Contribution ID: 98207f4f-c918-4918-bec4-f0787ebe4c44
Date: 23/01/2025 12:21:21

Animal testing in chemical safety assessments – Commission roadmap to phase it out – First stakeholder survey

Fields marked with * are mandatory.

Background information

WSP is providing technical assistance to the European Commission for the **development of a roadmap towards phasing out animal testing in chemical safety assessments**.

The roadmap will aim to **accelerate the development, validation, regulatory acceptance, and uptake of non-animal test methods for chemical safety assessment across sectors and regulatory areas**. This will contribute to the transition to more sustainable and ethical practices in the EU.

As part of this project, **we are seeking your views on what should be included and/or considered in the development of the roadmap**. This is an opportunity for you to help steer the development of the roadmap and let the Commission know how the roadmap might affect you. The consultation activities undertaken in this project build on the Commission's call for evidence launched in September 2024 by asking more specific questions to specific stakeholders.

If you have any questions, please reach out directly to the project team (kristina.flexman@wsp.com and emily.hickery@wsp.com)

The data obtained will be anonymised and reported in a way that views cannot be traced back to your organisation name.

Mandatory questions are marked with an *

This survey will close at 18:00 CET on 24/01/2025.

Part A - About you

* **Name**

Francesca Rapolla

* **Organisation**

The Cosmetic, Toiletry and Perfumery Association

*** Email**

frapolla@ctpa.org.uk

*** Stakeholder type**

- ○ Company
- ○ Contract research organisation
- ○ Citizen/consumer
- ○ EU authority/agency
- ◉ Industry association
- ○ Member State authority/association
- ○ NGO (environment and health)
- ○ NGO (animal welfare)
- ○ Non-EU authority/agency
- ○ Research institute, university, or Commission partnership
- ○ Other (please specify)

*** Size of organisation**

- ○ Micro (1 to 9 employees)
- ◉ Small (10 to 49 employees)
- ○ Medium (50 to 249 employees)
- ○ Large (250 or more)
- ○ N/A (I am representing myself as an individual)

*** Country**

- ○ Austria
- ○ Belgium
- ○ Bulgaria
- ○ Croatia
- ○ Republic of Cyprus
- ○ Czech Republic
- ○ Denmark
- ○ Estonia
- ○ Finland
- ○ France
- ○ Germany
- ○ Greece
- ○ Hungary
- ○ Ireland
- ○ Italy
- ○ Latvia
- ○ Lithuania
- ○ Luxembourg

- ○ Malta
- ○ Netherlands
- ○ Poland
- ○ Portugal
- ○ Romania
- ○ Slovakia
- ○ Slovenia
- ○ Spain
- ○ Sweden
- ○ N/A (international)
- ◉ Other (please specify)

*** Other country**

United Kingdom

*** Language of my contribution**

- ○ Bulgarian
- ○ Croatian
- ○ Czech
- ○ Danish
- ○ Estonian
- ◉ English
- ○ Finnish
- ○ French
- ○ German
- ○ Greek
- ○ Hungarian
- ○ Irish
- ○ Italian
- ○ Latvian
- ○ Lithuanian
- ○ Luxembourgish
- ○ Maltese
- ○ Dutch
- ○ Polish
- ○ Portugese
- ○ Romanian
- ○ Slovak
- ○ Slovene
- ○ Spanish
- ○ Swedish
- ○ Other (please specify)

Do you agree to potential further contact in the context of the Commission's roadmap development?

- ◉ Yes

- [ ] No

Section B - General questions on challenges and opportunities

This section asks about the challenges and opportunities with non-animal test methods for assessing risks in a regulatory context. Feel free to skip parts that are not applicable to your organisation.

