unsuitable for some substances or applications. Some results for eye may be inconclusive requiring a confirmatory study *in vivo* and some regulatory areas (e.g. medical devices) still require animal tests. For biological products, a successful product specific validation of the alternative method is required before it can be used for regulatory purposes. This is the case for the *in vitro* pyrogenicity tests.

The described limitations may partly explain continued use of animals in these areas.

The Commission repeatedly reminds Member States of their legal obligations. Additional guidance has been issued and collaboration between regulatory authorities is encouraged. Some Member States are taking specific measures to improve the situation. The Commission has also discussed with the European Chemicals Agency (ECHA), which in the context of testing under the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals<sup>2</sup>, requires justification for using animals as part of the completeness check of dossiers for registered chemicals.

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<sup>1</sup> 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, Article 13(1).

<sup>2</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396, 30.12.2006.