# CTPA Position Paper on the Promotion and Uptake of Non-Animal New Approach Methodologies (NAMs) for Chemical Risk Assessment in the UK

December 2024

## 1. Introduction

Representing all types of companies involved in making, supplying and selling cosmetics and personal care products, the Cosmetic, Toiletry and Perfumery Association (CTPA) acts as the voice of the UK industry. CTPA represents more than 225 member companies of diverse sizes, from micro and SMEs through to multinationals. Collectively, this represents between 85-90% of a UK market valued at £9.5 billion in 2023 (at retail sales price).

The series of bans on animal testing of cosmetic products and ingredients began entering into force from 2004 in the UK and EU. In the UK, the cosmetics industry was already seeking alternatives to animal testing in the 1980s, and in 1997 was able to completely move away from animal testing of products through a voluntary industry initiative. The UK and EU cosmetics industry wholeheartedly supports the animal testing bans and has invested over €50 million over the past 25 years, making it a global leader in Non-Animal New Approach Methodologies (NAMs)[1]. CTPA member companies operate globally, therefore global collaboration and progress on the advancement of NAMs is vital.

Using data from a combination of NAMs to conduct a risk assessment that is exposure-led, hypothesis-driven and designed to prevent harm is termed Next Generation Risk Assessment (NGRA)[2]. As well as meeting an ethical objective, animal-free safety assessment methods have the potential to offer improved human and environmental relevance.

The move towards regulatory uptake of NAMs and NGRA approaches is progressing in other global regions; for example, USA, Canada and the EU3. The UK has the opportunity to also demonstrate global scientific leadership by participating in this movement and contributing its scientific expertise to global projects, to promote a coordinated approach.

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[1] See further information at https://www.thefactsabout.co.uk/cruelty-free

[2] M.P. Dent, E. Vaillancourt, R.S. Thomas, P.L. Carmichael, G. Ouedraogo, H. Kojima, J. Barroso, J. Ansell, T.S. Barton-Maclaren, S.H. Bennekou, K. Boekelheide, J. Ezendam, J. Field, S. Fitzpatrick, M. Hatao, R. Kreiling, M. Lorencini, C. Mahony, B. Montemayor, R. Mazaro-Costa, J. Oliveira, V. Rogiers, D. Smegal, R. Taalman, Y. Tokura, R. Verma, C. Willett, C. Yang, Paving the way for application of next generation risk assessment to safety decision-making for cosmetic ingredients, Regulatory Toxicology and Pharmacology, Volume 125, 2021, https://doi.org/10.1016/j.yrtph.2021.105026.

[3] USA: https://www.nih.gov/news-events/news-releases/roadmap-guide-progress-toward-replacing-animal-use-toxicity-testing#:~:text=The%20roadmap%20was%20developed%20to,method%20developers%20with%20end%20users.
Canada: Draft Strategy to Replace, Reduce or Refine Vertebrate Animal Testing under the Canadian Environmental Protection Act, 1999 - Canada.ca
EU: https://single-market-economy.ec.europa.eu/document/download/8718fcbb-cc3b-4695-b48d-b6cfa5e9fc96_en?filename=C_2023_5041_1_EN_ACT_part1_v6.pdf

## 2. UK Position on NAMs (December 2024)

In early 2024, the UK Government expressed its commitment to publishing a detailed plan, initially expected in 2024, to set out how the Government will accelerate the development, validation and uptake of technologies to reduce the use of animals in science in the UK. The plan is expected to be developed in consultation with a wide group of stakeholders[4].

Following a change of Government in Summer 2024, the current UK Government position is awaited.

UK Government departments and their individual experts have been contributing to national and international activities to support the development and evaluation of NAMs over many years. UK-based scientists from industry, academia, NGOs and other stakeholder organisations are pioneering cutting-edge approaches to animal-free chemical risk assessment across many different sectors and are actively involved in collaborations taking place across diverse sectors and geographies.

Therefore, to move forwards with the advancement and adoption of NAMs, it is equally important to identify and prioritise the key opportunities and challenges to achieve this ambition.

## 3. Key Challenges Associated with the Uptake of NAMs in the UK

There are clear advantages to moving towards a human health and environmentally relevant, exposure-led flexible framework for chemicals regulation, with no compromise on safety, which does not require the use of animals. There are also significant challenges to overcome when moving to a completely new way of understanding and assessing the safety risks from chemicals and defining this within regulatory frameworks. Non-animal methods and approaches exist to demonstrate that cosmetic ingredients are safe without the use of animals; however, as this document describes, more work needs to be done to build the science and confidence for their regulatory use.