* **1. What are currently the main hurdles to overcome in expanding the replacement of animal-based methods with non-animal test methods?** (multiple answers possible)

- [x] Scientific barriers / lack of methodologies
- [x] Communication / awareness
- [ ] Market trust
- [ ] Economic costs
- [x] Regulatory acceptance
- [ ] I don't know
- [x] Other (please specify)

* **Other**

Whilst there are some endpoints that lack methodologies, there is extensive research ongoing into the development of non-animal New Approach Methodologies (NAMs). The main challenges are related to: the availability of standardised, accessible approaches, and education and uptake of the methods by both industry and regulators; regulatory acceptance by authorities; as well as collaboration and communication between all the relevant stakeholders. In regard to regulatory acceptance, the main challenge to obtain this for complex endpoints, as there is no like-for-like replacement of animal testing. It is important to highlight that the non-animal NAMs and the safety assessment using Next Generation Risk Assessment (NGRA) approaches do not directly substitute the traditional methods, because they require a new mindset and approach to safety assessment.

To help with method development, acceptance and uptake, it is important to establish open dialogue between authorities, industry and other stakeholders. This will help industry to feel more confident in using new approaches, if there is a significant chance of regulatory acceptance.

Another important point to add is that if industry feels more confident in using these new approaches, Contract Research Organisations (CROs) will also have increased demand and offer that will support the implementation and uptake of these methods.

2. Where do you see benefits/advantages for industry when transitioning to non-animal test methods? (multiple answers possible)

- [ ] Cost saving (when non-animal methods have become mature and mainstream)
- [ ] Shortened time for products to reach the market (products subject to registration, e.g. chemicals under REACH, or authorisation, e.g. medicines, plant protection products)
- [ ] Improved certainty on compliance with regulatory requirements
- [x] Reduced administrative burden if validated test methods are aligned with international approaches
- [x] Brand image / corporate social responsibility
- [x] Safer and more sustainable products (due to better scientific understanding of toxicity mechanisms)
- [ ] No benefits foreseen

- [ ] I don't know
- [x] Other (please specify)

* **Other**

In regard to the identified benefits related to cost saving and reduced administrative burden, it is important to highlight that these will reach their full potential once the full transition takes place. Particularly in the transition phase, appropriate milestones have to be identified and resources will have to be assigned for the implementation at the involved European and member state agencies.

The transition to non-animal tests methods can also unlock the development of new / innovative cosmetic ingredients and chemicals for other sectors. It can therefore positively impact the current reduction of palette of ingredients such as sunscreen, preservatives.

* **3. Where do you see benefits/advantages for authorities when transitioning to non-animal test methods?** (multiple answers possible)
  - [ ] Faster receipt of tests conducted by companies for regulatory compliance
  - [ ] Companies are more willing to conduct additional studies requested by authorities
  - [x] The opportunity to align regulatory requirements with new scientific developments and ethical goals
  - [ ] International harmonisation
  - [ ] No benefits forseen
  - [ ] I don't know
  - [x] Other (please specify)

* **Other**

Another key benefit for authorities is to be able to make safety decisions on data that is more human-relevant and protective, vs animals and traditional methods.

* **4. Where do you see benefits/advantages for other stakeholders when transitioning to non-animal test methods?** (multiple answers possible)
  - [x] Consumer benefits - higher levels of consumer satisfaction
  - [ ] Consumer benefits - higher level of protection of human health or the environment
  - [x] Emergence of new markets for developers of non-animal test methods, contract research organisations and scientific research
  - [ ] No benefits foreseen
  - [ ] I don't know
  - [x] Other (please specify)

* **Other**

CTPA didn’t select the answer “consumer benefits – higher protection of human health or the environment” because the wording of this answer may give the wrong impression on the safety of chemicals today. Cosmetic ingredients are already safe today. However, transitioning to non-animal NAMs and NGRA approaches will allow to make safety decisions based on more biologically relevant models.

