



National Centre
for the Replacement
Refinement & Reduction
of Animals in Research



Vision for a Modern Science-Based Approach to UK Chemicals Regulation

UK Chemicals Regulations: Time for change

1. As the result of exit from the European Union, the UK Government has a unique opportunity to modernise the UK's approach to assuring the safety of chemicals (including industrial chemicals, pesticides and biocides). The Government can now make important changes to domestic regulations to improve the scientific quality and relevance of chemical safety assessment to protect human health and the environment.
2. Embracing a modernised approach to UK chemicals regulation that embeds the latest science and technology into an agile system will yield significant benefits. These include scientific, business and economic advantages as well as reducing the reliance on animal-based testing methods and developing a more sustainable approach to safety assessment. The purpose of this short position paper is to share a vision for a science-based approach to chemicals regulation which positions the UK as a world-leader within global markets. The paper focuses on what can be achieved now and why change is important, rather than mapping out the hurdles that must be negotiated to deliver the vision.

A vision that embraces modern safety science

3. Modernising UK chemicals regulations entails adopting revised paradigms for safety assurance which embrace new technologies and ensure a coordinated regulatory framework. The changes required are not insignificant and require an appetite for progress away from current approaches, the principles of which have remained largely unaltered for more than half a century and still widely rely on animal testing methods. Much of the scientific evidence base and infrastructure required to implement modern testing strategies are already in place but need to be applied in practice. Leadership from Government and policymakers is essential for the further investment and resource that will be necessary to realise these opportunities, as well as to deliver the underpinning legislative and behavioural changes.
4. The application of a science-based approach to chemicals regulation in the UK is dependent on:
 - **Adoption of risk-based approaches that make full use of exposure data:** 'The dose makes the poison' with the risk of a harmful effect being determined by both the intrinsic properties of a

chemical (the hazard) and the level and conditions of exposure to that chemical (the risk). Current approaches within chemicals regulations typically base safety assessments on hazard alone, which provides an incomplete picture of the potential for harm and fails to consider exposure. Modern hazard and exposure science address these limitations and incorporating both into chemicals regulations would increase focus on those that pose the greatest risk to human health and environmental safety.

- **Widespread deployment of New Approach Methodologies (NAMs)¹:** NAMs have the potential to improve the accuracy and reliability of safety assessments for human and environmental health protection, as well as reducing reliance on animal tests and cost. They provide an important opportunity to strengthen the relevance of human safety assessments because they can incorporate human cells and tissues into complex models such as organ-on-chips. Computational technologies could increase testing capacity and efficiencies by maximising the use of large and complex data sets to facilitate predictive testing and screening. Coordination of research, validation and implementation efforts alongside investment linked to policy development is essential to realise the full potential of NAMs.

5. Adopting these principles of modern safety science would deliver substantial scientific and economic benefits to the UK. They are the foundation of a science-based approach to UK chemicals regulation policy that:

- Protects human health and the environment.
- Provides a more efficient and agile regulatory policy that encourages innovation and new product development in all industrial sectors.
- Creates opportunities for UK business including SMEs to deliver innovations in toxicological sciences and exposure assessment to a global market.
- Makes best use of the UK's expertise in toxicological sciences, exposure science and risk assessment to strengthen public confidence in the safe use of chemicals.

Supporting progress towards the vision

6. We have identified four key areas where progress is needed to deliver a modernised approach to chemical safety assessment in the UK.

¹ There are various definitions for NAMs but we are using the term here in line with how it is used in the life sciences community to specifically describe replacement of animal technologies (full and partial) for use in assessing chemical or drug toxicity.

- **A common goal:** Transforming UK chemicals regulations to improve human health protection, safeguard the environment and stimulate the economy. The current regulatory framework should incorporate the best available science and technology to drive improvements in human and environmental health protection. A more efficient and flexible regulation would stimulate investment and facilitate the delivery of new products to market.
- **Government commitment:** A long-term financial commitment within Government, combined with clear leadership and ambition is consistent with the UK's '[Science and Technology Superpower](#)' aspiration.
- **A coordinated approach to deliver the new regulatory framework:** A redesigned regulatory framework that facilitates cooperation and consistency between agencies together with a career structure for regulators that encourages the recruitment and retention of strong scientific talent is essential.
- **Harmonisation:** For the UK to play a leading role on the international stage promoting modern chemicals regulation and fostering international cooperation and trade.

Concluding thoughts

7. This vision aims to harness the strength of the UK science and technology sectors to place it as a world leader with chemicals regulations that are innovative and grounded in the latest risk-based approaches. Our intention is that this paper catalyses the commitment, investment and activity required to drive changes in regulatory science and safety assessment, in line with the national aspiration that the UK is recognised as a science and technology superpower.

January 2024

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