CIA Position Statement
November 2024

Reducing and Refining the Reliance on Animal Testing in Chemicals Regulation

Background

Chemical regulations often require the testing of chemicals on vertebrates to ensure safety of consumers, workers, and the environment. Back in 1959 the principle of the '3Rs' was first introduced, whereby scientists should seek the replacement, reduction, and refinement of animal tests [1; 2]. This principle has since become the steadfast of regulatory bodies & stakeholders and become embedded within chemical legislation in many jurisdictions such as EU REACH (Registration, Evaluation, Authorisation and restriction of Chemicals), EU CLP (Classification, Labelling and Packaging) Regulations and in sectoral legislations in both the UK and Europe. The UK established its own UK-REACH legislation after withdrawing from the EU and both the UK/EU-REACH contain legislative Articles (13(1) and 25(1)) requiring companies to use alternative methods whenever possible, and that testing using vertebrates can only be completed as a last resort. In November 2024, guidance was published by the Health and Safety Executive on minimising animal testing in UK-REACH [3]. Both the UK and EU promote the use of non-animal methods. In the case of cosmetics testing, the UK banned testing on animals in 1998 but there are some circumstances where testing may 'still' be required e.g. for worker or environmental safety [4].

Current Status

Companies and regulatory bodies are looking to New Approach Methodologies (NAMs) as the future. Whilst today it is recognised that animal testing cannot be replaced altogether, the question is whether ultimately they can be eliminated.

In the UK, the Animals (Scientific Procedures) Act 1986 regulates procedures carried out on defined 'protected animals' – this includes all vertebrates and cephalopods (marine molluscs who have a head, body and tentacles e.g. squid [5]). Under this legislation the Home Office report annual figures of the number of animal procedures in Great Britain (the latest data, for 2022, reports that 6.5 % of the total 2.76 million procedures were undertaken for regulatory toxicity and other safety tests including pharmacology, and specific legislative requirements accounted for: industrial chemicals 2 % of the total procedures, biocides 0.04 % of total and plant protection products 1.1 % of total). For Northern Ireland this is reported by their Department of Health. Many other countries also report on the number of animal procedures carried out each year. In May 2023, the Home Office published a regulatory update, stating that no new licences would be granted for animal testing for chemicals when exclusively intended as ingredients in cosmetics [6].

In June 2023 Defra published its first report, due every 5 years under UK-REACH (Article 117(4), on the amount and distribution of funding made available by the Department for the development and evaluation of alternative test methods [7]. This included £20,648 spending on development of tools, guidance, and analysis for the Organisation for Economic Co-operation and Development (OECD), and £333,594 to the Centre for Environment Fisheries and Aquaculture Science (CEFAS) for work on OECD test guidelines (in the 2022/23 financial year). In November 2024, Defra published 'Recommendations

Policy Contacts
Dr Roger Pullin, Head of Chemicals Policy and Health at CIA
Nishma Patel, Policy Director at CIA

for the Adoption of New Approach Methodologies (NAMs) in UK Chemical Regulation' produced by its Hazard Substances Advisory Committee (HSAC) [8].

In the EU, chemical legislation does encourage the replacement of animal test methods. The European Commission in 2011 established the EURL ECVAM (European Union Reference Laboratory for Alternatives to Animal Testing) to help achieve this; the UK however is no longer part of this following its exit from the EU [9]. Their mandate includes alternative method development, validation for regulatory acceptance and seeking international recognition. EURL ECVAM maintains the database 'Tracking System for Alternative methods towards Regulatory acceptance' (TSAR).

Looking to the U.S., the Environmental Protection Agency (EPA) having announced in 2019 to eliminate all animal testing by 2035 has since removed this timeline. In 2024, the EPA announced that they will not be bound by any time limits and instead would follow the best available science for reducing the use of animals in testing [10].

Our Opinions and Actions

- CIA and its members fully support the 3Rs principle (replacement, reduction, and refinement of animal tests) and consequently:
    - Do not want to have to conduct or repeat any animal test where reliable data already exist (including through substance grouping or read across); and
    - Are working to develop and validate non-animal testing methods.

- CIA and its members do not agree with 'tick box' approaches for filling data gaps or that (eco)toxicity testing/data needs should be linked to production/import volume as a proxy for exposure. We believe the need for data requirements should be driven by science, as espoused by New Approach Methodologies (NAMs), defined approaches and Integrated Approaches for Testing and Assessment (IATA).

- We therefore support targeted testing approaches, which are pragmatic, and that additional information which involves animal testing is only requested when absolutely necessary which **fully adheres** to the last resort principles enshrined by Articles 13 and 25 of UK/EU REACH.

- We recognise the conflict between UK/EU-REACH and the sectoral cosmetic product regulations regarding animal testing on cosmetic ingredients; the latter does not allow it.

- We believe the UK has a clear opportunity to implement pragmatic risk-based legislation that concretely addresses all 3 objectives of the European Citizens Initiative to Save Cruelty Free Cosmetics [11].

- As the UK moves forward with implementing its own chemicals regime and putting in place a UK-wide Chemicals Strategy, we strongly encourage decision makers to accept and promote use of NAMs in demonstrating safe use of a chemical substance especially when evaluating grouping and read-across or through adoption of novel risk-based Next Generation Risk Assessment (NGRA) approaches (e.g. NC3Rs and BTS Vision, 2024 [12]; Berggren and Worth 2023 [13]; Ball et al. 2022 [14]).

Policy Contacts
Dr Roger Pullin, Head of Chemicals Policy and Health at CIA
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- It is encouraging to see the UK authorities are already engaged in NAMs approaches, noting in particular the work being undertaken jointly by both UK and Dutch authorities on the use of non-animal test methods for classification of health hazards within the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals.

- CIA and its members believe the UK should become a 'champion' for regulatory acceptance of NAMs by establishing a programme beyond that of OECD for validation and promotion of these at the international level with the aim of achieving multi-regulatory acceptance and use across all regulations.

- The UK chemical industry is keen to continue developing partnerships with appropriate parties (universities – alternative test providers etc), to further develop and promote NAMs for everyone to use.

- We are also keen to continue working with relevant UK authorities on the goal to accept use of NAMs in a regulatory context.

Conclusion

With the UK now adopting its own chemicals legislation following its exit from the EU and the development of a UK Chemicals Strategy [15], the opportunity is here now for the UK science community to be at the forefront and lead the way towards better testing strategies globally. The chemicals sector strongly encourages the UK government to maximise this prospect.

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