* **5. Are non-animal test methods currently more or less costly than animal-based methods?**

- ○ Non-animal test methods are generally less costly
- ○ Non-animal test methods are roughly the same cost
- ○ Non-animal test methods are generally more expensive
- ◉ Costs vary greatly by hazard endpoint
- ○ I don't know

*** Costs vary greatly by hazard endpoint - please explain**

NAMs and NGRA approaches are components of a broader strategy, leading to different possible costs. For example, when using the NGRA SEURAT framework, a safety decision can be made at tier 0 or at the higher tiers and the costs associated to gathering data at the different tiers may vary. In conclusion, costs vary based on the hypothesis being investigated via the NAMs and NGRA strategy.

6. Do you have any other evidence or information on costs of non-animal test methods (including cost estimations for specific methods)?

As a trade association, we don't directly perform any test for the safety assessment of chemicals. We therefore do not have access to detailed information about costs to input into this answer.

However, we have received some additional input from members, please see below.

- In order to establish the safety of an ingredient used for a specific end point, a company will likely be required to employ a combination of non-animal testing methods so to build a convincing safe weight of evidence. In such case, the cost associated with the demonstration of safety may be cumulative.
- In general, costs for NAMs and NGRA approaches are expected to decrease as their use becomes more widespread. It is important to also note that, even if NAMs and NGRA approaches may currently be more expensive nowadays, they provide significantly more valuable, useful and reliable data that compile an extensive weight of information that overall may be more cost-effective.

Part C - Non-animal test methods for human health hazard assessment

This section asks about the availability of non-animal test methods for human health hazard assessment. Feel free to skip this part if you are not familiar with any non-animal test methods for human health hazard assessment.

7. Are you aware of non-animal methods (as stand-alone or in combination, including exposure-based considerations) that can already be used to replace an animal-based method for any of the following health hazard endpoints?

Hazard type	Yes (validated non-animal test methods exist and can already be used)	Yes (non-validated but scientifically mature non-animal test methods exist and can already be used)	No, only animal tests can be used for the foreseeable future	I don't know
* Acute toxicity	○	◉	○	○

* Repeated dose toxicity	○	◉	○	○
* Specific target organ toxicity	○	○	○	◉
* Skin corrosion /irritation	◉	○	○	○
* Skin sensitisation	◉	○	○	○
* Aspiration hazard	○	◉	○	○
* Eye corrosion /irritation	◉	○	○	○
* Respiratory sensitisation	○	◉	○	○
* Carcinogenicity	○	◉	○	○
* Mutagenicity	◉	○	○	○
* Reproductive toxicity	○	◉	○	○
* Developmental toxicity	○	◉	○	○
* Neurotoxicity	○	◉	○	○
* Immunotoxicity	○	◉	○	○
* Endocrine disruption	○	◉	○	○
Other (please specify)	○	○	○	○

7.1. Please use the boxes below to describe one of the non-animal test methods that you are aware of. You will have the opportunity to describe more methods in the subsequent sections if you are aware of multiple tests.

7.1.1. Which hazard endpoint is this test for?

- ○ Acute toxicity
- ○ Repeated dose toxicity
- ○ Specific target organ toxicity
- ○ Skin corrosion/irritation
- ○ Skin sensitisation
- ○ Aspiration hazard
- ○ Eye corrosion/irritation
- ○ Respiratory sensitisation

- ○ Carcinogenicity
- ○ Mutagenicity
- ○ Reproductive toxicity
- ○ Developmental toxicity
- ○ Neurotoxicity
- ○ Immunotoxicity
- ○ Endocrine disruption
- ◉ Other (please specify)

Other hazard endpoint

We don't refer to a specific endpoint. The cosmetics industry can demonstrate safety and make safety decisions with non-animal NAMs and NGRA approaches for all the above endpoints.

