Technical assistance for the development of the Commission roadmap towards phasing out animal testing for chemical safety assessments

First stakeholder survey background document

1. Introduction

WSP has been contracted by the European Commission to provide technical assistance for the development of the Commission roadmap towards phasing out animal testing for chemical safety assessments. As part of this project, we are undertaking various consultation activities to gather information from a range of stakeholders. You are invited to partake in the first survey for this project, available here:

https://ec.europa.eu/eusurvey/runner/Animal_testing_phase_out_CSA_roadmap_survey_1_2024 .

The survey will be open until 17/01/2025.

1.1 This document

This document sets out:

- The project background (the purpose of this project) (section 1.2)
- The purpose of the survey and how it fits into the Commission's work (why we need your inputs) (section 2)
- An overview of the survey questions (what we will ask you) (section 3).

1.2 Project background

The aim of this project is to help accelerate the phasing out of animal testing in EU chemical safety assessment. In accordance with Directive 2010/63/EU, animal testing can only be conducted if there are no viable alternatives and if the expected benefits outweigh the potential harm to the animals. This Directive aims ultimately to fully phase out all animal use for research and for regulatory purposes. Significant steps to phase out animal testing have been made in the last decade or so, with a full ban on animal testing for cosmetics introduced in 2013. Further efforts from the scientific community focus on developing, validating, and applying non-animal test methods. Nevertheless, avoiding animal testing is still challenging in some cases due to scientific limitations or difficulties in the uptake of non-animal methods.

The move to non-animal methods is at different stages of uptake and implementation for different endpoints. For many hazards there is a lack of available models or consensus on which (combination of) method(s) can replace current animal methods. There is a need to accelerate the development, validation and implementation of non-animal methods and identify a path for uptake across legislation.

The objective of this project is to synthesise information that can contribute to the Commission's roadmap towards phasing out animal testing for chemical safety assessment.

2. Purpose of the survey

This survey forms part of wider work to review the current state of play on phasing out animal testing, to identify barriers to implementation of non-animal methods, and to identify the steps that will form part of the Commission's roadmap. Information is needed on: specific endpoints or hazards; advantages and disadvantages in using non-animal test methods in chemicals safety assessments; barriers to regulatory uptake across different sectors and legislation; and how to navigate barriers and opportunities related to non-animal methods.

The Commission committed in Communication C(2023) 5041, replying to the European Citizens' Initiative (ECI) 'Save cruelty-free cosmetics – Commit to a Europe without animal testing', to develop a roadmap towards phasing out animal testing for chemical safety assessments. The roadmap will aim to identify the steps that are needed to replace animal testing in both environmental and health hazard assessment, under relevant EU chemicals legislation, whilst ensuring a high level of protection. Input from stakeholders that will be involved in the development and use of non-animal methods is needed to develop a successful and implementable strategy.

The consultation activities build on the Commission's call-for-evidence launched in September 2024 by asking more detailed questions to specific stakeholders. This survey asks about your organisation's knowledge and current use of non-animal methods or methods that minimise animal testing, as well as challenges and opportunities on the validation, implementation and uptake of these methods.

The information collected in this survey will be used in conjunction with the previous call for evidence, workshops, desk research and further consultation activities to build a picture from a range of stakeholders and support the development of the roadmap.

3. Overview of survey questions

The survey includes a mix of mandatory and optional questions, and multiple-choice and free text answers. It is divided into 11 parts as follows:

A. **About you**: this section aims to identify the respondent, and the organisation represented.

B. **General questions on challenges and opportunities:** this section asks about the challenges and opportunities with non-animal methods for assessing hazards and risks in a regulatory context. In particular, we will ask about the main challenges in the use of non-animal methods, benefits and disadvantages for different stakeholders and costs.

C. **Non-animal test methods for human health hazard assessment**: this section asks about the availability of non-animal methods for human health hazard assessment. In particular, we will ask about existing non-animal methods by hazard type, their level of maturity and the legislation they can be used for.

D. **Non-animal test methods for environmental hazard assessment**: this section mirrors section C but focuses on environmental hazards assessment.

E. **Non-animal test methods being developed by your organisation:** this section asks about your organisation's work on developing non-animal methods: what type of methods, for which endpoint, if they have a regulatory purpose and their level of maturity.

F. **The 3Rs**: The 3Rs refers to the principle of reduction, refinement and replacement of animals used in research and testing. This section asks about the reducing and refining part of the 3Rs and asks about methods within human health and environmental assessments.

G. **Scientific basis for non-animal tests**: this section asks about the ability of non-animal methods to provide data on chemical safety that is as robust and accurate as data from animal tests.

H. **Test method development and validation**: generally, the use of non-animal methods for regulatory purposes requires the validation of methods after the method has been developed. This section is made up of open questions on how to improve regulatory acceptance and validation, any barriers and funding needs.

I. **What support do you need?** This section asks about your organisation's skills and training needs.

J. **Development and implementation of Commission's roadmap for phasing out animal testing**: This section asks open questions about what needs to be included in the Commissions' roadmap.

K. **Other**: this section is an opportunity to share any additional information via a free text box or by uploading an attachment.

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Document revisions

No.	Details	Date
1	Draft survey background document	27/11/2024
2	Final survey background document	28/11/2024