

The last resort requirement under REACH:

From principle to practice

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ABSTRACT

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) is a European Union regulation that aims to protect human health and the environment from the risks posed by chemicals. Article 25 clearly states that: "[i]n order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort." In practice, however, the standard information requirements under REACH are still primarily filled using animal studies.

This paper presents examples illustrating that animal testing is not always undertaken only as a last resort. Six over-arching issues have been identified which contribute to this: (1) non-acceptance of existing animal or non-animal data, (2) non-acceptance of read-across, (3) inflexible administrative processes, (4) redundancy of testing, (5) testing despite animal welfare concerns and (6) testing for cosmetic-only ingredients.

We, members of the Animal-Free Safety Assessment (AFSA) Collaboration, who work together to accelerate the global adoption of non-animal approaches for chemical safety assessment, herein propose several recommendations intended to aid the European Commission, the European Chemicals Agency and registrants to protect human health and the environment while avoiding unnecessary animal tests - truly upholding the last resort requirement in REACH.

(AFSA, 2018). The AFSA Collaboration brings together leading industry and not-for-profit organisations with a shared goal to better protect people and our planet, by replacing animal testing with more predictive and relevant approaches. It has several key areas of activity, including:

- Increasing the understanding, uptake and acceptance of non-animal approaches in jurisdictions with or without cosmetic animal-testing bans through educational resources and targeted publications

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Protection of Animal Welfare & Avoidance of Animal Testing Under EU Law

- Animal welfare **enshrined as an objective** at very highest level of EU law - Article 13 of the **Treaty** on the Functioning of the European Union
 - Prominent position in the Treaty, compels the EU institutions and Member States, since animals are sentient beings, to pay full regard to the welfare requirements of animals, when drafting and implementing EU legislation
- **2010 EU Directive** on the protection of animals used for scientific purposes (2010/63)
 - Key secondary legislation which calls out TFEU objective and governs all use of animals for testing
 - Clearly provides that wherever possible, a scientifically satisfactory testing strategy, not entailing the use of live animals is required

EU REACH and Animal Testing

Article 25 of EU REACH is clear, and consistent with the animal protection EU objective:

“IN ORDER TO AVOID ANIMAL TESTING, TESTING ON VERTEBRATE ANIMALS FOR THE PURPOSES OF THIS REGULATION SHALL BE UNDERTAKEN ONLY AS A LAST RESORT”

Various EU and Member States' case law confirms that animal testing for REACH purposes must be as a last resort

Esso Raffinage (2020 ECJ): “... [the registrant has].. not simply the possibility but **the obligation** to generate information obtained by means other than animal testing ‘whenever possible’ and to undertake such testing ‘only as a last resort’”



Exploring examples where animal testing was not always a last resort within REACH

- Non-acceptances of existing animal or non-animal data
- Non-acceptance of read-across
- Inflexible administrative processes
- Redundancy of testing
- Testing despite animal welfare concerns
- Testing for cosmetic-only ingredients

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- Increasing the understanding, uptake and acceptance of non-animal approaches in jurisdictions with or without cosmetic animal-testing bans through educational resources and targeted publications

1. Introduction

1.1. The Animal-Free Safety Assessment collaboration

The Animal-Free Safety Assessment (AFSA) Collaboration is a multi-stakeholder initiative developed to accelerate the global adoption of modern chemical safety assessment using non-animal approaches

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Recommendations for governance and enforcement of the last resort requirement

- European Commission
- ECHA
- Registrants

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