7.1.2. What is the name of the test?

100 character(s) maximum

N/A

7.1.3. Please briefly describe the test

500 character(s) maximum

Below are some relevant references (list not exhaustive):

- https://doi.org/10.1016/j.yrtph.2021.105094
- https://doi.org/10.1016/j.yrtph.2021.104964
- https://doi.org/10.3389/fphar.2024.1345992
- https://doi.org/10.1093/toxsci/kfaa048
- https://doi.org/10.3389/ftox.2022.838466
- https://doi.org/10.1016/j.tox.2024.153835
- https://doi.org/10.3389/fphar.2024.1421601
- https://doi.org/10.3389/fphar.2024.1421650

7.1.4. Is your organisation using this non-animal method?

- ○ Yes
- ◉ No – the method(s) is/are not applicable to our organisation's activities
- ○ No – the method(s) is/are applicable, but there are barriers to our adoption of the method(s)

7.1.5. In which regulatory areas can this test be used? (multiple answers possible)

- ☐ None yet
- ☑ REACH
- ☐ CLP
- ☑ Cosmetics
- ☐ Food or feed safety
- ☐ Pharmaceuticals
- ☐ Plant protection products
- ☐ Biocidal products
- ☐ I don't know

☐ Other (please specify)

7.1.6. Methods are usually developed and validated for a set of substances with certain properties (e.g. structural features or biological activity), defining the chemical space for which the methods can be applied (domain of applicability). **Can you provide information on the domain of applicability of the method described above?**

For established NAMs, evaluation reports and regulatory guidelines (e.g., OECD Test Guidelines) detail their applicability, including chemical space, biological activity (MoA, pathways, organ-specificity), regulatory endpoints, and assay conditions. These reports also address limitations, such as applicability to mixtures, highly reactive substances, or unknown/ uncovered mechanisms. Ongoing research through case studies further evaluates these tools, addressing limitations and refining their regulatory scope.

7.2. Do you wish to provide information on another non-animal test method that can already be used to replace animal test methods for human health assessment?

- ○ Yes
- ◉ No

Part D - Non-animal test methods for environmental hazard assessment

This section asks about the availability of non-animal test methods for environmental hazard assessment, with similar questions to Part C. Feel free to skip this part if you are not familiar with any non-animal test methods for environmental hazard assessment.

8. Are you aware of non-animal methods (as stand-alone or in combination, including exposure-based consideration) that can already be used to replace an animal-based method for any of the following environmental hazard endpoints?

Hazard type	Yes (validated NAMs exist and can already be used)	Yes (non-validated but scientifically mature NAMs exist and can already be used)	No, only animal tests can be used for the foreseeable future	I don't know
* Aquatic acute / short-term studies	◉	○	○	○
* Aquatic chronic / long-term studies	○	◉	○	○
* Avian toxicity	○	○	○	◉
* Terrestrial toxicity (invertebrates)	○	◉	○	○
* Sediment toxicity	○	◉	○	○

* Bioaccumulation	◉	○	○	○
Other (please specify)	○	○	○	○

8.1. Please use the boxes below to describe one of the non-animal test methods that you are aware of. You will have the opportunity to describe more methods in the subsequent sections if you are aware of multiple tests.

8.1.1. Which hazard endpoint is this test for?

- ○ Aquatic acute / short-term studies
- ○ Aquatic chronic / long-term studies
- ○ Avian toxicity
- ○ Terrestrial toxicity (invertebrates)
- ○ Sediment toxicity
- ○ Bioaccumulation
- ◉ Other (please specify)

*** Other hazard endpoint**

We don't refer to any specific endpoint. The Cosmetics Industry can make robust, exposure-led safety decisions which are protective for all these hazard endpoints using a variety of methods.

