

Non-compliance with REACH Regulation provisions concerning conduct of animal testing

Case opened

Case 1568/2012/AN - **Opened on** 19/09/2012 - **Decision on** 11/12/2014 - **Institution concerned** European Chemicals Agency (Settled by the institution) |

Allegation(s)

- 1) ECHA does not apply correctly the provisions of the REACH Regulation (and potentially Directive 2010/63/EU) concerning animal testing requirements and it thereby fails to fulfil some of its specific responsibilities under EU law.
- 2) When conducting detailed evaluations of selected dossiers, ECHA fails to evaluate properly whether the "*last resort*" principle (that is, that animal testing should be undertaken only as a last resort) has been applied.
- 3) ECHA allows and even rewards the use of illegal animal tests, by accepting data resulting from animal tests which are potentially non-compliant with the REACH Regulation.

Claim(s)

- 1) Wherever IT tools identify evidence of possible breaches of Articles 13 and 25 of the REACH Regulation (for instance, when the test study dates are subsequent to the validation of alternative methods and when testing is conducted without prior testing proposals where these are required), steps should be taken to investigate the reasons for non-compliance. If evidence of non-compliance is found, competent MemberState enforcement authorities must be informed.
- 2) The compliance check should include an evaluation of compliance with the requirements of Articles 13 and 25 and Annexes VI and XI to the REACH Regulation. In the event that any non-compliance is identified, competent MemberState enforcement authorities must be informed. Effective evaluation would require ECHA to develop clear and regularly updated guidance for registrants and its own staff about what would constitute a breach of the requirements of Articles 13 and 25 for any given information requirement.



3) ECHA should reject dossiers containing avoidable animal tests on the ground that they infringe EU law.