There will be significant costs to business associated with investing in NAMs and NGRA approaches and compliance with a changing regulatory framework. For example, investing in new infrastructure, training and adapting to new timelines for launching products. It is crucial that progress supports the mutual acceptance of methods across countries, to enable cosmetic products and their ingredients to be permitted in the UK and international markets. This is of particular importance concerning the movement of goods between UK and Europe, and other global markets, considering businesses operate global supply chains. Therefore, it is vital to avoid incompatible global approaches, as this topic moves forward in different regions.

[4] HC Deb 19 February 2024, vol 745, cols 180WH – 184WH Hansard https://hansard.parliament.uk/Commons/2024-02-19/debates/0C64E6BD-AE31-4DD7-80BB-3CEDC6272C2E/a accessed 29.04.24

Building confidence amongst all stakeholders in investing in NAMs and using these data to make safety decisions is an important challenge to overcome. The Recommendations presented below all work towards this aim.

Improving lines of communication between Government regulatory scientists and those within companies submitting safety data for regulatory purposes is crucial, as well as ensuring that diverse Government departments with a chemical safety remit work closely together.

Scientific research and new method development requires funding. Once methods have been developed and agreed, establishing new systems for chemicals safety testing, decision-making and capacity building, can be a significant financial investment for companies. Training industry and Government regulatory staff also incurs a cost. Ensuring that funding for the transition to NAMs and NGRA-based approaches is sufficient and appropriately targeted is a key challenge.

Finally, education and training have been identified as both a financial and resource challenge and an urgent need; it is important to fully integrate NAMs within academic settings and university programmes so that newly trained life and environmental scientists are familiar with NAMs and NGRA-based approaches. The British Toxicology Society's 'Skills Gap Initiative' training programme is an example of such training and education[5].

[5] https://www.thebts.org/news/skills_gap_report_2022/

## 4. Recommendations for Key Priorities to Help the Promotion and Uptake of NAMs in the UK

The outcomes from the CTPA seminar 'For a Government Strategy on Non-Animal Methodologies' (25.04.24) formed an important building block for this Recommendation, amongst other considerations. Industry representatives from both the cosmetics and chemicals sectors, NGOs, UK Government representatives, academics and NAMs experts collaborated to develop potential key content of a UK Government NAMs strategy. The objective of the seminar was to convene key parties with a shared interest in progress, to expedite the UK's strategy for moving to animal-free science.

The following Recommendations outline CTPA's view on the key priorities that will help enable the promotion and uptake of NAMs in the UK, and practical examples of how these can be achieved. The Recommendations address the key challenges outlined above.

## Communication and Collaboration

### Introduce a mechanism for dialogue between industry and regulators

- Develop clear and transparent guidance on NAM/NGRA approaches to fulfil regulatory requirements and provide an opportunity for both parties to discuss the proposed approach prior to testing and data submission.
- Incorporate a feedback mechanism to allow approaches to be further developed, or accepted, for future work.
- Fully enforce the 'last resort' requirement for conducting any animal testing that is currently in the text of UK REACH[6], by setting clear processes to determine the absence of suitable NAM/NGRA approaches and a mechanism to appeal against proposals and regulatory requests for animal testing. The process should ensure industry and regulators apply the 'last resort' requirement.

### Enable close collaboration between UK Government agencies

- Enable cross-sector acceptance of data to remove any requirement to repeat animal testing for a different regulatory or sector purpose.
- Empower and support the existing UK Government scientific advisory committee structure, working with NC3Rs, to act as change enablers for the development, agreement and international recognition, and uptake of NAMs.
- Nominate champions for NAMs and NGRA within each relevant Government agency and consider nominating a lead agency.

### Ensure global participation

- Promote communication and knowledge-sharing between the Government and expert stakeholders within the UK and globally.
- Ensure active UK participation in global projects to develop and harmonise NAM/NGRA approaches.