8.1.2. What is the name of the test?

100 character(s) maximum

N/A

8.1.3. Please briefly describe the test

500 character(s) maximum

Below some relevant references (list not exhaustive): https://www.frontiersin.org/journals/toxicology/articles/10.3389/ftox.2021.640183/full
https://cefic-lri.org/toolbox/bioaccumulation-assessment-tool-bat-a-quantitative-weight-of-evidence-qwoe framework-to-aid-bioaccumulation-assessment/
https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model
https://www.epa.gov/comptox-tools/toxicity-estimation-software-tool-test

8.1.4. Is your organisation using this non-animal test method?

- ○ Yes
- ◉ No – the method(s) is/are not applicable to our organisation's activities
- ○ No – the method(s) is/are applicable to use but there are barriers to our adoption of the method(s)

8.1.5. In which regulatory areas can this test be used?

- ☐ None yet
- ☑ REACH
- ☐ CLP

- [ ] Food or feed safety
- [ ] Pharmaceuticals
- [ ] Plant protection products
- [ ] Biocidal products
- [ ] I don't know
- [ ] Other (please specify)

8.1.6. Methods are usually developed and validated for a set of substances with certain properties (e.g. structural features or biological activity), defining the chemical space for which the methods can be applied (domain of applicability). **Can you provide you have information on the domain of applicability of the method described above?**

For established NAMs, evaluation reports and regulatory guidelines (e.g., OECD Test Guidelines) detail their applicability, including chemical space, biological activity (MoA, pathways, organ-specificity), regulatory endpoints, and assay conditions. These reports also address limitations, such as applicability to mixtures, highly reactive substances, or unknown/ uncovered mechanisms. Ongoing research through case studies further evaluates these tools, addressing limitations and refining their regulatory scope.

8.2. Do you wish to provide information on another non-animal test method you are aware of that can already be used to replace animal test methods for environmental safety assessment?

- ( ) Yes
- (•) No

Part E - Non-animal test methods being developed by your organisation

This section asks about your organisation's work on developing non-animal test methods. Please skip this section if this does not apply to you.

9. Does your organisation develop non-animal test methods?

- ( ) Yes, my organisation develops animal-free methodologies
- (•) No

Part F - The 3Rs

The 3Rs principle (replace, reduce and refine) aims to encourage more humane practices in chemical safety assessments. Replace aims to avoid the use of animals (by using non-animal test methods), reduce aims to minimise the number of animals used (e.g. using tests that maximise the data obtained per animal), and refine aims to minimise animal suffering and improve animal welfare (e.g. using tests that require the use of species generally considered to be less sentient).

While the ultimate goal of the roadmap is to provide a framework for phasing out animal testing for use in chemical safety assessment (replace), the other two elements are also considered relevant to the overall transition away from animal testing, especially for the time until animal-free methods are available. The following questions in this section focus on reducing and refining.

10. Do you think there are any promising options for reducing the number of animals needed?

- (●) Yes
- ( ) No
- ( ) I don't know

10.1. In which area(s) of (eco-) toxicological concern are there options/methods for reducing the number of animals needed?

- [ ] Acute toxicity
- [ ] Repeated dose toxicity
- [ ] Specific target organ toxicity
- [ ] Skin corrosion/irritation
- [ ] Skin sensitisation
- [ ] Aspiration hazard
- [ ] Eye corrosion/irritation
- [ ] Respiratory sensitisation
- [ ] Carcinogenicity
- [ ] Mutagenicity
- [ ] Reproductive toxicity
- [ ] Developmental toxicity
- [ ] Neurotoxicity
- [ ] Immunotoxicity
- [ ] Endocrine disruption
- [ ] Aquatic acute / short-term studies
- [ ] Aquatic chronic / long-term studies
- [ ] Avian toxicity
- [ ] Terrestrial toxicity (invertebrates)
- [ ] Sediment toxicity
- [ ] Bioaccumulation
- [x] Other (please specify)

* **Other hazard**

Please see answers to previous questions which outline where the alternative methods are. These can provide opportunities for applications in other chemicals regulation, to lead to a reduction if not replacement of traditional methods.

10.2. In what test methods do you see options for reducing the number of animals needed?

Please refer to previous answers outlining which methods have not only reduced, but fully replaced animal testing.

It is also important to mention that the main challenge here is not just on method availability. The regulatory frameworks have to be updated to allow the implementation and use of the alternative approaches to demonstrate safety; as well as the regulatory adoption by authorities has to be achieved.

