Revision of GB Biocidal Products Regulation Annexes II and III consultation response

Thank you for the opportunity to provide a response to the **Revision of GB Biocidal Products Regulation Annexes II and III consultation**. This response was collated by **Understanding Animal Research**, combining feedback from our stakeholders and evidence available to the public.

UAR is a non-profit member organisation that aims to explain how animals are used in scientific research. We are supported by universities, companies, government agencies, scientific societies, charities and main research funding bodies within the UK.

Context

Public health is best served by applying the best available model for spotting human, animal and environmental toxicities at the upper end of typical exposures to chemicals and combinations of chemicals.

Animal models are a useful tool for detecting both primary toxicities and unexpected off-target effects. As was found with the recent re-examination of the safety of homosalate, in vitro models were equivocal and could not provide a clear answer on safe exposures. Animal models showed that, although the primary animal model was not visibly sickened, they experienced infertility and stillbirth.

Whilst a definitive translation of this animal model to humans is not assumed to exist, it is sufficient to recommend the strict limitation of chemical as an ingredient following the precautionary principle.

However, in other cases, in vitro tests have advanced to the point that they may be sufficient to demonstrate the safety or otherwise of chemicals at the anticipated exposures and so should be adopted as soon as practicable.

UAR is strongly supportive of the proposed changes to regulations that would introduce a tiered approach to safety testing, cascading from literature search to *in-vitro* testing and, if necessary, animal tests.

A more flexible approach to regulation, which considers the context of the decision such as the necessity of certain tests, can help to avoid unnecessary animal use and administrative costs. In cases where in vitro tests demonstrate unmanageable toxicities, the secondary advantage of the animal model – its ability to spot off-target effects as well as assess expected risks – can become obsolete since sufficient data exists to support a decision.

The caution showed in the suggested changes towards the use of in vitro methods to determine reproductive toxicity is welcome given the relatively serious impacts of these changes.

Routinely testing for the endocrine-disrupting properties of compounds is welcome, especially given the circumstances leading to recent new controls on homosalate and other similar chemicals.

Alignment with the OECD is welcome, although a mechanism should exist for the UK to depart from its guidance where the regulator considers that the scientific evidence diverges from the OECD assessment.

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