[6] UK Registration, Evaluation and Authorisation of Chemicals (REACH) Regulation, found within the REACH etc. (Amendment etc.) (EU Exit) Regulations 2020 https://www.legislation.gov.uk/uksi/2020/1577/contents/made

## Legislation that encourages the use of animal-free methods, whilst maintaining human and environmental safety

**Ensure flexibility within regulatory frameworks**

- Support an exposure-based, human or environmentally relevant approach to risk assessment within regulatory frameworks.
- Publish official guidance on NAM/NGRA approaches for addressing certain types of safety decisions. Guidance which is complementary to existing regulatory frameworks will support the use and regulatory acceptance of these approaches without the immediate requirement to amend legislation.

**Identify opportunities during the development of new legislation, or amendment of existing legislation, to integrate NAM/NGRA approaches**

- If chemicals legislation such as GB CLP[7] or UK REACH[6] are updated in the future, the integration of exposure-led NAM/NGRA approaches should be part of the revision:
    - For example, the ongoing amendment of the UK REACH legislation provides an opportunity for integration of NAM/NGRA approaches to meet information requirements.

**Ensure frameworks for establishing scientific confidence in NAMs are embedded, to enable animal-free approaches to be used instead of animal testing**

- It is not appropriate to establish fixed deadlines for phasing out animal testing or adopting new approaches. The transition is dependent on scientific developments and ensuring sufficient confidence in new methods.
- Require the use of a NAM/NGRA where scientifically robust and recognised approaches exist instead of *in vivo* methods; for example, for testing conducted for regulatory purposes. This could be achieved through a policy statement.

[7] The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 No. 720 as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020

**Enable NAM/NGRA principles to be applied to the safety assessment of chemicals for a wide variety of uses**

- Promote the principles of NAM/NGRA approaches for the safety assessment of chemicals within differing sectors because the principles of NGRA approaches for cosmetic ingredients are equally applicable to some other chemicals.
- Ensure there is a process in place to understand levels of human or environmental exposure to chemicals; for example, from both specific and cumulative uses, because this is crucial to improving safety decision-making.
- Establish partnerships between regulators and other safety scientist stakeholders, to develop exposure modelling and assessment case studies:
    - For example, within the US Environmental Protection Agency (EPA), investment in exposure science, toxicology and modelling capabilities have been brought together in one centre (Centre for Computational Toxicology and Exposure (CCTE).

## Funding and Incentives

**Ensure funding is sufficient and appropriately targeted to infrastructure that focusses on establishing confidence and uptake of NAM/NGRA approaches**

- Ensure Government allocates sufficient funding to its own departments to perform research activities and evaluate proposed approaches.
- Provide Government funding and support for UK-developed methods to access the international validation process through the Organisation for Economic Co-operation and Development (OECD).

**Provide incentives to support investment in animal-free approaches**

- Incentivise Contract Research Organisations (CROs) to invest in the uptake and use of NAMs, especially at a time when the regulatory landscape remains uncertain.
- Expedite regulatory review of NAM/NGRA-based testing proposals for regulatory purposes.

| Education and Building Confidence |
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| **Embed animal-free testing methods within the education system** |
| ▪ Equip the next generation of toxicologists and safety scientists with the most appropriate skill set to develop, use or evaluate NAM/NGRA approaches from an industry, academic or regulatory perspective.<br>▪ Issue a Government recommendation to higher education institutions regarding the inclusion of education and training on animal-free methods.<br>▪ Introduce continuing training courses for experts in safety evaluation, focussing on NAM/NGRA approaches. |
| **Initiate demonstrator projects** |
| ▪ Demonstrator projects designed and operated by a cross-functional group including regulatory scientists, industry safety scientists, academics and other stakeholders will develop common approaches, and build confidence in moving through the process from regulatory question, to data generation, to safety decision-making. |
| **Enable UK-based evaluation/validation** |
| ▪ Define a clear approach in the UK for building confidence that NAMs are scientifically reliable and relevant for regulatory decisions, in line with the ongoing global discussion on updating OECD principles for validation that are future-proof and appropriate to the science used within NAMs/NGRA. |

## 5. Conclusion

CTPA does not consider it appropriate to establish fixed deadlines for phasing out animal testing or adopting new approaches for chemicals safety assessment, because the transition must be science-driven with sufficient confidence in our ability to protect human health and the environment.

CTPA fully supports efforts to accelerate the development, validation and uptake of technologies to reduce the use of animals in science in the UK and this Position Paper outlines practical steps which can help to achieve this important objective. CTPA looks forward to continuing to work with key parties with a shared interest in progress, with the aim of expediting the UK's strategy for moving to animal-free safety science.

For further information, please contact info@ctpa.org.uk.