

EN

E-002535/2020

Answer given by Mr Sinkevičius  
on behalf of the European Commission  
(27.7.2020)

Union legislation recognises alternatives to skin/eye corrosion/irritation and pyrogenicity testing since several years. Alternative methods for skin sensitisation were introduced into the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)<sup>1</sup> in 2016<sup>2</sup>.

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

In line with Directive 2010/63/EU<sup>3</sup>, before authorising a project the competent authority must be assured that the result sought cannot be obtained using alternatives. Once authorised, each project has a named person responsible for its compliance with the authorisation<sup>4</sup> who should require alternatives to be taken up once recognised by the legislation of the union.

The described limitations may partly explain continued use of animals in these areas. However, the Commission remains concerned, even if the numbers are decreasing in most cases.

The Commission is repeatedly reminding Member States of their legal obligations, has issued additional guidance, and encourages collaboration between regulatory authorities. Furthermore, the European Chemicals Agency (ECHA), in the context of testing under REACH, requires justification for using animals as part of the completeness check of dossiers for registered chemicals.

---

<sup>1</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).

<sup>2</sup> Commission Regulation (EU) 2016/1688 of 20 September 2016 amending Annex VII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin sensitisation (Text with EEA relevance), OJ L 255, 21.9.2016, p. 14–16.

<sup>3</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.

<sup>4</sup> Article 40(2)(b) of Directive 2010/63/EU.