11. Do you see options for refining certain animal methods (reducing the severity of suffering of animals)?

- ○ Yes
- ○ No
- ◉ I don't know

Part G - Scientific basis for non-animal tests

This section asks about the scientific basis for non-animal tests, in terms of the scientific confidence in the ability of non-animal tests to provide data on chemical safety that is as robust and accurate as data from animal tests.

12. Do you think that a combination of exposure-based considerations and the use of appropriate animal-free methods could help replace animal tests in certain circumstances?

- ◉ Yes
- ○ No
- ○ I don't know

Please explain

Yes: the cosmetic industry has been demonstrating safety with this approach for years. This mode of demonstrating safety can be used also for wider chemicals safety assessment.

13. Some non-animal methods provide information on events taking place at the molecular level, on toxicokinetics or toxicodynamics. Do you see any benefits of or limitations to the use of such information for switching to non-animal methods? (multiple answers possible)

- ☑ There are benefits
- ☑ There are limitations
- ☐ I don't know

Please explain

The benefits are: increased species relevance and mechanistic understanding, as well as preventing unnecessary animal testing. The limitations are: these molecular events do not necessarily lead to an adverse effect, which means the points of departure are generally conservative. The fact that NAMs do not predict adverse effects in animals is not necessarily a limitation, it is a different approach from the traditional one.

14. What is needed to have an appropriate level of scientific confidence to be able to predict the effects of chemicals on entire living organisms and populations based on models or other non-animal test methods? (multiple answers possible)

- ☑ Case studies showing that non-animal methods work
- ☑ Sufficient information on performance parameter (accuracy, precision, selectivity/specificity, robustness etc.)
- ☑ Sufficient information on the domain of applicability
- ☐ Comparison of outcome with in vivo studies
- ☑ Independent review of the method
- ☑ Other (please specify)

* **Other**

It is important to reiterate that non-animal NAMs and NGRA approaches cannot be compared like-for-like with animal testing. Therefore, the comparison is needed on the final safety decision made using non-animal NAMs and NGRA approaches vs animal testing.

Furthermore, not all methods can be equally applied to every chemical. So it is necessary to know which method to use depending on the chemical being assessed and the hypothesis being investigated.

Part H - Test method development and validation

Depending on the area of chemical legislation, the use of new animal-free methods for regulatory purposes requires the validation of methods after the method has been developed.

15. How can regulatory acceptance be incorporated in the development phase of test methods?

Collaboration between all stakeholders is vital; these include industry, NGOs, regulators, CROs, academics, trade associations and other organisations active in this field. This allows the sharing of expertise and knowledge, as well as alignment of best practices and standardisation on the use of non-animal NAMs and NGRA.

Initiate demonstrator projects, or set up a specific scientific committee, designed and operated by a cross-functional group including regulatory scientists, industry safety scientists, academics and other stakeholders. The aim would be to develop common and standardised approaches at the early stages, and build confidence in moving through the process from regulatory question, to data generation, to safety decision-making of the methods under development.

15.1. How could the process of OECD test guideline development be accelerated?

As previously mentioned, non-animal NAMs and NGRA approaches are not like-for-like substitutions of animal testing, especially as NAMs and NGRA approaches offer the possibility for more human-relevant results. Therefore, the formal validation process under OECD as it currently stands is not always suitable. Furthermore, there needs to be mindset shift from standard validation to a more flexible mechanism for ensuring that the approaches are scientifically valid, helping to enable regulatory acceptance or adoption for these alternative methods. The framework proposed in the Van der Zalm paper (Van der Zalm et al., 2022) is worth of consideration.

Standardisation of these alternative methods, as well as setting up criteria that define what is a scientifically valid method will be key work in this area. These will allow the definition of an approach that builds confidence that NAMs and NGRA methods are scientifically reliable and relevant for regulatory decisions.

15.2. Should the development of certain methods or specific (eco-)toxicological endpoints or hazards be prioritised? Which one(s) and why?

