

Senedd Cymru
Y Pwyllgor Materion Allanol a
Deddfwriaeth Ychwanegol
Ymadael â'r Undeb Ewropeaidd:
Paratoadau yng Nghymru ar gyfer
diwedd y cyfnod pontio
EAAL(5) EUP01
Ymateb gan Cruelty Free International

Welsh Parliament
External Affairs and Additional
Legislation Committee
Exiting the European Union:
Preparedness in Wales for the end of
the transition period
Evidence from Cruelty Free
International

1. Submission to the ongoing Senedd Cymru consultation: Exiting the European Union: Preparedness in Wales for the end of the transition period

1.1 CrueltyFreeInternational is a UK-based organisation working to end animal experiments worldwide. Our scientists have had stakeholder observer status at the European Chemicals Agency (ECHA) since its establishment, an expert seat at the Member State and Risk Assessment Committees since stakeholders were first permitted, and a seat on the Competent Authorities for REACH (Registration, Evaluation, Authorisation and Restrictions of Chemicals) and CLP (Classification, Labelling and Packaging) expert advisory group to the Commission since 2012. We have submitted complaints to the European Ombudsman and intervened in Board of Appeal cases; produced reports on alternative methods to assist registrants avoid animal testing and are in a strong position to comment on the animal testing implications of UK exit from EU REACH and ECHA. We are also a member of the UK Chemical Stakeholder Forum.

Executive Summary

- If the UK was not to seek membership of the European Chemicals Agency (ECHA), it could - without a robust data-sharing agreement - lose access to the world's largest chemical database, in turn meaning that chemical companies in Wales would have to generate the data necessary to comply with a future UK chemical regulatory framework, potentially including duplication of animal tests.
- If the UK were to maintain its position of no associate membership of ECHA and non-alignment with EU REACH, it is essential that important principles currently contained in REACH are retained by the UK, particularly the principles of animal testing as a last resort and to promote alternatives to animal testing.
- However, any UK REACH system that might arise should seek to be better at replacing animal testing with a toolbox of alternatives.

2. Retaining membership of the European Chemicals Agency (ECHA)

2.1 In the document published by the Welsh government entitled *the Future UK relationship negotiating priorities for Wales*, it is stated that Britain should continue 'participation in EU bodies and agencies such as the European Chemicals Agency to support dynamic alignment'. We believe that it is important that Britain maintains as close as possible a relationship with ECHA and its database, the largest on chemicals in the world containing information in English on more than 16,500 chemicals - much of which is the result of animal tests. From January 1st, 2021, for continued access to the UK market, chemicals with a current EU REACH registration - will need to be registered under the new UK REACH equivalent.

2.2 According to the chemicals industry, registering a single chemical under UK REACH could cost up to £300,000 if companies are required to buy "letters of access" to existing data that supports the EU registration, as held by ECHA in Helsinki. This data is information that is expensive to produce and often owned by third parties. Worse still, if letters of access to ECHA-held data cannot be obtained then additional testing may be required to generate the data anew. This testing could include animal tests.

2.3 As things currently stand, within two years of the UK leaving the EU, chemical companies in Wales are to provide the UK Health and Safety Executive with the full data package that supported their original EU REACH chemical substance registrations. This will not only be costly for industry but could also mean duplicate testing on animals of substances for UK REACH already tested on animals for EU REACH.

2.4 We are convinced that neither the Welsh public nor the chemicals industry in Wales would countenance repeat animal tests for political and bureaucratic reasons nor, going forward, the potential of two chemicals safety regimes - one in the EU and one in the UK - requiring double the number of animal tests for new registrations.

2.5 If continued associate membership of the ECHA or alignment with EU REACH are not on the table, then a fundamental data-sharing agreement enabling mutual access to full registration dossiers - including the commercial information often held by third parties - will be essential.

3. New approach methods better for human health and the environment

3.1 The EU REACH legislation includes two key principles - the promotion of alternatives to animal testing and animal testing as a last resort. Whilst these are protected in the Environment Bill currently under consideration in the Westminster parliament, these principles, to be meaningful, must be directed at all relevant bodies and mechanisms to ensure that they are upheld. This is not currently evident.

3.2 We believe that if there is to be a divergent legislation for the safety of chemicals, then the UK should, from the start, set out to be more ambitious with regard to the replacement of animal testing, looking for example to the US Environmental Protection Agency which has set a deadline of 2035 for an end to eliminate all requests and funding for tests involving mammals.

3.3 We note the UK's 2020 Budget objective of increasing investment in R&D to 2.4% of GDP by 2027, with plan to increase public R&D investment to £22 billion per year in science and technologies, but it is essential that specific, well-funded programmes are put in place within that to deliver high quality, non-animal methods for assuring the safe use of chemicals.¹

3.4 We have seen that the issue of the relevance of animal testing for protecting human health and the environment is rarely addressed directly; it has been assumed by default based on a system of testing developed 60 years ago. Unfortunately, animal tests have become accepted as the standard way of predicting human toxicity with very little confidence that their results are valid.

3.5 We see concerns being voiced that tests on animals are not fit-for-purpose for protecting human health or the environment because of species difference and differences between strains of the same species (e.g. laboratory-bred mice vs the natural population); effects of stress due to an artificial laboratory environment; and the widely different exposure pattern associated with an animal test compared to real-world exposure. As an example, Federica Madia, a biologist and scientific officer in the Chemical Safety and Alternative Methods Unit of the Commission's Joint Research Centre wrote recently: "We therefore highlight the need for new approaches for carcinogenicity assessment. We also call into question the standard testing procedures relying on animal studies. At the moment, we are testing chemical effects on mice and rats. But the results obtained are not totally reliable for humans."²

¹ Alliance for Human Relevant Science, Accelerating the Growth of Human Relevant Life Sciences in the United Kingdom, (March 2020).

² F. Madia, Chemicals in our life, 'New Study shows how to better assess chemicals and prevent cancer', https://chemicalsinourlife.echa.europa.eu/quest-corner/-/asset_publisher/vcrQSpI9IebF/blog/new-study-shows-how-to-better-assess-chemicals-and-help-preventing-cancer (Accessed 18.03.202, Time: 09.21).