As mentioned in a previous answer, whilst there are some endpoints that lack methodologies, there is extensive research ongoing into the development of non-animal NAMs. Technically, the endpoints lacking specific methods may be prioritised (e.g. endocrine disruption). Prioritisation may also occur for chemicals with higher risk profiles: for specific hazard categories and high levels of exposure, identifying the data gaps. However, non-animal NAMs and NGRA approaches are not like-for-like substitutes of animal testing.

Therefore, when suitable approaches for the above-mentioned endpoints have been developed, what also needs to be prioritised is the education and uptake of these methods and approaches by industry, and the regulatory adoption by authorities. This is done with a strong education programme that builds confidence and capacity, as well as collaboration between all relevant stakeholders, who can share expertise and knowledge among both industry and the authorities.

16. How could the process of test method validation/standardisation be improved?

Please see answer to question 15.1
Also, data sharing platforms and computational methods may be combined and made more accessible, to improve scrutiny of the data.

16.1. Should the validation/standardisation of certain methods or specific (eco-)toxicological endpoints or hazards be prioritised? Which one(s) and why?

Please see answer to question 15.1. As mentioned in previous answers, it is the education and uptake of these alternative methods that should also be prioritised, as well as their standardisation.

16.2. Do you have any views on the funding of, and incentives for, validation studies or validation or standardisation in general? Do you have suggestions for how to increase the funding and strengthen the incentives?

To encourage validation of new methods, it would be helpful to support the method developers in meeting these costs, which can be high. One suggestion would be to allocate funding to relevant regulatory authorities' departments to perform related research activities and evaluate proposed approaches for validation. Also, incentives should be allocated to CROs to invest in the uptake and use of NAMs, especially at a time when the regulatory landscape remains uncertain. This will help to ensure that new methods have a commercial future, thereby encouraging them to be sent through the validation process.

17. The EU is a major funding source for the development of non-animal methods. Do you have suggestions for how to ensure that funding for the development of new methods matches regulatory needs?

It is a positive and welcomed step that the EU is already funding a number of initiatives for the development of non-animal NAMs. This funding should be expanded beyond the development of new methods, to also include education programmes and other initiatives that aim to promote the uptake and practical use of these alternative methods.

Furthermore, it is important that the development of any new method is tailored to the regulatory needs for industry and addressing existing gaps. Examples of these are: endocrine disruptors and chemicals of priority for further assessment.

18. Often the lack of global harmonisation of test methods is mentioned as a hurdle for the use of non-animal methods accepted in one region/country. Do you have any suggestions how to accelerate global harmonisation?

It is important that non-animal NAMs and NGRA approaches are standardised and accepted worldwide. This will avoid trade barriers, the risk of duplicating testing or assessments, and the risk of having different requirements for animal testing in different markets, which is very challenging and expensive for industry. Other benefits of global harmonisation include an increased sharing of best practice for the development of scientific policy. Close collaboration between international authorities and organisations through existing project frameworks, as well as global collaboration within industry, is vital to achieve global harmonisation.

Part I - What support do you need?

19. Does your organisation have the right expertise for transitioning to non-animal testing or do you need training or other support? How will your organisation get the necessary expertise?

- ○ We have the right expertise already and will be able to address the new developments in the field
- ○ We are not experts in non-animal test methods and will need training to be able to use them
- ○ We intend to sub-contract the necessary safety tests and not to build in-house expertise on non-animal test methods
- ○ Not applicable
- ◉ Other (please specify)

* **Other**

As a trade association, our role is primarily to work with the authorities to promote the acceptance of NAMs and NGRA, and to support our members with training and education on transition to NAM and NGRA methods. We bring together varied stakeholders to help achieve the first point, and we facilitate experts within our network to deliver training and education to our members and the wider industry.

It is important to highlight that from the industry side there are companies which are expert in this field, and companies which will need support to transition to using non-animal NAMs for chemicals safety assessment (e.g. SMEs). The latter will very likely have to outsource testing and consultancy in this area. At the moment, the CROs and external stakeholders available to support SMEs in this area are limited.

20. What training does your organisation offer on non-animal testing? (multiple answers possible)

- ☑ We have in-house training
- ☐ We offer training to other organisations
- ☐ We do not offer training

Part J - Development and implementation of Commission's roadmap for phasing out animal testing

21. What are, in your view, essential elements that should be included in the roadmap being developed by the European Commission? What would be important actions (short-term, mid-term and longer-term) or milestones?

CTPA provided information on this point in its response to the EU Commission's call for evidence in October 2024. The key points are reported below for easier reference.

Collaboration between all stakeholders is vital; for example, industry, NGOs, regulators, CROs, trade associations and other organisations active in this field. This allows the sharing of expertise and knowledge, as well as alignment of best practices and standardisation on the use of non-animal NAMs and NGRA.

However, when there are many stakeholders involved, it is important that the roadmap is further structured into clear objectives, actionable steps and timelines to be taken to reach each objective. Furthermore, the stakeholders responsible for delivering each objective shall be identified to ensure accountability and promote participation as one of the ways to ensure success.

Animal welfare remains a priority for many countries, which means collaboration with stakeholders should also consider interactions at a global level. It is important that non-animal NAMs and NGRA approaches are standardised and accepted worldwide, in order to promote their use and acceptance globally, share best practice scientific policy development, avoid trade barriers, and/or risk duplicating testing or assessments, and/or risk having different requirements for animal testing in different markets.

The roadmap should include consideration on the need to update EU chemicals and sectorial legislation, if required, to introduce flexibility to incorporate the use of non-animal NAMs and NGRA approaches to meet regulatory requirements. Furthermore, regulatory updates across sectors may also consider focusing on exposure and exposure-led approaches, in order to unlock the full potential of NAMs and NGRA approaches.

In order to achieve regulatory acceptance of non-animal NAMs and NGRA approaches, key focus should be given to confidence-building amongst all stakeholders. Whilst there are a number of experts in these methods across industry and regulators, it is important that all those involved into chemicals risk assessment are trained and build confidence in the use and application of these methods. This can be achieved through education programmes, as well as proactive dialogue between industry experts and regulators to provide the opportunity for discussion and feedback on the new methods.

The roadmap should also consider a mode to make the deployment of existing and new NAMs and NGRA methods accessible to the whole industry, including SMEs. It is important to consider that SMEs may not have significant resources to invest into the uptake of the non-animal NAMs and NGRA approaches, further highlighting the need for Contract Research Organisations (CROs) and consultants to adopt new tools and ensure appropriate training in their application.

22. Changes to how chemical safety assessments are done will mostly occur after the roadmap is published, during its implementation phase. How could your organisation contribute to the implementation of the roadmap?

An important initiative for CTPA is also providing practical, case-study based training and other useful educational resources. The most recent example of our practical training involved safety assessors reviewing a fully NAM/NGRA based data package for a UV filter, benzophenone-4, to reach a safety conclusion. The assessors were supported by facilitators with expert knowledge of the data set to help the attendees. CTPA also held discussion events where cosmetic safety assessors meet together and share best practice.

Park K - Other

This is your opportunity to share any other information you feel is relevant to the development of the roadmap. Please note that the responses to the call-for-evidence published in September 2024 are being analysed simultaneously to this survey, so please refrain from uploading the same feedback. Please submit only non-confidential information.

Please upload your file(s)
(max file size 5 MB e.g. approximately 20-page PDF document including a few diagrams / low-resolution images)
86ba80bd-1510-40b6-9696-83866e92d334/CTPA_NAMS_Position_Paper_December_2024.pdf

Any other information
1000 character(s) maximum

Thank you for participating in this survey. Please direct any questions or feedback to kristina.flexman@wsp.com or emily.hickery@wsp.com.

Contact

Contact Form